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Intervening with Smoking Parents of Inpatients to Reduce Exposure: The INSPIRE Randomized Controlled Trial

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Dr. Wilson conceptualized and designed the study, supervised the study procedures, oversaw data analysis, drafted the initial manuscript, and revised and edited the manuscript.

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Ms. Lowary designed the study, directed the study procedures, oversaw data management, and drafted, revised and edited the manuscript.

Ms. Gambino and Ms. Holstein recruited participants, collected data, managed the database, and revised and edited the manuscript.

Dr. Kerby designed the study, supervised study procedures, and revised and edited the manuscript.

Drs. Klein, Winickoff and Hovell conceptualized and designed the study, provided input into the study procedures and changes, and revised and edited the manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Conflicts of Interest Statement

The authors have no conflicts of interest related to this article to disclose.

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Abstract

Background: Hospitalized children have high rates of tobacco smoke exposure; parents who smoke may be receptive to interventions during their child's hospitalization.

Objective: We tested the efficacy of a smoking cessation intervention for parents of hospitalized children.

Methods: We conducted a randomized, single-blind clinical trial from 12/14–5/18 at the Children's Hospital Colorado. Hospitalized children who had a parent who smoked tobacco were eligible. Intervention: Intervention participants received motivational interviewing sessions, 2 weeks of nicotine replacement therapy; both groups received referral to the Quitline Consenting parents completed a questionnaire; urine was collected from the child for measurement of cotinine. Our primary outcome was: 1) increase in reporting "no one is allowed to smoke anywhere" in the home (smoke-free home rule). Additional outcomes included: 2) change in child's cotinine from baseline to 1 year, and 3) parental quitting at 1 year. Data were analyzed using Chi-square and t-tests for bivariable data, and multivariable logistic and linear regression.

Results: Of 1641 eligible families approached, 252 were randomized (15%); 149 families had follow-up data at 12 months (59%). In the adjusted analysis, there was no difference between the groups in smoke free home rules, or child cotinine level; in an intention-to-treat analysis, 15% in the intervention group vs. 8% of controls reported quit (p=0.07).

Conclusions: A smoking cessation intervention can be delivered to parents of hospitalized children. While hospitalization provides an opportunity to help parents quit smoking, more efficient and effective engagement strategies are needed to optimize tobacco control success.

Keywords

Smoking cessation; Secondhand tobacco smoke exposure; Clinical trials

Introduction:

Child tobacco smoke exposure (TSE) causes or contributes to a variety of illnesses, from acute otitis media,[1] asthma, bronchiolitis, and pneumonia, to sudden infant death syndrome.[2,3–6,7,8,9] While cigarette smoking rates in the US have declined significantly,[10] great disparities in smoking rates persist, with higher rates for those with lower incomes, and for young adults.[10] In 2014, 37.9% of children ages 3–11 years had biological evidence of TSE,[11] this was higher for those living in poverty (47.9%). Smoke free homes are an important, but not perfect, way to reduce children's exposure and they are associated with increased cessation rates.[12] In 2013 only 54% of smoking adults reported smoke free home rules, and this rate was much lower (36%) among 25–44 year olds, who are most likely to be parents.[13]

Approximately 40% of hospitalized children are exposed to tobacco smoke,[9,14–16] and parents may be more receptive to counseling in this setting.[17–20] The hospitalization of a

child represents an important opportunity to connect parents who smoke with cessation and exposure reduction resources and information.[17] Building cessation programs into pediatric hospitals represents an opportunity to expand access to services.

The 5As model of smoking cessation includes **asking** about tobacco use, **assessing** willingness to quit, **advising** the smoker to quit, **assisting** with cessation efforts, and **arranging** for follow-up.[21] Studies in the outpatient setting have demonstrated success in helping parents quit using the 5As, or Ask, Advise, Refer models.[22–26] Small studies in the inpatient setting have shown a consistent baseline cessation rate of 15–18%, but no significant impact from the intervention itself,[18,27] though a large scale quality improvement initiative was able to increase the percent of parents receiving an intervention.[28] Since there was limited evidence about the best way to intervene, we developed a 5As-based intervention designed specifically for parents of hospitalized children and completed a randomized, controlled trial to determine its efficacy. We hypothesized that our intervention group would have *1) increased report of a smoke free home rule (no one is allowed to smoke anywhere), and for our secondary hypotheses*, *2) increased parent quit rates*, *3) decreased reported child exposure*, and *4) decreased child exposure as measured by cotinine,* compared with our control group.

Methods:

Setting:

The study took place at Children's Hospital, Colorado from 12/2014–5/2018. Prior to the study, providers were encouraged to refer parents to the Colorado Quitline.

Enrollment and eligibility:

All children were screened for smoke exposure with the question: "Does anyone who lives in your home or who cares for your child smoke". Families of all children ≤17 years of age admitted to the hospital during the study period who screened positive for secondhand smoke exposure, who had at least one custodial parent who smoked and who spoke English or Spanish, and who were in the hospital for ≥24 hours were invited to participate in the study.

Ethics, consent and permissions:

We obtained written consent, and assent for children >6, for all study procedures. The Colorado Multiple Institutional Review Board approved the study. The study was overseen by a Data Safety Monitoring Committee, with no concerns raised.

Compensation:

We gave participating families $25 after completion of the baseline survey and child urine collection, and additional $25 upon completion of the 6 month follow-up survey, and $75 on completion of the 12 month follow-up survey and child and parent urine collections.

Families who resided more than 100 miles away were also provided reimbursement for mileage.

Baseline Procedures:

Baseline survey: After consent, the participant completed the baseline survey. We assessed pediatric TSE and parental tobacco using the standardized questions developed by the American Academy of Pediatrics/Julius B. Richmond Center of Excellence.[29] These questions include standard demographic information and information about other potential sources of exposure, and smoke-free home and car rules.[30] We asked about the child's health history, reason for admission, and primary care practice.

Baseline urine collection: We collected up to 50 mLs of urine from patients at enrollment using a specimen cup, hat, cotton balls placed in the diaper, a catheter (if already in place for routine care), or a urine bag applied by a trained study team member. Urine was stored at −80˚C and shipped to the University of California San Francisco (UCSF) for analysis of cotinine by liquid chromatography-tandem mass spectrometry.[31,32]

Allocation: After the survey was completed, the family was randomized using a block randomization scheme in REDCap to ensure balanced allocations. The research coordinator completing follow-up surveys was blind to the randomization group.

Provider Training: As part of the study, the INSPIRE team provided educational sessions to providers and staff; all were asked to reinforce the benefits of reducing exposure and quitting smoking for the health of the children.[33] To ensure that the control group received the standard of care, they received the Ask, Assess, and Advise components, and were also offered referral to their State's Quitline on enrollment.

All participants:

Ask: Any child with a positive screen was automatically provided a cessation coach consult order, and tobacco smoke exposure was added to the child's medical problem list.

Assess: A member of the research team performed an in-depth assessment of caregiver smoking behaviors, using our baseline survey tool.

Advise: Cessation coaches gave brief advice about the importance of quitting smoking and/or reducing their child's exposure.

Intervention arm only:

Assist:

Cessation coaches: We identified a diverse cohort of personnel to deliver brief motivational interviewing (MI), including respiratory therapists and research staff. Cessation coaches attended a 3–4 hour online or in person workshop on MI at the University of Colorado, and a 1-hour tobacco-specific MI training. For intervention parents, the cessation coaches offered daily brief (15–30 minute) MI sessions; our goal was 3–5 sessions, and these were done by phone after discharge. The maximum number was 10. MI directs the provider to help clients explore and resolve ambivalence to change, and to create their own goals for success;[34] MI and similar strategies have been demonstrated to decrease SHS among children.[35,36] Parents received information about protecting children from smoking in the home, including other

smokers, or visitors. For parents interested in quitting, we focused on resolving barriers, identifying triggers, promoting alternatives, and setting a quit date. The cessation coaches had ongoing practice sessions addressing different scenarios and assessing skills, as well as periodic in-person observation by study leadership. Intervention parents were also given a referral to their state's Quitline at the conclusion of their MI sessions.

Nicotine replacement therapy (NRT): We offered 14 days of free dual NRT (based on funding availability), with the patch, and lozenges or gum dosed according to number of cigarettes smoked per day. We provided standard guidance on NRT use from the package insert.

Arrange: The cessation coaches completed a discharge summary at the end of the child's hospital stay describing the interventions delivered to the parent.

6 Month follow-up: Parents completed a survey by phone, web, or in person at 6 months post discharge. The questions included those asked at the baseline and follow up questions about their child's health since discharge, and any additional visits for health care. We asked parents about their own quit attempts in the prior 6 months, and about their child's current TSE.

12 Month follow-up visit: At the final 12-month visit the parent completed another survey, with the same questions as at 6 months.

Follow-up urine collection: We collected approximately 30 mLs of urine from both the parent and child at 12 months. The child's urine was prepared and tested as at baseline at UCSF using liquid chromatography-tandem mass spectrometry. Parents provided a sample in a cup, which was tested for cotinine using chemiluminescent Immunoassay at the University of Colorado Laboratories.

Chart review: We completed a chart abstraction using Epic, including reason for admission and any complications. We classified the primary diagnosis as "respiratory illness" or "not respiratory illness" using Clinical Classifications Software Refined (CCSR) for *International Classification of Diseases, 10th Revision, Clinical Modification* (ICD-10-CM).[37]

Outcome measures: Our outcome measures were: *1) Parent report of having smoke-free homes 12 months after hospitalization as measured by questionnaire (**primary outcome**) with a response to the question "Where is smoking allowed in your home" with the answer "No one is allowed to smoke anywhere, 2) Decreases in child cotinine levels 12 months post-hospitalization as measured by child urine cotinine analysis; and 3) Parent quit rates 6 and 12 months after hospitalization as measured by questionnaire and confirmed by parent urine cotinine analysis at 12 months.* The cutoff for cessation was set as < 10 ng/mL.[31]

Sample size calculation: We *a priori* estimated sample size based on our primary specific aim. Overall, 30% of smoking parents in a British study had a home smoking ban in place.[38] Prior studies found increases in smoke free homes of 33%−42%.[38,39] Using a conservative estimate of a 15% increase in home smoking bans for the intervention group and 80%

power (two-tailed alpha=0.05), we planned to recruit 150 families per arm, for a total of 300 patients. Ultimately, we enrolled 252 hospitalized children, with at least one parent who smoked. This would have allowed us to detect a ~17% difference with 80% power (alpha=0.05) between intervention and control groups. [40]

Statistical analysis: Baseline characteristics were compared using Pearson's $\chi 2$ (Fisher's exact when appropriate) for categorical data and t tests or Wilcoxon rank sum tests for continuous variables. The number of motivational interviewing sessions was examined using descriptive statistics to assess intervention fidelity.

To compare changes in smoke free homes over time (primary outcome) between randomization groups, multivariable longitudinal logistic regression was used with an interaction term between time points (baseline and 12 months) and treatment group. Baseline demographics were chosen based on clinical importance and statistical association with outcome and added to the model as covariates ($p<0.1$).

To analyze child cotinine levels, single imputation was used for values below the limit of quantitation (LOQ), replacing those values <LOQ with LOQ/2. Children with differences in cotinine levels from baseline greater than 50 ng/ml were considered outliers. Regression analysis was performed with and without these outliers. Multivariable longitudinal linear regression with log transformed cotinine was performed with an interaction term for randomization group and time first, and again after adding covariates to the model. An analysis of only those with follow up for parent reported quitting (secondary outcome) was performed using multivariable longitudinal logistic regression. Confounders were chosen based on clinical importance and statistical association with outcome ($p<0.1$).

Three sensitivity analyses were performed. First, the potential effect of 5 outlying values was evaluated in the analysis of cotinine levels. Second, families who were unable to be reached at follow up were assumed to have not quit and were analyzed in the original group to which they were assigned for the primary analyses (intention to treat analysis, ITT). In the ITT analysis, cross-sectional multivariable logistic regression models were used assuming loss to follow up as not quit. Third, a sensitivity analysis of the intervention effect by confirmed quit based on cotinine level, parent report quit, and NRT/Ecig use was assessed by multivariable logistic regression. Since NRT or ECIG use could contribute to cotinine levels, these factors were used to further classify subjects who had high cotinine levels but self reported as quit. If NRT or ECIG was reported as used in these subjects, they were considered to be quit.

Other analyses included an agreement analysis of parent report with parent urinary cotinine levels, assessing kappa, Gwet's AC1, and percent agreement. Parent cotinine values was dichotomized with <10 as quit and values >=10 considered not quit. Agreement was interpreted based on the guidelines of Landis & Koch:[41] <0.2 poor, 0.21–0.4 fair, 0.41–0.6 moderate, 0.61–0.8 strong, >0.8 almost perfect. All statistical analyses were performed using SAS v9.4.[42] All statistical tests were performed as two tailed tests with a level of significance of 0.05.

Results:

Of 1641 eligible families approached, 263 enrolled in the study (16%), 11 withdrew prior to randomization; our CONSORT diagram is in Figure 1. There were 122 families allocated to the intervention group, with 74 (61%) with 12 month follow up, and 130 families allocated to the control group, with 75 (58%) with 12 month follow up. Some children were unable to produce urine during the study visit; samples were obtained from 214 at baseline and 106 children at follow-up, and there were 115 parents with cotinine values at 12 months. At the baseline assessment (Table 1) 73% of the intervention vs. 64% of control parents reported smoke-free home rules (p=.13), and there was no difference in the child's geometric mean cotinine level (1.0 ng/mL for the intervention group vs. 0.9 ng/mL for the control group; p=.70).

Intervention fidelity:

In the intervention group, 82% of the parents received motivational interviewing (the most common reason for not receiving was discharge prior to the cessation coach being able to engage). Parents receiving MI had on average 3.1 sessions (range 1 to 10), over an average of 5.5 weeks (range 1 to 23); the median total number of MI minutes was 452 (range 5 to 201). Most (59%) of the parents were given NRT, and 34% set a quit date at the first visit.

Outcomes:

In the unadjusted analyses, the primary outcome of smoke free home rules, at the 12 month follow up assessment, 75% of the intervention group and 73% of the control group reported smoke-free home rules (p=.74) (Table 2). For a secondary outcome of cotinine levels, geometric mean cotinine levels in both groups had increased, to 1.4 ng/mL in the intervention group and 1.6 ng/mL in the control group (p=.57). Of the parents who followed up at 12 months, 25% of those that received the intervention parents vs. 15% of those who received the control had quit smoking; p=0.13.

In the regression with interaction analyses, the primary analysis of the trial (Table 3) showed no effect of the intervention in the outcome of smoking ban, with a difference in the proportion of homes with smoking bans of 75% (95% CI: 70, 80) vs 76% (95% CI: 72, 81) in the intervention versus the control group at 12 months (p=0.23). In the secondary outcomes there was no evidence of an intervention effect with differences of 1.85 (95% CI: 1.35,2.54) ng/mL vs +1.35 (95% CI: 1.06,1.72) ng/mL (p=0.24) in the geometric mean cotinine levels at 12 months, and 25% (95% CI: 21, 29) vs 17% (95% CI: 14,20) (p=0.26) in the proportion of report quit at 12 months. When analyzed using an intention-to-treat analysis of parent report quit, showed no significant difference between treatment and control groups, with a difference of 15% in the intervention group vs. 8% in the control group in the proportion of parent report quit (p=0.07) (Table 4).

In the adjusted multivariable analyses with interaction all results were consistent with the primary analyses (Table 5). The adjusting covariates for each model are listed in Table 5. A sensitivity analysis performed without the 5 outlying child cotinine values was consistent with the results in Table 3 (results not shown).

For the agreement analysis, four subjects were confirmed as quit by urinary cotinine with values <=10ng/ml, and 13 subjects reported as quit but were not confirmed as quit. Overall, there was substantial agreement between parent report quit and confirmed quit by urinary cotinine (Gwet's AC1: 0.85 (0.74,0.96), percent agreement: 89%).

Discussion:

We fielded a randomized controlled trial of an evidence-based intervention to help parents of hospitalized children quit smoking and reduce their children's exposure, demonstrating the feasibility of offering a comprehensive hospital-based program for parents. The differences observed were not statistically significant in report of smoke-free home rules, child cotinine levels, or parent-reported quit status; in fact, smoke free home rules increased more in the control group. However, our intervention group had a trend towards higher quit rates, with clinically meaningful differences.

While we had planned our primary outcome as smoke-free home rules based on a 2012 study showing a prevalence of 30% among smoking parents in a UK study,[38] our baseline rates were much higher (68%). The prior study is also more consistent with the 36% smoke free home rule proportion in 24–45 year olds from the NYTS[13]. The high baseline SFH rates are a positive sign overall for children's smoke exposure, and may have been impacted by higher rates of smoke free home rules overall in Colorado, than in the national population.[43].

With the more conservative intention-to-treat estimate, we saw a 15% quit rate among intervention parents, compared to an 8% quit rate among controls (p=0.07, Table S2). This effect size is similar to the quit rate found in prior studies for inpatient interventions. However, the control group quit rate was much lower than the 20% found previously.[18] While it is likely that there was some follow-up bias, the differences between the groups in the more- and less-conservative analyses are similar. We believe that the intervention was successful in helping some of our parents quit smoking, and that it provided added benefit over Quitline referral alone. It is important to recognize that Quitline referral was rarely delivered as an intervention for families prior to this study; while we weren't structured to evaluate Quitline referral as a cessation tool, our study does suggest that it can be an effective, low-burden way to bring cessation services to inpatient settings.

We found that the cotinine levels were higher at follow up than at baseline, even when controlling for the number of smokers in the home, and time since last exposure. This finding highlights the challenge of reducing exposure even with cessation; further research is needed to understand the specific reasons behind this increase, such as parents who aren't answering honestly, or the off-gassing from third hand smoke.

Providing the MI was a challenge. Our initial reliance on respiratory therapists as cessation coaches became untenable during the winter, and we trained research staff to provide the intervention. There was large variation in numbers of sessions delivered and in number of minutes per patient. While they performed well according to our training and observed performance, we may have had better outcomes with experienced tobacco cessation providers.

While we didn't find a statistically significant impact from our intervention on smoking cessation, the hospitalization of a child remains a critical window of opportunity to address tobacco use and exposure. This study revealed some of the challenges with offering tobacco cessation to parents of hospitalized children, including finding personnel to do the counseling needed for success. Future research is needed on how to maximize the effectiveness of cessation interventions, and deliver them to more parents, at a cost that is manageable. Adding newer technologies such as automated referrals to Quitlines, smoke-free texting programs may help to refine the intervention for increased acceptability, lower cost, and improved effectiveness. Even in our study with NRT provided at no cost, we still had a significant proportion who did not receive it. While some insurance plans will cover NRT, not all do, and the cost can be significant. Offering NRT that is both free of charge and easy to obtain, especially during a child's hospitalization, could help more parents quit as well.

Limitations:

Due to time constraints, we were unable to meet our enrollment target of 300 dyads; this and the high rate of loss to follow-up likely limited our power to detect a difference in our outcome measures. It is likely that our population represents parents with more motivation to quit smoking than the overall population of smokers. The high rate of parents who were lost to follow-up may have limited our power to detect a difference in smoking rates; distance to follow up may have impacted this as well. While we did get MI and NRT to most of our participants, there was significant variation in the number of MI settings and total MI minutes, which may have biased our results to the null. In addition, the control group received 3 of the 5 intervention elements, including enrollment in the Quitline that also provided free NRT to parents, which may have blunted the differences between groups. Finally, we were unable to completely assess all sources of tobacco smoke exposure for both the parent and the child; both could have been exposed in other settings, and likewise thirdhand smoke can remain a reservoir for nicotine exposure even after smoke-free home rules are in place.[44]

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Conclusion

Pediatric hospitals are an important site for engaging parents in tobacco cessation. A 5As based intervention can be delivered to parents of hospitalized children, and may help some parents quit smoking. However, more efficient and effective engagement strategies are needed to reach all of the parents who need help quitting.

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Abbreviations:

TSE	Tobacco smoke exposure
NRT	Nicotine replacement therapy
MI	Motivational interviewing

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What's new:

We report the results of an RCT of a smoking cessation intervention for parents of hospitalized children; finding that delivering an intervention to parents in this setting is feasible, and we still need to improve cessation rates in this population.

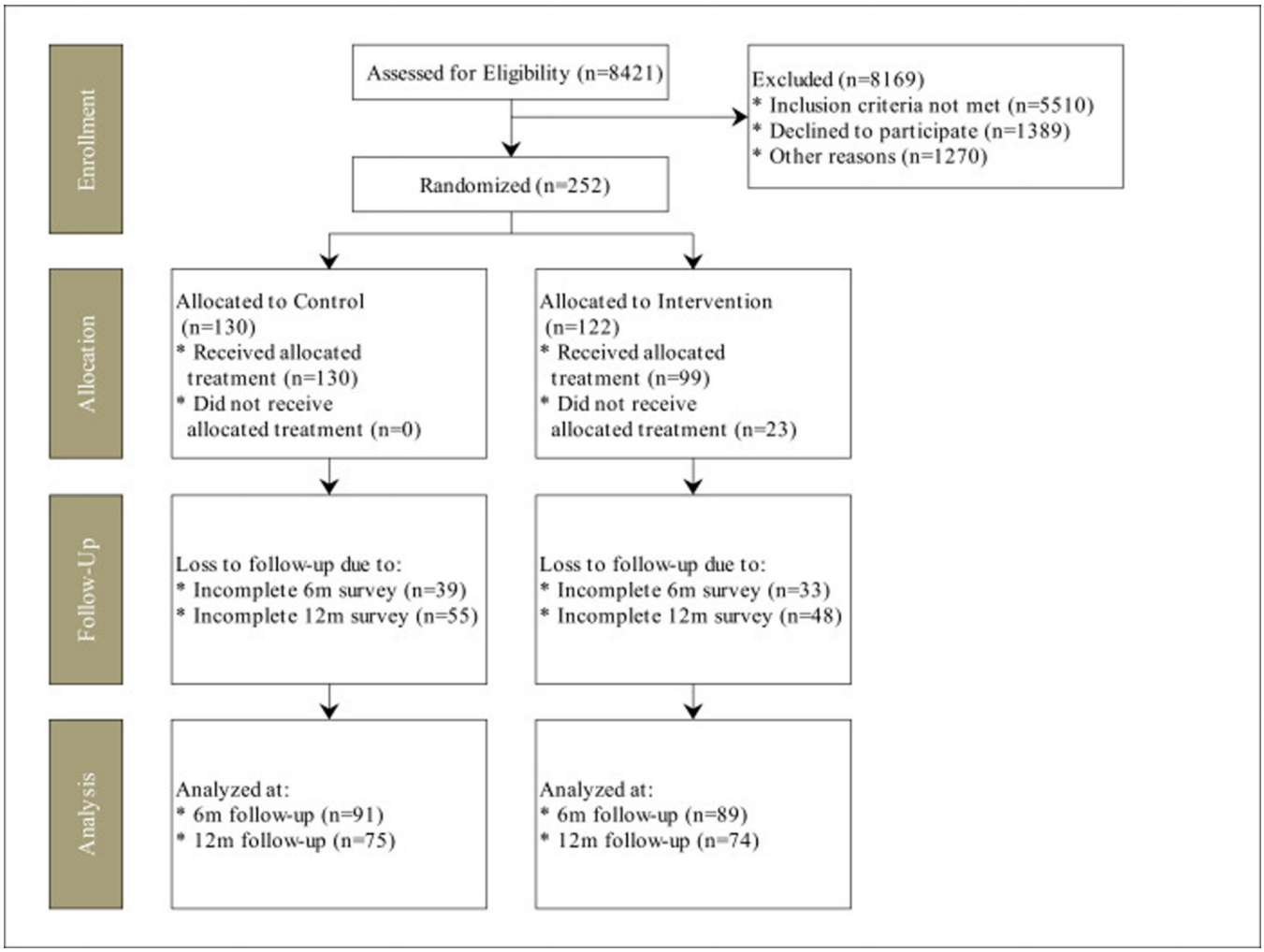

Figure 1.
CONSORT diagram for the INSPIRE Study

Table 1:

Baseline characteristics for control and intervention groups

Variables	Total (n=252)	Control (n=130)	Intervention (n=122)	P-value
Child's Gender				
Male	145 (58)	79 (61)	66 (54)	0.28
Female	107 (42)	51 (39)	56 (46)	
Age range of child				
Infants 0–1 yrs	72 (29)	34 (26)	38 (31)	0.72
Toddlers 1–2 yrs	54 (21)	31 (24)	23 (19)	
Preschool 3–4 yrs	27 (11)	15 (12)	12 (10)	
Grade school 5–12 yrs	76 (30)	40 (31)	36 (30)	
Teens 13+	23 (9)	10 (8)	13 (11)	
Race of child				
White	136 (54)	70 (54)	66 (54)	0.26
Black or African American	28 (11)	10 (8)	18 (15)	
Other	23 (9)	12 (9)	11 (9)	
Multiracial	65 (26)	38 (29)	27 (22)	
Ethnicity of Child				
Not Hispanic/Latino	158 (63)	78 (60)	80 (66)	0.35
Hispanic/Latino	92 (37)	51 (40)	41 (34)	
Subject's Relationship to Child				
Mother	170 (69)	86 (68)	84 (69)	0.77
Father	78 (31)	41 (32)	37 (31)	
Household income				
Less than $20,000	78 (34)	42 (36)	36 (33)	0.81
$20,001–$50,000	96 (42)	50 (42)	46 (42)	
More than $50,000	54 (24)	26 (22)	28 (25)	
Parent education				
Some high school or less	39 (16)	17 (13)	22 (18)	0.45
Grade 12 or GED (high school graduate)	64 (26)	37 (29)	27 (23)	
College 1 year to 3 years (some college)	119 (48)	63 (49)	56 (47)	
College 4 years or more (college graduate)	25 (10)	11 (9)	14 (12)	
Relationship status				
Married or member of a couple	154 (62)	80 (62)	74 (61)	0.77
Single (never been married)	62 (25)	30 (23)	32 (26)	
Divorced, widowed, separated	34 (14)	19 (15)	15 (12)	
Home ownership				
Own home	49 (21)	22 (19)	27 (24)	0.40
Rent home	180 (79)	93 (81)	87 (76)	
Housing type				

Variables	Total (n=252)	Control (n=130)	Intervention (n=122)	P-value
Stand-alone housing	151 (61)	76 (60)	75 (63)	0.67
Attached housing	96 (39)	51 (40)	45 (38)	
Government assistance for housing				
No	208 (85)	106 (83)	102 (86)	0.43
Yes	38 (15)	22 (17)	16 (14)	
Categorical hours child is out of the house				
0–10 hours	95 (45)	48 (43)	47 (47)	0.49
11–40 hours	76 (36)	44 (39)	32 (32)	
40+ hours	42 (20)	20 (18)	22 (22)	
Season of enrollment				
Spring(Mar-May)	71 (28)	37 (28)	34 (28)	0.92
Summer(Jun-Aug)	41 (16)	23 (18)	18 (15)	
Fall(Sep-Nov)	59 (23)	29 (22)	30 (25)	
Winter(Dec-Feb)	81 (32)	41 (32)	40 (33)	
Time to urine collection				
<=24 hours	38 (17)	18 (16)	20 (19)	0.54
>24 hours	180 (83)	95 (84)	85 (81)	
Parent's Age				
MEAN (STD)	32.0 (7.4)	32.2 (7.6)	31.8 (7.3)	0.69

Table 2:

Bivariate comparison on outcomes measures for the control and intervention groups

Time	Outcome	Total n(%)	Control n(%)	Intervention n(%)	P-value
Baseline		**n =252**	**n =130**	**n =122**	
	Smoke free home rule (Primary)				
	No one is allowed to smoke anywhere	165 (68)	79 (64)	86 (73)	0.13
	Smoking is permitted in some places/any where	77 (32)	45 (36)	32 (27)	
	Missing	10	6	4	
	Urinary Cotinine (n=214)				
	Geometric Mean (95%CI)	0.9 (0.8,1.1)	1.0 (0.8,1.3)	0.9 (0.7,1.2)	0.70
6 month		**n =180**	**n =91**	**n =89**	
	Smoke free home rule (Primary)				
	No one is allowed to smoke anywhere	130 (73)	66 (73)	64 (73)	0.98 (P)
	Smoking is permitted in some places/any where	49 (27)	25 (27)	24 (27)	
	Missing	1	0	1	
	Parent report quit				
	No	134 (79)	72 (83)	62 (75)	0.20 (P)
	Yes	36 (21)	15 (17)	21 (25)	
	Missing	10	4	6	
12 month		**n =149**	**n =75**	**n =74**	
	Smoke free home rule (Primary)				
	No one is allowed to smoke anywhere	109 (74)	54 (73)	55 (75)	0.74
	Smoking is permitted in some places/any where	38 (26)	20 (27)	18 (25)	
	Missing	2	1	1	
	Urinary Cotinine (n=106)				
	Geometric Mean (95%CI) *Parent report quit* No Yes Missing	1.5 (1.1,2.1) 112 (80) 28 (20) 9	1.6 (1.0,2.7) 58 (85) 10 (15) 7	1.4 (0.8,2.3) 54 (75) 18 (25) 2	0.57 0.13 (P)

Table 3.

Analysis of primary and secondary outcomes. Expected means of outcomes (95% confidence limits)[^]

Outcome	Time (Months	Control	Intervention	Pvalue[*]
Smoke free home rule	0	0.69 (0.65,0.73)	0.70 (0.66,0.74)	0.23
Smoke free home rule	6	0.77 (0.73,0.81)	0.71 (0.67,0.76)	
Smoke free home rule	12	0.76 (0.72,0.81)	0.75 (0.70,0.80)	
Cotinine	0	0.91 (0.75,1.10)	0.93 (0.75,1.17)	0.24
Cotinine	12	1.35 (1.06,1.72)	1.85 (1.35,2.54)	
Parent report quit	6	0.21 (0.18,0.24)	0.21 (0.18,0.25)	0.26
Parent report quit	12	0.17 (0.14,0.20)	0.25 (0.21,0.29)	

[^]Expected mean proportions are reported for smoke free home rule or parent report quit outcomes. Expected geometric means are reported for cotinine outcome.

[*]pvalue for interaction between time and randomization group. The model contains a term for time and the interaction between time and randomization group.

Table 4:

Parent self-report of quit (intention to treat)

Time	Variables		Control n(%)	Interventio n n(%)	P-value*
6 month			**n =130**	**n =122**	
	Do you consider yourself to now be quit?				
	No		115 (88)	101 (83)	0.20 (P)
	Yes		15 (12)	21 (17)	
12 month			**n =130**	**n =122**	
	Do you consider yourself to now be quit?				
	No		120 (92)	104 (85)	0.07 (P)
	Yes		10 (8)	18 (15)	

Table 5:

Multivariable regression analysis on outcomes measures

	Primary Outcome		Secondary Outcomes			
	home smoking ban[a],*		log cotinine[b],** ^		parent report quit at 12 months[a],***	
Predictor	Odds Ratio (95% CI)		Geometric Mean Ratio (95% CI)		Odds Ratio (95% CI)	
Randomization: Itvn vs Control	1.16 0(.60,2.23)		0.69 (0.41,1.16)		1.70 (0.73,3.95)	
Time: 12 mo vs baseline	1.35 (0.65,2.82)		1.63 (1.04,2.54)		0.847 (0.42,1.70)^^	
Time * randomization	0.96 (0.33,2.82)		1.55 (0.78,3.09)		1.21 (0.485,3.02)	

[a] Longitudinal Logistici regression

[b] Longitudinal Linear regression

* ***additional covariates in model include*** receiving government assistance for housing, car rules, allowing child to ride in car of smoker, and smoking in home in last 3 months

** ***additional covariates in model include:*** time spent outside home, number of smokers in home, exposed in last 24 hours, receiving government assistance for housing, car rules, allowing child to ride in car of smoker, smoking in home in last 3 months, number of cigarettes smoked per day, home owner, and attached/detached housing

*** ***additional covariates in model include :*** car rules and parent education

^ Excluding 5 subjects with extreme differences from baseline

^^ Reference category is 6 months