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WIC FAMILIES WHO SMOKE: A BEHAVIORAL COUNSELING STUDY**

**I. INTRODUCTION**

***A. Nature of the Research Problem***

Parents' smoking endangers their own and their children's health. Interventions have shown that behavioral counseling can help parents reduce children's exposure to ETS in absence of parents quitting.

***B. Purpose, Scope, and Methods of the Investigation***

We tested a combined intervention of ETS and smoking cessation counseling, using a two group repeated measures design with objective verification of reported ETS and smoking and families recruited from the Women, Infants, and Children Supplemental Food and Nutrition Assistance Program (WIC).

***C. Nature of the Findings***

The results provide further evidence for the generalizability of our ETS counseling procedures. Children's reported ETS exposure and urine cotinine concentration decreased in both groups over time, and the decrease in reported measures was greater for counseled families than for controls. Group differences were sustained at follow-up measures collected 12 months post-intervention. The counseled group also reported a higher number of short-term quit attempts.

**II. REVIEW OF THE LITERATURE**

The World Health Organization has concluded that there is no "safe" level of exposure to ETS,<sup>1</sup> and estimated that ETS threatens the health of half of the world's children.<sup>2</sup> Effects include increased risk of respiratory illness, otitis media, Sudden Infant Death Syndrome (SIDS), asthma induction and exacerbation, wheezing, reduced lung function, school absence, and heart disease and cancer later in life.<sup>3-11</sup> ETS may play a greater adjuvant role in autoimmune disease than air pollution.<sup>12</sup> Recent studies found children's ETS exposure associated with increased respiratory symptoms following surgery,<sup>13</sup> dental caries,<sup>14</sup> lower plasma Vitamin C concentration,<sup>15</sup> fussy infant behavior,<sup>16</sup> lower cognitive test scores,<sup>17</sup> nocturnal asthma symptoms,<sup>18</sup> atopic eczema,<sup>19</sup> inpatient sickle cell crises,<sup>20</sup> development of glucose intolerance among young adults,<sup>21</sup> and higher incidence of sick leave as adults.<sup>22</sup> The California Air Resources Board recently identified ETS as a Toxic Air Contaminant causally associated with breast cancer especially in younger (primarily pre-menopausal) women.<sup>23</sup>

ETS exposure has an adverse impact on children's health and costs almost \$1 billion in excess medical care, and over \$4.5 billion in loss of life costs per year.<sup>24,25</sup> Healthy People 2010 Objectives are to reduce to less than 10% the prevalence of children under six years old exposed to ETS.<sup>26</sup> National Health Interview Survey data show that children's ETS exposure declined from 36% to 25% from 1992 to 2000,<sup>27</sup> yet among some lower SES populations the proportion exposed may be as high as 84%.<sup>28</sup> Effective interventions are needed to reach the 2010 target.

Since smoking cessation rates for successful trials in which participants enroll to quit smoking range from as low as 5% for minimal interventions without nicotine replacement therapy (NRT), to as high as 60% for intensive counseling with NRT,<sup>29,30</sup> interventions to help parents smoke outdoors or away from their children, in absence of smoking cessation, may yield important benefits. Outdoor-only smoking can protect children from respiratory symptoms,<sup>31</sup> and one study found higher risk of hospitalization with respiratory infection if mothers smoked in the same room as their child versus not.<sup>32</sup> However, smoking exclusively outdoors at home may not completely protect children. Cotinine levels of children whose parents reported always smoking outdoors were intermediate between children of non-smoking parents and parents who smoked indoors.<sup>33,34</sup>

Minimal ETS interventions have been ineffective in reducing children's exposure<sup>35-40</sup> or helping parents quit smoking.<sup>35,36,40-43</sup> Several trials have reduced children's exposure with individualized parent counseling. Our clinic-based study reduced reported ETS exposure for asthmatic children,<sup>44,45</sup> and our trial with low-income mothers and healthy babies reduced reported exposure and prevented increases in cotinine.<sup>46</sup> Our study of Latino asthmatic children obtained effects based on reported ETS and cotinine assays.<sup>47</sup> Other investigators have found benefits in reported ETS exposure,<sup>48</sup> decreased air nicotine,<sup>49</sup> and reduced children's asthma-related healthcare.<sup>50</sup> Thus we believe individualized intensive counseling can be efficacious for reducing healthy and asthmatic children's ETS exposure for low to middle income and racially mixed families. Home based interventions with frequent contacts appear most effective.<sup>51</sup>

Based on our Behavioral Ecological Model and anecdotal evidence and early trends from our previous trials,<sup>44-47</sup> we hypothesized that parents with no interest in smoking cessation might acquire such interest during the process of ETS exposure counseling. Thus, we expanded our counseling intervention in the present trial to provide assistance with quitting smoking in addition to reducing children's ETS

exposure. Counseling and NRT (patches and/or gum) were offered to all adults in the intervention group. We also offered additional sessions over a longer period of time, with a higher proportion in-person at participants' homes so that all family members might more conveniently participate. This family-centered intervention was provided to 150 low-income families.

### **III. STUDY DESIGN AND METHODS**

#### **A. Study Design**

The study was a randomized double blind controlled trial with a two-group repeated measures design. Families were randomized to the intervention ( $n = 76$ ) or control condition ( $n = 74$ ) after three baseline measures one week apart, and were measured at 3 months (mid-intervention), 6 months (end of treatment posttest), 12 months, and 18 months. Assignment was stratified by child's gender, ethnicity (Hispanic, non-Hispanic White, Black/other), and recruitment site. Research assistants who obtained measures were blind to group assignment, and control families were unaware of counseling procedures. Investigators were blind to results until all data were collected. Study procedures were approved by the San Diego State University Institutional Review Board.

#### **B. Population Studied**

We recruited English-speaking mothers with children < 5 years old. Baseline measures were conducted if children were exposed to a minimum of three of their mothers' cigarettes per day in the home or car. Families were randomized only if children remained exposed to a minimum of ten cigarettes per week at the third baseline, or at an additional fourth baseline three months after. Breastfeeding children were excluded, as cotinine is passed through breast milk and confounds urine cotinine analyses.<sup>52,53</sup>

#### **C. Sample Selection**

Mothers were identified from 19,935 preliminary screening forms collected at seven sites of the two largest WIC systems in San Diego County, California. For 24 months beginning February 2001, research assistants completed secondary telephone screening (Figure 1). Research assistants explained that the purpose of the study was to learn more about children's health and mothers' health habits, and the study measurement requirements. It was explained that the family would be randomly assigned to one of two free health education programs, although the purpose of these programs was not explained to participants until after baseline measures and random assignment. Therefore the intervention was tested with participants who were not seeking assistance with quitting smoking or reducing children's ETS exposure. Mothers were offered financial incentives of up to \$150, or \$160 if they had a fourth baseline, and additional gift cards and raffle chances for their participation.

Research assistant supervision and training. Interviewers and counselors each received approximately 30 hours of group and individual didactic training and role-playing practice of interviews and counseling sessions from the Project Coordinators. Ongoing training was provided at weekly staff meetings with quality control feedback based on audio recordings of interviews and counseling.

#### *Intervention Procedures*

Counseling protocol. The intervention employed ETS counseling procedures that have been effective in our previous trials.<sup>44-47</sup> Counseling is based on our Behavioral Ecological Model (BEM), derived from Learning Theory<sup>54</sup> and emphasizing hierarchical physiological, environmental, and cultural contingencies of reinforcement and their interactions as causal agents of behavior.<sup>55,56</sup> Families were offered 14 sessions over six months; ten in person at participants' homes, and four by telephone. Pre- and post-quit day telephone support calls were also provided. All adults living in the home were invited to participate. Each session included behavioral contracting for reducing children's ETS exposure and ongoing problem solving with praise and feedback. Counselors assisted mothers and other participants to develop long- and short-term goals and rewards for gradually shaping their and other household members' behavior.

Smoking cessation component. Counselors presented smoking cessation topics in a semi-structured manner, according to participants' interests. Topics included nicotine addiction, NRT, health benefits of quitting, triggers, personal positives and negatives of smoking, urge control, coping strategies, quit preparation, and relapse prevention. Strategies for relaxation, healthy eating and exercise were discussed. Counselors provided a list of community referrals and ongoing help in locating assistance with a variety of social welfare issues. Counselors provided free nicotine patches and/or nicotine gum to all mothers and other smokers living in the home who wanted to use them to assist with quitting smoking.

#### **D. Instruments Used**

##### **Measures of Children's ETS Exposure and Parents' Smoking**

Mothers' reports. In-person interviews were conducted at participants' homes, or by telephone if mothers moved outside of San Diego County. Content included demographics and mothers' health behaviors with

a focus on tobacco use and children's ETS exposure. Mothers reported their smoking and their child's ETS exposure on typical work and non-work days (or week and weekend days) during the past seven days, including exposure from mothers, other residents and visitors in the home, and outside of the home including in the car. When possible, "other parents" (mothers' husbands or partners) answered questions regarding their own smoking. If they refused or were unavailable, mothers reported for them. Exposure was defined as the number of cigarettes smoked while the child was in the same indoor room or car. Children's weekly exposure to mothers' cigarettes in the home and "total exposure" to all cigarettes in the home, car, and elsewhere were calculated. These measures have shown acceptable test-retest reliability and validity in relation to cotinine and nicotine assays in our past studies.<sup>57,58</sup> To further examine the test-retest reliability of our measures, a subset of questions was re-asked of a random sample of 65 mothers within 2 days following the 6-month interview.

Children's urine cotinine concentrations. Urine samples were collected at each study measure for analysis of cotinine, a nicotine metabolite which is the recommended biomarker for ETS exposure.<sup>59,60</sup> Samples were analyzed at the University of California at San Francisco using liquid chromatography-tandem mass spectrometry (LC/MS/MS) with a limit of quantitation of 0.2 ng/ml.<sup>61</sup> Samples from children who were not toilet trained were obtained by placing two cotton panty shields (Natracare LLC; Denver, CO, USA) in the diaper. When wet, each was packed into a separate sterile 20 ml syringe without needle (Becton, Dickinson, and Company; Franklin Lakes, NJ, USA), and the urine was expressed into a 5 ml sterile vial. Our previous research showed that cotton rolls do not alter cotinine concentration.<sup>62</sup> Samples from toilet trained children were collected with a standard urine collection cup. The laboratory was blind to participants' identity and group assignment.

Mothers' and other parents' smoking status. At each interview, mothers and other parents were asked if they had smoked a single cigarette, even a puff, in the past 30 days and the past 7 days. They were asked to report the start date of their latest quit, if any. Mothers and other adults living in the home who reported that they had not smoked within the past seven days were asked to provide saliva samples for objective verification. Those concurrently using nicotine replacement products were also asked to provide a urine sample. Samples were analyzed at the University of California at San Francisco. Saliva was analyzed by gas chromatography, and cotinine concentration  $\leq 15$  ng/ml was considered verification of reported quit. Urine was analyzed for anabasine and anatabine concentration by gas chromatography-mass spectrometry.<sup>63</sup> These tobacco-specific alkaloids can be used to validate abstinence in persons undergoing nicotine replacement therapy.<sup>64</sup> Self-reported quits were confirmed by anabasine and anatabine levels below 2 ng/ml.

Nicotine monitors. We conducted nicotine monitoring to provide objective validation of mothers' reported levels of smoking and to enhance reporting accuracy. To sensitize mothers to possible confirmation of their reports of exposure, inactive monitors were placed in three rooms where children's greatest ETS exposure was reported. At the second baseline interview and one week before the 6-month interview, an active monitor was placed in the room of primary exposure for a randomly selected 40% of homes. This monitor was a 37 mm diameter cassette containing a Teflon coated glass fibre filter (Emfab TX 40h120WW, Pallflex, Putnam, CT) saturated with 4% sodium bisulphate and 5% ethanol and dried. Analysis of nicotine concentration by gas chromatography was conducted at the University of California at Berkeley School of Public Health.<sup>65,66</sup>

### ***E. Statistical Techniques Employed***

Analyses were based on intention to treat. To control for skewness, we adjusted dependent variables by logarithmic transformation. Geometric means are reported to show clinically meaningful metrics. To investigate the validity of parent-reported indoor smoking and ETS exposure we examined Pearson correlations with children's urine cotinine concentrations and home air nicotine levels. The test-retest reliability of mothers' reports was examined by comparing mean smoking and exposure levels reported at the 6-month interview and their retests using one-sample *t* tests. Differential rate of change in reported exposure and cotinine estimates of exposure relied on analyses of repeated measures over time. Estimated power to detect differential change between groups exceeded 0.80 for all dependent variables. We analyzed the effects of counseling using the generalized estimating equations approach (GEE), with linear components of time as "within subjects" factors and the interaction as a "between subjects" factor (SAS version 6.12).<sup>67</sup> We calculated differential change from baseline to six-month posttest (counseling effect) and from six months to 18 months follow-up (maintenance effect). Cross-sectional group differences at baseline were examined using oneway ANOVA and Pearson's chi square tests. Mothers' smoking cessation was assessed with chi-square tests for group differences for self-reported and biochemically confirmed quits at each measurement point. Mothers who were lost to follow-up and not measured were counted as smokers.

## **IV. DETAILED FINDINGS**

### ***Participant Flow and Follow-up***

Figure 1 shows the number of participants enrolled through completion of measures. Of the 180 mothers who completed their first baseline measures, 2 were disqualified. We lost contact with 8 mothers before they completed their third baseline. Of the 170 families who completed their third baseline measures, 141 qualified for randomization based on a minimum 10 cigarettes/week reported exposure from the mother at home or in the car. We were able to complete a fourth baseline (after 3 months) with 22 of these 29 families, and 9 then qualified for randomization. Therefore we randomized a total of 150 families: 76 to the intervention and 74 to the control condition. Three month mid-intervention measures were completed by 129 (86%) families, 6-month posttest by 130 (86.7%), 12 month measures by 121 (80.7%), and 130 (86.7%) families completed final 18-month follow-up measures.

For three families, posttest measures were completed greater than 15 months after baseline measures (versus the planned 6 months), and for five additional families, 18 month measures were conducted greater than 15 months past posttest (versus the planned 12 months). These observations were excluded from further analyses, as their interpretation is unreliable.

### ***Participants and Success of Random Assignment***

Demographic characteristics of mothers and children are shown in Table 1. About one third of mothers were racial/ethnic minorities, and only 5% graduated from college. About one third were single parents and one third were employed. There were no statistically significant group differences in these characteristics at baseline, or in age, children's gender, mother's smoking rate, whether or not the mother had quit smoking for 24 hours in the past year, or home smoking policies.

### ***Intervention Implementation***

Counseling participation. Of the 76 mothers assigned to the counseling condition, 41 (53.9%) completed all 14 sessions, and 60 (84.5%) completed at least 7 sessions. Of the 71 mothers who participated in counseling, 46 (64.8%) lived with their husband or boyfriend during the intervention. Thirty five of these "other parents" smoked, and 21 (60%) of the smokers participated in counseling. Ten attended only one session, and only three attended 7 or more sessions. Only 1 of the 11 nonsmoking other parents participated in counseling (5 sessions). Other residents who lived in the home participated in counseling with 17 mothers, none in more than 4 sessions.

Provision of nicotine replacement therapy. Nicotine patches and/or gum were provided to 56 (73.7%) mothers in counseling; 40 (52.6%) received patches and 38 (50%) received gum. Of these mothers, 16 (44.4%) reported that they used the patches daily, and only 5 (18.5%) reported using the gum daily. Nicotine products were also provided to 21 other parents and to one or more other adult residents in 14 families.

### ***Reliability of Mothers' Reports***

Test-retest correlations for mothers' reports of their children's ETS exposure were .40 for non-workdays, .54 for workdays, .81 for weekdays, and .82 for weekend days. For mothers' indoor smoking rate at home, correlations were .67 - .88. There were no statistically significant differences in means for these reported variables at the 6 month interview versus 24-48 hour retest (Table 2).

### ***Convergent Validity of Outcome Measures***

Correlations between reported ETS exposure and indoor smoking rates, children's urine cotinine concentrations, and environmental nicotine range from .40 to .78 (Figure 2).

### ***Intervention Effects***

Children's reported ETS exposure. Table 3 shows the means for children's exposure to environmental tobacco smoke and smoking rates at baseline, 6, 12, and 18 months. Children's reported exposure to ETS from their mothers at home declined steeply in both groups from baseline to 6 months posttest ( $p = .001$ ), with a larger decrease among the experimental group ( $p = .052$ ). Group differences remained from 6 through 18 months ( $p = .018$ ), with the counseling group's exposure decreasing 79.0% and the controls 43.2% from baseline through 18 months.

Children's reported "total exposure" to all tobacco smoke showed a similar pattern, with a steep decline from baseline to 6 months posttest in both groups ( $p = .000$ ) and group by time differences ( $p = .009$ ). Group differences remained through 18 months ( $p = .001$ ), with the counseling group's exposure decreasing 85.3% and the controls 44.0% (Figure 3) from baseline to 18 months.

Children's urine cotinine concentration. Baseline cotinine concentrations ranged from .10 to 122.14 ng/mL. As in our past studies, at subsequent measurement points there were a small number of cotinine values that were well within the range of smokers' values. These included values as high as

3,070 ng/ml. For subsequent analyses, the nine cotinine values of greater than 423 ng/ml were excluded, as the integrity of these urine samples in the highest 10% was questionable.

Children's urine cotinine concentration showed a significant decrease in both groups from baseline to 18 months ( $p = .001$ ) and a near significant decrease at 6 months ( $p = .072$ ). Cotinine concentration did not differ over time by group assignment (Figure 4).

To further investigate the effects of the intervention on children's urine cotinine concentration, we included mother's perceived harm of ETS to children's health and its interaction with group assignment as covariates in GEE analyses. The interaction term was a significant covariate ( $p < .05$ ) from baseline to 6 months and 6 to 18 months, with higher perceived harm associated with lower cotinine concentration. To explore this moderating relationship, we conducted separate GEE analyses for participants who reported that they thought ETS harms the health of children "a lot" and those reported it harms children "none", "not much", or "some". For the group reporting low perceived harm, children's mean urine cotinine concentration did not decrease over time in either group. For the group reporting high perceived harm, mean cotinine decreased from baseline to 18 months in both groups ( $p = .007$ ).

Smoking rates. The patterns of means for mothers' indoor smoking and indoor smoking by everyone living in and visiting the home were similar to those for ETS exposure. From baseline to 18 months, there was a significant decrease in both groups and group by time differences were significant ( $p < .05$ ). There was a sharp decrease from baseline to posttest in each group, which was greater among the counseling group ( $p = .151$  for mothers' and  $p = .130$  for all indoor smoking) and maintained through follow-up. At 18 months, the counseling group mothers' indoor smoking decreased 77.6% from baseline, and controls decreased 47.2%. All indoor smoking decreased 79.9% in the counseling group and 47.7% in controls. At the 6 month post-intervention measure, mothers in the counseling group reported a significant decrease in their overall smoking rate (34.4%) compared to controls (5.1% decrease). These effects were not sustained during the follow-up period.

Mothers' and others' smoking cessation. Twelve (15.8%) mothers in the intervention group reported that they had quit smoking for at least 7 days prior to one or more study measures, without contradiction of saliva cotinine or urine anabasine or anatabine concentration, versus four (5.4%) controls (Chi-square  $p = .039$ ). Only two intervention mothers and two controls reported that they sustained their smoking cessation for at least 6 months, and one intervention mother had quit for 11 months by her final study measure. Biochemical testing indicated possible deception for 20% of mothers reporting quits in each group.

In seven families assigned to counseling and two controls, a family member other than the mother reported that they had quit smoking for at least seven days prior to one or more study measures. This difference in favor of the intervention was not statistically significant (Fisher's exact test  $p = .17$ ). In most cases we were unable to collect saliva or urine samples from these other adults, so the reports were not confirmed.

## **V. DISCUSSION AND INTERPRETATION OF FINDINGS**

### **A. Conclusions to be Drawn from Findings**

These results provide further evidence for the generalizability of our ETS counseling procedures to a low income, racially and ethnically diverse, high risk population. Children's reported ETS exposure and urine cotinine concentration decreased in both groups over time as a function of decreased smoking in the same room as the child and all indoor smoking in homes of both groups. The decrease in reported exposure and indoor smoking was greater for counseled families than for those assigned to the control condition, and group differences were sustained at follow-up measures collected 12 months post-intervention.

The overall decrease in cotinine levels for both groups is consistent with previous studies where we demonstrated the reactive nature of our measures.<sup>44-47</sup> Unlike non-behavioral research, these types of studies involve comprehensive measures that promote change in the very behavior we are studying. Thus, we suffer loss of power due to measurement induced change in control families. However, practical ramifications suggest that counseling should be implemented with similar measures in order to obtain the benefits of both. Future studies also should be designed to analyze the change due to measurement versus change due to counseling. Indeed, this might show that measurement alone could serve as a powerful intervention.

This study also adds to the research literature by showing that children whose parents perceived ETS exposure as most harmful to children showed decreased mean cotinine levels over time, whereas children whose parents reported that ETS exposure was less harmful did not. This suggests that counseling is most effective with families who already know that ETS exposure is harmful to children, and that some families might benefit from additional education that could change the perception that it is not.

The additional behavioral changes reported by experimental group families were insufficient to reduce the exposure to children from contaminated home and car environments, as measured by children's urine cotinine concentration. Research on the physical and chemical properties of ETS indicates that it not only contaminates the air we breathe but the entire indoor environment in which we live. Volatile ETS components sorb into surfaces within minutes of emission, contaminating furniture, carpets, walls, clothes, and skin.<sup>68,71</sup> In indoor environments, in which smoking occurs regularly over an extended period of time, the sorbed mass of these compounds (e.g., nicotine, benzene, pyrene and other carcinogens) can become large relative to the mass emitted by a single cigarette. Consequently, re-emission for these compounds from indoor surfaces may become significant relative to direct emission, and may continue for weeks and months after cigarettes have been smoked.<sup>72-75</sup> Controlled chamber studies suggest that 80-90% of nicotine by mass was deposited and sorbed on the surfaces of a stainless steel environmental chamber within the first 1 to 2 hours.<sup>68</sup> These findings suggest that only 10-20% of nicotine by mass (and very likely other VOCs and SVOCs) were emitted in the air, with the majority sorbed on surfaces. Consequently, these surfaces provide a significant reservoir for the re-emission of ETS. Carpets sorbed approximately 100 times more nicotine per m<sup>2</sup> than did the stainless steel walls.<sup>71</sup>

Therefore, home smoking bans may take months to have the desired effect because of pre-existing contamination of surfaces, dust, and air in the home. Also, smoking bans in the home often mean that smokers light cigarettes on a balcony, outside the home near the front door, or near an open window. These strategies cannot prevent ETS contamination and ETS exposure in the home because of air movement and contamination of clothes and skin.

Because of their developmental stage, small children are at a higher risk than adults to be exposed to ETS through dust and surface contamination. Young children are more exposed to dust, because they spend more time on or close to floors where dust settles and ETS is absorbed. Compared to adults, children exhibit much higher mouthing (e.g., hand-mouth, toy-mouth) and pica behaviors (i.e., ingesting nonfood objects) than adults, increasing exposure risk via ingestion and skin contact with contaminated objects. Because surfaces remain reservoirs for ETS weeks and months after indoor smoking has ceased, children are likely to be exposed to ETS for an unknown time period even if smoking bans are implemented.

Establishing designated smoking sections at home does not eliminate the risk of ETS exposure. Particularly in small homes and apartments, tobacco smoke easily spreads throughout the house.<sup>76,77</sup> Volatile components of ETS sorb on surfaces and are re-emitted long after a cigarette was smoked. Part of the particulate matter component of ETS eventually settles out and becomes part of household dust, collecting in carpets, on furniture, and toys. Even if rooms are well ventilated, carpets, walls, doors, etc. are reservoirs of ETS from which ETS is re-emitted weeks and months later. That is, a child may inhale, ingest, or come in skin contact with ETS many days and weeks after a parent or visitor has smoked and even if she was not present in the room at that time. Thus, our observations of no overall differential reduction in cotinine may be due to these on-going exposures.

This was our first of our ETS intervention trials to combine ETS counseling with formal counseling and nicotine replacement products for quitting smoking. Mothers in the intervention group had a higher number of short-term quits, yet the intervention did not produce long-term smoking cessation. However, study participants did not volunteer for a smoking cessation program and it has also been noted that decreasing end-of-treatment abstinence rates for smoking cessation trials over time may be caused by the increasing recalcitrance of individuals who continue to smoke despite social, regulatory, and medical pressures to quit.<sup>78</sup> Over one quarter (26.7%) of participants in the present study reported difficulties with finding or keeping housing or that they stayed in a motel or shelter while they were in the study, 27.9% reported problems with finding or keeping a job, 22.5% lost telephone service, the mother or another family member was incarcerated for 23.3%, 24.0% reported their own or a family member's alcohol or other drug abuse, 11.6% reported domestic violence, and 7.8% reported loss of gas or electrical service and 7.8% problems with child custody. Therefore, these low-income families experienced significant life challenges that may have compounded difficulties with achieving their goals for quitting smoking and/or reducing children's ETS exposure.

The planned family intervention may have been more effective if we had been able to involve more family members in counseling sessions. This was difficult because mothers enrolled their families in the study but other family members were not necessarily willing to participate. It was also common that mothers and other adults accepted nicotine replacement products to aid with their plans to quit smoking, but they reported they didn't use them properly (i.e., not daily or for the recommended time period.)

Overall, this study showed that blending smoking cessation counseling with ETS counseling for low-income mothers who did not volunteer for a smoking intervention, can increase mothers' quit

attempts. However, additional research testing refined interventions is needed to determine how to promote sustained cessation for a larger proportion of families.

Parent reports of exposure and smoking levels showed relatively strong correlations with children's urine cotinine levels and home air nicotine monitors. These correlations were equivalent to those found in our past studies.<sup>57,58,79</sup> These findings also confirm our previous observations that parents' reports of smoking and ETS exposure rates are about as accurate as biomarker or environmental assays of nicotine.

***B. Explanation of Study Limitations***

This trial does not allow a separation of the effects of ETS exposure counseling versus counseling and NRT for smoking cessation. This was mainly a cost consideration. To segregate these effects would have required a third experimental group/condition for families who would receive cessation assistance without ETS counseling. This would have increased costs beyond the allowed budget.

Another limitation concerns the accuracy of reported information. While all measures include error, our attention to quality control, e.g. audio recordings, reduced interviewer error. Our measures of environmental and biological markers of ETS, including bogus pipeline procedures, probably reduced reporting error to a minimum. This is especially true for measures of ETS and smoking cessation.

***C. Comparison with Findings of Other Studies***

These results confirmed previous work by us and other investigators, showing the efficacy of individualized behavioral counseling with smoking parents for reducing young children's ETS exposure. This study provided the longest follow-up period we have tested, and we demonstrated sustained decreases in ETS exposure and indoor smoking among the counseled group.

***D. Possible Application of Findings***

This study confirmed the efficacy for ETS counseling with smoking parents of young children of diverse race/ethnicity. These services might be implemented in various clinical or community settings, including WIC programs that serve over eight million low-income women, infants, and children nationwide.

***E. Policy Implications***

The results obtained in this study and many of those we have published previously, show significant effects for reducing ETS exposure and promoting short-term smoking cessation by counseling. However, most of the families in the experimental condition had not completed their efforts to change by the end of the funded time allowed for this experimental test. This implies that services provided under normal clinical conditions might result in greater reductions in ETS exposure and a larger proportion and longer duration of quits, as counseling would not normally be stopped during progressive change toward these goals. Thus, this study suggests that ETS counseling offers a clinically important service to high risk families. These results, along with those from our earlier studies, suggest that WIC and other social service providers for low income populations should include routine assessment and counseling to protect the health of ETS-exposed children. For ETS counseling to be implemented successfully into WIC services or well-child medical care, adequate resources must be available to hire well-trained counselors who are able to provide flexible scheduling and bilingual and in-home services as needed.

***F. Suggestions for Further Research***

Future interventions should stress the importance of complete home smoking bans for protecting children from ETS, and possibly on replacing contaminated carpets, wall coverings, and drapes that serve as reservoirs for nicotine and other chemicals comprising ETS. Behavioral changes such as not smoking in the home when children are present, or in the same room as children do not appear adequate. Future interventions should consider other methods to ensure involvement from all family members, especially all smokers, including the possibility of providing incentives for each individual's participation and/or for confirmed abstinence from smoking.<sup>80-82</sup>

## **VI. LIST OF PRODUCTS**

### **Peer-Reviewed Articles**

1. Gehrman CA, Hovell MF. Protecting children from ETS exposure: A critical review. *Nicotine & Tobacco Research* 2003; 5:289-301.
2. Matt GE, Quintana PJE, Liles S, Hovell MF, Zakarian JM, Jacob P, Benowitz NL. Evaluation of urinary trans-3'-hydroxycotinine as a biomarker of children's environmental tobacco smoke exposure. *Biomarkers* 2006; 11(6):507-523.
3. Matt GE, Hovell MF, Quintana PJE, Zakarian JM, Liles S, Meltzer SB, Benowitz NL. The variability of urine cotinine levels in young children: Implications for measuring ETS exposure. *Nicotine & Tobacco Research* 2007; 9(1):83-92.
4. Liles S, Hovell MF, Matt GE, Zakarian JM, Jones JA. Parent quit attempts after counseling to reduce children's passive smoke exposure: main and moderating relationships. *Nicotine & Tobacco Research*, under review.
5. Hovell MF, Zakarian JM, Matt GE, Liles S, Hofstetter CR, Benowitz NL. Reducing children's ETS exposure and helping adults quit smoking: A combined behavioral counseling program. In preparation.

### **Presentations**

6. Nordahl Larson S, Jones JA, Rich CD, Hovell MF, Zakarian JM. *Healthy Tots Project– A case report of a smoking mom in the intervention condition*. Poster presented at the California WIC Association Annual Conference (Sacramento, CA), March 2002.
7. Zakarian JM, Liles ST, Hovell MF, Noderer ML, Valtulini S, Elchlepp MC, Jones JA. *Predictors of children's exposure to environmental tobacco smoke in the home*. Poster presented at the National Conference on Tobacco or Health (San Francisco, CA), November 2002.
8. Zakarian JM, Liles ST, Hovell MF, Valtulini S, Noderer ML, Elchlepp MC, Jones JA. *Effect of measurement on children's reported exposure to environmental tobacco smoke*. Poster presented at the National Conference on Tobacco or Health (San Francisco, CA), November 2002.
9. Jones JA, Hovell MF, Zakarian JM, Nordahl Larson S, Rich CD, Kerstetter DM, Shadoan-Ozbun CL, Yap BS. *Three case studies of smoking moms in the intervention condition of the Healthy Tots Project*. Poster presented at the National Conference on Tobacco or Health (San Francisco, CA), November 2002.
10. Hovell MF. *Reducing passive smoke exposure among disenfranchised families*. Poster presented at the National Conference on Tobacco and Health Disparities (Tampa Bay, FL), December 2002.
11. Hovell MF, Zakarian JM, Liles S, Jones JA, Concepcion, ME, Weisinger JA. *Predictors of children's exposure to environmental tobacco smoke in the home*. Poster presented at the Society for Research on Nicotine and Tobacco's 9th Annual Scientific Sessions (New Orleans, LA), February 2003.
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15. Nordahl Larson S, Rich CD, Jones JA, Hovell MF, Zakarian JM, Liles ST, Yap BS. *Healthy Tots Program to reduce children's passive smoke exposure and to help mothers quit smoking is endorsed by mothers*. Poster presented at the National WIC Association 2004 Annual Meeting (Anaheim, CA), April 2004.
16. Hovell MF. *Decreasing Children's ETS exposure in their home: The state of the science and lessons learned*. Invited presenter at The Smoke-Free Families Program, Phase III Grantees' Meeting, Robert Wood Johnson Foundation (Princeton, NY), September 30 –October 1, 2004.
17. Hovell MF. *Decreasing Children's ETS exposure in their home: The state of the science and lessons learned*. Invited presenter at Philadelphia FRESH Program meeting, University of Pennsylvania Transdisciplinary Tobacco Use Research Program (Philadelphia, PA), October 1, 2004.
18. Zakarian JM, Liles ST, Hovell MF, Hill LL. *A tobacco control intervention for low-income families with young children: Combined counseling for passive smoking and smoking cessation*. Poster presented at the 36<sup>th</sup> Union World Conference on Lung Health (Paris, France), October 2005.
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Figure 1. Flow of participants through the trial.

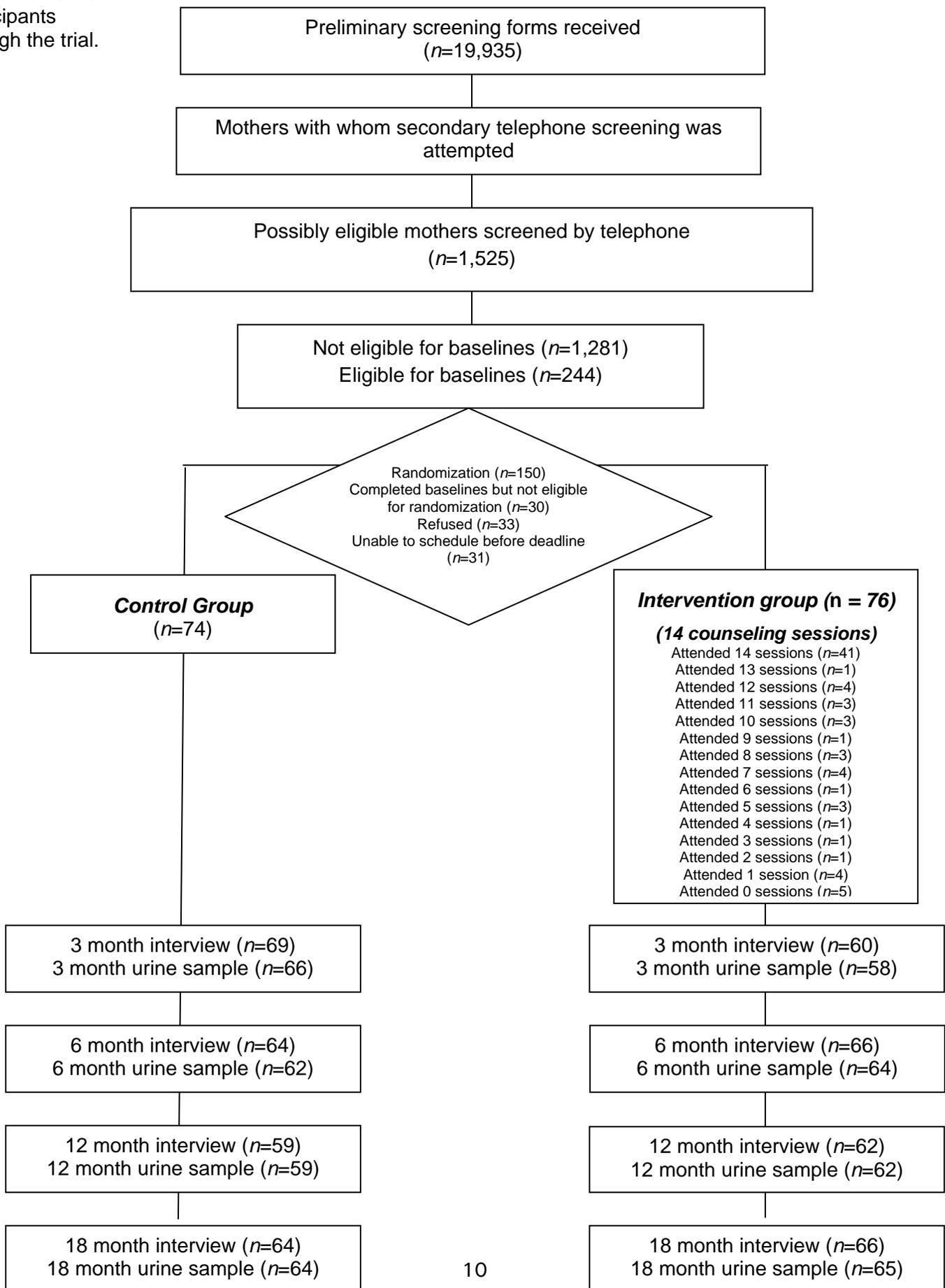


Table 1. Baseline characteristics of study participants. Values are numbers (percentages) or means (standard deviations).

Variable *	Intervention group (n = 76)	Control group (n = 74)
Mothers' racial/ethnic group		
non-Hispanic White	50 (65.8)	52 (70.3)
Hispanic	11 (14.5)	7 (9.5)
Black	8 (10.5)	5 (10.8)
Other	5 (6.6)	4 (5.4)
Asian or Pacific Islander	2 (2.6)	3 (4.1)
Children's gender (girls)	44 (57.9)	40 (54.1)
Single parent families	25 (32.9)	26 (35.1)
Employed mothers	25 (32.9)	28 (37.8)
Mothers' education:		
Less than high school or GED**	21 (27.6)	17 (23.0)
GED**	9 (11.8)	8 (10.8)
High school graduate	17 (22.4)	17 (23.0)
Trade school	2 (2.6)	1 (1.4)
Some college	23 (30.3)	27 (36.5)
College graduate	4 (5.3)	4 (5.4)
Home smoking policy		
No one allowed to smoke in home	23 (30.3)	16 (21.6)
Only special guests allowed	5 (6.6)	4 (5.4)
Only allowed in certain areas	31 (40.8)	38 (51.4)
Smoking allowed anywhere	17 (22.4)	16 (21.65)
Mothers' mean number of cigarettes smoked per day	10.6†	11.5†
Mother quit for 24+ hours past year	25 (33.3)	30 (40.5)
Mothers' mean age (years)	30.2 (6.9)	30.0 (7.4)
Children's mean age (months)	22.7 (13.9)	23.8 (12.3)

\* Pearson's chi-square analyses for categorical variables and ANOVA for continuous variables showed no statistically significant group differences (all  $p > .05$ ).

\*\* GED=Generalized equivalency degree

† These are geometric means and so do not include standard deviations. These estimates provide an indication of the levels in clinically meaningful units.

Figure 2. Validity correlations among biological, environmental, and reported measures of exposure and contamination.

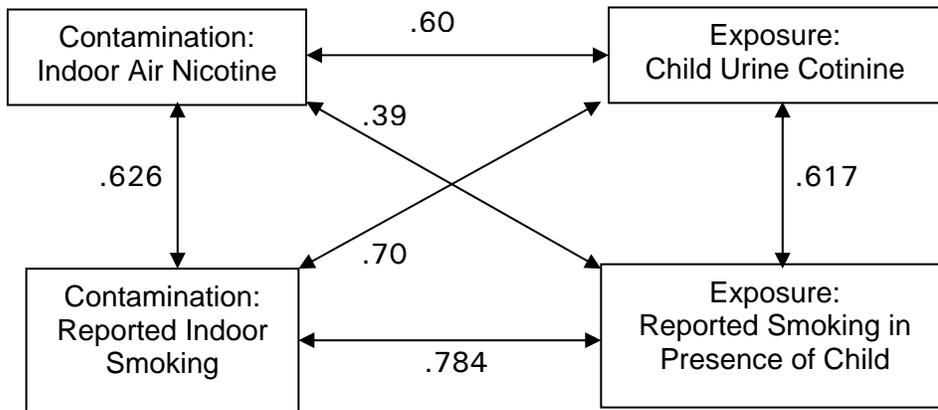


Table 2. Test-retest correlations for mothers' reports of indoor smoking and children's ETS exposure, and probability values for dependent t-tests comparing means.

Variable	<i>n</i>	<i>r</i>	Mean 1	Mean 2 (retest)	<i>p</i>
Mothers' smoking rate indoors at home (# cigs/day) *					
workdays	19	.67	1.30	1.32	.956
weekdays	39	.87	1.78	2.04	.271
non-workdays	17	.88	2.18	2.28	.761
weekend days	40	.77	1.87	1.65	.449
Children's ETS exposure at home from mothers (# cigs/day) *					
workdays	11	.54	1.68	1.15	.212
weekdays	21	.81	2.15	2.47	.436
non-workdays	13	.40	1.45	1.44	.987
weekend days	24	.82	1.95	1.79	.582

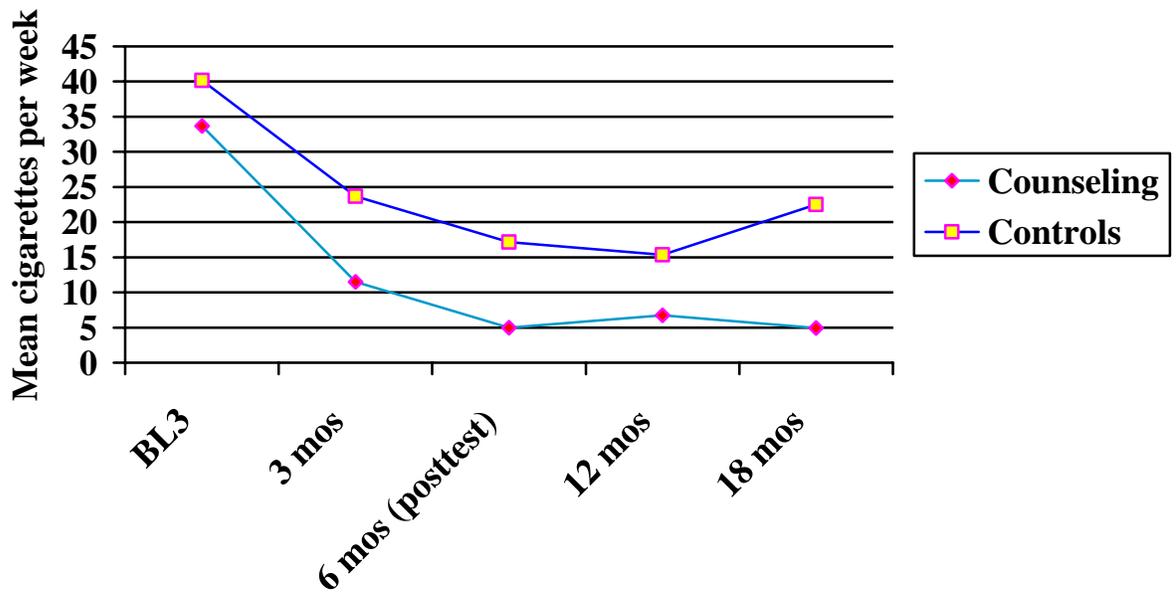
\* These geometric means provide an indication of the levels in clinically meaningful units.

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Table 3. Children's exposure to environmental tobacco smoke, indoor smoking, and mothers' smoking at baseline, mid-intervention, posttest, and follow-up measures. Values are geometric means for all variables except mothers' reported smoking.

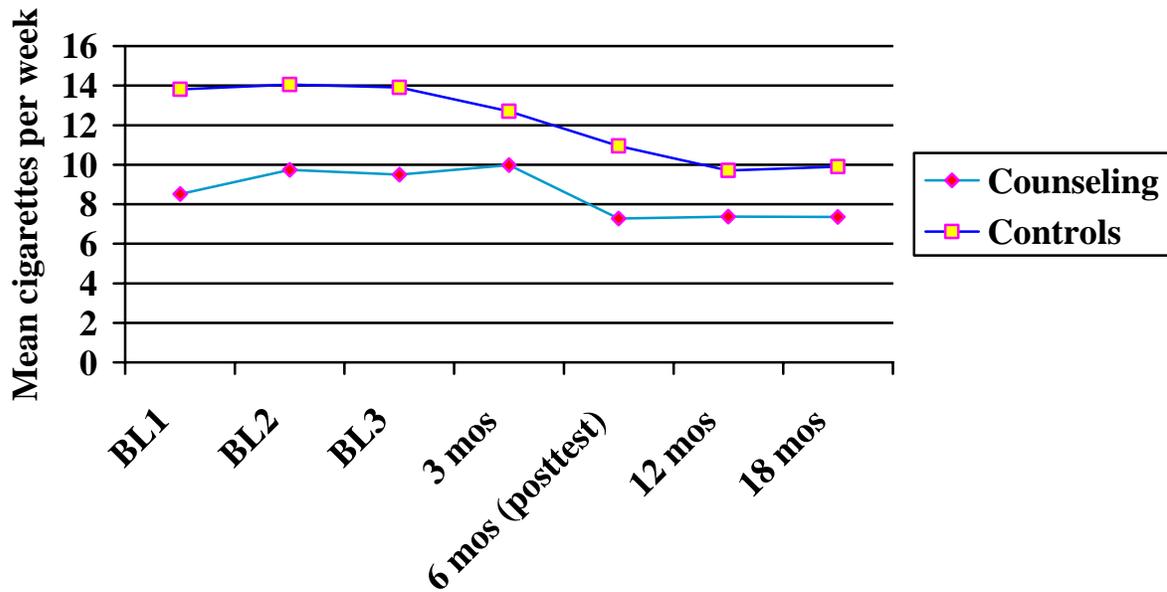
Variable	Baseline 1	Baseline 2	Baseline 3	3 months (mid- intervention)	6 months (posttest)	12 months (follow-up)	18 months (follow-up)
<b>Reported exposure to environmental tobacco smoke (number of cigarettes/week)</b>							
Exposure from mothers at home							
Counseled families			8.73	3.19	1.76	2.04	1.83
Control families			10.37	6.51	4.68	4.38	5.89
Total exposure from all smokers inside and outside the home							
Counseled families			33.67	11.51	4.99	6.74	4.94
Control families			40.17	23.68	17.16	15.33	22.49
<b>Children's urine cotinine concentration (ng/ml)</b>							
Counseled families	8.52	9.74	9.49	9.98	7.27	7.38	7.35
Control families	13.81	14.05	13.91	12.70	10.95	9.70	9.90
<b>Mothers' reported smoking (number of cigarettes/week)</b>							
Counseled families			89.23	77.2	58.53	69.79	77.47
Control families			93.58	89.35	88.83	90.77	92.13
<b>Reported smoking indoors at home (number of cigarettes/week)</b>							
From mothers							
Counseled families			15.84	6.64	3.51	4.09	3.55
Control families			18.81	10.34	8.72	9.55	9.94
From all smokers living in and visiting the home							
Counseled families			27.18	9.69	5.46	7.23	5.7
Control families			35.58	18.95	14.81	14.95	18.6

Figure 3. Children's total ETS exposure: Number of parent-reported cigarettes per week smoked in the same room or car as the child.



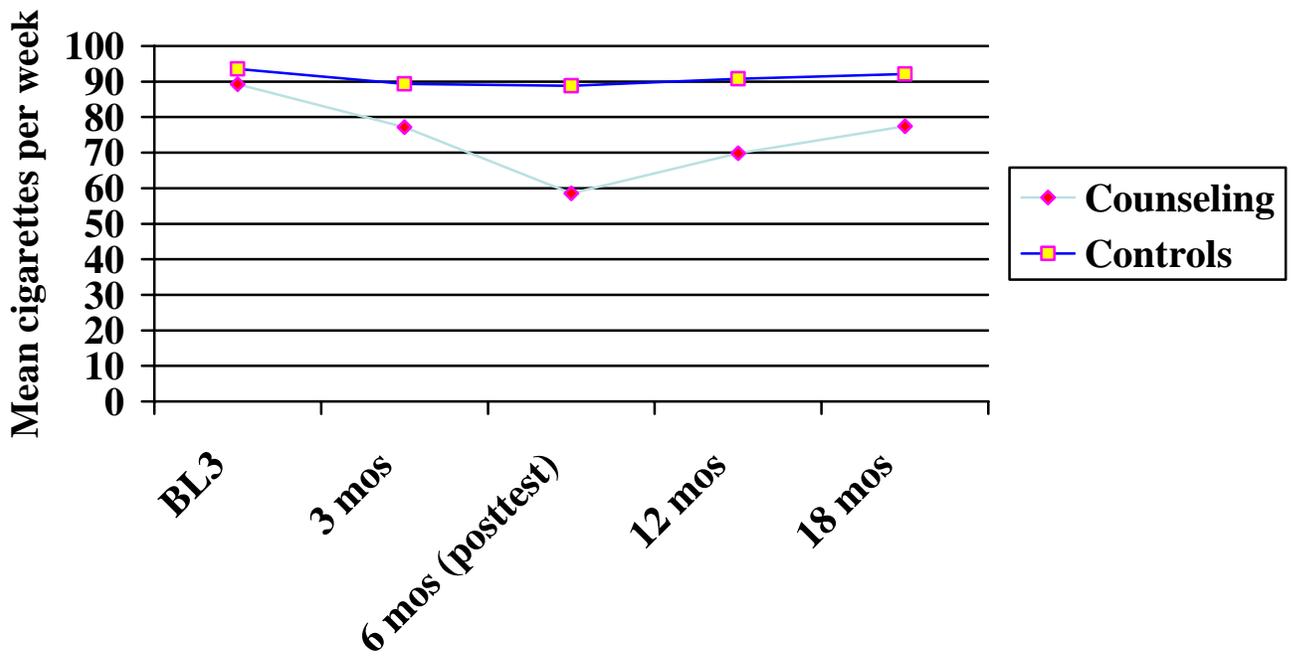
Baseline to 18 months: group  $p = .000$ , time  $p = .011$ , group by time  $p = .000$ .  
Baseline to 6 months: group  $p = .000$ , time  $p = .000$ , group by time  $p = .009$ .  
6 to 18 months: group  $p = .001$ , time  $p = .277$ , group by time  $p = .453$ .

Figure 4. Children's urine cotinine concentration (ng/ml).



Baseline to 18 months: group  $p = .007$ , time  $p = .001$ , group by time  $p = .323$ .  
Baseline to 6 months: group  $p = .059$ , time  $p = .072$ , group by time  $p = .349$ .  
6 to 18 months: group  $p = .026$ , time  $p = .660$ , group by time  $p = .426$ .

Figure 5. Mothers' reported smoking (number of cigarettes per week).



Baseline to 18 months: group  $p = .015$ , time  $p = 0.724$ , group by time  $p = 0.196$ .  
Baseline to 6 months: group  $p = .001$ , time  $p = 0.291$ , group by time  $p = 0.037$ .  
6 to 18 months: group  $p = .001$ , time  $p = 0.353$ , group by time  $p = 0.140$ .

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