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Efficacy of a Gender-Relevant Smoking Cessation Intervention Among Women in Brazil: Findings from a Group Randomized Controlled Trial

Isabel C. Scarinci, PhD, MPH,[1] Nadia Kienen, PhD,[2] Thaís D. Wiltenburg, BA,[2]
Lorna Bittencourt, MS,[3] and Sharina D. Person, PhD[4]

Abstract

Background: There is scarcity of smoking cessation programs that take gender into account during its development, implementation, and evaluation. We evaluated the efficacy of a theory-based, culturally, and gender-relevant smoking cessation intervention delivered by Community Health Workers (CHWs) among Brazilian women that augments the smoking cessation program offered through the public health system (PHS).
Materials and Methods: A total of 328 women current smokers (100% cigarette smokers) were recruited across 8 towns in a tobacco producing state in Brazil between 2014 and 2017. Four towns were randomly assigned to the intervention (12 home visits by a CHW and a scheduled appointment to attend the smoking cessation program at the PHS) and four towns to the control condition (scheduled appointment to attend the cessation program at the PHS). The primary outcome was self-reported 7-day smoked tobacco abstinence at 7-month follow-up with biochemical verification.
Results: Retention at 7-month follow-up was 80.7% (intervention) and 85.1% (control). Using intention-to-treat analysis, abstinence at 7-month-follow-up was 20% in the intervention arm versus 11% in the control arm. Multivariable modeling showed that participants in the intervention arm had 1.88 times the odds of self-reported smoking cessation than control participants after adjustment for depressive symptomatology, self-efficacy, and having someone in the house who smokes. Besides the intervention, only self-efficacy remained significant in the full model as a predictor of cessation. Replication of these analyses using the objective measure of carbon monoxide at a cutoff score of 8 ppm yielded similar results.
Conclusions: A theory-based, culturally, and gender-relevant intervention, delivered by CHWs, can successfully promote smoking cessation among women.
Clinical Trial Registration No. NCT03845413.

Keywords: smoking cessation, group randomized trial, women, Brazil

Introduction

At the global level, it has been well documented that daily smoking is higher among men (25.0%) than women (5.4%).[1] The most recent national data (2015) showed that tobacco use among Brazilian men and women 15 years of age were 15.4% and 8.9%, respectively.[2] However, overall prevalence can be misleading because it does not account for intragender differences. For instance, consistent with other studies in high-, low-, and middle-income countries, tobacco

[1]Department of Obstetrics and Gynecology, University of Alabama at Birmingham, Birmingham, Alabama, USA.
[2]Department of Psychology and Behavior Analysis, Universidade Estadual de Londrina, Londrina, Paraná, Brazil.
[3]Division of Preventive Medicine, University of Alabama at Birmingham, Birmingham, Alabama, USA.
[4]Department of Quantitative Health Sciences, University of Massachusetts Medical School, Worcester, Massachusetts, USA.

use is higher among low-income and less-educated Brazilian women as compared with women with high income and higher levels of educational attainment.[3–5]

A large epidemiological survey was conducted among 2153 adult women in the state of Paraná (southern Brazil) and the results found that prevalence of tobacco use among women with less than high school education was 16%, with high school education it was 12%, and with post-high school education it was 7%. The same pattern was observed across per capita income as prevalence of tobacco use in lowest income bracket was 25% compared with 11% among women in the highest income bracket.[3]

Gender differences in tobacco use and the need for gender-relevant strategies throughout the entire tobacco control continuum has been well recognized.[6–9] However, for the most part, tobacco control efforts at global, country, and local levels do not take gender into account. The plea for incorporating gender in tobacco control efforts is not new[6–10] and has been one of the priorities of the World Health Organization Framework Convention on Tobacco Control.[11]

With regard to smoking cessation, it has been known that women tend to smoke less but are less likely to quit and remain abstinent than men.[9,12,13] A number of reasons have been attributed to these differences. For instance, studies have shown that while addictive and automatic smoking behavior are similar between men and women, women are more likely to provide emotional (*e.g.*, coping with stress) and social reasons for smoking than men.[14–16] However, there are scarcity of studies addressing the efficacy of gender-relevant smoking cessation programs, particularly in low-resource settings considering the limitations and strengths of the health care system.

Although some studies have focused on gender, most have been restricted to pregnant women, have been pilot/feasibility studies, and/or have used quasi-experimental designs.[17–24] The exception was a study examining the efficacy of a nurse-managed smoking cessation intervention that was delivered by lay individuals among low-income women attending primary and women's health clinics in the Appalachia (United States) with significant results.[25]

In 1988, Brazil decentralized primary care services and relocated Basic Health Units (BHUs) to the communities in which they served. BHUs are staffed by health care teams (*e.g.*, physicians, nurses, social workers, as well as paid Community Health Workers [CHWs]), and they tend to serve between 250 and 1500 households. With regard to smoking cessation, the Brazilian National Cancer Institute has implemented an evidence-based smoking cessation program within the public health care system to be delivered through the BHUs.[26] These guidelines were developed based on a review of evidence-based practices, including the U.S. guidelines.[27] It consists of group-based cognitive-behavioral therapy (CBT) that is delivered, at minimum, in four sessions and pharmacological aids (bupropion, nicotine patch, and nicotine gum) are provided free of charge.

Therefore, Brazil is an ideal country to understand how to optimize smoking cessation through primary care. Although all BHUs employ CHWs whose primary responsibilities are to identify and address the health needs of inhabitants in the coverage area, they have not been directly involved in the existing smoking cessation programs beyond assessment of tobacco use status and referral.[28] This group examined the efficacy of a theory-based, culturally, and gender-relevant smoking cessation intervention delivered by CHWs among Brazilian women that augments the smoking cessation program offered through the public health system (PHS).

Materials and Methods

Study setting

The study took place in the State of Paraná, which is one of the three Southern states that are responsible for 98% of Brazilian tobacco production.[29] The state also borders Paraguay, the largest supplier of illicit cigarettes to Brazil.[30] Eight towns in different regions of the state as well as large, medium, and small towns were identified. Within these towns, BHUs that (1) provided smoking cessation program at least four times per year, and (2) had a catchment area of at least 1000 households were identified to assure that recruitment goals could be met because a previous study showed that tobacco use prevalence among adult women was between 10% and 19.1% across the participating towns.[3]

The Social Cognitive Theory (SCT) guided the formative assessment, intervention development, and intervention implementation.[31] This theoretical framework guided intervention development and implementation, whereas CBT principles guided the strategies used in the intervention to promote cessation.[27] Details on how these constructs were incorporated within the intervention are detailed in Kienen et al.[32]

Intervention development

Extensive formative assessments were conducted (*e.g.*, focus groups with women smokers and former smokers who have gone through the smoking cessation program in the PHS, women who have not gone through such program, interviews with CHWs, interviews with the health care professionals who provided smoking cessation through the PHS, and administrators at the state, municipal, and clinic levels).[28,32–34] For instance, we found that esthetics and family and social cues were relevant motivators toward cessation among women, whereas tobacco use for mood management and weight control, lack of social support, unassertiveness, and not perceiving themselves as smokers were frequent barriers that were incorporated in the intervention.

Based on these results, theoretical framework (SCT), gender analysis, and CBT strategies, the next step was to proceed with developing intervention content, materials, format, unit of randomization, and so on, as well as determining the comparison group. All these steps were taken in collaboration with the PHS at the state level and network members.

In a nutshell, the intervention consisted of three major components: (1) preparing women to quit (*e.g.*, setting goals and expectations, identifying the specific smoking cessation motivators/barriers, personalizing benefits of quitting, understanding nicotine dependence, identifying reasons to quit/reasons not to quit, diary of tobacco use, how to appropriately seek social support, anticipating challenges and building coping skills); (2) development and adherence to the quit plan (*e.g.*, deciding on quitting method, dealing with physical and psychological craving, preventing weight gain, revisiting reasons to quit and advantages of staying abstinent); and (3) relapse prevention and plans for long-term abstinence

(*e.g.*, dealing with slips and relapses, protecting families and loved ones from environmental tobacco exposure, dealing with social pressure, benefits of a tobacco-free lifestyle). Specific details on intervention strategies for each of the phases are provided in Kienen et al.[32]

Because the PHS already had a smoking cessation program, it was decided that this standard of care would serve as the comparison group for the ''enhanced'' intervention, which consisted of smoking cessation intervention being delivered through the PHS, boosted by 12 home visits by CHWs for a period of 6 months. The first four visits occurred weekly in parallel with the four sessions offered through the PHS and they focused on the cessation process. Visits 5 to 9 occurred biweekly and focused on relapse prevention, and the last three visits occurred monthly (refer to Kienen et al. for specific intervention content).[32]

Given the low literacy, a ''character'' was created that conveyed most of the messages through illustrations and behavioral cues (*e.g.*, sticker indicating that their homes were tobacco free, refrigerator magnet with the quit date). The intervention consisted of a binder in which the CHW would deliver the materials for each session at the time of the respective visit.

The control arm consisted of a home visit by the CHW scheduling an appointment for the participant to attend the smoking cessation program at the local BHU. Thus, participants in both conditions were encouraged to attend to the smoking cessation program at the local BHU (which included pharmacological aids if deemed needed by medical provider).

CHW training

Based on the results of the formative assessments and meetings with the BHUs, a CHW training program (intervention arm) was developed with adaptations from existing CHW training programs.[35–37] As part of their training, role playing to practice the skills learned was recorded and provided to them on a DVD.[37] CHWs in the control arm only received a brief training on tobacco control strategies and their role was limited to identification of participants and referral to the smoking cessation offered through the PHS.

Recruitment, enrollment, and randomization

Before randomization, CHWs in all participating towns conducted a screening to identify women who were smoked tobacco users within their catchment areas and explored their willingness to participate in the research program. The purpose of this ''prerecruitment'' was to assure that there were enough participants to start the trial. Participants were also recruited through word of mouth at the BHUs and in the community. Once an acceptable number of participants were identified, the towns were randomized to intervention and control arms. Staff at the local university contacted the women interested in participating, renewed their commitment, and scheduled a home visit for the consenting procedures and baseline assessments.

Randomization occurred at the town level to avoid contamination across participants and CHWs. As previously described, the BHUs serve specific neighborhoods where people tend to socialize together. In addition, CHWs tend to live in these neighborhoods and it would be difficult to randomize at the individual level. By randomizing towns, we also assured that CHWs in the intervention towns did not have any contact with CHWs in the towns assigned to the control condition.

The inclusion criteria included the following: (1) ≥18 years of age; (2) women; (3) lived in the town assigned to the intervention or control conditions; (4) current smoked tobacco use in the previous 7 days; and (5) had no plans of moving in the next 8 months. Institutional Review Board approvals were obtained from the University of Alabama at Birmingham, Pontíficia Universidade Católica do Paraná, Universidade Estadual de Londrina as well as from the Brazilian National Ethics Committee, and all participants provided informed consent.

Assessments

All assessments were interviewer administered by university staff and were not accessible to the CHWs. Baseline assessments included (the ones with an * were also administered at 7-month follow-up): demographics, tobacco use history, having someone who smokes in the house, nicotine dependence (Fagerstrom Test for Cigarette Dependence [FTCD]; also, referred to as Fagerstrom Test for Nicotine Dependence),[38] smoking self-efficacy* (Smoking Self-Efficacy Scale),[39] and depressive symptomatology* (Center for Epidemiologic Studies Depression Scale [CES-D]).[40] The CES-D and FTCD had already been translated to Portuguese and psychometric properties established.[41,42] The other assessments were translated by following recommended translation procedures (translation and back translation for independent translators).

Exhaled carbon monoxide (CO) levels were recorded at baseline, and 7-month follow-up (COVITA™).[43] Although serum or urine cotinine levels are considered the gold standard, CO levels have been shown to have high specificity and positive predictive values for determining nicotine exposure and are easily obtained in a community setting.[44] Consistent with previous studies, a CO cutoff score of 8 ppm was used.[45]

Outcome at follow-up related to smoked tobacco use status was obtained from responses to the question, ''Have you smoked any tobacco product in the past 7 days?'' Respondents could indicate that they smoked daily, less than daily, or that they did not smoke. Those who indicated that they smoked daily or less than daily were labeled as ''smokers,'' whereas those who indicated that they did not smoke were labeled ''nonsmokers.'' None of the participants reported using smokeless tobacco at both baseline and follow-up.

A number of activities to assure treatment fidelity were also implemented as recommended by Bellg et al.[46] To assure receipt of treatment and reenactment of skills, 10 participants in the intervention arm were randomly chosen to be interviewed by the Program Manager, using a 10-item questionnaire.

The Program Manager was tasked with probing participant answers to understand the concepts as well as their overall opinion of the program. Interviews were recorded and transcribed. Questions 1–7 were then rated by one of the Principal Investigators and a staff member on a scale of 1–5 for understanding and/or application of knowledge and/or skills. Scores were assigned by two independent coders based on participants' ability to demonstrate the acquired knowledge

and/or skills. The Program Manager also attended sporadic sessions in the intervention arm to assure treatment fidelity. A total of 21 sessions were video recorded, and feedback was provided to the CHW. In addition, they were coded by two independent coders to assure that the CHW displayed the expected skills.

Power calculations

Because the outcome was primarily prevalence, power calculations used a two-sided, two-group, continuity-corrected chi-square test of equal proportions and equal n's with alpha = 0.05. Consistent with the literature, it was expected that the intervention would achieve a quit rate of 25% at 7 months.[47,48] It was assumed that the quit rate in the control arm would be 10% based on estimates from the State Health Department. Calculations based on these inputs were further increased by an inflation factor that accounted for the average number of participants per town and the intra-class correlation to properly account for clustering of participants in towns. Resulting power calculations indicated that a total of $N = 344$ participants were needed to detect the aforementioned difference in quit rates with 80% power.

Statistical analysis

All analyses followed an intent-to-treat approach, that is, towns once randomized participants were retained in their treatment conditions regardless of if they were present for follow-up measurements with participants lost to follow-up assumed to still smoke.

Baseline smoking characteristics of the entire sample were examined using descriptive statistics. Next, a comparison was made of participants randomized to the intervention condition to those randomized to the control condition on demographics and behavioral characteristics with both general and smoking specific using random effects models that allowed for clustering of participants within towns. To assess the accuracy of self-reported smoked tobacco use status, the participants smoking status determined through this means was compared to detectable rates of CO using both McNemar's test and the kappa statistic.

Independent variables for examination were selected based on their known or expected impact on smoking cessation. Traditional multivariable modeling best practices suggest that, at minimum, 20 observations are necessary for each independent variable included to ensure model stability.[49] As a result, there was an examination of the association of each variable in a bivariate sense with self-reported smoking status to reduce the number of candidate variables to be included in final multivariable models. Variables found to be significant at $p < 0.15$ were included in a final model. An attempt was made to also replicate the findings from the final model of self-reported smoking status using the objective measure of detectable CO using an intention-to-treat framework.

As ancillary analyses, an examination of the association of the intervention and self-reported smoking status after adjustment for important groupings of variables was made, regardless of those variables' statistical significance in bivariate analysis. In the first model, the relationship of the intervention and smoking status after adjusting for demographics (age, education, marital status, monthly income available per dependent) was examined.

The second model examined the relationship of the intervention and outcome after inclusion of general behavioral characteristics including CES-D and self-efficacy scores. The final model adjusted for smoking-specific behaviors (age at initiation, cigarettes per week, illicit cigarette use, living with a tobacco user, and nicotine dependence). The results of these analyses would better elucidate the effect of the intervention on smoking cessation after adjustment for important variables that may not have achieved statistical significance.

All models used generalized linear mixed models to account for the group randomized trial and were adjusted for lack of independence among participants from the same town. An exchangeable correlation structure modeling a binomial distribution with a logit link was used. To remove potential sample bias owing to the small number of groups, a Sandwich Variance Estimation procedure based on a root estimator,[50] which improves the standard errors of the model and protects against inflated type 1 errors, was used. Simulation studies have recommended this approach for binary outcomes.[51] All analyses were performed using SAS Version 9.4.

Results

The final analytic sample included 328 participants ($n = 166$, intervention and $n = 162$, control). This sample included 56 participants (17% overall: $n = 32$, intervention [19%] and $n = 24$, control [15%]) lost to follow-up who were included as part of an intent-to-treat analysis and were assumed to continue to smoke tobacco products (Fig. 1). In general, there were no baseline differences between participants in the intervention and control conditions (Table 1). Intervention participants had slightly higher educational attainment ($p = 0.06$) and had higher monthly income per dependent ($p = 0.006$; Table 1). Participants did not report smoking clove cigarettes, Bidis, pipes, or cigars, and <1% used hookah or electronic cigarettes.

At follow-up, 25.4% of intervention versus 13% of control participants had CO levels under 8 ppm. Comparison of self-report of smoking status at follow-up and verification by CO reading under 8 ppm showed that of those self-reporting being a nonsmoker 3.2% had detectable CO levels at or above 8 ppm, whereas 84.6% had CO levels under 8 ppm. Among those self-reporting being a smoker, 15.4% had CO levels <8 ppm and 96.8% had CO levels at or above 8 ppm. McNemar's test yielded a p-value of 0.8, which indicates no statistically significant difference in proportion of smokers between self-report and CO levels. There was also a kappa value of 0.82, which represents an almost perfect agreement between the two methods of assessing smoking status.

Self-reported smoking cessation at 7-month follow-up was 20% ($n = 33$) in the intervention group as compared with 11% ($n = 18$) in the control group. Bivariate analyses found that self-efficacy, CES-D score, and having someone who smokes in the house were associated with self-reported smoking cessation at least the $p < 0.15$ level. Specifically, for every unit increase in CES-D score, a participant was 2% less likely to quit smoking (odds ratio [OR] = 0.98, $p = 0.05$); lower self-efficacy was associated with lower likelihood of smoking cessation (OR = 0.54, $p = 0.006$); and having someone who smokes in the house was associated with lower odds of quitting smoking ($p = 0.12$; Table 2).

The intervention was also significantly associated with smoking cessation (OR = 1.95, $p = 0.03$; Table 2). Age

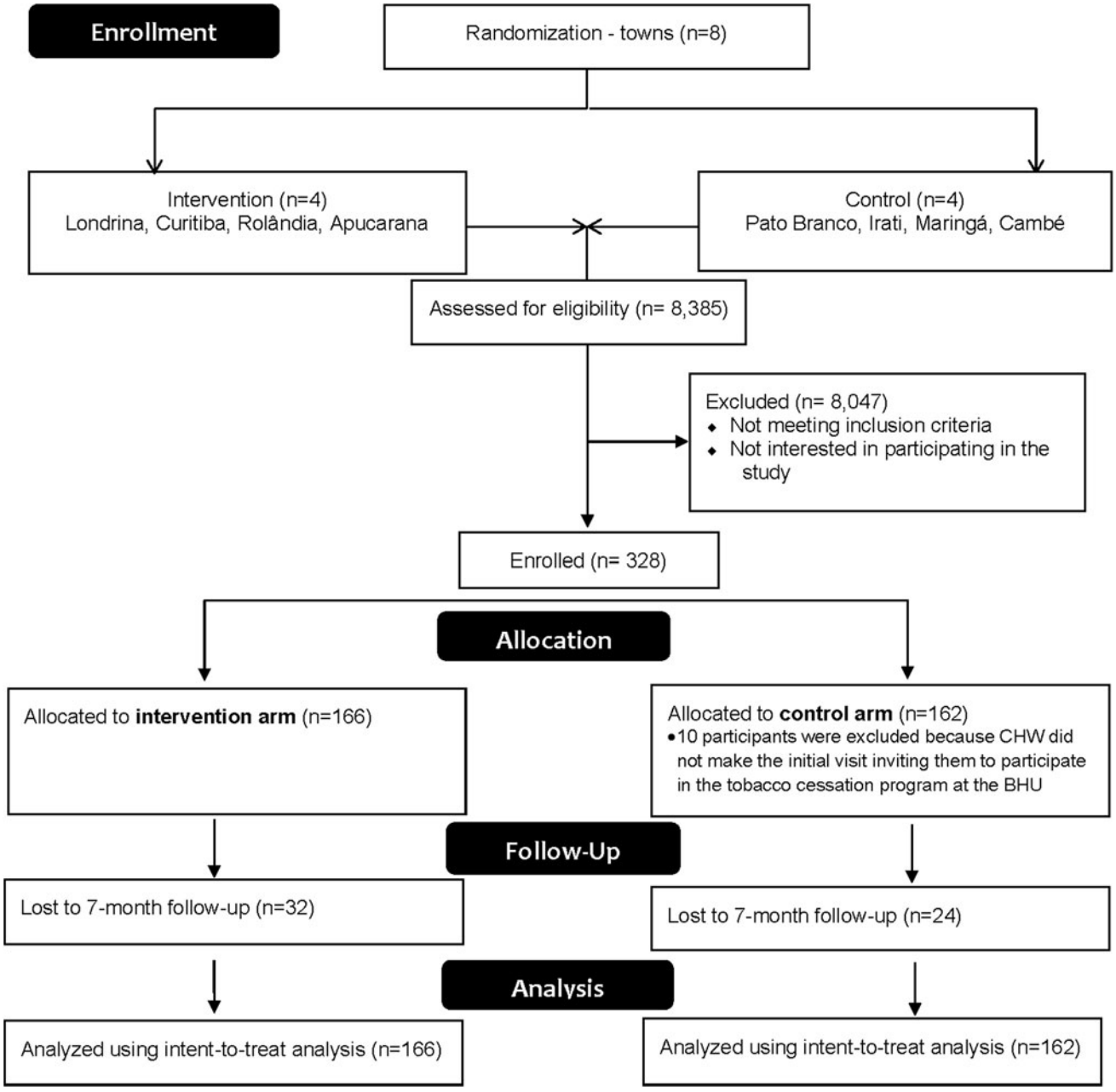

FIG. 1. Recruitment and retention of participants.

($p=0.68$), education ($p=0.99$), marital status ($p=0.79$), income ($p=0.9$), age at initiation ($p=0.94$), cigarettes per week ($p=0.17$), illicit cigarette use ($p=0.18$), and nicotine dependence ($p=0.4$) were not significantly associated with smoking cessation.

Multivariable modeling showed that participants in the intervention arm had 1.87 times the odds of smoking cessation than control participants after adjustment for CES-D score, self-efficacy, and having someone in the house that smokes. Besides the intervention, only self-efficacy remained significant in the full model (Table 2).

Although found to be different between conditions but not significantly associated with smoking cessation, a model including educational attainment and monthly income available per dependent yielded identical results (not shown) to those presented. Replication of these analyses using the objective measure of CO at undetectable rates yielded the same results as the self-reported outcome. In multivariable models, after adjustment for several groupings of covariates (demographics, general behavioral characteristics, and smoking related behaviors), intervention participants were still more likely to report quitting smoking than control participants.

Treatment fidelity

Overall treatment fidelity for intervention showed that participants had a good understanding of the knowledge and skills addressed in the intervention and how to implement them in the process of quitting. In particular, participants were able to elaborate on how they have used what they

Table 1. Participant Characteristics per Condition

Characteristic	*Intervention (n = 166)*	*Control (n = 162)*	p[a]
Demographics			
Age[b]	47.4 (12.3)	47.2 (12.8)	0.86
Educational attainment, *n%*			
<12 years	69.3	80.8	0.06
High school diploma	23.5	15.5	
13 or more years	7.2	3.7	
Marital status, *n%*			
Single	16.3	12.4	0.60
Married/living together	53	60.3	
Separated/divorced	16.9	16.2	
Widowed	13.9	11.2	
Monthly income available per dependent (in Brazilian Real)[b]	*R*$871.1 (R$761.4)	*R*$557.3 (R$386.7)	0.006
Behavioral characteristics			
CES-D score[b]	24.4 (14.3)	26.8 (14.8)	0.29
Self-efficacy score[b]	3.7 (0.7)	3.7 (0.7)	0.73
Smoking specific behaviors			
Age at initiation[b]	15.1 (4.8)	15.3 (5.5)	0.81
Cigarettes per week[b]	128.7 (75.7)	127.2 (89.1)	0.85
Illicit cigarette use, *n%*	64.8	72.8	0.35
Someone who smokers in the house, *n%*	52.4	55.6	0.57
Nicotine dependency (Fagerstrom), *n%*			
Low	12.7	18.1	0.10
Low to moderate	18.8	21.3	
Moderate	54.6	40.6	
High	13.9	20.0	

[a]*p*-values accounts for clustering.
[b]Values are given as mean (standard deviation).

learned and how they were able to manage physical and psychological cravings and appropriately deal with relapses and slips (Table 3). The ones who had quit smoking were able to elaborate on how they apply the learned strategies to remain abstinent.

When asked their overall opinion of the program, all the responses were positive with the most frequent responses being that the CHWs were a source of support during the process of quitting smoking and gave them clear information and explanations. When asked what they disliked most, the most frequent responses were nothing should be changed. Participants also mentioned that the order of some visits could be modified and the need to adapt the material to be less extensive and in a simpler language.

Discussion

Results showed that a theory-based, gender-, and culturally relevant intervention delivered by CHWs to promote smoking cessation among women that augments the smoking cessation offered through the Brazilian public health care system was efficacious in promoting smoking cessation at 7-month follow-up.

Wewers et al. conducted two randomized trials among low-income Appalachian women in the United States and, to this group's knowledge, they are the only gender-relevant tobacco cessation randomized trials among women.[25,52] They assessed point prevalence at 3, 6, and 12 months in both studies and the control conditions were less intense than the control condition in this group's study. In one study, they compared a nurse-managed, lay-led tobacco cessation program with a letter from the participant's personal physician encouraging them to quit tobacco use, and self-report point prevalence quit rates at 6 months were 21.8% and 5.8%, respectively. In a subsequent study, they compared a CHW face-to-face intervention with a CHW quitline condition, and self-reported point prevalence quit rates at 6 months were 16.7% and 10.5%, respectively. Results indicated a

Table 2. Bivariate and Multivariate Associations of Factors of Interest and Self-Reported Tobacco Cessation

	Bivariate associations			*Multivariate models*		
	Odds ratio	*95% CI*	p	*Odds ratio*	*95% CI*	p
Intervention	1.95	(1.09–3.62)	0.03	1.87	(1.02–3.44)	0.04
CES-D	0.98	(0.95–1.00)	0.05	0.99	(0.96–1.01)	0.27
Self-efficacy	0.54	(0.35–0.83)	0.006	0.56	(0.37–0.87)	0.009
Someone who smokers in the house	0.66	(0.39–1.12)	0.12	0.62	(0.35–1.08)	0.09

CES-D, Center for Epidemiologic Studies Depression Scale; CI, confidence interval.

Table 3. Treatment Fidelity—Tobacco Cessation Program ($N = 10$)

Question	*Score/responses*[a]
Q1. What have you learned in your visits with the Community Health Worker? Have you used what you learned? (Give examples.)	3.7
Q2. What have you learned about tobacco products and quit smoking?	3.8
Q3. How did you prepare yourself to quit smoking?	3.6
Q4. How have you deal with cravings when you felt you needed to smoke? What have you learned about dealing with cravings?	4.6
Q5. Have you experienced relapses or slips? That is, you quit but started smoking again? How have you dealt with these relapses or slips? What have you learned about how to deal with relapses and slips after an individual quits smoking or to use a tobacco product?	4.0
Q6. Please role play a scene in which a female smoker is communicating with a health care professional about questions regarding difficult situations, such as relapse	4.8
Q7. (If the participant quit smoking) What could you do to motivate you to stay abstinent from smoking or using a tobacco product?	5.0
Q8. Tell us about your short and long-term goals to be healthy?	3.9
Q9. What did you like most about the work the Community Health Worker did with you?[b]	50%—support/availability 36%—explanations 14%—CHW as a model
Q10. What would you change in the work the Community Health Worker did with you?[b]	78%—nothing 11%—order of some visits 11%—length of the visits/adapt material with simpler language

[a]Scores for questions 1–5 ranged from 1 (no understanding/application) to 5 (good understanding/application).
[b]Open question—listed responses reflect most frequent feedback from participants.

self-reported point prevalence quit rate at 7-months of 20% and 11%, respectively. Together, these results are encouraging with regard to integrating CHWs in smoking cessation efforts among women.

Although it has been shown that the integration of CHWs in health promotion efforts is effective, most interventions, including this group's work, have focused on relatively simplistic behavior change (*e.g.*, cancer screening) as compared with addressing addictive behaviors.[53,54] CHWs can be instrumental in augmenting smoking cessation programs if they are suitably trained and supervised and their role is well defined.[25,28,52,55–58] However, most studies have not examined the obtained outcomes from a gender perspective, except for one study among low-income Appalachian women in the United States.[25,52] Therefore, future studies are needed to compare the effectiveness of a CHW intervention among women across different settings.

When demographic, behavioral, and smoking-related variables were examined, self-efficacy was the only other variable (besides intervention) associated with smoking cessation in the multivariate model. Manfredi et al. conducted a path analysis to better understand how five factors associated with smoking cessation (motivation, self-efficacy, confidence, action, and intention to quit) influenced cessation among low-income women.[59] Although all five were associated with the likelihood of quitting, only immediacy of plans to quit and self-efficacy were directly associated with quitting. Of interest, they found that actions toward quitting were not directly associated with self-efficacy and self-efficacy was not directly associated with increased motivation to quit. However, situational self-efficacy increased confidence. That is, when smokers are successful in refraining from smoking in high-risk situations (particularly negative affect situations), it boosts their generalized confidence in their ability to quit.[59]

The relevance to this study is that one can speculate that CHWs were trained to assist participants in identifying at-risk situations and developing strategies to cope with the situations. In subsequent sessions, they would revisit which strategies were effective and which ones were not. In addition, having the ongoing visits with the CHWs served as reinforcers of their ''small successes'' and provided them with the skills to prevent relapses. One of the major components pointed out by CHWs in debriefings as well as participants during treatment fidelity assessments was the approach to relapse prevention—''slip'' versus ''relapse.'' CHWs were trained to treat ''slips'' as part of the norm and the quitting process and assist participants in ''getting back on course.'' That is, slips were not treated as failure, but an opportunity to reflect on factors that contributed to slips and how to cope with them in the future. This ongoing support may have been built on their situation self-efficacy, and, consequently their confidence to quit and remain abstinent.

This study has some limitations that should be mentioned. First, because this was a pragmatic trial implemented in a real setting by CHWs who deliver their services during business hours, they tended to reach participants who did not work outside their homes. In addition, the smoking cessation program offered at the PHS takes place during working hours. Second, as evidenced by the reported monthly income the sample consisted primarily of low-income women who are mostly served by the PHS.

Third, primary outcomes were assessed at 7 months after enrollment and it was limited to point prevalence rather than prolonged abstinence. Therefore, long-term abstinence data were not collected. Fourth, given that the intervention was an augmentation of the smoking cessation program offered through the PHS, it was more intense than the control condition, and, thus, intensity of personal attention may have

influenced the obtained outcomes. Fifth, although unlikely that participants used other interventions in addition to this program given the unavailability of such in Brazil, the participants were not directly asked if they did so. Sixth, although great concordance between self-report of smoking status at follow-up and verification by CO assessment was obtained, it has been argued that when participants know their self-report will be validated by a biological indicator, this can influence their responses.[60] Nonetheless, given the intention to make this program sustainable, it provides with some assurance that self-report may be sufficient to assess its effectiveness.

Conclusion

This study represents, to this group's knowledge, one of the first studies to demonstrate efficacy of a theory-based, culturally, and gender-relevant CHW intervention for Brazilian women that augments the smoking cessation program offered through the PHS.

Evidence has been established that CHWs, with appropriate training and supervision, can play an important role in smoking cessation, particularly among women to whom social support is critical in the process of cessation and relapse prevention. That is, CHWs, although lay individuals without a background or formal training in psychology, can be trained to promote behavior change of complex behaviors such as the ones involved in the process of smoking cessation and staying abstinent.

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Authors' Contributions

I.C.S.—Conceptualization of the study, overall supervision for the study, primary writing of the article.

N.K.—Conceptualization of the study, overall supervision of CHWs, and assistance with overall writing of the article.

T.D.W.—Treatment fidelity, and assistance with overall writing of the article.

L.B.—Data management and assistance with overall writing of the article.

S.D.P.—Statistical analysis, and primary writing of the statistical analysis section and results.

All authors conceptualized the article, contributed to and have approved the final version of the article.

Author Disclosure Statement

No competing financial interests exist.

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Address correspondence to:
Isabel C. Scarinci, PhD, MPH
Department of Obstetrics and Gynecology
University of Alabama at Birmingham
176F, 10360F, 619 19th Street South
Birmingham, AL 35294
USA

E-mail: scarinci@uab.edu