



Original Contribution

Effect of Reducing Indoor Air Pollution on Women's Respiratory Symptoms and Lung Function: The RESPIRE Randomized Trial, Guatemala

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Initially submitted June 10, 2008; accepted for publication April 1, 2009.

Exposure to household wood smoke from cooking is a risk factor for chronic obstructive lung disease among women in developing countries. The Randomized Exposure Study of Pollution Indoors and Respiratory Effects (RESPIRE) is a randomized intervention trial evaluating the respiratory health effects of reducing indoor air pollution from open cooking fires. A total of 504 rural Mayan women in highland Guatemala aged 15–50 years, all using traditional indoor open fires, were randomized to either receive a chimney woodstove (plancha) or continue using the open fire. Assessments of chronic respiratory symptoms and lung function and individual measurements of carbon monoxide exposure were performed at baseline and every 6 months up to 18 months. Use of a plancha significantly reduced carbon monoxide exposure by 61.6%. For all respiratory symptoms, reductions in risk were observed in the plancha group during follow-up; the reduction was statistically significant for wheeze (relative risk = 0.42, 95% confidence interval: 0.25, 0.70). The number of respiratory symptoms reported by the women at each follow-up point was also significantly reduced by the plancha (odds ratio = 0.7, 95% confidence interval: 0.50, 0.97). However, no significant effects on lung function were found after 12–18 months. Reducing indoor air pollution from household biomass burning may relieve symptoms consistent with chronic respiratory tract irritation.

biomass; bronchitis, chronic; carbon monoxide; developing countries; pulmonary disease, chronic obstructive; smoke; spirometry; wood

Abbreviations: CI, confidence interval; COPD, chronic obstructive pulmonary disease; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; RESPIRE, Randomized Exposure Study of Pollution Indoors and Respiratory Effects.

Worldwide, approximately 3 billion people rely on solid fuels for everyday cooking and heating, mostly in the form of biomass (wood, animal dung, or crop wastes) but also coal (mainly in China) (1). The use of solid fuels in poorly ventilated conditions results in high levels of indoor air pollution, most seriously affecting women and their youngest children (2). Indoor air pollution, smoking, and occupational hazards are the most important risk factors for the development of chronic obstructive pulmonary disease (COPD) in developing countries (3, 4). COPD is responsible for 2% of the total global burden of disease. Unless urgent action is taken to control smoking and indoor air pollution, COPD is projected to rank as the third-leading cause of death among women in the world by 2015 (5).

Recent observational studies (4, 6–17) have suggested that exposure to wood smoke is a risk factor for COPD in women. However, these studies have had important limitations: None were randomized intervention trials, and they could not exclude the possibility of residual confounding by overcrowding, poor nutrition, prior respiratory infections, and other poverty-related factors. Few of the studies included measurements of lung function taken by spirometry (6, 10, 11, 13, 15–17), which is the gold standard method for the diagnosis of COPD. Moreover, few studies included direct measurements of exposure, relying instead on surrogate measures such as fuel and/or stove type or amount of time spent near the fire (6, 7, 9–12). Accurate assessment of exposure is essential in order to reduce the likelihood of

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misclassification and to allow estimation of exposure-response relations.

The Randomized Exposure Study of Pollution Indoors and Respiratory Effects (RESPIRE) was designed as a household randomized trial assessing the impact on respiratory health of reduced indoor air pollution from biomass fuel use in rural Guatemala (18). The intervention consisted of the installation of an improved woodstove with a chimney (*plancha*) that has been shown to substantially reduce kitchen indoor air pollution (19). Detailed measurement of exposure was undertaken (20). Separate components of the trial investigated the impacts, inter alia, on acute lower respiratory infection in children aged 18 months or younger (21) and blood pressure in older women (22).

In this report, we present results for the main effects of the intervention (use of the *plancha* in the intervention group vs. continued use of open fires in the control group) on women's respiratory symptoms and lung function over a period of 12–18 months. A previous analysis of baseline measurements among the women had shown that they had normal lung function but a high prevalence of respiratory symptoms (20).

MATERIALS AND METHODS

Study site and population

The study was conducted in a poor, rural Mayan community in San Marcos Department, northwestern Guatemala. The study area lies at an altitude of 2,200–3,000 m, with a cool climate, especially between December and April, when nighttime temperatures occasionally reach 0°C. Therefore, homes are generally enclosed with wooden doors and shutters, although open eaves are common. Wood is the main household fuel; it is burned indoors, most commonly in 3-stone open fire pits. Pilot studies in a neighboring area showed typical 24-hour average particulate matter (particulate matter with a diameter below 10 µm (PM₁₀)) concentrations in the range of 800–1,000 mg/m³ (23), approximately 15–20 times the World Health Organization guideline levels (24, 25). This area was selected as a suitable site for the intervention following feasibility studies (26–28).

Illiteracy is common in this indigenous population, whose principal language is Mam (29). Smoking is uncommon among Mayan females. Women spend on average 5 hours per day in a room with a lit fire (30), and most of them own and regularly use a traditional sauna (*temascal*) in which extremely high levels of wood smoke can be present (31).

Study design, recruitment, and intervention

The women in this study were mothers of children recruited into RESPIRE. An initial census identified 777 families fulfilling the household eligibility criteria: exclusive use of an open fire for cooking and heating and the presence of a pregnant woman or an infant less than 4 months of age. After informed consent was obtained for 534 study children, randomization of households was carried out in blocks of 10. The blocking factors were inaccessible to field personnel and remained unknown to study investigators until data collection was complete. The intervention households received

an improved stove (*plancha*) at the beginning of the study, and the control households were offered a *plancha* upon study completion. Thirty mothers declined to participate in the adult part of the study. Thus, 504 women (mean age = 27.7 years (standard deviation, 7.2); range, 15–50 years), mothers of the study children and the principal cooks for their families, were recruited in 2 rounds. The selection of recruitment group A (300 women, 153 receiving a *plancha*) occurred between October and November 2002, and the selection of recruitment group B (204 women, 106 receiving a *plancha*) occurred between April and May 2003 (20). The fieldwork was conducted between October 2002 and December 2004.

A *plancha* is a stove with a thick metal heating surface for cooking of tortillas and holes with removable concentric rings for pots. It has a firebrick combustion chamber with baffling, a cement block and brick body, tile surfaces around the cooking area, a metal fuel door, and a metal chimney with a damper (19). It is locally produced and widely disseminated among other communities in Guatemala.

Assessment of health outcomes

Fieldwork took place through home visits made by 2 locally recruited, bilingual (Mam and Spanish) field-workers. Baseline information was gathered using 3 interviewer-led questionnaires. Detailed information about the questionnaires has been published elsewhere (19, 20). Because of an unforeseen overload of work early in the study, the third questionnaire, which included respiratory symptoms and baseline spirometry, had to be delayed by 4 months in recruitment group A. By then, intervention households in this recruitment group had already been using the *plancha* for 1 month; thus, information on preintervention symptoms and lung function was available only for recruitment group B.

After baseline, the women were assessed every 6 months with interviewer-administered questionnaires and spirometric measurements until their children reached 18 months of age (up to 12 months in recruitment group A and 18 months in recruitment group B). The different assessments for recruitment group A and recruitment group B, as well as loss to follow-up, are illustrated in Figure 1. Because of these differences, some of the information is presented separately for recruitment groups A and B. The main reason for loss to follow-up was internal migration for seasonal work.

Participants were asked about chronic airway symptoms (cough, phlegm, wheeze, and tightness in the chest) using questions in Mam developed from standard questionnaires on COPD (Medical Research Council/International Union Against Tuberculosis and Lung Disease) and asthma (International Study of Asthma and Allergies in Childhood) (32–35). The original English questions were translated into Spanish with back-translation and were modified through extensive local piloting to versions with both health terminology and symptom time patterns that were adequate and understandable for the local women (20). Lung function was measured using Micro Medical Microloop turbine spirometers (Micro Medical Ltd., Rochester, United Kingdom), in accordance with American Thoracic Society guidelines (36). Details regarding data quality assurance, questionnaire

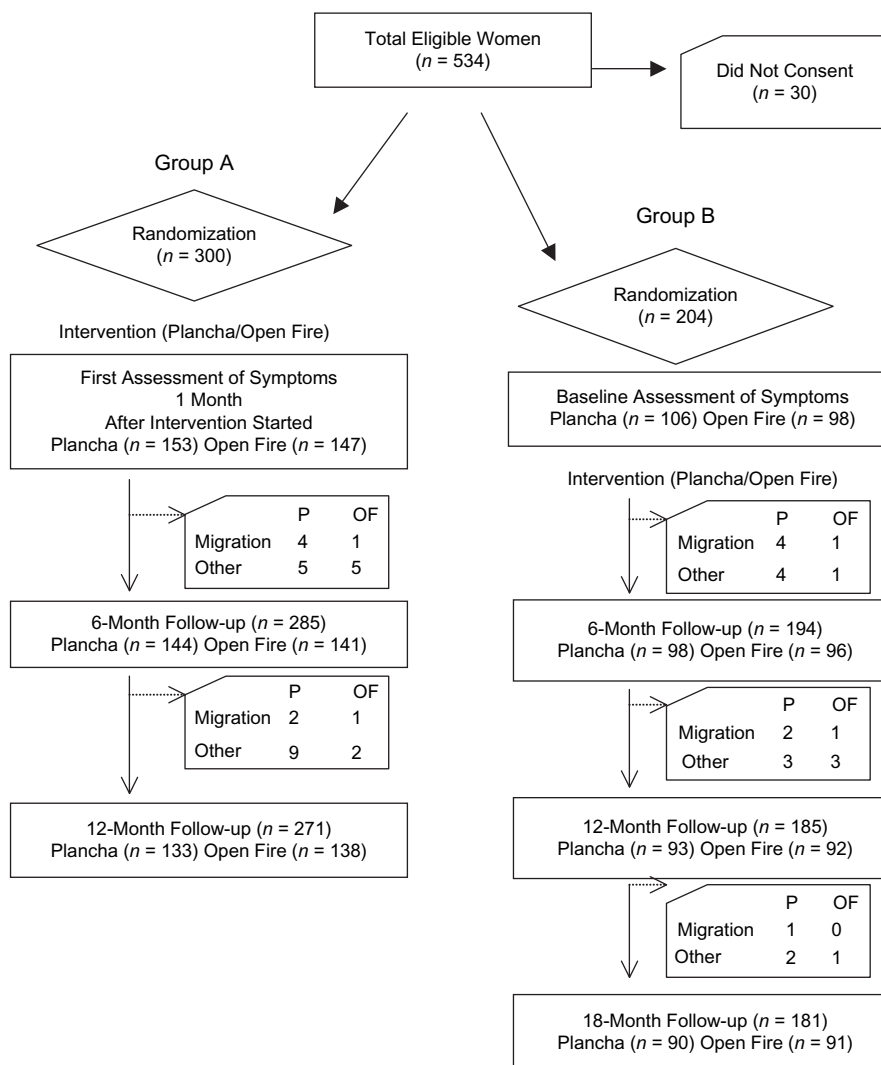


Figure 1. Distribution of the study population from baseline through follow-up, San Marcos, Guatemala, 2002–2003. OF, open fire; P, plancha.

development, field-worker training and surveillance, spirometry procedures, and interobserver variability for spirometry have been published elsewhere (20).

Exposure assessment

Drawing on earlier work (23, 37) that was validated after the trial, we measured 48-hour personal exposure to carbon monoxide with GASTEC carbon monoxide passive diffusion tubes (GASTEC Corporation, Tokyo, Japan) in all women at baseline and every 6 months (see the Web Appendix, which is posted on the *Journal's* Web site (<http://aje.oxfordjournals.org/>)).

Statistical methods

We assessed the balance of randomization on baseline measurements using appropriate hypothesis testing (chi-squared test for categorical variables, *t* test for comparison of mean values (normally distributed variables), and Mann-

Whitney *U* test for comparison of median carbon monoxide values).

Longitudinal analyses of the effect of the intervention on respiratory symptoms (binomial data) and assessment of possible change in the effect over time were conducted with tests of effects and estimation of relative risks in log binomial generalized estimating equations analyses. All analyses were checked for consistency with alternative random-intercept Poisson regression analyses. These analyses accounted for the correlation in repeated measurements made on the same woman.

Since each woman may have had several respiratory symptoms (up to 4 were recorded), we also performed an analysis of the effect of the intervention on the number of symptoms reported by each woman. Ordinal logistic regression was used to estimate the effect of the intervention on the odds of having a certain number of symptoms. Binary logistic regression analyses may be used to estimate odds ratios by applying cutpoints at any number of symptoms

Table 1. Baseline Characteristics of the Intervention (Plancha) and Control (Open Fire) Groups, by Recruitment Group, San Marcos, Guatemala, 2002–2003

	Recruitment Group A (n = 300)						Recruitment Group B (n = 204)					
	Plancha (n = 153)			Open Fire (n = 147)			Plancha (n = 106)			Open Fire (n = 98)		
	Mean (SD)	No.	%	Mean (SD)	No.	%	Mean (SD)	No.	%	Mean (SD)	No.	%
Characteristics of the women												
Mean age, years	27.7 (7.2)			28.3 (7.3)			26.9 (7.3)			27.9 (6.8)		
Pregnant	13		8.5	11		7.5	73		68.9	65		66.3
Mean no. of children aged <12 years	3.7 (1.7)			3.8 (1.7)			3.6 (1.8)			3.8 (1.6)		
Current cigarette smoking	1		0.7	1		0.7	0			0		
Symptoms experienced while cooking												
Cough ^a	105		68.6	98		66.7	70		66.0	66		67.3
Headache ^b	107		69.9	100		68.1	87		72.6	74		75.6
Sore eyes ^c	141		92.1	133		90.5	95		89.7	85		86.7
Mean forced expiratory volume in 1 second, L ^d	2.63 (0.33)			2.68 (0.38)			2.65 (0.35)			2.63 (0.32)		
Mean forced vital capacity, L ^d	3.01 (0.38)			3.08 (0.43)			3.07 (0.42)			3.10 (0.36)		
Household characteristics												
Relative smoked inside home	32		20.9	42		28.6	20		18.9	24		24.5
Mean no. of cigarettes smoked per day by husband	1.04 (0.2)			1.06 (0.2)			1.20 (0.4)			1.05 (0.2)		
Have temascal ^e	124		81.0	115		78.2	101		95.3	91		92.9
Use of temascal more than once per week	55		35.9	55		37.4	45		42.5	41		41.8
Kitchen separate from bedroom	128		83.7	126		85.7	87		82.1	85		86.7
Socioeconomic status (asset index ^f)												
0	24		15.7	25		17.0	13		12.3	17		17.3
1	83		54.2	87		59.2	52		49.1	51		52.0
2	33		21.6	19		12.9	27		25.5	22		22.4
3	12		7.8	12		8.2	12		11.3	8		8.2
≥4	1		0.7	4		2.8	2		1.8	0		0.0
Mean 48-hour carbon monoxide exposure ^g , ppm	3.32 (1.9)			3.54 (2.7)			3.29 (3.1)			3.43 (3.2)		
Meteorologic factors												
Mean rainfall, mm/day	0.22 (0.4)			0.24 (0.5)			1.69 (3.7)			2.01 (3.9)		
Mean temperature, °C	11.8 (1.4)			11.9 (1.3)			13.3 (0.7)			13.5 (0.7)		

Abbreviation: SD, standard deviation.

^a Question posed: "When you are cooking, does the smoke make you cough or irritate your throat?" (Yes = sometimes/always.)

^b Question posed: "When you are cooking or immediately afterward, do you get a headache?" (Yes = sometimes/always.)

^c Question posed: "When you are cooking, do your eyes get irritated?" (Yes = sometimes/always.)

^d Values from women who fulfilled American Thoracic Society criteria (36) at baseline. Women in recruitment group A had been using the plancha for 1 month at the time of these measurements.

^e Local sauna bath.

^f Total number of consumer goods (radio, television, refrigerator, bicycle, motorcycle, and car) the family owned (44). Values ranged from 0 for not having any of the specified items to 6 for having all of them.

^g Measured by diffusion tubes.

from 1 to 4. We accounted for correlation between repeated observations of the same women by using clustering and robust estimation of variances and confidence intervals.

Effects of the intervention on change in lung function were estimated in Gaussian random-intercept regression models for continuous variables, treating subsequent measurements on the same woman as a random effect and the

presence of a plancha as a fixed effect. Changes in effect over time were also assessed. We repeated the analyses by first calculating the change in lung function measurements for each woman at each follow-up assessment by subtracting her baseline measurement (results not shown).

In all regression analyses, we included time and recruitment group as covariates. We also checked for differences in

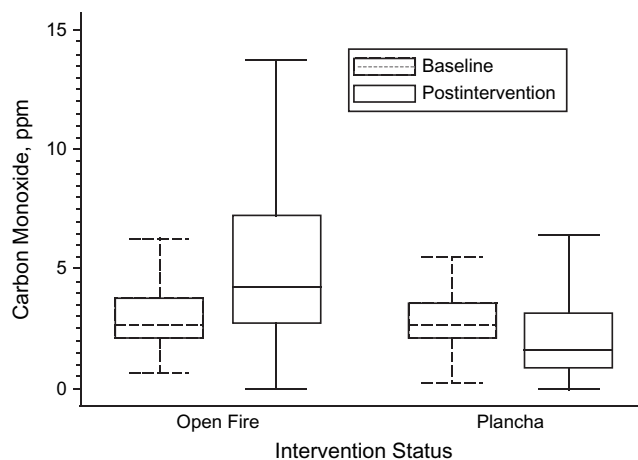


Figure 2. Median 48-hour personal exposure to carbon monoxide, by intervention status (plancha vs. open fire), San Marcos, Guatemala, 2002–2004. Carbon monoxide levels were measured by means of passive diffusion tubes. Postintervention data represent the average of all post-intervention measurements. Outliers were excluded. Bars, interquartile range (25th–75th percentile).

intervention effect between the 2 recruitment groups. Since the first 6 months of follow-up may be too short a time period to detect effects on chronic symptoms and lung function, we also performed subanalyses excluding the 6-month observation.

Finally, random-effects logistic and linear regression were used for preliminary analysis of the relation between exposure and respiratory symptoms. For analysis in this paper, the mean of all postintervention readings for each woman taking part in the adult study was used, both as a continuous variable and in quartiles based on the distribution of natural logs of the mean values. Analyses were adjusted for age, time, altitude, and socioeconomic status (based on ownership of a television, a bicycle, and cattle).

All analyses were carried out in Stata, version 9.1 (Stata Corporation, College Station, Texas).

The adult component of RESPIRE was approved by the research ethics committees of the universities of Bergen (Bergen, Norway), Liverpool (Liverpool, United Kingdom), and Del Valle Guatemala (Guatemala City, Guatemala).

RESULTS

Randomization

Table 1 shows data on principal background characteristics, the prevalence of symptoms while cooking (assessed in the second baseline questionnaire), and exposure as measured by carbon monoxide tubes at baseline for both recruitment groups. No indications of differences between intervention and control households were found.

Exposure assessment

The median postintervention carbon monoxide values were significantly reduced in the plancha group (1.63 ppm) as compared with the open fire group (4.24 ppm) ($P = 0.0001$) (Figure 2).

Chronic lung symptoms

Figure 3 shows changes in the prevalence of cough and phlegm from baseline through each follow-up point (based on recruitment group B, for whom appropriate baseline data were available). An overall decrease was seen in both the intervention group and the control group, with the lowest prevalence for the intervention group being observed at the last time point. The same pattern was also seen for the other respiratory symptoms (data not shown).

The plancha intervention was found to be protective for each of the respiratory symptoms (Figure 4), although the effect was significant only for wheeze (relative risk = 0.42, 95% confidence interval (CI): 0.25, 0.70). The overall reduction over time, independent of intervention, was significant only for cough and phlegm. There was no evidence that the effect of the intervention changed over time or that it was different for the 2 recruitment groups for any symptom (results not shown).

Results from the ordinal logistic regression analysis indicated that the plancha significantly reduced the odds of having a certain number of symptoms (or more) relative to having a lower number of symptoms by 30% (odds ratio = 0.7, 95% CI: 0.50, 0.97; $P = 0.03$).

Lung function

The proportion of women who fulfilled American Thoracic Society criteria for spirometry increased with experience—that is, with each successive round (from 86.6% (412 women) at baseline to 93.7% (429 women) at 6 months, 95.2% (414 women) at 12 months, and 100% (175 women) at 18 months (recruitment group B only)). Forced vital capacity (FVC) values increased from baseline through follow-up in both the intervention group and the control group. For women who fulfilled American Thoracic Society criteria at both baseline and 12 months, there was an overall mean increase in FVC of 167 mL (180 mL in the

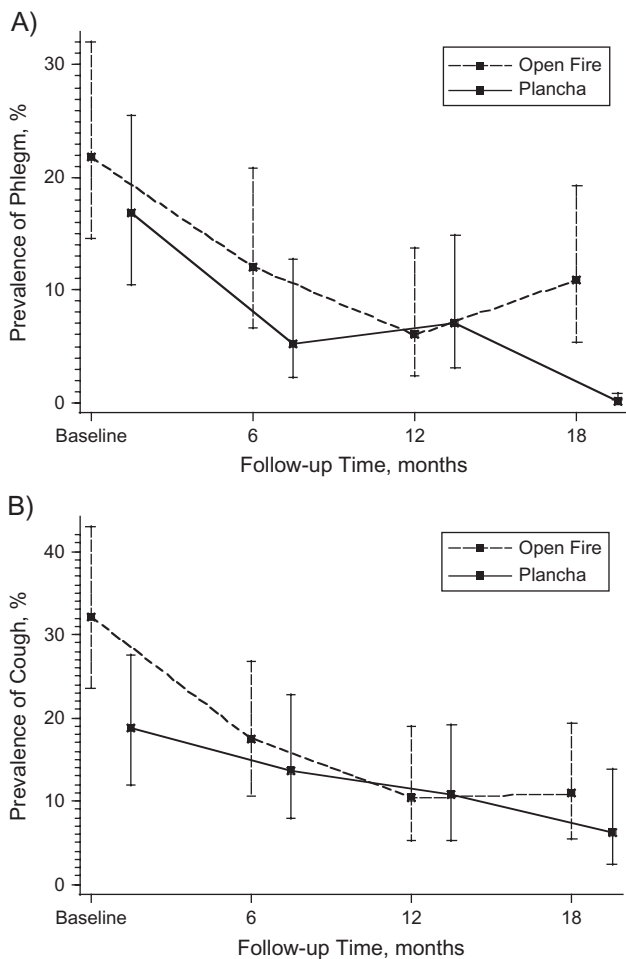


Figure 3. Prevalences of phlegm (part A) and cough (part B) in the intervention (plancha) and control (open fire) groups from baseline to 18 months, recruitment group B, San Marcos, Guatemala, 2002–2004. For questions, see Appendix 1. Bars, 95% confidence interval.

control group and 136 mL in the intervention group) after 1 year, and the FVC values declined after this point (recruitment group B only). Forced expiratory volume in 1 second (FEV_1) increased from the first measurement to the 6-month follow-up but then declined slightly. Since there was a consistent increase in FVC values over time, the ratio of FEV_1 to FVC declined over time.

Longitudinal analyses confirmed a decrease of 0.012 L per 6 months in FEV_1 (95% CI: -0.022 , -0.001) and an increase of 0.020 L per 6 months in FVC (95% CI: 0.007, 0.033) from 6 months of follow-up to 18 months of follow-up. According to the Global Initiative for Chronic Obstructive Lung Disease criteria ($FEV_1:FVC < 70$) (38), none of the participants had COPD.

The plancha had no statistically significant effects on lung function within the follow-up period (Table 2). These results were consistent with those from a similar analysis of the change in measurements for each woman at 6, 12, and 18 months obtained by subtracting her baseline measurements (data not shown).

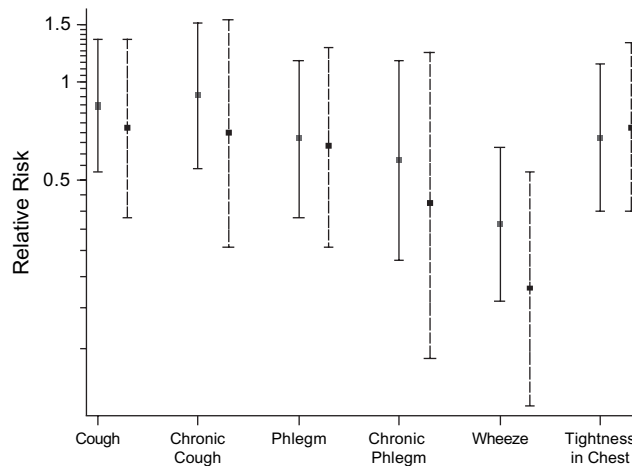


Figure 4. Relative risk of respiratory symptoms in the intervention group (women who received a plancha), San Marcos, Guatemala, 2002–2004. Relative risks were derived using generalized estimating equations. For each symptom, the solid line represents all postintervention assessments and the dashed line represents only the 12- and 18-month assessments. For questions and definitions, see Appendix 2. Bars, 95% confidence interval.

Relation between respiratory health and exposure

As Table 3 shows, the risk of all respiratory symptoms was greater in the higher 3 quartiles of exposure relative to the lowest quartile.

DISCUSSION

Our study of young Mayan women confirmed that households adopting the use of improved stoves (planchas) had a significant reduction in carbon monoxide exposure during an 18-month period (19). The prevalence of chronic respiratory symptoms, especially wheeze, was reduced among women in the plancha group, but their lung function did not differ significantly from that of women who were still using open fires after a period of 12–18 months.

The most important strength of this study was its design, it being (to our knowledge) the first randomized controlled trial to study the effect of indoor air pollution on health. The intervention and control groups were balanced with regard to potential confounders; hence, the randomization appears to have been successful. Although there were some differences between recruitment groups A and B—for example, in proportion of pregnant women and use of a temascal—these differences were balanced between intervention and control women, and we found no evidence of inconsistent results between the 2 groups. Participating women had their lung function measured every 6 months during the study, although we did not perform reversibility tests. Exposure measurements were undertaken for all of the participants, allowing for comparisons with future studies. The plancha stoves achieved a statistically significant 61.6% reduction in personal carbon monoxide exposure levels as measured by diffusion tubes.

Table 2. Regression Coefficient^a (β) for the Mean Longitudinal Effect of Use of a Plancha on Lung Function, San Marcos, Guatemala, 2002–2004

Outcome	Follow-up Time Points Included			
	6, 12, and 18 Months		12 and 18 Months Only	
	β	95% CI	β	95% CI
FEV ₁ ^b	-0.02	-0.09, 0.04	-0.01	-0.09, 0.05
FVC ^b	-0.04	-0.01, 0.03	-0.04	-0.12, 0.04
(FEV ₁ :FVC) \times 100 ^c	0.41	-0.44, 1.27	0.50	-0.42, 1.42

Abbreviations: CI, confidence interval; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity.

^a Estimation was performed in a Gaussian regression random-intercept model with time and recruitment group (A or B) included as covariates.

^b Measured as excess change in liters (relative to baseline) in the plancha group relative to the control group across the follow-up time.

^c Measured as a percentage score (relative to baseline) in the plancha group relative to the control group across the follow-up time.

Table 3. Odds Ratio for Respiratory Symptoms According to Carbon Monoxide Exposure^a Among Mayan Women, San Marcos, Guatemala, 2002–2004

Lung Symptom and Quartile of Carbon Monoxide Exposure ^b	Odds Ratio ^c	95% Confidence Interval
Cough		
First	1.0	
Second	2.65	1.29, 5.47
Third	1.68	0.79, 3.57
Fourth	1.72	0.81, 3.65
Phlegm		
First	1.0	
Second	2.99	1.20, 7.46
Third	2.25	0.87, 5.80
Fourth	2.98	1.20, 7.42
Wheeze		
First	1.0	
Second	1.80	0.73, 4.46
Third	2.50	1.03, 6.06
Fourth	2.46	1.02, 5.90
Tightness in chest		
First	1.0	
Second	2.45	1.02, 5.88
Third	2.60	1.07, 6.30
Fourth	2.35	0.98, 5.65

^a In quartiles based on the distribution of the natural log of carbon monoxide ppm values.

^b Measured by diffusion tubes.

^c Adjusted for age, time, altitude, and socioeconomic status (based on television, radio, and bicycle ownership).

Potential limitations of the study included a lack of blinding and therefore the possibility of bias; this appeared to be evident from the tendency of women to report a favorable response to the plancha regardless of its physiologic efficacy. Such bias might have inaccurately increased the estimated effect of the intervention. However, although some participants might have given the “right” answers to please the study investigators, the control women, who were still waiting to receive their planchas, would have been at least as inclined to provide perceived appropriate responses.

Another possible limitation of this study concerns lifetime differences in exposure. Mayan women begin to cook for their families when they get married, and they will already have been helping their mothers in the kitchen for some years during later childhood. Women in the study were the main family cooks. Although the randomization seemed to be effective, we did not ask women how long they had been cooking at study inception; hence, we cannot be absolutely sure that the intervention and control groups were comparable regarding preintervention exposure. Also regarding exposure, sources of neighborhood pollution were not addressed in detail or modified in this study. The exposure of women in the plancha group to smoke from neighbors will have contributed to higher levels of carbon monoxide in the plancha group and therefore to underestimation of the plancha’s effect.

The study questionnaires were developed in the Mam language. Although some other studies on indoor air pollution and respiratory health have also observed a significantly higher prevalence of wheeze with higher exposure (8, 17), this is a term that is not easily translated into different languages and is thus difficult to interpret. Further detailed qualitative studies conducted after RESPIRE identified 2 main key terms for wheeze in Mam, namely *nxwisen* and *ntzarrin* (39). The most important, *nxwisen*, was the principal term used by the field-workers in the current study. However, Thompson et al. (39) found that clear understanding of this word required explanation, including a demonstration to emphasize that while the symptom originates in the chest, it is heard in the neck. This level of understanding about the nuances of meaning and comprehension was not available at the time of the surveys. Nevertheless, relative risks for all respiratory symptoms were reduced, with reductions for the total number of symptoms and wheeze achieving statistical significance. These reductions in symptoms provide evidence consistent with decreased chronic respiratory tract irritation.

The prevalence of respiratory symptoms was reduced over time in both the intervention group and the control group. One possible reason is that women might have tired of answering the same questions periodically and learned that the interviews would be shorter if they did not report symptoms (avoiding subsequent questions on symptom frequency and persistence). This effect, however, would have applied equally to both the intervention and control groups and hence would have caused only nondifferential misclassification. Another explanation is the possible learning effect: By taking part in the study, many of these women may have realized that smoke exposure was undesirable (40) and partially avoidable—for example, through better ventilation

or other behavioral changes. Such adaptations could have led to a reduction in exposure (observed for both groups—see Web Appendix (<http://aje.oxfordjournals.org/>)) and the burden of symptoms in the control group to some extent. Observation bias could also be a possible explanation for our findings, since the field-workers periodically visited the women and could see whether they had planchas in their homes. Nevertheless, the significant reduction in objectively measured indoor air pollution detected in the intervention group as compared with the control group and the significant relation between 1) women's exposure and respiratory symptoms at baseline (20) and 2) the symptoms and exposure presented in this paper (Table 3) support the conclusion that the significant reduction in the number of respiratory symptoms is probably a consequence of the significant reduction in exposure achieved through the use of the plancha.

The quality of lung function measurements was not optimal at the beginning of the study. As was discussed in a previous paper (20), the field-workers improved their spirometry technique with experience. In addition, there was probably a learning effect among the participants, whose FVC values increased during the first year of the study. Nevertheless, these figures are still within the acceptable difference of 200 mL for FVC between blows (American Thoracic Society criteria) (36), and our FEV₁ values are very similar to those from Ecuador (10) and other countries in Latin America (41). Consequently, we can trust the FEV₁ values and probably the FVC values—especially those recorded at follow-up—but the FEV₁:FVC ratios should be interpreted with caution.

Although we did find a significant effect of the intervention on respiratory symptoms as assessed by questionnaire, we did not detect such an effect on lung function (an objective measurement), even though we detected a relation between symptoms and exposure. In other community studies carried out in developing countries, investigators found that although biomass exposure was consistently associated with chronic respiratory symptoms, effects on lung function were variable or small (10, 17, 42). Both RESPIRE and the above studies recruited rural women regardless of previous health status, as opposed to previous case-control studies (6, 43). In addition, women in RESPIRE were younger than those taking part in most of the earlier studies on indoor air pollution, in an age group in which chronic pulmonary disease would not usually have become established. Lastly, the sample size for RESPIRE was driven primarily by the requirement to detect a reduction in the incidence of child pneumonia (the main aim of RESPIRE). A sample size of 500 households was sufficient (with 80% power) to detect a reduction in adult respiratory symptom prevalence from 25% to 15% and a difference in FEV₁ of 0.09 L at a significance level (2-sided *P* value) of 5%. The calculation used an estimated population mean FEV₁ of 2.70 L and a standard deviation of 0.35 L. Taking all of these factors into consideration, the most probable reasons for our spirometry findings by intervention group were the young age of the participants (who had normal lung function at the start of the study) and the relatively short follow-up period. According to a recent intervention-based study carried out in China by Chapman et al. (9), a follow-up of approximately 10 years would be

needed to detect an unequivocal effect of the intervention on self-reported (physician-diagnosed) COPD.

In summary, in intention-to-treat analysis, the substitution of traditional open fires with locally produced improved stoves significantly reduced exposure to indoor air pollution and the risk of wheeze and the total number of respiratory symptoms but did not result in a significant effect on lung function within a follow-up period of 1.5 years. Longer follow-up will be needed to detect statistically significant changes in lung function among young women.

ACKNOWLEDGMENTS

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Funding was obtained from the Norwegian Research Council for this supplement to the main randomized trial (RESPIRE), which was funded by the US National Institute of Environmental Health Sciences.

The authors thank the staff at the field site for their excellent work. They also appreciate the support of the Guatemalan Ministry of Health.

Conflict of interest: none declared.

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APPENDIX 1

Questions pertaining to the prevalence of phlegm or cough (Figure 3):

Phlegm—

Baseline: “Do you produce or have you produced a lot of phlegm?”

Follow-up: “During the past 6 months, have you produced a lot of phlegm?”

Cough—

Baseline: “Do you cough or have you coughed a lot?”

Follow-up: “During the past 6 months, have you coughed a lot?”

APPENDIX 2

Questions and definitions pertaining to respiratory symptoms (Figure 4):

Cough: “During the past 6 months, have you coughed a lot?”

Chronic cough: Morning, day, or evening cough for more than 3 months during the last 6 months.

Phlegm: “During the past 6 months, have you produced a lot of phlegm?”

Chronic phlegm: Morning, day, or evening phlegm for more than 3 months during the last 6 months.

Wheeze: “During the past 6 months, have you had attacks in which you [wheezed]?” (See text for further explanation of this question.)

Tightness in chest: “During the past 6 months, have you woken up in the morning with the sensation of pressure on your chest?”