ELSEVIER

Contents lists available at ScienceDirect

## **Contemporary Clinical Trials**

journal homepage: www.elsevier.com/locate/conclintrial

## A tailored video intervention to reduce smoking and environmental tobacco exposure during and after pregnancy: Rationale, design and methods of Baby's Breath

Patricia Markham Risica, DrPH<sup>a,b,c,\*</sup>, Adam Gavarkovs<sup>b</sup>, Donna R. Parker, Scd<sup>a,d,e</sup>, Ernestine Jennings, PhD<sup>f,g</sup>, Maureen Phipps, MD, MPH<sup>a,h,i</sup>

<sup>a</sup> Department of Epidemiology, Brown School of Public Health, Brown University, Providence, RI, United States

<sup>b</sup> Department of Behavioral and Social Sciences, Brown School of Public Health, Brown University, Providence, RI, United States

<sup>c</sup> Institute for Community Health Promotion, Brown School of Public Health, Brown University, Providence, RI, United States

<sup>d</sup> Memorial Hospital of RI, Center of Primary Care and Prevention, Pawtucket, RI, United States

<sup>e</sup> Department of Family Medicine, Warren Alpert Medical School of Brown University, Providence, RI, United States

<sup>f</sup> Center for Behavioral and Preventive Medicine, The Miriam Hospital, Providence, RI, United States

<sup>g</sup> Department of Psychiatry and Human Behavior, Warren Alpert Medical School of Brown University, Providence, RI, United States

h Department of Obstetrics & Gynecology, Warren Alpert Medical School of Brown University, Providence, RI, United States

<sup>1</sup> Women & Infants Hospital of Rhode Island, Providence, RI, United States

#### ARTICLE INFO

Article history: Received 6 July 2016 Received in revised form 28 October 2016 Accepted 29 October 2016 Available online 04 November 2016

Keywords: Smoking Cessation Environmental Tobacco Smoke Exposure Pregnancy Prenatal

### ABSTRACT

Low-cost interventions to decrease environmental tobacco smoke (ETS) exposure of pregnant women and their newborns are needed to lower health risks of exposed fetuses and infants. Baby's Breath is a tailored video intervention developed and tested in a randomized controlled trial. The study aimed to test the efficacy of tailored video versus usual care approaches to reduce the ETS exposure of fetuses of low-income women during and after pregnancy; and to assess this intervention separately among non-smoking and smoking women. Participating women, recruited early in pregnancy, who spoke English, were at least 18 years old, smoke exposed (current smokers, quit smoking on their own, or were exposed to smoke of others), pregnant with only one baby, and had access to a telephone and video player, were randomized to experimental or control conditions. Intervention participants received newsletters containing content aimed at smoking cessation and avoidance (5 during and 3 after pregnancy), in addition to videos (3 during and 2 after pregnancy) individually tailored on behavioral theory-based survey questions. Comparison participants received newsletters and videos on healthy pregnancy topics. Outcomes included salivary cotinine of both mother and baby (32 weeks gestation and 6 months postpartum) as well as self-reported ETS exposure and avoidance behaviors. This study may demonstrate the efficacy of a low-cost intervention to decrease ETS exposure, and will fill an important gap in describing the utility of this innovative intervention technology, as well as demonstration of potential benefits to this type of intervention. © 2016 Published by Elsevier Inc.

1. Introduction

Environmental Tobacco Smoke (ETS) is associated with increased risk of several deleterious health outcomes, especially for pregnant women and infants [1]. ETS, can be emitted from the end of a cigarette,

E-mail addresses: Patricia\_risica@brown.edu (P.M. Risica),

adam\_gavarkovs@brown.edu (A. Gavarkovs), Donna\_Parker@brown.edu (D.R. Parker), ernestine\_jennings@brown.edu (E. Jennings), Mphipps@wihri.org (M. Phipps).

pipe, or cigar, or exhaled by a smoker [2]. Infants are especially vulnerable as the particle size of ETS is much smaller than mainstream smoke, which can more easily penetrate an infant's airway [3]. Additionally, fetuses can be exposed to the harmful chemicals found in ETS in utero [3].

ETS exposure of pregnant women or infants is related to the development of several deleterious pregnancy outcomes including reduced fertility [4], ectopic pregnancy [4], stillbirth [4,5], low birth weight [4, 6], sudden infant death syndrome [1,4,7], as well as infant/child asthma and allergies [1,3,7,8], poor lung function [1,7], and lower respiratory tract infection [1,3,7]. Also, children whose parents smoke are more likely to smoke themselves later in life [5,9,10].

These health outcomes are particularly concerning given that an estimated 10% of women in the United States smoked in the last 3 months of pregnancy, and of those who quit smoking during pregnancy 40%



Abbreviations: ETS, Environmental Tobacco Smoke; TV, Tailored Video; UC, Usual Care; SCT, Social Cognitive Theory; TTM, Transtheoretical Model; DVD, Digital Versatile Disk; VCR, Video Cassette Recorder; WIH, Women & Infants Hospital; MHRI, Memorial Hospital of Rhode Island; WPCC, Women's Primary Care Center.

<sup>\*</sup> Corresponding author at: Brown University, Box G-121S, Providence, RI 02912, United States.

relapsed within 6 months after delivery [11]. Also, many women who quit smoking during pregnancy continue to be ETS exposed. Those below the poverty level and with lower levels of education are more likely to smoke cigarettes [12]. Efforts to reduce ETS exposure during pregnancy are needed, especially in vulnerable populations.

Behavioral strategies to improve the parent's ability to reduce ETS in their home may contribute to reduction of ETS during and after pregnancy according to a review of intervention strategies aimed at this important time period [13]. Several previous interventions have utilized these strategies to reduce the ETS exposure of pregnant women and infants [2,14]. In fact, all five clinical interventions to reduce ETS exposure in pregnant women included in a review by Tong and colleagues were characterized as psychosocial interventions, with four explicitly including a counseling component [15]. Furthermore, all five interventions illustrated positive outcomes, which included a mix of biochemical and self-report exposure measures across studies. Intervention content has been delivered through a variety of mediums, including in-person conversations, telephone calls, and face-to-face support [14,16,17].

Tailoring has been demonstrated as an effective component of health message delivery. Many previous interventions tailor behavior change content using direct personal interface [18], though the involvement of a trained, professional staff at the time of delivery might not be feasible due to logistical or resource-related factors. Few studies have utilized non-personal tailored communications in ETS reduction interventions. In lieu of personal contact, "Expert Systems," are computer programs with established tailoring algorithms that tailor message content to an individual based on their responses to a questionnaire or other input measure [19,20], which have been utilized in the smoking cessation field with demonstrated effectiveness [21–23]. However, to our knowledge, there have been no published interventions that have used an expert system to develop tailored videotapes as a means to deliver an ETS exposure intervention.

Therefore, the purpose of this paper is to describe the intervention development, protocols, and measures used for the 'Baby's Breath' research study. Formative research, intervention design, and evaluations methods will be detailed in depth. The primary aims of the intervention study were to: 1) test the efficacy of tailored video (TV) versus usual care (UC) approaches in terms of reducing the exposure to ETS of the fetuses of low-income women during pregnancy at 34 weeks gestation and to their infants at 6 months postpartum; and to 2) assess this intervention separately among non-smoking and smoking women.

#### 2. Methods

Baby's Breath is the tailored video intervention developed and tested in a randomized controlled trial designed to decrease ETS among pregnant women who smoke or are exposed to the smoke of others, and later, their infants.

A series of five tailored videos and newsletters addressing issues of tobacco smoke avoidance, including smoking cessation, were compared with written materials containing no tobacco related content. The study aimed to assess smoke exposure at 32 weeks gestation (replacing the initial 34 weeks to avoid missing women who delivered early) for the pregnant woman and 6 months postpartum for the infant.

#### 2.1. Formative research

Formative research was conducted during the first year of the project to inform the production staff on many aspects of the smoking cessation or tobacco smoke avoidance process for pregnant women. Focus groups (11) and individual interviews (11) were conducted with many members of the potential target group and their immediate partners including pregnant smokers, ETS exposed non-smokers, women who had quit smoking during pregnancy and partners of pregnant women.

Focus group and interview guides were designed to elicit thoughts, attitudes, motivators and barriers from pregnant women and their partners. We interviewed pregnant smokers regarding their struggles with quitting; pregnant women who had quit regarding their struggles and successes; and non-smoking pregnant women regarding ETS exposure. Audio tapes of the focus groups were transcribed, then coded for important themes and summarized separately by more than one project team member. Findings were discussed to find consensus on important points. The agreed-upon themes identified many of the thoughts, attitudes, motivators, barriers, and even the vernacular used by women to describe these issues. In particular, ways that partners, roommates, and other significant people who are living with or close to the pregnant woman have considerable influence on her ability to quit smoking, stay quit smoking, or avoid ETS. We next conducted interviews with partners to better understand their thoughts, attitudes, motivators and barriers.

It became clear throughout this process that the participant's partner and other household family members were often key to her choice and motivation to succeed in smoking cessation or ETS avoidance. So, we added a video to the intervention specifically directed to the partner or others in the household to help them to support a woman's smoking cessation, cessation maintenance or ETS avoidance. We also focused some of the smoke associated video messages and newsletter segments on social negotiation techniques to improve the likelihood of success. Concerns about the strong influence of partners and others in the household also helped the research team to identify the resistance or receptivity of others in the household as a tailoring variable.

#### 2.2. Intervention materials

The newly developed intervention included a series of five DVD's for the pregnant/postpartum participant, a single DVD for her partner or household member, and a total of eight newsletters created to provide information regarding the risk of smoke exposure to both the participant and the unborn fetus, as well as to identify strategies for smoking cessation and reducing or eliminating ETS exposure. Within the video, tailored messages were subtly delivered to the participant along with other prenatal topics. The non-smoking prenatal topics of interest to the population were identified through a prior pilot study, and were based upon past focus group information. We presented the materials as Baby's Breath (Fig. 1); a prenatal and postpartum series for a healthier pregnancy and a healthier baby, rather than accentuating the smoke exposure subject matter, in an effort to increase interest and higher viewership/readership.



Fig. 1. Baby's Breath logo.

# دريافت فورى 🛶 متن كامل مقاله

- امکان دانلود نسخه تمام متن مقالات انگلیسی
  امکان دانلود نسخه ترجمه شده مقالات
  پذیرش سفارش ترجمه تخصصی
  امکان جستجو در آرشیو جامعی از صدها موضوع و هزاران مقاله
  امکان دانلود رایگان ۲ صفحه اول هر مقاله
  امکان پرداخت اینترنتی با کلیه کارت های عضو شتاب
  دانلود فوری مقاله پس از پرداخت آنلاین
  پشتیبانی کامل خرید با بهره مندی از سیستم هوشمند رهگیری سفارشات
- ISIArticles مرجع مقالات تخصصی ایران