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Baby's Breath II protocol development and design: A secondhand smoke exposure prevention program targeting infants discharged from a neonatal intensive care unit

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Abstract

Background—Over one-third of all children live with at least one parent who smokes cigarettes, which is associated with compromised child health. The impact of secondhand smoke exposure (SHSe) in medically fragile infants born prematurely is likely to be much higher. The *Baby's Breath II* study tests whether a hospital-initiated, motivational-enhancement program will result in less SHSe relative to conventional care in high-risk, low birthweight (LBW) infants discharged from a neonatal intensive care unit (NICU). The design and protocol for the ongoing BBII trial is described.

Methods/design—Eligible participants are: (1) primary caregivers (typically mothers) of NICU infants who were born at LBW (<2500 g) or ventilated for more than 12 h; and (2) who smoke or live with at least one smoker. This randomized controlled trial has two conditions: Motivational interviewing plus incentives (MI+) and conventional care (CC). MI+ participants receive two hospital-based and two home-based counseling sessions, as well as incentives (i.e., prize-based draws) for (a) intervention attendance and (b) biochemical validation (i.e., urine cotinine dipstick) indicative of low or no infant SHSe. Participants in the control group receive conventional education-based care. Assessments are completed at baseline, mid-point, and 1- and 4-months post-intervention.

Discussion—This study is the first to determine the efficacy of a brief intervention for reducing SHSe among high-risk, LBW infants discharged from a NICU, with the potential for saving lives and healthcare costs. Strengths, limitations and challenges to the conduct of this trial are discussed.

Keywords

Secondhand smoke; Environmental tobacco smoke; Motivational interviewing; Contingency management

1. Introduction

Each year, about 5000 child deaths are attributed to tobacco exposure, which is 3 times the number of childhood cancers combined [1,2]. The impact of SHSe in medically fragile populations is likely to be much higher. Infants born prematurely and at low birthweights (LBW) who are admitted to a Neonatal Intensive Care Unit (NICU), often on mechanical ventilation for under-developed lungs, are especially vulnerable to the effects of SHSe [3–5]. National trends in the U.S. indicate a steady increase in preterm delivery and in LBW rates.

LBW infants and infants who required mechanical ventilation are vulnerable to SHSe for both social and medical reasons. These infants are often born in impoverished and minority populations; our own data indicate that the most disadvantaged families are least likely to have SHSe protective practices in place [6]. Smoking is more common among these groups and is known to decrease birth weight and increase the risk of neonatal respiratory problems, ultimately leading to disparate health and financial tolls [7,8]. Effective interventions to eliminate SHSe in LBW infants may reduce infant morbidity, mortality, and associated costs for infants at high respiratory risk (HRR), and may reduce tobacco-related health disparities.

Prolonged hospitalization in the NICU for LBW and other infants at HRR provides a unique opportunity to intervene with young adults when they may be motivated to change high-risk behaviors in preparation for their infants' discharge home. Providing effective SHSe interventions to parents via the NICU targets a younger, low-income, minority population among which smoking rates are higher and treatments are accessed less often relative to the general population. Results from our initial pilot trial (*Baby's Breath I*) indicated: (1) it is feasible to recruit parents to a SHSe prevention study in the NICU; (2) the majority of smokers are the fathers, however; (3) fathers and other household members are less likely to attend counseling sessions at the hospital; and (4) two sessions of Motivational Interviewing (MI) counseling in the hospital is insufficient to affect change in objectively measured household SHSe, although MI was associated with increased home smoking bans [9]. More powerful strategies targeting parental motivation are needed and have been included in the current efficacy design.

Specifically, motivational incentives targeting both intervention attendance and infant urine cotinine levels may be effective in improving outcomes of SHSe counseling with NICU parents. Reinforcement in the form of incentives for positive behavior is highly effective relative to other treatments in disadvantaged populations, including the promotion of smoking cessation during pregnancy [10,11]. Although not without controversy, multiple studies, including two meta-analyses, provide compelling evidence that positive reinforcement for attendance and/or drug abstinence leads to positive behavioral changes [10–13].

MI combined with incentives theoretically provides maximal impact on motivational targets. Emphasis on both external motivation (reinforcement for attendance and cotinine levels through financial incentives) and internal motivation (heightened recognition of personal goals and prospective planning through MI) in combination may exert maximal influence on SHSe behavior change as well as overall parental involvement, particularly among the

fathers who are most often the household smokers yet least likely to engage in treatment. Incentive-based programs are gaining acceptance and creative avenues to implement them efficiently are being explored (e.g., community donations) [14,15]. Motivational incentives have been combined with motivational interviewing in only one previous study to our knowledge, and with success [16].

The most successful SHSe reduction studies to date have used home-based counseling [17,18]. Home-based counseling allows for a more targeted focus on SHSe protective behaviors as they occur in the natural environment, which may increase the likelihood of change. Also, a recent meta-analysis of hospital-based smoking cessation interventions for adults indicated higher success rates for interventions extending into the first month post-discharge [19].

Thus, in this subsequent study, *Baby's Breath II (BBII)*, we propose to assess whether a 4-session MI protocol, including 2 *home-based* sessions, plus *motivational incentives* contingent on (a) mother's and father's attendance at counseling sessions; and (b) low or no infant cotinine (according to urine dipstick) will be efficacious in reducing infant SHSe, compared to conventional care (CC), among parents of NICU infants. This study conducted in a non-traditional setting for delivery of smoking treatments has 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. This paper outlines the BBII study design and protocol.

2. Design and method

BBII is a randomized, controlled trial comparing hospital- and home-based motivational interviewing plus incentives (MI+) with a conventional care (CC) condition. We hypothesize that relative to the CC group, MI+ will decrease infant SHSe as measured by infant salivary cotinine assays at 1 and 4 months post-intervention. We further hypothesize that the MI+ will reduce household *indoor* smoking compared to CC at 1 and 4 months post-intervention as measured by: (a) parental report of household smoking bans and number of cigarettes smoked in the home; and (b) air nicotine level ($\mu\text{g}/\text{m}^3$). Secondary hypotheses include: (1) Fathers and/or other household members receiving the MI+ intervention will attend counseling sessions more frequently than those in CC; (2) MI+ will decrease parental smoking compared to CC at 1 and 4 months post-intervention; and (3) MI+ will be associated with more positive infant health outcomes (e.g., respiratory illnesses, clinic and ER visits, hospitalizations, pediatric ICU admissions) relative to CC.

The study is funded by the National Heart, Lung, and Blood Institute (HL107404), was approved by the University of Texas Medical School at Houston Institutional Review Board, and is registered on clinicaltrials.org (NCT01726062). A certificate of confidentiality from the National Heart, Lung, and Blood Institute was also obtained.

2.1. Participants and eligibility criteria

Eligible primary caregivers of any age or ethnic background must: (1) have an infant that is at least 1 week prior to the estimated date of hospital discharge in the NICU at Children's Memorial Hermann Hospital (CMHH; ensuring time for the intervention); (2) have an infant born at 2500 g or less, or at high respiratory risk (HRR: received mechanical ventilation for >12 h; a criterion that avoids including ventilated infants who had minimal need for respiratory support); (3) report at least one person living in the home who smokes; (4) agree to attend intervention sessions and to invite other household members; (5) live within 50 miles of our center; and (6) have access to a telephone.

2.2. Setting and recruitment

As one of the largest NICUs in the U.S., the CMHH typically has over 1000 admissions annually to its 128-bed Level III NICU. All infant admissions to the NICU are screened for birth weight and ventilation status using electronic medical records (EMR). Primary caregivers, typically the mothers, are screened face-to-face in the NICU to identify households meeting eligibility criteria. Eligible primary caregivers are consented immediately following screening. Recruitment procedures are well-established from our initial pilot study [9].

2.3. Study course

The study timeline is depicted in Fig. 1. Following consent, a home-based, baseline assessment is scheduled which includes a face-to-face interview, self-report measures, carbon monoxide (CO) sample from the primary caregiver and surface wipe nicotine sample [20] from a surface (e.g., a wall or cabinet) in the home to assess level of indoor smoking. Interview and self-report measures are administered on encrypted laptops or tablets using the Audio Computer-Assisted Self-Interviews (ACASI) software, version 2.6.1, available from NOVA Research Company [21]. The self-report ACASI interview was audio-enabled for low-literacy participants and participants who wished to have the questions and responses read aloud to them.

After completing an in-home baseline assessment, participants are scheduled for a randomization visit at the hospital. Participants are randomized using an urn randomization macro program written using SAS 9.3, stratifying across groups on mothers' current smoking status (Yes or No) at the time of the baseline interview. MI+ participants complete their first session immediately following randomization. Research staff schedule the brief, CC education session on a later date corresponding with the MI+ session 2, to evaluate the secondary hypothesis regarding intervention attendance at a hospital-based, SHSe intervention. MI+ participants are scheduled for a second in-hospital session approximately 1 week after their first session. All participants are provided vouchers for parking or public transportation. Infants' EMRs are monitored daily for discharge dates. When possible, study staff members meet participants in the hospital on the day of the infant's discharge to remind them about upcoming study visits. MI+ sessions 3 and 4 are completed in the home at 2 and 5 weeks post-discharge. All participants receive a mid-point assessment at approximately 2 weeks post-discharge.

Follow-up assessments are completed at 1-month post-intervention, for proximal effects, and 4 months post-intervention for more distal effects. Longer-term follow-up will not be pursued in this first test of the novel intervention in order to conserve resources if indeed the intervention is not successful in producing even proximal effects. Approximately two weeks prior to the follow-up visits, a research staff member drives to a participant's home to hang an air nicotine monitor that measures indoor SHSe. The monitor is placed in the room where the participant reports that the infant spends the most time and remains hanging for at least two weeks before the follow-up appointment is conducted. Air nicotine samples were not collected at baseline because many parents are not residing at home or are at home very rarely while their infant is in the NICU, and infants with shorter lengths of stay would be discharged prior to monitor retrieval. Baseline group differences on level of indoor smoking will be assessed using surface wipe nicotine samples, which, if necessary, will be used as a covariate in subsequent analyses. All participants are compensated for providing baseline (\$30), midpoint (\$25), and follow-up data (\$40 at 1 month; \$60 at 4 months). Each assessment takes between 45 and 75 min to complete, with the midpoint and follow-ups taking slightly longer than the baseline.

2.4. Outcome measures

Baseline, midpoint, and follow-up interviews and questionnaires were designed to capture smoking behaviors and attitudes of household members, specifically the primary caregiver. See Table 1 for a representation of all administered measures by time point.

2.4.1. Secondhand smoke—Infant SHSe, the primary outcome, is assessed via biological, parental self-report and environmental sampling methods. Saliva samples will be collected from study infants at midpoint and follow-up assessments and analyzed for the presence of cotinine, a nicotine metabolite. Saliva cotinine analyses have a reported lower limit of sensitivity of .05 ng/ml, range of sensitivity of .05–200 ng/ml, and average intra- and inter-assay coefficients of variation of less than 5.8% and 7.9%, respectively [22]. Saliva samples are not collected at baseline as infants are protected from SHSe while in the NICU. The Timeline Followback, modified for infant SHSe [23,24], is a retrospective structured interview used to obtain continuous data regarding number of cigarettes smoked in the household and in the presence of the infant in the seven days prior to the interview day. Passive sampling diffusion filters attached to air monitors and clipped to curtains or lamps are used to measure household nicotine levels. Vapor-phase nicotine emissions from tobacco combustions have been established as a valid and reliable marker for passive smoke [e.g., 25]. Diffusion filters have been found to be an effective and relatively unobtrusive means of assessing household nicotine concentrations [26] and have been used in many SHSe intervention studies [e.g., 27]. Saliva cotinine analyses allow for quantification of the infants *total* SHSe. Air-nicotine collection provides estimates of SHSe in the infant's home. Thirdhand smoke (THS), i.e., tobacco pollutants that collect on surfaces, are assessed via surface wipe nicotine samples and will be used to control for baseline levels of indoor smoking. Surface wipe procedures provide decreased measurement reactivity relative to air monitors and may be less affected by other changes in the home (e.g., ambient temperature), providing an accurate estimate of indoor household smoking at baseline. Each outcome will be analyzed and interpreted separately as each is associated with unique error or bias in measuring infant SHSe and therefore not expected to be entirely consistent.

2.4.2. Infant health—Infant health outcomes will be based on parent report: The incidence of acute lower-respiratory illness reported by parents as having “cough, wheezing and rattling in the chest” &/or reported physician diagnosis during the interval since the last data collection time point. This definition has a sensitivity of 88% and specificity of 68% compared with a physician's diagnosis alone [28]. The prevalence of persistent lower-respiratory symptoms is defined as parents' reports that their infants “usually cough” or “occasionally wheeze.” Such symptoms have been associated with pulmonary function abnormalities and have been reduced in prevalence by at least one SHSe intervention [29].

2.4.3. Healthcare utilization—Assessment of health care utilization will include parent report and, when possible, medical record review of: (1) Acute care medical visits defined as any visit to a primary care or specialist physician's office due to respiratory symptoms or illness, or in which respiratory symptoms or illness are discovered; (2) Re-hospitalization defined as an admission requiring an overnight stay in the hospital [30]. Length of hospitalization and causes of re-hospitalization will be recorded as respiratory or other; (3) Emergency Department (ED) visits defined as any instance in which the infant is evaluated by an ED physician for respiratory symptoms or illness, or in which respiratory symptoms or illness are discovered; (4) Intensive Care Unit (ICU) admissions defined as any instance in which the infant is admitted to an ICU. Length of time in the ICU will also be documented.

2.4.4. Smoking and potential moderators—Smoking history and nicotine dependence measures, as well as additional secondary measures of potential moderators of treatment,

e.g. depression, stress, SHSe knowledge, self-efficacy, and social influence, are listed in Table 1.

2.5. MI+: motivational interviewing component

The MI component consists of: (1) two hospital-based, face-to-face sessions; and (2) two home-based sessions. Sessions will consist of 30–45 min of individual counseling using MI strategies. This format is based on previous SHSe studies and previous MI or Motivational Enhancement Therapy interventions [17,31] and attempts to balance intensity with potential for generalizability.

The proposed MI intervention is designed to promote protective behaviors by parents or other caregivers that will reduce infant passive smoke exposure. It is expected that parents with infants at HRR who are smoking will experience significant ambivalence regarding their behavior and potential for change. The desire to protect their infant will likely be in conflict with well-learned smoking habits often triggered by stress and negative affect, for example, caring for a sick child. The MI counselor capitalizes on strong parental desires for optimal outcomes, assists parents and families in resolving ambivalence by clarifying personal goals and values (e.g., infant health, family health), and amplifying the discrepancy between these goals/values and their current behavior (e.g., smoking). Other strategies include providing the client with specific feedback on his/her own situation and condition, emphasizing personal responsibility for change, and offering a menu of specific, cognitive and behavioral strategies for the parent(s) to use in changing their smoking behaviors. Other family and household members are specifically invited to attend and participate in counseling sessions. See Table 2 for a description of the treatment elements.

2.5.1. Counselor training and treatment integrity—Masters-level counselors were trained, using didactic and role-play methods, by expert MI coaches who have experience providing MI in multiple MI intervention studies. Several methods used in our previous trials, [e.g., 32,33], are used to ensure fidelity of intervention delivery. To monitor deviation or drift from the study protocol, all sessions, including pilot sessions, are audio recorded and listened to by the PI or MI coaches; remediation follows, if necessary. A checklist is used to serve as a cue for the counselor to provide each intervention component as designed, and is used to measure the “dose” of the intervention delivered to each participant. Independent raters rate randomly selected audiotaped samples using the Motivational Integrity Treatment Inventory [MITI; 34] to ensure treatment adherence.

2.6. MI+: contingency management (incentive) component

Contingency management, that is, reinforcement in the form of incentives for positive behavior, is highly effective relative to other treatments for substance use disorders, including the promotion of smoking cessation during pregnancy [10,11]. Multiple studies, including two meta-analyses, provide compelling evidence that contingency management leads to positive behavioral changes [10–13]. Motivational targets are most typically attendance in treatment and abstinence from the target substance, with larger effect sizes found for the latter [13].

Inadequate exposure to evidence-based, outpatient interventions is often a primary explanation for intervention failure [e.g., 18], and was a challenge in our initial SHSe pilot study in the NICU where about 30% of the intervention group failed to receive the 2 MI sessions in the hospital. Missed sessions result in lost opportunities to provide care, and in clinical trials, to evaluate treatment. Motivational incentives for attendance will increase exposure to the MI intervention which in turn will improve SHSe outcomes as well as our ability to evaluate the intervention.

One of the more promising methods for providing motivational incentives, colloquially referred to as the ‘fishbowl’ procedure, is the variable magnitude of reinforcement procedure [35,36]. Participants receive draws, often from a fishbowl containing slips of paper with labeled ‘prizes’, for achieving the target behavior (e.g., attending a treatment session or submitting a biological specimen negative for drug use). Each draw has a chance of winning a prize which varies in value, typically ranging from \$1 to \$100. The probabilities of winning prizes are inversely proportional to the magnitude of the prizes. Bonus draws can be given for consecutive session attendance or submission of a given number of consecutive negative specimens. This method has proven more cost-effective, and equally if not more effective, compared to other reinforcement-based methods [37].

In the current protocol, for each MI+ visit attended the participant, typically the mother, and up to two household members (ideally the father and one other) each earn draws from our attendance “fish bowl.” The attendance fishbowl has 100 marbles in it. A color system is used to denote the value of each marble (50 clear marbles = \$5, 20 blue marbles = \$10, 19 red marbles = \$25, 10 gold marbles = \$50, 1 clear marble with a flower inside = \$100), which are traded for giftcards equaling the total amount drawn. Participants and other attendees earn progressive draws for each session (i.e., one draw for attending one session, two draws for attending two sessions, etc.). Additionally, during the third and fourth home-based sessions parents are given a \$30 giftcard if their infant’s urine is free of cotinine, according to the urine cotinine dipstick (i.e., “TobacAlert”; available from Nymox Corporation, Hasbrouck Heights, New Jersey).

2.7. CC: conventional care

Currently upon admittance to the NICU, nurse case managers, or “Family Care Coordinators,” provide families with a packet of materials related to the care of their premature infants. On several pages of this packet there is information regarding the dangers of smoking and recommendations to not smoke around the baby or to quit. Prior to discharge Family Care Coordinators meet with patients’ families on at least two occasions on which they are provided infant care information, car seat instruction, and are also given a written sheet describing the dangers of secondhand smoke. The Fact Sheet presents health information such as, “...young children are particularly susceptible to secondhand smoke. Exposure to secondhand smoke is associated with an increased risk for SIDS, asthma, bronchitis, and pneumonia in young children.” Following randomization to this condition, study staff will schedule a separate educational session in order to reinforce messages in the packet and answer any questions about the materials. Thus, the CC condition consists of interactions with Family Care Coordinators (coordinated by hospital staff) and the educational session (i.e., CC Session in Fig. 1) coordinated by study staff, to ensure the material has been covered consistently for all CC participants. The CC will offer basic information about smoking, including treatment options, but will not directly provide motivational strategies or incentives. Evaluation of the extent to which CC was implemented will be monitored via session checklists and audiotaped sessions.

3. Statistical methods

3.1. Sample size

Power and sample size considerations for the current trial are based on expected differential changes in SHSe via cotinine analyses as a function of treatment. Pilot data [9] indicated that recruitment would yield $N = 396$ randomized families over 4 years of recruitment, with a 20% attrition rate in the follow-up period. Thus, we anticipate $N = 316$ in the final sample. Gerhman and Hovell’s [27] critical review of interventions for reducing childhood SHSe found a range of effect sizes (Cohen’s $d = -0.14$ to 1.04) with a mean Cohen’s $d = 0.34$. For

studies testing face-to-face counseling and reporting child cotinine outcomes, the mean Cohen's $d = 0.28$. Adding incentives to counseling is likely to substantially increase the effect size. To be conservative, however, we chose an effect size of Cohen's $d = 0.28$. Using a generalized linear mixed model with two follow-up measurement points, an intra-class correlation of $\rho = 0.75$, and $\alpha = 0.05$ (two-sided), the anticipated sample size ($N = 316$) provides 83.2% power.

3.2. Data analysis

All outcome analyses will be conducted on an intention-to-treat basis. Per-protocol analyses will also be conducted to evaluate relations between intervention dose and SHSe outcomes as well as father attendance and SHSe outcomes. Statistical analyses will be conducted using SAS v.9.3 (SAS Institute, Inc., Cary, North Carolina) and MPlus v.5.1 [38]. Between-group differences on continuous outcomes will be evaluated using one-way ANOVAs (Proc GLM). Count and dichotomous data will be examined using Poisson and logistic regression respectively (Proc GENMOD). Longitudinal analyses will employ generalized linear mixed models (GLMM; Proc GLIMMIX). Distributional assumptions will be evaluated using residual plots and, where possible, by formal statistical tests. Violation(s) of assumptions will be addressed through the use of transformations, robust estimators, and scaling coefficients. Outcomes occurring so infrequently that classical, frequentist analyses will be minimally informative (e.g., healthcare utilization and medical outcomes), will be evaluated in Bayesian fashion [39]. Differential patterns of missingness will be assessed using Little's Test of MCAR [40,41] approaches for continuous and discrete outcomes, respectively. Cross-sectional analyses with missing values will utilize multiple imputation [42]; Proc MI and Proc MIANALYZE). Longitudinal analyses will rely on GLMMs to maximize use of existing data. Non-ignorable missingness will be addressed through pattern-mixture modeling [43]. Robustness of findings will be evaluated using sensitivity analyses.

4. Discussion

National trends in the U.S. indicate a steady increase in preterm delivery and in LBW rates, particularly in lower SES populations. Studies of household smoking in very-low birth weight (VLBW: <1500 g) populations suggest substantially increased odds of asthma and wheezing [4,5], longer duration of hospitalization for respiratory symptoms [5] and reduced airflow and air-trapping in VLBW children [3,4] with a smoker in the home. While the adverse effects of SHSe in infants at much lower risk are well-documented, the effects of SHSe on infants discharged from NICUs is a neglected area of study, and to our knowledge no programs to reduce NICU infants' SHSe have been developed and tested.

The BBII protocol is an extension of our work with pregnant smokers [33,44–46] and informed by a previous pilot study in which a 2-session, hospital-based MI protocol was tested with parents of VLBW and/or ventilated infants [9]. While mothers who received the intervention reported higher frequencies of implementing a home smoking ban, objective air nicotine levels were not different between the intervention and control groups at follow-up. Intervening with NICU families proved to be challenging. In particular, it was difficult to engage fathers and other family members in the intervention, resulting in households divided on the importance and/or the methods of reducing household SHSe. The hospital-based sessions, while useful for educating families and increasing awareness of the dangers on infant SHSe, seemed less useful in producing actual behavior changes in the home. It was also clear that NICU families, typically of lower SES status, were facing numerous financial and social challenges, similar to women who continue to smoke through pregnancy. As in this population, the addition of incentives to stimulate external motivation may be the best way to draw attention to the seemingly less imminent problem of infant SHSe [10,11]. Thus, the pilot protocol was adapted to include two additional MI sessions conducted in the home

after the infant is discharged and motivational incentives (for each household member who wished to participate).

The protocol has a number of strengths. Gold-standard, randomized clinical trial methodology is used allowing us to draw strong conclusions on whether our motivational intervention is indeed superior to conventional care, consisting primarily of education. Outcome measures include biological and environmental samples for determining infant and household SHSe, rather than relying exclusively on parent self-report. Each SHSe measure has its own sources of error and thus using multiple methods will increase confidence in the findings. Multiple assessment time points allow for assessing change over time in the post-discharge period. With regard to the intervention, providing incentives for attending MI counseling sessions offers high probability of exposure to the intervention procedures from which we expect to see a reliable decrease in child SHSe. The intervention combines two evidence-based treatments for substance abuse and dependence. Theoretically, we expect the combination of MI and incentives to address the full range of motivational targets (internal and external) which in turn will promote behavior change. This will be the first RCT to test incentive-based treatments for reducing SHSe. Finally, specifically targeting fathers and other household members may improve the effectiveness of the intervention for reducing infant SHSe.

The study is not without limitations. A number of assessments are necessarily conducted in order to evaluate the effects of the intervention. Assessment alone, however, has been found to alter secondhand smoke protective practices in parents of young children [47], thus potentially diluting differential intervention effects. Also, the lack of formal admission procedures conducted by NICU staff precludes us from speaking with each family as their infant enters the NICU. Thus, while recruitment is expected to be strong, some infants will be discharged before study screening can occur; based on our pilot study this will be less than 8%. The nature of the target population, i.e., infants in a NICU, precludes variability in a pre-test measure of infant SHSe exposure, which complicates longitudinal analyses. Air monitor placement at baseline is not feasible as many parents are not residing at home or are at home very rarely while their infant is in the NICU. The current design also does not allow for the assessment of longer-term treatment effects 6-months or one year beyond intervention completion; we believe long-term follow-up at this point would be premature. Finally, with regard to intervention dissemination, the ultimate goal of developing and validating any behavioral treatment is to transfer the technology into community settings in which it can become mainstream treatment. While treatment providers generally agree with the concept of using incentives to promote behavior change, they often object to the cost and labor of implementing such programs [48]. The newer, lower-cost “fishbowl” method, to be used in this study, has helped to reduce these objections, and efforts to promote community adoption are underway in other areas [49,50].

Challenges to implementation are noted. Our pilot data indicate that NICU parents who are smokers are an extremely disadvantaged and underserved group. NICU parents face many competing demands, such as earning enough money to feed the family, figuring out how to physically get to the NICU to visit their baby, and, once home, caring for a medically fragile infant, not to mention the all too common stressors of unemployment, substance abuse, domestic violence and divorce. As such, participant compliance with the study protocol will be a challenge. Fortunately, knowledge and experience gained from our pilot trial allowed us to add protocol features to enhance compliance, such as parking and other transportation costs, and small baby gifts. We expect the home-based baseline assessment to also reduce resistance to future home-based visits.

5. Conclusions

The primary aim of this study is to develop and test an innovative intervention for reducing SHSe among high-risk, LBW infants discharged from a NICU, with the potential for increasing healthy life years and saving millions in healthcare dollars. This trial may also demonstrate a practical means of accessing young, minority and economically disadvantaged families, particularly fathers, for preventive services, who are unlikely to present to traditional clinics for such care. If effective, our intervention will reduce tobacco-related health disparities by reducing disease, emergency department visits, and re-hospitalization in these vulnerable infants.

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Fig. 1.
Study procedures and timeline.

Table 1

Study measurements by time point of administration.

Measure	Time points of administration			
	In hospital	Post discharge		
	Baseline	Midpoint	1 M	4 M
<i>General:</i>				
Participant & household characteristics	X			
<i>SHSe and THS:</i>				
Surface nicotine wipes	X			
Passive sampling diffusion filters (air monitors)			X	X
Saliva cotinine levels		X	X	X
Home and car smoking ban assessment	X	X	X	X
Timeline followback-infant SHSe		X	X	X
<i>Infant health measures & healthcare utilization:</i>				
Acute lower respiratory illness		X	X	X
Persistent lower respiratory symptoms		X	X	X
Acute care medical visits		X	X	X
Re-hospitalization		X	X	X
Emergency department visits		X	X	X
Intensive care unit admissions		X	X	X
<i>Household smoking:</i>				
Parental smoking	X	X	X	X
Number of household smokers	X	X	X	X
FTND (for participants who smoke) [51]	X		X	X
<i>Potential moderators:</i>				
Center for epidemiological studies, depression subscale [52]	X	X	X	X
Confidence to avoid secondhand smoke [53] ^a	X	X	X	X
Environmental tobacco smoke knowledge, attitudes & preventive efforts [54]	X			
Perceived stress scale [55]	X	X	X	X
Miles NICU perceived stress scale [56]	X			
Social influence of smoking [57]	X		X	X
Secondhand smoke aversion [58]	X		X	X

Note. SHSe = secondhand smoke exposure; FTND = Fagerstrom test of nicotine dependence.

^aAdapted for secondhand smoke by authors.

Table 2

Motivational interviewing (MI) session elements.

Session # (location)	Session content
Session #1 (hospital)	<ol style="list-style-type: none"> (1) Describing the overview of the program and motivational interviewing style^b (2) Building rapport and gathering general information (3) Assessing current motivation for reducing infant and family secondhand smoke exposure (4) Evaluating personal values and discussing importance related to decreasing secondhand smoke exposure (5) Discussing current household/car practices and policies regarding smoking (6) Assessing current knowledge and education on the effects of secondhand and thirdhand smoke^a exposure on infants and children using “Elicit-Provide-Elicit” approach^b (7) Eliciting a change plan regarding household/car smoking practices and/or smoking cessation if readiness for change is high (8) Giving informational brochures on secondhand and thirdhand smoke
Session #2 (hospital)	<ol style="list-style-type: none"> (1) Re-establishing rapport (2) Reviewing any changes discussed previously regarding household/car smoking, as well as progress with regard to smoking cessation, if applicable (3) Providing personalized feedback about smoking from objective measures (4) Assessing importance and confidence with regard to the house/car smoking ban using scaling techniques to elicit change talk (5) Developing a more detailed goal setting and change plan and identifying action steps as appropriate (6) Identifying strategies that may be useful in achieving goals, and barriers that may impede progress
Session #3 (home)	<ol style="list-style-type: none"> (1) Discussing general changes that have occurred since the infant has been home (2) Re-discussing household/car practices and policies regarding smoking and any changes that have occurred to those practices since the infant has been home, as well as progress toward smoking cessation if applicable (3) Assessing readiness for change with regard to the house/car smoking ban using scaling techniques to elicit and reinforce change talk and commitment language^b (4) Assessing and practicing assertiveness skills related to asking others not to smoke in the home or car (for those that are high in readiness to begin/maintain a smoking ban in the house/car) (5) Focusing on additional motivation building by discussing thoughts on smoking and how it relates to the infant; modifying or exploring additional change goals (6) Exploring barriers to change and problem solving as needed (7) Collecting and testing infant urine for cotinine with a dipstick measure and providing monetary reinforcement for a negative test result
Session #4 (home)	<ol style="list-style-type: none"> (1) Determining the participant’s needs, related to smoking, for the last session (2) Discussing any changes that have occurred since the last session (3) Reviewing the goal setting and change plan and making modifications, if necessary (4) Identifying effective, individualized strategies for the home and family (5) Strengthening support and interpersonal interaction in the household with regard to smoking behaviors (6) Building self-efficacy of participants and household members for maintaining the house/car smoking ban (7) Discussing future plans to minimize secondhand/thirdhand smoke exposure and/or to quit smoking (8) Identifying future barriers that may make it difficult to maintain the house/car smoking ban (9) Collecting and testing infant urine for cotinine with a dipstick measure and providing monetary reinforcement for a negative test result

^aThirdhand smoke: Tobacco smoke toxins or pollutants that linger because they are absorbed by surfaces, such as walls, floors, carpets, upholstery.

^bRollnick, S., Miller, W.R., Butler, C.C. (2008). *Motivational Interviewing in Health Care*. New York: The Guilford Press.