

Reducing Tobacco Smoke Exposure in High-Risk Infants: A Randomized, Controlled Trial

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Objective To evaluate a hospital-initiated intervention to reduce tobacco smoke exposure in infants in the neonatal intensive care unit.

Study design A randomized, controlled trial compared motivational interviewing plus financial incentives with conventional care on infant urine cotinine at 1 and 4 months' follow-up. Mothers of infants in the neonatal intensive care unit (N = 360) who reported a smoker living in the home were enrolled. Motivational interviewing sessions were delivered in both the hospital and the home. Financial incentives followed session attendance and negative infant cotinine tests postdischarge.

Results The intervention effect on infant cotinine was not significant, except among mothers who reported high baseline readiness/ability to protect their infant ($P \le .01$) and mothers who completed the study within 6 months postdischarge (per protocol; $P \le .05$). Fewer mothers in the motivational interviewing plus financial incentives condition were smoking postdischarge ($P \le .01$). More mothers in the motivational interviewing plus financial incentives group reported a total home and car smoking ban at follow-up ($P \le .05$).

Conclusions Motivational interviewing combined with financial incentives reduced infant tobacco smoke exposure in a subset of women who were ready/able to protect their infant. The intervention also resulted in less maternal smoking postpartum. More robust interventions that include maternal and partner/household smoking cessation are likely needed to reduce the costly effects of tobacco smoke exposure on children and their families. (J Pediatr 2020;218:35-41).

Trial registration ClinicalTrials.gov: NCT01726062.

lthough rates of tobacco smoking have decreased overall in the US to 15.5% in 2016, nearly 40% of children aged 3-11 years, including 7 of every 10 black children, are regularly exposed to tobacco smoke. ^{1,2} Children exposed to tobacco smoke have diminished pulmonary function and are more likely to suffer from neurocognitive deficits, sudden infant death syndrome, and respiratory disease, including a 70% increased risk of incident wheezing and asthma.³⁻⁵ Infants who require neonatal intensive care incur even greater health risks from tobacco smoke exposure and have a greater need for respiratory care, ⁶⁻⁸ including longer respiratory-related hospitalizations. ⁹⁻¹¹ Acute respiratory disease is the most common reason for rehospitalization among infants discharged from the neonatal intensive care unit (NICU). 12

NICU hospitalization may be an optimal time during which to introduce a parent tobacco smoke exposure–reduction intervention, as motivation to improve health behaviors is high after the birth of an unexpectedly fragile, hospitalized infant.¹³ Research and development to create successful interventions may assist in offsetting the more than \$4 billion spent annually on infants in the NICU in their first year of life. 14 Systematic reviews continue to report no or small effects for child tobacco smoke exposure-prevention interventions conducted in either "well child" or "ill child" settings, particularly when outcomes

are biologically validated. 15,16 Studies that successfully have reduced child tobacco smoke exposure involved more intensive counseling approaches or motivational interviewing. 17-20 Our first study 21 and others 22 testing motivational interviewing to reduce tobacco smoke exposure among parents during NICU hospitalization supported the feasibility and potential efficacy of implementing

CO Carbon monoxide F1 1-month follow-up

F4 4-month follow-up Limit-of-quantification Midpoint of treatment

RR Relative risk

LOQ MP NICU Neonatal intensive care unit From the Departments of ¹Family and Community Medicine, ²Pediatrics, ³Psychiatry and Behavioral Science, McGovern Medical School at UTHealth, Houston, TX; ⁴Center for Behavioral Epidemiology and Community Health, School of Public Health, San Diego State University, San Diego, CA; ⁵School of Social Work, University of Texas, Austin, TX; ⁶Division of Environmental Health, School of Public Health, University of California, Berkeley, CA; ⁷Division of Environmental Health, School of Public Health, San Diego State University, San Diego, CA

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tobacco interventions in the NICU setting, yet indicated a need to boost the intervention effect.

Reinforcement for positive behavior in the form of monetary incentives is highly effective in changing behavior and has been implemented with tobacco-using populations, including pregnant smokers. ²³⁻²⁸ Financial incentives typically target tobacco abstinence. However, targeting attendance is also important, as inadequate exposure to interventions is often a primary explanation for failure ²⁹ and was a challenge in our initial trial, in which only 44% of parents in the intervention group attended the 2 hospital-based motivational interviewing sessions. ²¹

We conducted a randomized controlled trial of a motivational interviewing plus financial incentives intervention with families of infants in the NICU, which began during infant hospitalization and extended into the home postdischarge. The primary aim was to demonstrate lower infant tobacco smoke exposure upon discharge relative to conventional hospital care. Secondary aims included increasing participation among fathers or other household members, establishing home and car smoking bans, reducing parental smoking, reducing child healthcare use, and exploring prespecified effect modifiers (eg, readiness to act).

Methods

The Baby's Breath 2 trial used a parallel group, randomized controlled design. Eligible participants who completed a baseline interview were assigned randomly on a 1:1 to either motivational interviewing + incentives (motivational interviewing plus financial incentives) or a conventional care control (Figure 1; available at www.jpeds.com). A midtreatment assessment was completed approximately 2 weeks posthospital discharge, with follow-up at 1 and 4 months' post-treatment (on average, 2 and 6 months' postdischarge). Hospital and university institutional review boards approved the protocol. All participants provided written, informed consent.

Primary caregivers (N = 360) with an infant admitted to a large children's hospital NICU in Houston, Texas, were enrolled if they reported a smoker living in the home; lived within 50 miles of the hospital; and spoke English or Spanish. Participants with severe cognitive or psychiatric impairment were ineligible.

We used a computerized, SAS-run randomization procedure to assign participants to condition with maternal smoking status as a stratification variable to ensure comparability between groups. As with any behavioral treatment trial, participants were not blind to their treatment condition. Interventionists were not involved in assessment of outcomes. We conducted analyses blind to treatment group.

Interventions

In the motivational interviewing plus financial incentives group, participants received two 30-minute motivational interviewing counseling sessions in the hospital by masterslevel counselors. Partners and additional household members were encouraged to attend. Two additional counseling sessions, 2 weeks apart, were conducted in participants' homes beginning 2 weeks after NICU discharge. Motivational interviewing sessions targeted tobacco smoke exposure-protective strategies (eg, smoking outside), using health information, values, goal-setting, and readiness ruler exercises, similar to previous motivational interviewing protocols. 21,30-32 A personalized feedback letter also was developed and reviewed in session 3. Financial incentives were provided for attendance using a prize-bowl procedure in escalating fashion.³³⁻³⁵ The primary caregiver and up to 2 household members earned draws from a marble bag for each occurrence of the target behavior (ie, attendance). Color-coded marbles were associated with varying gift card magnitudes from \$5 to \$100. Each attended visit resulted in an additional draw (maximum = 4 draws per person at session 4). At the 2 postdischarge, in-home, motivational interviewing plus financial incentives sessions, participants earned a \$30 bonus gift card if their infant's cotinine dipstick test (TobacAlert, Nymox Corporation, Hasbrouck Heights, NJ)

Sessions were audiotaped and reviewed weekly for supervision and fidelity purposes. Session checklists assured adherence to the protocol. The primary supervisor was a member of the Motivational Interviewing Network of Trainers and coded all motivational interviewing sessions using the Motivational Interviewing Treatment Integrity 3.1.1 scale. Mean adherence ratings for primary Motivational Interviewing Skills (evocation, collaboration, autonomy/support, direction, and empathy) on a 5-point Likert scale ranged from 2.99 to 5.00 (1 = low; 5 = high), with an overall Motivational Interviewing Spirit mean of 3.06 (SD 0.46), indicating acceptable motivational interviewing integrity overall.

Participants in the conventional care group received 1 educational session in the NICU by research staff discussing the harms of secondhand and thirdhand tobacco smoke exposure. The conventional care session corresponded in time with the motivational interviewing plus financial incentives session 2, which were used for attendance comparisons. Partners and additional household members were encouraged via mothers to attend.

The primary outcome measure was infant urine cotinine level at the midpoint of treatment (MP), 1-month (F1), and 4-month (F4) follow-up. Cotinine (ng/mL) is an objective means of capturing tobacco smoke exposure from all potential sources, as well as change in tobacco smoke exposure across time. ^{15,37} Research staff adhered to standardized protocols for collection, storage, and shipping of urine for analysis. Published methods were used for quantifying cotinine with a limit-of-quantification (LOQ) of 0.05 ng/mL. ³⁸

Prespecified effect modifiers were investigated, including infant birth weight, race, total number of smokers in the home, and baseline readiness to protect infant from tobacco smoke exposure. A 1-item Contemplation ladder, ³⁹ adapted for tobacco smoke exposure, was used to measure readiness

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to keep infant from tobacco smoke exposure. The 11-point scale indicates at baseline parents' plans to keep their infant away from all sources of tobacco smoke exposure (0 = "No thought of or impossible to keep my child away from all smoking"; 10 = "Taking action now to keep my child away from all smoking").

Secondary outcomes included self-reported home and car smoking bans (multiple choice question reported previously)^{21,40}; air-nicotine levels, measured by passive sampling diffusion filters placed in each home at follow-up for both conditions⁴¹; maternal report of smoking around the infant using a memory-enhancing Timeline FollowBack procedure^{42,43}; self-reported maternal smoking status confirmed via carbon monoxide (CO) breath sample; mother-reported partner smoking status; father and other household members attendance at counseling sessions; and parent-reported infant healthcare use as measured by clinic and emergency department visits and hospitalization due to respiratory illness.

Statistical Analyses

Intention-to-treat analyses used all randomized participants. A final sample size of N = 316 was planned to provide 83% power assuming an effect size of Cohen d = 0.28, using a preplanned generalized linear mixed model, an intraclass correlation of 0.75, alpha = 0.05, and a 12% loss to follow-up rate. Analyses used SAS, version 9.4 (SAS Institute, Cary, North Carolina) and included the stratification variable maternal baseline smoking status. Cross-sectional and longitudinal analyses used generalized linear and generalized multilevel linear modeling, respectively. Analyses of cross-sectional dichotomous outcomes used Poisson regression with robust SEs to provide estimates of adjusted relative risk (RR). Longitudinal analyses of dichotomous outcomes used multilevel binary logistic regression. Cross-sectional analyses analyzed complete cases and longitudinal analyses used maximum likelihood estimation. Cotinine outcomes were logtransformed to improve model fit and analyzed continuously. Outcome values below the LOQ were imputed to a value 0.5 LOQ.

Results

Between October 2012 and June 2017, a total of 360 patients were enrolled in this study. A detailed description of recruitment and retention is presented in Figure 1. More than 95% of participants received both hospital-based motivational interviewing plus financial incentives sessions, with nearly 85% of the intervention group also receiving 2 home-based sessions. Follow-up rates ranged from 84% to 93%, despite the transient nature of the population (ie, approximately one-third of participants moved residences at least once during the study).

Participants on average were 26 years of age, with a high school education and primarily African American and Hispanic. Few were married; most were unemployed, using Medicaid insurance; and had 2-3 children. At baseline, approximately 20% of mothers reported smoking or had a positive CO-breath sample. Mothers reported that 78.7% of their partners (n = 310) were smokers. Approximately 50% of mothers reported having a smoking ban in both home and car at baseline. No group differences were found on baseline characteristics (**Table I**).

Cross-sectionally, treatment failed to demonstrate a direct effect on infant urine cotinine at MP, F1, or F4 (**Table II**; MP: F [1, 303] \leq 0.001, $P \leq$.98; F1: F [1, 290] = 0.12, $P \leq$.73; F4: F [1, 289] = 1.35, $P \leq$.25). Longitudinal evaluation of continuous infant urine cotinine values failed to find differential change over time as a function of treatment (F [1, 574] = 2.42, $P \leq$.12). When restricting the analysis to include only the subsample of participants who completed the protocol as intended (ie, within 6 months of posthospital discharge; n = 319), differential change over time as a function of treatment was demonstrated (F [1, 236] = 5.45, $P \leq$.02). Simple effects models within each treatment condition found that infant cotinine levels increased by 0.31%/d (P < .001) for participants receiving conventional care compared with no discernable change

Table I. Participant characteristics at baseline									
Variables	Motivational interviewing plus financial incentives (n = 182)	Conventional care (n = 178)							
Race/ethnicity, n (%)									
African American	117 (64.3)	111 (62.4)							
Hispanic	32 (17.6)	33 (18.5)							
White	19 (10.4)	19 (10.7)							
Other	14 (7.7)	15 (8.4)							
Currently working, n (%)	41 (22.5)	46 (25.8)							
Relationship status, n (%)	(-/	. ()							
Married	40 (22.0)	39 (21.9)							
Living together, not married	77 (42.3)	70 (39.3)							
Single, widowed, divorced	65 (35.7)	69 (38.8)							
Annual household income, n (%)	, ,	, ,							
<\$15 000	64 (35.2)	69 (38.8)							
\$15 000-\$24 999	36 (19.8)	30 (16.85)							
\$25 000-\$34 999	29 (15.9)	21 (11.8)							
\$35 000-\$44 999	14 (7.7)	15 (8.4)							
\$45 000-\$54 999	5 (2.8)	9 (5.1)							
>\$55 000	23 (12.7)	19 (10.7)							
Unsure	11 (6.0)	15 (8.4)							
Medicaid recipient, n (%)	158 (86.8)	155 (87.1)							
Maternal smoking, n (%)	37 (20.3)	32 (18.0)							
Current pregnancy	129 (70.9)	138 (77.5)							
unplanned, n (%)									
Age, y, mean (SD)	27.0 (5.9)	26.5 (5.9)							
Years of education, mean (SD)	12.8 (2.1)	12.5 (2.0)							
No. pregnancies, mean (SD)	3.4 (2.1)	3.0 (2.2)							
No. births, mean (SD)	2.6 (1.6)	2.2 (1.4)							
No. births that were	0.6 (0.8)	0.5 (0.8)							
premature, mean (SD)									
Infant birth weight, g, mean (SD)	2213.6 (932.8)	2230 (969.8)							
Gestational age at	33.7 (4.7)	33.9 (4.5)							
delivery, wk, mean (SD)		40.0 (70.7)							
Length of NICU stay, d, mean (SD)	43.4 (51.7)	42.3 (52.5)							

Table II. Infant cotinine means, geometric means, and IQRs by assessment time point											
	Mid-treatment		F1			F4					
Conditions	GM	IQR	M (SD)	GM	IQR	M (SD)	GM	IQR	M (SD)		
Motivational interviewing plus financial incentives Conventional care	1.41 1.31	2.08 2.06	4.76 (10.33) 5.24 (19.25)	1.76 1.56	2.05 2.44	5.94 (14.79) 6.64 (19.67)	1.60 1.85	2.55 2.28	5.86 (12.59) 8.09 (26.18)		

GM, geometric mean; M, raw mean.

over time for participants receiving motivational interviewing.

Although there was no evidence for differential treatment changes over time as a function of birth weight (F [1, 572] = 1.22, $P \le .27$), total smokers in the home (F [1, 570] = 1.07, $P \le .30$), or race/ethnicity (F [3, 568] = 0.14, $P \le .94$), subgroup effects were found for baseline readiness to protect infant from tobacco smoke exposure (F [1, 560] = 8.63, $P \le .003$). Among mothers with lower baseline motivation, groups did not differ on infant cotinine over time (F [1, 197] = 2.62, $P \leq .11$). Among mothers with greater readiness, infant cotinine differed over time as a function of treatment (F [1, 363] = 7.4, $P \le .006$). For mothers with greater readiness in the motivational interviewing plus financial incentives condition, infant cotinine values remained stable across time (P = .34), whereas for mothers with greater readiness in the conventional care condition, infant cotinine values significantly increased across follow-up by 0.29% per day (P = .005). For context, 65% of mothers chose a 10 on the 0-10 readiness scale (mean = 8.78, SD = 2.24). Finally, no relations were found between counselor competence/adherence (eg, Motivational Interviewing Treatment Integrity scores) and the primary outcome, infant cotinine.

Secondary Outcome Analyses

Attendance by mothers at motivational interviewing plus financial incentives session 2 was similar to that of mothers attending the one conventional care session (which served as the attendance comparison time point; 96% vs 97%, respectively). The motivational interviewing plus financial incentives intervention was successful, however, in increasing the attendance of fathers/partners relative to conventional care (32.7% vs 11.6%) ($\chi^2[1] = 21.52$, $P \le .0001$; RR 2.14, 95% CI 1.53-3.01). Increased attendance by other household members also was found for motivational interviewing plus financial incentives vs conventional care (43.1% vs 20.3%) ($\chi^2[1] = 21.52$, $P \le .0001$; RR 2.85, 95% CI 1.79-4.53).

Cross-sectional analyses failed to find effects for treatment at F1 on continuous log-transformed air-monitor values (F [1,250] = 0.02, $P \le .88$) or F4 (F [1,249] = 0.31, $P \le .58$). Longitudinal analyses failed to identify differential change over time (F [1,216] = 0.42, $P \le .52$).

Cross-sectional evaluation of total home and car smoking bans as a function of treatment found differences for MP ($\chi^2[1] = 6.40$, $P \le .01$) and F1 ($\chi^2[1] = 4.34$, $P \le .04$), but not for F4 ($\chi^2[1] = 0.01$, $P \le .97$) (**Figure 2**). The motivational interviewing plus financial incentives condition demonstrated a greater likelihood of reporting a total smoking ban at MP (RR 1.32, 95% CI 1.06-1.64) and

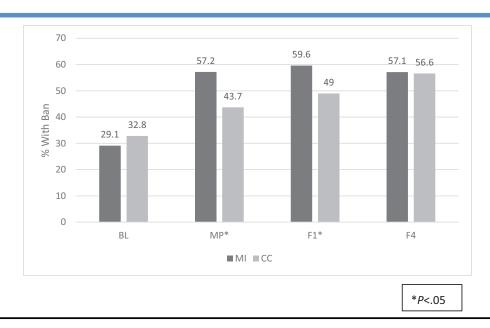


Figure 2. Percent of participants who reported a total home and car smoking ban. *BL*,baseline; CC, conventional care; MI, motivational interviewing plus incentives intervention.

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F1 (RR 1.24, 95% CI 1.01-1.52). Longitudinal analyses failed to identify differential change over time (F [1, 918] = 0.02, $P \le .88$).

Treatment differences for maternal report of infant to-bacco smoke exposure were found at F4 only ($\chi^2[1] = 5.77$, $P \le .02$), with motivational interviewing plus financial incentives showing reduced risk of tobacco smoke exposure relative to conventional care (RR 0.63, 95% CI 0.43-0.92). Longitudinal modeling of infant tobacco smoke exposure also found differential change over time as a function of treatment (F [1, 586] = 3.94, P < .05). Simple effects of time showed that for every additional day in study there was a decrease in the odds of tobacco smoke exposure for motivational interviewing plus financial incentives (OR 0.997, 95% CI 0.99-1.003) relative to conventional care (OR 1.005, 95% CI 0.999-1.010); however, neither estimate is different from zero.

Biologically confirmed maternal smoking differed as a function of treatment in cross-sectional analyses. Relative to conventional care, motivational interviewing plus financial incentives reduced the risk of CO-confirmed, maternal smoking at MP ($\chi^2[1] = 5.42$, $P \le .02$; RR 0.74, 95% CI 0.58-0.95), F1 ($\chi^2[1] = 8.27$, $P \le .004$; RR 0.68, 95% CI 0.53-0.88) and F4 $(\chi^2[1] = 4.79, P \le .03; RR 0.75, 95\% CI 0.58-0.97)$ (Figure 3). Longitudinal modeling of CO-confirmed maternal smoking status failed to converge, likely due to small cell sizes. Analyses failed to identify differences in partner smoking status as a function of treatment at MP ($\chi^2[1] = 0.12$, $P \le .73$), F1 ($\chi^2[1] = 0.11$, $P \le .74$), and F4 ($\chi^2[1] = 0.18$, $P \leq .68$). No group differences were detected in parentreported respiratory-related clinic visits, emergency department visits, or hospitalizations.

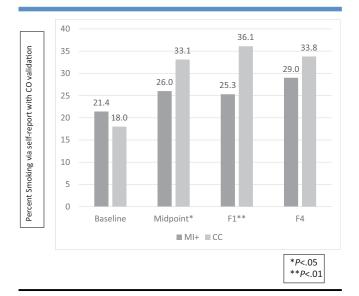


Figure 3. Percent of participants (mothers) who reported smoking with CO validation.

Discussion

The current study approached young, economically disadvantaged, primarily minority parents during their infants' NICU hospitalization and intervened to reduce child tobacco smoke exposure. Although overall this may be considered a negative trial, a number of important findings worthy of exploration resulted. The effect of the motivational interviewing plus financial incentives intervention was strongest among mothers who indicated at baseline they were ready and able to keep their infant away from all sources of tobacco smoke. Further, a large subset (89%) of infants of motivational interviewing plus financial incentives mothers who completed the protocol within 6 months postdischarge as scheduled (perhaps another indicator of readiness to act) also had lower biochemically confirmed infant tobacco smoke exposure relative to conventional care. In addition, mothers in the motivational interviewing plus financial incentives group reported greater rates of total smoking bans at mid-intervention and at the first follow-up and were less likely to be smoking at all postdischarge time points. Air nicotine levels, however, were not different between groups.

Mothers who indicated greater readiness and ability to actively keep their infants away from tobacco smoke exposure or who completed the protocol as planned benefited from the motivational interviewing plus financial incentives intervention. Yet, a smaller subset of unaffected families proved impervious to change. Readiness and/or the ability to protect ones' infant from tobacco smoke exposure may be influenced by external, contextual factors. For example, many young mothers lived with their parents or partners who were smokers and were powerless to change smoking policies in the home. More effectively engaging all household members may improve effects of child tobacco smoke exposure interventions.

Financial incentives improved the odds of mothers, partners, or other family members attending the intervention compared with previous studies without incentives²¹; however, the overall rates of attendance by non-mothers remained fairly low. Only one-third of partners and less than one-half of other family members attended sessions along with mothers, likely due to barriers to attendance such as employment, caring for other children, and family conflict. Overall, however, maternal exposure to the intervention was very high, and mothers in the motivational interviewing plus financial incentives condition who smoked benefited, indicating incentives were effective. Financial incentives are being adopted increasingly by community-based providers, including the recent national implementation of financial incentives for substance users in the Department of Veterans Affairs.44

Mothers in both arms of the study reported greater rates of smoking at follow-up relative to baseline, indicating postpartum return to smoking. Without specifically targeting relapse prevention, however, mothers in the motivational interviewing plus financial incentives group had lower biologically-confirmed smoking rates at each postdischarge time point, ie, postpartum relapse occurred at greater rates in the control condition. This is an important finding in that the most assured way to decrease child tobacco smoke exposure is to elicit smoking cessation among parents, 45,46 and few interventions specifically targeting postpartum smoking relapse have been found effective.⁴⁷ A large pragmatic smoking cessation trial⁴⁸ found the provision of free, evidence-based smoking treatments along with incentives significantly improved sustained abstinence over free cessation aids alone or e-cigarettes. Our study indicated that parents of children receiving NICU care are amenable to change and that directly providing smoking treatment with incentives may be a next step. Treatment strategies that can be effectively implemented in real-world settings are especially needed.46,49

Lack of stronger effect on the primary outcome in the full sample may be, in part, inherent to conducting the research itself. Pronounced measurement effects (ie, asking the control group numerous questions about tobacco smoke exposure–protection behaviors repeatedly throughout the study) have been identified in previous studies and clearly do not represent usual care. ^{29,50} Our first study of tobacco smoke exposure in the NICU²¹ included a reduced measurement condition that proved inferior to motivational interviewing and usual care (which were not different from one another) on tobacco smoke exposure outcomes. Few interventions may be powerful enough to override such effects. Design innovation is critical in future studies to detect intervention effects separate from measurement, to prevent the premature elimination of potentially effective treatments, particularly in such high-risk, high-need populations.

Infant healthcare use was not found to be reliably different across conditions, perhaps because of exclusive reliance on parental report for these data. The development of accessible, citywide hospital databases is underway for use in future studies. Also, air nicotine monitors, although sensitive to effects in other studies.⁵¹ have proven challenging in our NICU population. Participants and families appeared suspicious of these filters clipped to curtains and lampshades and were also highly transient; therefore, many monitors were discarded or irretrievable from vacated apartments. Also, only one active (and one dummy) monitor was used per home, perhaps decreasing our chances of an effect. Regardless, overall, this was a sufficiently powered study that enrolled a large sample and achieved high retention and follow-up rates, and high treatment integrity, with multi-method assessment of tobacco smoke exposure.

The burden of disease from tobacco smoke exposure is quite large, and among the largest burdens are infant/toddler lower respiratory infections and childhood asthma, ⁵² which are especially dangerous for already-weakened infants in the NICU. Parents who are dependent on tobacco are the primary source of child tobacco smoke exposure. ⁴⁶ The NICU is one setting in which to identify for intervention a young and

underserved population of women and families with high-respiratory-risk infants, and parents in the NICU, especially mothers, were amenable to change. Resources invested during infant hospitalization to reduce child and family tobacco smoke exposure have the potential to reduce health risks in medically fragile children as well as mothers and fathers in their child-bearing years, potentially saving years of quality life and millions in healthcare dollars.

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Data Statement

Data sharing statement available at www.jpeds.com.

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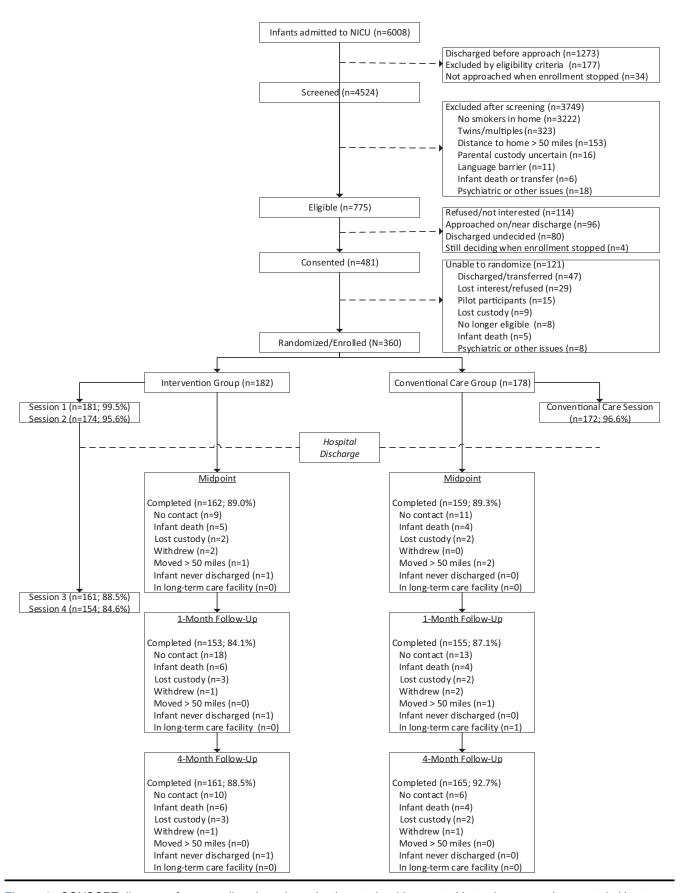


Figure 1. CONSORT diagram of a secondhand smoke reduction study with neonatal intensive care unit parents in Houston, Texas.

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