

# Efficacy of a Couple-Based Randomized Controlled Trial to Help Latino Fathers Quit Smoking during Pregnancy and Postpartum: The Parejas Trial

Kathryn I. Pollak<sup>1,2</sup>, Pauline Lyna<sup>1</sup>, Alicia K. Bilheimer<sup>1</sup>, Kristina C. Gordon<sup>3</sup>, Bercedis L. Peterson<sup>4</sup>, Xiaomei Gao<sup>1</sup>, Geeta K. Swamy<sup>5</sup>, Susan Denman<sup>6,7</sup>, Alicia Gonzalez<sup>8</sup>, Pilar Rocha<sup>9</sup>, and Laura J. Fish<sup>2</sup>

## Abstract

**Background:** Although many Latinos in the United States smoke, they receive assistance to quit less often than non-Latinos. To address this disparity, we recruited Latino couples into a randomized controlled trial and provided a smoking cessation program during a teachable moment, when men's partners were pregnant.

**Methods:** We compared two interventions: (i) written materials plus nicotine replacement therapy (NRT) to (ii) materials, NRT, and couple-based counseling that addressed smoking cessation and couples communication. We recruited 348 expectant fathers who smoked via their pregnant partners from county health departments. Our primary outcome was 7-day point prevalence smoking abstinence and was collected from November 2010 through April 2013 and analyzed in February 2014.

**Results:** We found high rates of cessation but no arm differences in smoking rates at the end of pregnancy (0.31 vs. 0.30,

materials only vs. counseling, respectively) and 12 months after randomization (postpartum: 0.39 vs. 0.38). We found high quit rates among nondaily smokers but no arm differences (0.43 vs. 0.46 in pregnancy and 0.52 vs. 0.48 postpartum). Among daily smokers, we found lower quit rates with no arm differences but effects favoring the intervention arm (0.13 vs. 0.16 in pregnancy and 0.17 vs. 0.24 postpartum).

**Conclusions:** A less intensive intervention promoted cessation equal to more intensive counseling. Postpartum might be a more powerful time to promote cessation among Latino men.

**Impact:** Less intensive interventions when delivered during teachable moments for Latino men could result in a high smoking cessation rate and could reduce disparities. *Cancer Epidemiol Biomarkers Prev*; 24(2); 379–85. ©2014 AACR.

## Introduction

The smoking rate among Latino men living in the United States is comparable with non-Hispanic white men (1), yet Latinos are at higher risk for cardiovascular disease than whites (2). Also, given Latinos are less likely to receive cancer screening and present with later stage cancer (3), preventing cancer is imperative in this population. Despite these disparities, Latinos are underrepresent-

ed in smoking cessation studies (4–7). A limited number of trials have tested culturally sensitive cessation interventions among Latino smokers, and fewer have been tested using experimental designs (8). Interventions have included self-help written materials, nicotine replacement therapy (NRT), group, individual, and telephone counseling (5, 9–13). Results from the few trials testing cessation interventions for Latinos indicate that NRT and telephone counseling may help Latinos quit, but biochemically validated rates are low (~20%), and none has examined or found significant effects 12 months after the intervention. One study indicated that acculturation might play a role in cessation (14); however, this trial did not include random assignment. Clearly, more randomized controlled trials with long follow-up are needed to assess whether an effective intervention can promote smoking cessation among Latinos.

An important factor to consider when developing interventions for Latinos is that most are nondaily smokers or light smokers (i.e., smoke 10 or fewer cigarettes per day; ref. 15). Because they differ from traditional heavy smokers, it might be that less intensive approaches are enough to promote cessation. One less intensive and easily disseminable approach is using written materials; it is unknown whether intensive interventions are needed to help Latino smokers quit smoking.

Furthermore, existing interventions can be strengthened by intervening at a time when smokers feel compelled to quit,

<sup>1</sup>Cancer Control and Population Science, Duke Cancer Institute, Durham, North Carolina. <sup>2</sup>Department of Community and Family Medicine, Duke University School of Medicine, Durham, North Carolina. <sup>3</sup>Department of Psychology, University of Tennessee at Knoxville, Knoxville, Tennessee. <sup>4</sup>Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, North Carolina. <sup>5</sup>Department of Obstetrics and Gynecology, Duke University School of Medicine, Durham, North Carolina. <sup>6</sup>School of Nursing, Duke University, Durham, North Carolina. <sup>7</sup>University of North Carolina, Greensboro, North Carolina. <sup>8</sup>Duke AHEC Program, Duke University School of Medicine, Durham, North Carolina. <sup>9</sup>El Centro Hispano, Durham, North Carolina.

**Note:** This trial is registered with ClinicalTrials.gov: NCT01040949.

**Corresponding Author:** Kathryn I. Pollak, Duke University, 2424 Erwin Road, Suite 602, Durham, NC 27705. Phone: 919-681-4757; Fax: 919-681-4785; E-mail: kathryn.pollak@duke.edu

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namely a teachable moment. A teachable moment is a naturally occurring event or situation that increases motivation for behavior change through changes in risk perceptions, emotions, and self-image (16). For instance, when their partner becomes pregnant, Latino men might feel differently about the risk of smoking around her, might have positive or negative emotions related to smoking that they did not have before she was pregnant, and might view themselves differently especially when thinking about their smoking (e.g., a good role model for my children is someone who does not smoke). Pregnancy has been shown to be a teachable moment for women as many quit smoking upon learning of their pregnancy (16); whether it is a teachable moment for partners, and particularly Latino partners, needs further exploration.

Our pilot work indicates that Latino expectant fathers have a strong desire to quit smoking (17); thus, targeting smoking cessation during pregnancy might have increased efficacy over other times. What also is unknown is whether motivation to quit increases after the birth of the baby as pregnancy might be a relatively abstract event for men (not women) until the baby is born.

Furthermore, the cultural value of *familismo* emphasizes trust between family members, loyalty to the family, and a general orientation to the family (18). This central aspect of Latino culture suggests that intervening with individuals, particularly those who are less acculturated, may not be the best approach for promoting smoking cessation among Latino men. Thus, couple-based interventions may be powerful, sustainable, and culturally appropriate as it capitalizes on *familismo*, the influence of the male in the family (*machismo*), and the fathers' motivation for protecting the fetus and new baby. It also is important to examine whether an intervention during pregnancy is more or less effective than promoting cessation postpartum. Furthermore, the effectiveness of an intensive couples-based intervention may vary for daily smokers versus nondaily smokers, as daily smoking likely might require a more intensive intervention. To answer these many questions about how best to promote cessation among Latino men, the aim of this randomized controlled trial was to compare a culturally tailored couples-based intervention plus written materials (self-help smoking cessation guide or *Guia*) and free NRT with a minimal intervention involving written materials plus NRT in promoting smoking cessation among expectant Latino fathers during pregnancy and postpartum. The main aim was to determine whether a more intensive intervention outperformed a less intensive intervention during these potential teachable moments.

## Materials and Methods

### Sample

This study was approved by the Duke University School of Medicine Institutional Review Board (Durham, NC). We recruited pregnant Latinas and their partners who smoked from 10 urban and rural county health departments in North Carolina. Eligible women had to be at least 16 years of age, between 13 weeks and 29 weeks gestation, and not smoking. Eligible men had to have smoked at least 100 cigarettes in their lifetime, have smoked in the past 30 days (to include nondaily smokers), and be at least 16 years old. For women and men who were 16 to 18 years old, they were required to be married and thus emancipated (does not require parental consent).

At all of the clinics, nurses introduced the "Parejas" (couples) study during women's initial prenatal appointment. Nurses asked women to sign a form agreeing to be contacted by our research staff about the study. Parejas study staff called only women who signed the contact form and assessed eligibility. Staff asked women whether their partner had ever smoked (some women were unaware of men's current smoking but knew he had smoked at some point). If women were eligible and willing to participate, we asked permission to contact her partner. Staff called men and assessed eligibility. If the man was eligible and willing to participate, staff went to the couples' home to obtain written consent and conduct a baseline survey with the couple. After the baseline survey, staff randomized the couple to one of two study arms from a preset randomization list that was stratified on whether men were daily or nondaily smokers and first time fathers or not. Men randomized to the written materials only arm received the booklet, *No lo deje para mañana deje de fumar hoy: Guía para Dejar de Fumar* and the option of up to 6 weeks of free NRT (nicotine gum or patch). Men randomized to the intensive intervention arm received the booklet, an option of up to 6 weeks of NRT, and also were told that they would receive three counseling sessions during pregnancy (one face-to-face and two via phone) and three postpartum (one face-to-face and two via phone) to help them identify and achieve their goals for quitting smoking and improve their communication with their partner. In both arms, staff briefly discussed elements of the written materials as some of the participants could not read. Staff went to couples' homes again to administer a follow-up survey at the end of pregnancy (~34 weeks gestation) and 12 months postrandomization. We paid all participants \$10 for each survey and an extra \$10 for any saliva samples provided to biochemically validate 7-day point-prevalence abstinence. We collected data from November 2010 through April 2013 and analyzed it in February 2014.

### Intervention

This study was a community-based partnership from the inception of the project idea throughout the entire project. In the first year of this study, we worked with our community partner, the local Latino community center, El Centro Hispano, to culturally adapt the intervention. We also convened a Community Advisory Panel that met monthly to review the intervention components, recruitment procedures, and surveys. In addition, we conducted focus groups with expectant Latino couples to obtain their input on integral intervention components.

One thing we learned during our formative work was that for men to be receptive to working on their smoking, we needed to also ask women to make behavior changes. If both members worked on changing a behavior, men reported that they would not "lose face" and feel stigmatized by our intervention. On the basis of our formative work, we identified written materials and revised the counseling sessions to also promote healthy nutrition and physical activity for the pregnant partners. In addition, the couple-based as well as individual counseling sessions focused on teaching couple's communication skills, namely speaking/listening skills and problem solving. It was hypothesized that when couples communicate better, they will feel less stress and more effective support for quitting and staying quite, which will lead to higher cessation rates.

The first session was with both couple members together in the couple's home and lasted approximately 2 hours. A male and

female counselor presented didactic information on smoking and quitting including a narrated Powerpoint presentation. The first part of the two-part presentation was designed to specifically evoke emotions related to family such as love, pride, protectiveness, and responsibility by including pictures of fathers with infants and children. Information presented in the second part included the health risks of smoking for the smokers and health risks from environmental tobacco smoke for the family. The male counselor talked individually with the man to build motivation to quit, identify barriers to quitting, and to set a goal to quit or move toward quitting during the pregnancy. The female counselor talked individually with the woman to identify whether she wanted to work on nutrition or physical activity, build motivation for change, identify barriers to change, and to set realistic goal to work toward pregnancy. In each session, the counselors also taught and asked couples to practice effective communication skills to understand each other's barriers to changing their health behaviors and problem-solve on how to support each other in making these changes. The two subsequent counseling sessions were conducted over the phone (~15 minutes) with men only and focused on reviewing progress toward quitting and setting new goals, if necessary, to quit smoking and practicing couples communication skills. Postpartum, the male counselor conducted a phone counseling session with men around 4 weeks postpartum, a face-to-face counseling session with both couple members together at 8 to 10 weeks, and one last counseling call with men at 4 months postpartum.

The counseling protocol was based on Social Cognitive Theory (19) and the teachable moment model (16). The teachable moment model asserts that for a moment to motivate people to change, it should affect their risk perceptions, emotions, and self-concept. The elements of the face-to-face sessions attempted to address each of these components (e.g., smoking around pregnant women/newborns puts babies at risk, children want their dads to be around for important events, and the role of the dad is to protect his children). The counseling also was informed by Motivational Interviewing (MI; ref. 20). Counselors attended a 40-hour training to learn the counseling protocol and MI. Finally, the dyadic portion of the session used communication skill protocols from Cognitive-Behavioral Couple Therapy (21). Counselors audio recorded all of their sessions with participants. The clinical supervisors listened to the first three cases for each counselor and then randomly chose 10% of cases to review and provide feedback throughout the study to minimize drift.

### Measures

We assessed 7-day point-prevalence abstinence and 30-day point-prevalence abstinence at baseline, at the end of pregnancy (~34 weeks gestation), and 12 months postrandomization. We also assessed continuous abstinence at both follow-up time-points. Our primary outcome was 7-day point prevalence abstinence; however, given many of the smokers were not daily smokers, we also analyzed secondary effects on 30-day point prevalence abstinence. We biochemically validated men's reports of 7-day point prevalence abstinence. We asked men to provide a 1-mL saliva sample. Saliva samples were analyzed for the presence of cotinine using radioimmunoassay. The presence of cotinine was tested on the basis of an antiserum produced by injecting trans-4-carboxycotinine bound to albumin. Both the inter- and intra-assay variations are lower than 6%, and results are comparable with those produced by gas-liquid chromatography.

The sensitivity of this procedure is 0.5 mg/dL. Cotinine is a highly sensitive measure for identifying smokers. A cut point of 16 ng/mL for saliva cotinine was used to discriminate abstainers and smokers.

### Statistical analysis

The primary objectives of the trial were to test for arm differences in 7-day point prevalence abstinence rates at end of pregnancy and at 12 months postrandomization. Each test was calculated in a logistic regression model with a one-sided  $\alpha$  of 0.0125; thus the overall  $\alpha$  level of the trial was controlled at 0.025. As planned at the time the trial was designed, baseline covariates previously shown to be related to the outcome were used as covariates: education ( $\leq 9$ th grade vs.  $>9$  grade), wantedness of pregnancy (yes/no), and number of cigarettes per day ( $\leq 5$  vs.  $>5$ ). Secondary objectives were to estimate arm differences in 30-day point-prevalence abstinence and continuous abstinence at end of pregnancy and at 12 months postrandomization. Logistic regression models were used to estimate these two arm effects, using the three covariates listed above; *P* values for these outcomes were not assessed for significance. In all analyses, men who were lost to follow-up were imputed to be smokers, as were men whose cotinine levels indicated that they were active smokers. Given we expected larger intervention effects among nondaily smokers, we analyzed arm differences in nondaily and daily smokers separately.

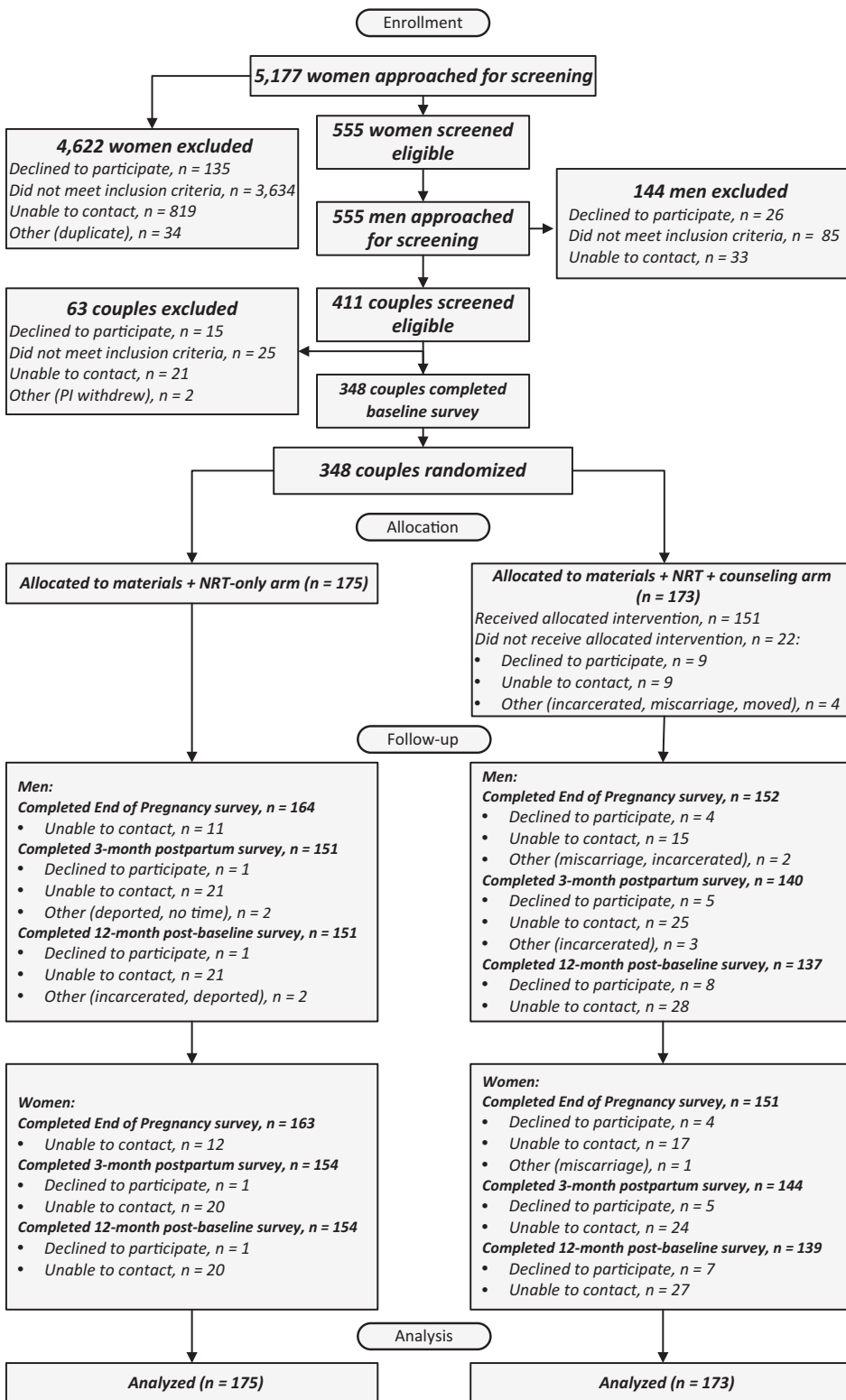
## Results

### Sample characteristics

Figure 1 shows our recruitment numbers. Table 1 shows the demographic characteristics of the sample. Follow-up rates for end of pregnancy and 12 months postrandomization were 0.89 and 0.81, respectively. More couples were lost in the intervention arm at the end of pregnancy survey than the control arm (Tx: 14% and control: 7%). There were no lost-to-follow-up differences by arm at 12 months postrandomization (Tx: 21% and control: 17%). We examined differential attrition by baseline characteristics. At the end of pregnancy, men who reported monthly income  $\geq \$1001$  and Spanish as the only language spoken at home were lost to follow-up more than those with less monthly income (14% vs. 7%,  $P = 0.03$ ) and Spanish and English spoken at home (14% vs. 5%,  $P = 0.01$ ). NRT was given about equally to men in the intervention and control arms (Tx: 52% vs. 45%). However, more men in the intervention arm than the control arm reported using it (Tx: 41% vs. control: 28%).

### Cessation

Table 2 shows cessation rates by intervention arm. At the end of pregnancy and 12 months postrandomization, we found high cessation rates in both arms with no added benefit of the more intensive couples-based counseling for 7-day (primary) and 30-day (secondary) cessation. Because we expected differential responses from daily and nondaily smokers, we examined arm differences within these two subgroups at both follow-up time-points (Table 2). Cessation rates were higher among nondaily smokers than daily smokers; in both subgroups, we found no clinically meaningful arm differences. However, unlike among nondaily smokers, arm differences among daily smokers were in the expected direction, favoring the intervention arm for both 7-day and 30-day abstinence but were not statistically significant.



**Figure 1.** Flow of participants in the Parejas trial.

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Among both nondaily smokers and daily smokers, cessation rates were higher postpartum than they were in pregnancy. For continuous abstinence (secondary), we found no arm difference in cessation rates with the same pattern for nondaily and daily

smokers' cessation rates (Table 2). Sensitivity analyses were run to assess the impact of lost-to-follow-up on the primary and secondary effects of interest. The findings were similar to the intent-to-treat analyses (data not shown).

**Table 1.** Baseline characteristics of participants

	Totals	Materials alone (N = 175)	Materials + counseling (N = 173)
	M (SD)/% (N)	M (SD)/% (N)	M (SD)/% (N)
Age, M (SD)	30 (6)	29 (5)	30 (6)
Education (%)			
<9 years	66 (229)	69 (120)	63 (109)
Employment (%)			
Full time	66 (226)	67 (116)	64 (110)
Part time	28 (96)	27 (46)	29 (50)
Not currently employed	6 (23)	6 (11)	7 (12)
Country of origin (%)			
Mexico	78 (269)	79 (139)	76 (132)
Length of time in U.S. (%)			
>3 years	94 (326)	94 (165)	93 (161)
Language spoken at home (%)			
Spanish only	68 (237)	70 (133)	66 (114)
Length of relationship (%)			
>3 years	67(231)	65 (113)	69 (118)
Number of children (%)			
1 or more	77 (267)	76 (133)	77 (134)
Wanted baby now (%)	65 (225)	69 (120)	61 (105)
Difficulty paying bills (%)	38 (131)	36 (62)	40 (69)
Smoking (%)			
Everyday (n = 134)	39 (134)	37 (64)	41 (70)
Some days (n = 214)	61 (214)	63 (111)	60 (103)
Cigarettes per d M (range)			
Daily (n = 134)	8 (5)	8 (5)	8 (6)
Some days (n = 214)	3 (3)	3 (2)	4 (3)
Smoking inside home (%)	3 (11)	3 (6)	3 (5)

**Table 2.** Adjusted cessation rates and ORs with 95% confidence interval (95% CI) for men at the end of pregnancy (EPS) and 12-month postrandomization (postpartum)<sup>a</sup>

	Less intensive (N = 175)		More intensive (N = 173)		Adjusted OR (95%CI)
	N	Rate	N	Rate	
Primary outcome					
7-Day point prevalence					
End of pregnancy	59	0.31	55	0.30	0.96 (0.60-1.55)
12-Mo postrandomization	69	0.39	66	0.38	-1.02 (0.65-1.60)
Secondary outcomes					
30-Day abstinence					
End of pregnancy	30	0.14	36	0.19	1.42 (0.81-2.49)
12-Mo postrandomization	51	0.30	52	0.30	1.14 (0.78-1.84)
Continuous abstinence					
End of pregnancy	19	0.09	27	0.15	1.63 (0.86-3.10)
12-Mo postrandomization	16	0.07	24	0.12	1.79 (0.90-3.60)
Nondaily smokers (n = 214)					
7-Day point prevalence					
End of pregnancy	51	0.46	44	0.43	0.92 (0.53-1.60)
12-Mo postrandomization	58	0.52	49	0.48	0.87 (0.50-1.50)
30-Day point prevalence					
End of pregnancy	29	0.26	30	0.29	1.26 (0.68-2.33)
12-Mo postrandomization	45	0.41	41	0.40	1.00 (0.58-1.75)
Continuous					
End of pregnancy	19	0.15	23	0.19	1.4 (0.71-2.80)
12-Mo postrandomization	16	0.14	21	0.20	1.5 (0.74-3.18)
Daily smokers (n = 134)					
7-Day point prevalence					
End of pregnancy	8	0.13	11	0.16	1.02 (0.34-3.10)
12-Mo postrandomization	11	0.17	17	0.24	1.59 (0.64-3.92)
30-Day abstinence					
End of pregnancy	1	0.02	6	0.09	— <sup>b</sup>
12-Mo postrandomization	6	0.09	11	0.16	2.12 (0.68-6.63)
Continuous					
End of pregnancy	0	0.00	4	1.00	—
12-Mo postrandomization	1	0.002	4	0.04	—

<sup>a</sup>Effects are controlled for education, number of cigarettes smoked per day, and wantedness of pregnancy.<sup>b</sup>Unable to model due to sample size.



## Discussion

There are three important findings from this trial. First, providing culturally adapted written materials and NRT to Latino expectant and postpartum fathers seems to be as powerful an intervention as providing one-on-one and couple-based counseling, particularly among nondaily smokers. Second, daily smokers might benefit from a more intensive intervention. Third, quit rates among Latino men are high postpartum.

It was surprising to find no arm differences given the intensity of the intervention. This might be because most of the smokers did not smoke daily, and nondaily smokers did not need an intensive intervention when their motivation was naturally increased. It also could be that we offered NRT, and more used it than we anticipated as others have reported low rates of NRT use among Latino smokers (22). This cessation effect is promising for future interventions and is higher than has been found in previous trials (8). If written materials and NRT alone plus home visits for assessment can produce close to 50% cessation rates during pregnancy and postpartum, then less intensive approaches should be used to promote cessation among Latinos, especially among those who are nondaily smokers. Written materials can only be effective, however, with men who know how to read. Future trials should assess the efficacy of written materials that are distributed without having a research assistant explain the highlights as this could serve as an intervention and without home assessment visits.

The arm differences for daily smokers were small and not statistically significant, but the trend favored the more intensive intervention. In the postpartum period, the 30-day cessation rates were almost double in the intervention arm and were almost the exact rates upon which we powered the trial. We might have been underpowered to detect this difference with only 134 daily smokers, less than a third of our sample. However, results show that the combination of couples-based and individual cessation counseling can help daily smokers quit more than materials.

Finally, cessation rates both among daily and nondaily smokers were highest postpartum. This is the opposite effect seen among pregnant smokers, where up to 50% quit smoking when learning they are pregnant and up to 90% return to smoking postpartum. It could be that even though *familismo* is a strong component of Latino culture, pregnancy was not as strong a trigger to motivate cessation as seeing an actual baby. Having the baby in his arms and seeing how environmental tobacco smoke and third-hand smoke can affect that child might be the impetus a Latino father needs to quit smoking. They might still believe that when they smoke away from their pregnant wife, they are protecting the baby, but they also might feel more compelled to quit once the baby has arrived. This effect should be replicated.

This study has limitations that affect interpretation of the results. First, we limited our study to Spanish speakers, and many were from Mexico; thus, our findings might not generalize to English-speaking Latinos or those from other countries. Second,

although our attrition rate was low, we were unable to reach some couples at follow-up, which also might affect generalizability. While our attrition rates were significantly lower than those in other recent RCT conducted with Latino smokers (5), we did find reasons other than wanting to participate in our study that contributed to our high no contact rate (e.g., fear, work schedules, etc.). We were unable to biochemically validate the 30-day abstinence rates, which for nondaily smokers is a better measure than 7-day point prevalence abstinence. It is possible that our rates are inflated by social desirability, which is more common among Latinos than whites (23). We have confidence in our 30-day rates, however, given they are considerably lower than our 7-day rates, which we were able to validate. Finally, we recruited smokers via their partners rather than directly; this might have biased our sample.

This was the first study to try to promote cessation among expectant Latinos throughout pregnancy and postpartum. We included light and nondaily smokers as this is the representative of Latino smokers in the United States and worldwide. We found that for nondaily smokers, providing written materials and NRT during pregnancy promotes cessation. Daily smokers might need a more intensive intervention even in the teachable moment of pregnancy and postpartum. Future interventions might focus only on postpartum and, to be more cost-effective, offer only written materials to nondaily smokers and more intensive counseling only to daily smokers. Interventions also might target postpartum rather than pregnancy as a teachable moment to motivate cessation.

## Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

## Authors' Contributions

**Conception and design:** K.I. Pollak, K.C. Gordon, B. Peterson, G.K. Swamy, S. Denman, L.J. Fish

**Development of methodology:** K.I. Pollak, K.C. Gordon, S. Denman, L.J. Fish  
**Acquisition of data (provided animals, acquired and managed patients, provided facilities, etc.):** K.I. Pollak, P. Lyna, K.C. Gordon, P. Rocha, L.J. Fish  
**Analysis and interpretation of data (e.g., statistical analysis, biostatistics, computational analysis):** P. Lyna, K.C. Gordon, B. Peterson, X. Gao, G.K. Swamy, L.J. Fish

**Writing, review, and/or revision of the manuscript:** K.I. Pollak, P. Lyna, A.K. Bilheimer, K.C. Gordon, B. Peterson, G.K. Swamy, S. Denman, A. Gonzalez, P. Rocha, L.J. Fish

**Administrative, technical, or material support (i.e., reporting or organizing data, constructing databases):** P. Lyna, A.K. Bilheimer, X. Gao

**Study supervision:** K.I. Pollak, A.K. Bilheimer, A. Gonzalez, L.J. Fish

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