Impact of reducing indoor air pollution on women's health.

RESPIRE Guatemala - Randomised exposure study of pollution indoors and respiratory effects

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“Tengo la impresión de que la ciencia y la tecnología se han ido aislando de las necesidades de la gente. En muchos casos, el ejercicio de la ciencia se convierte en un fin en sí mismo. En cambio, debería darse el reencuentro de la ciencia y las grandes mayorías de la población. Quizá así encontraría la humanidad formas de descubrir cosas nuevas.”

Rigoberta Menchú in Rigorberta: la nieta de los Mayas.

“My impression is that science and technology have been isolating themselves from the needs of the people. Often the use of science becomes an end in and of itself. Instead, there should be a mutual understanding between science and a large majority of the population. Perhaps that would lead mankind to new discoveries.”

Rigoberta Menchú in Rigorberta: the granddaughter of the Mayan people

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1. ACKNOWLEDGMENTS

In November 2003 I had been working as a full time general practitioner for eight years, and was ready to learn more about clinical research. I was not sure about what I wanted to research on, but for me it was of vital importance that the topic of the investigation could benefit the people in the world that needed it most. If possible, it should help the poorest among the poor.

My first gratitude goes, therefore, to my main supervisor, Tone Smith-Sivertsen. She kindly invited me to join her study on health among poor women in rural Guatemala, and guided me from the very basics of epidemiology and statistical analysis to international-level research. I was lucky enough to have two other experienced and supportive co-supervisors. Rolv Terje Lie, at the University of Bergen, was an invaluable help, especially regarding the statistical challenges that I found in the course of my doctoral work. Nigel Bruce, at the University of Liverpool, was priceless for planning and discussing each article as many times as it was necessary. Also in Liverpool, although not as a formal supervisor, Dan Pope was a crucial assistance for the development of my work, helping me both with the data and with the impossible English language. To all of them I want to express my most sincere gratitude.

The RESPIRE (Randomised Exposure Study of Pollution Indoors and Respiratory Effects) study was an international collaboration that had been carefully planned during many years. Professor Kirk Smith, at University of California Berkeley, was the main person behind the enormous amount of work that made RESPIRE possible. To him, and to Byron Arana, at the Del Valle de Guatemala University, I want to express my gratitude for letting me join the team. In addition, I want to thank the rest of the international group for the collaboration during these years, especially to Anaité Díaz, the field project manager, who patiently answered my numerous questions about fieldwork details.

It has been a pleasure to work at the Public Health and Primary Health Care Department at the University of Bergen during these years. While the combination of teaching and investigation has been a challenge in some periods, it has helped me to keep in mind that the purpose of investigation is not only writing papers, but also disseminating the results in other ways. Especially important at the Department have been the constructive discussions of each other's research questions with both the senior staff and other PhD students.

The really important people in this study are the women who agreed to answer our questions and gave us the possibility of studying indoor air pollution exposure and lung function in rural Guatemala. My deepest gratitude to them, and the hope that the results of this thesis, together with the rest of evidence that will come from RESPIRE, will one day help them, and other women and children in their situation, to attain a better life.

Last, but not least, my gratitude and love to my husband Sigmund and my children Daniel, Andreas and Carlos. They have been the ones to pay the price for the hours used on this thesis, as well as the source of inspiration and rest I needed to continue working.

2. LIST OF PUBLICATIONS

I. Díaz E, Bruce NG, Pope D, Lie RT, Díaz A, Arana B, Smith KR, Smith-Sivertsen T (2007). Lung function and symptoms among Indigenous Mayan women exposed to high levels of indoor air pollution. *International Journal for Tuberculosis and Lung Diseases* 11(12); 1372-1379.

II. Smith-Sivertsen T, Díaz E, Pope D, Lie RT, Díaz A, McCracken J, Bakke P, Arana B, Smith KR, Bruce NG. Effect of reducing indoor air pollution on women's respiratory symptoms and lung function: RESPIRE Guatemala randomised trial. *Submitted 2008.*

III. Díaz E, Smith-Sivertsen T, Pope D, Lie RT, Díaz A, McCracken J, Arana B, Smith KR, Bruce NG (2007). Eye discomfort, headache and back pain among Mayan Guatemalan women taking part in a randomised stove intervention. *Journal of Epidemiology and Community Health* 61; 74-79.

IV. Díaz E, Bruce NG, Pope D, Díaz A, Smith KR, Smith-Sivertsen T (2008). Self-rated health among Mayan women participating in a randomised intervention trial reducing indoor air pollution in Guatemala. *BMC International Health and Human Rights* 8:7.

3. ABBREVIATIONS

ALRI – Acute lower respiratory infection

CO – Carbon monoxide

COPD – Chronic obstructive pulmonary disease

FEV_1 – Forced expiratory volume in 1 second

FVC – Forced expiratory vital capacity

GOLD – Global Initiative for Chronic Obstructive Lung Disease

HRCT – High resolution computer tomography

IAP – Indoor air pollution

LPG – Liquefied petroleum gas

OR – Odds ratio

PEF – Peak expiratory flow

PM – Particulate matter

RESPIRE – Randomised exposure study of pollution indoor and respiratory effects

WHO –World health organisation

4. SUMMARY

Indoor air pollution (IAP) is a global health problem that affects the most impoverished communities in the world, and especially women and young children among them. Half of the world households, particularly in rural areas, still rely on solid fuels for heating and burning in simple stoves or open fires, often with poor ventilation systems. The high levels of IAP resulting from these practices have been linked to many health hazards. The scientific evidence is strong for a causal association between IAP and acute lower respiratory infections (ALRI) in children under 5 years of age and for chronic obstructive respiratory disease (COPD) and lung cancer (mainly from coal) for adults older than 30 years. The evidence is moderate for lung cancer from biomass smoke, asthma, adverse pregnancy outcomes, cataracts and tuberculosis.

The available data on health problems related to IAP comes form observational studies, where the possibility of residual confounding cannot be excluded. Most of these studies have not measured personal exposure to IAP, but rely on exposure proxies, such as time spent near the fire or number of years cooking for the family. In addition, a variety of definitions has been used to study chronic obstructive respiratory disease, and few studies have measured lung function, which is the gold standard for the diagnosis of COPD. Thus, a randomised controlled study that measured personal exposure and lung function of the participants was needed to better understand the effects of IAP on health. Also, to study directly the effects of an intervention, including on a group of younger women in whom COPD would not be well established.

RESPIRE (Randomised Exposure Study of Pollution Indoors and Respiratory Effects) is the first randomised controlled study to assess the impact on health of reduced IAP from biomass fuel use. In rural Guatemala, 534 children under 18 months and 504 mothers were included in the RESPIRE study. Wood burned in open fires was the main heating and cooking fuel in all the households. Half part of them (intervention group) received an improved stove with a chimney (*plancha*). The control households continued to use the open fires, and received a *plancha* at the end of the study, 18 months later. This thesis presents health outcomes among the mothers taking part in RESPIRE. The participants were young (mean age of 27.8 years), and did not smoke.

These women exposed to IAP since birth had a relatively high prevalence of respiratory symptoms at baseline: cough (22.6%), phlegm (15.1%), wheeze (25.1%), and tightness in the chest (31.4%), and reported even higher prevalence of non-respiratory symptoms: sore eyes (53%), headache (70%), and back pain (62%). Lung function at baseline was higher than the most relevant reference population identified (average above predicted FEV1 +4.5% and FVC +4.2%).

The randomisation of the households into intervention and control groups appeared to be successful. The *plancha* significantly reduced exposure to carbon monoxide (CO) by 61.6% as measured by diffusion tubes. For all respiratory symptoms, a consistent reduction in risk was observed in the *plancha* group for the follow-up period as a whole, the reduction being statistically significant only for wheeze (RR and 95% CI: 0.42 (0.25-0.70)). The number of respiratory symptoms reported by a woman at each follow-up time was also significantly reduced by the *plancha* (OR and 95% CI: 0.7 (0.50-0.97)). The odds of having sore eyes and headache were substantially reduced in the *plancha* group relative to the group using open fires for the follow-up period (RR and 95% CI: 0.37 (0.28-0.49); RR and 95% CI: 0.82 (0.70-0.97), respectively). No significant effects were, however, found on lung function measurements within the 18 months follow-up.

Among a subgroup of 89 intervention and 80 control women asked about change in health during the study period, 52.8% of the intervention women reported improvement in health, compared to 23.8% of the control women ($p<0.001$). When asked how the *plancha* had changed their lives, 84 intervention women reported a reduction of smoke in the kitchen; 88% of them linked this to improvement in their own health, particularly for non-respiratory symptoms (eye discomfort and headache); 57% linked reduced smoke to improvement in their children's health, particularly sore eyes.

The study had several limitations. The lack of baseline information on symptoms for one of the recruitment groups, the lack of validated questionnaires and of reference values for lung function in this population, the presence of other sources of exposure (*temascal*) and the relatively short follow-up, were the main challenges in our study.

In conclusion, in the frame of a randomised controlled trial, our study supports and strengthens the evidence of a link between long-term exposure to IAP and both respiratory and non-respiratory symptoms among young non-smoking women. The *plancha* proved to significantly reduce the levels of exposure in the intervention group.

Both respiratory and non-respiratory symptoms were significantly reduced in this group, although no effect in lung function could be detected 18 months after the intervention was introduced. The young age of the participants and the relatively short follow-up period are the most probable reasons leading to our inability to detect such an effect.

5. INDOOR AIR POLLUTION IN THE WORLD

5.1 Magnitude of the problem

Clean air is considered to be a basic requirement of human health and welfare. However, 2 million premature deaths each year are attributed to the effects of both outdoor (mainly urban) and indoor air pollution (IAP) (caused by the burning of solid fuels).[1] Approximately 3 billion people in the world, most of them in rural areas of developing countries, rely on solid fuels for cooking and heating. Of them, 2.4 billion people use biomass (wood, animal dung and crop wastes) and 0.6 billion use coal (most of them in China). Biomass fuels are typically burnt indoors in open fires or poorly functioning stoves, without appropriate ventilation, which cause high levels of IAP in kitchens in developing countries. IAP from solid fuels was ranked tenth among the risk factors assessed for the global burden of disease, and among environmental risk factors only poor water/sanitation causes more ill health.[2] Unfortunately, the use of biomass is not expected to decline over the next years, and the International Energy Agency estimates that 2.6 billion people will still be using biomass by 2030.[3]

Exposure to pollution is a function of both the concentration in an environment, and the person-time spent in the environment. People in developing countries, mainly women, who often carry their youngest children at their backs, are commonly exposed to high levels of IAP for 3-7 hours daily while cooking for their families over many years.[3] The fraction of material released that they actually inhale (*intake fraction*) is consequently orders of magnitude higher for indoor than for outdoor sources of air pollution.[4, 5] In fact, 76% of human exposure to particulate matter (PM) occurs in indoor environments in the developing world, while 9% of global PM exposure occurs in indoor environments in industrialised countries.[6, 7]

Conservative estimates of global mortality in 2000 showed that between 1.5 and 2 million deaths were attributed to IAP from solid fuels. This accounts for 4-5% of total mortality worldwide. Approximately one million of these deaths were due to childhood pneumonia, with chronic obstructive pulmonary disease (COPD) as the second most important cause of death.[7]

5.2 Biomass smoke exposure: a brief review

5.2.1 Chemical composition and toxicology

Smoke from household solid fuels is a complex mixture that contains many relevant components from a toxicological perspective. The mixture varies with characteristics determined by sources, materials burned, time since generation, humidity and other factors. The major health-damaging pollutants from biomass combustion can be divided into:[4]

i) Inorganic gases: Carbon monoxide (CO), Ozone (O3) and Nitrogen dioxide (NO2)

ii) Hydrocarbons: Polycyclic aromatic (PAHs; f. ex. benzo [a]pyrene), Monoaromatics (benzene)

iii) Oxygenated organics: Aldehydes (formaldehyde), Organic alcohols, Phenols, Quinones

iv) Particulate matter (PM)

Wood burnt on a typical three-stone wood-fire stove produces harmful levels of the mentioned gases, particles and other noxious compounds, that exceed many times the WHO air quality guidelines.[8] In addition, the cooking efficiency of this process is low: only about18% of the energy generated goes into the pot, while 8% goes into the smoke (products of incomplete combustion), and 74% is heat.[3]

The mechanisms by which some key pollutants from biomass combustion may damage health are shown in Table 1, updated form Bruce et al. [9-11] Biomass smoke causes chronic pulmonary disease by mechanisms only partially understood. Both macrophage dysfunction and increased activity of matrix metalloproteinase (MMP, a group of endopeptidases that can degrade most of the components of the extracellular matrix) have been reported. Rabbits exposed to acute wood smoke had impaired macrophage phagocytic function, surface adherence,[12] and reduced bacterial clearance.[13] Rats exposed to chronic wood smoke developed mild bronchiolitis with epithelial cell hyperplasia and hypertrophy, alveolar septal thickening, and mild emphysema.[14] Controlled animal exposures to concentrated ambient particulates have demonstrated induction of pulmonary inflammation.[15] Bronchoalveolar lavage samples from human subjects with COPD associated with woodsmoke exposure showed significantly higher MMP activity than those from healthy controls. The presence of these enzymes in the respiratory tract might degrade the interstitial extracellular matrix and basement membrane components, and cause lung damage similar to that observed in COPD associated with tobacco smoking.[16]

Table 1: Mechanisms by which some key pollutants from biomass combustion may damage health (updated from Bruce, 2002)[9]

Pollutant	Mechanism	Potential health effect
Particulate matter (PM)	Acute: bronchial irritation, inflammation and increased reactivity Reduced muco-ciliary clearance Reduced macrophage response and (?) reduced local immunity (?) Fibrotic reaction Autonomic imbalance, pro-coagulant activity, oxidative stress Systemic inflammatory response involving stimulation of the bone marrow, which can contribute to cardiorespiratory morbidity[17]	In children: Decreased pulmonary lung function Increased incidence of acute bronchitis and severity/frequency of wheezing and coughing Increased incidence, duration, and possibly severity of acute respiratory infections In adults: Chronic bronchitis, Chronic interstitial pneumonitis and fibrosis, Cor pulmonale, Interstitial lung disease, Pulmonary arterial hypertension Altered pulmonary immune defence mechanisms[18]
Carbon monoxide (CO)	Binding with haemoglobin to produce carboxyhaemoglobin, which reduces the oxygen-carrying capacity of the blood[19]	Anaemic hypoxemia Adverse pregnancy outcomes, (miscarriage, stillbirth, low birth weight, and early infant mortality) May contribute to cardiovascular mortality and early course of myocardial infarction[19]
Nitrogen dioxide (NO2)	Binding to hemoglobin to produce methemoglobin and hematologic aberrations Affects the activity of several enzyme systems Causes vascular membrane injury and leakage leading to oedema[13] Longer term exposures increase susceptibility to bacterial and viral lung infections	Bronchoconstriction in asthmatics at low levels Respiratory infections Reduced lung function (children)
Polyaromatic hydrocarbons (PAHs) (Benzo [a]pyrene)	Immunosuppressive in laboratory animals Carcinogenic in animals and possibly humans	Lung cancer Cancer of mouth, nasopharynx, and larynx
Aldehydes (Formaldehyde)	Upper airway irritation Impaired immunity[13]	Headaches / neurophysiologic dysfunctions Exacerbation of bronchial asthma Possibly cancer[13] (?) Increased susceptibility to infections
Biomass smoke (component uncertain)	Oxidative damage to the eye lens	Cataract

5.2.2 Health effects

Based on systematic reviews, the evidence is strong for a causal association between IAP and acute lower respiratory infections in children, and COPD and lung cancer (from exposure to coal smoke) among women older than 30 years. The evidence is moderate for COPD among men older than 30 years, lung cancer from biomass smoke in adults older than 30 years, asthma in both children and adults, adverse pregnancy outcomes, cataracts and tuberculosis.[5, 20]

I. Acute lower respiratory infections (ALRI)

More than two million children younger than five years die of pneumonia every year, making it the single most common cause of death among children under five years worldwide.[9] The incidence of pneumonia in this age group is estimated to be 0.29 episodes per child-year in developing and 0.05 episodes per child-year in developed countries. This translates into 156 million new episodes each year worldwide, of which 151 million episodes are in the developing world.[21] Childhood pneumonia is caused by a combination of exposure to risk factors related to the host, the environment and infection. The leading bacterial cause is Strep pneumoniae, being identified in 30–50% of pneumonia cases, followed by *H. influenzae* type b and *S. aureus*. Respiratory syncytial virus accounts for 15–40% of pneumonia or bronchiolitis cases admitted to hospital in children in developing countries, followed by influenza A and B and parainfluenza. The leading risk factors contributing to pneumonia incidence are lack of exclusive breastfeeding, malnutrition, IAP, low birth weight, crowding and lack of measles immunization.[21, 22]

There is strong and consistent evidence for the association between use of solid fuels and acute lower respiratory infection. In a meta-analysis of the available studies, ALRI was associated with cooking with wood or other biomass fuel with an OR of 2.0 (95% CI: 1.4-2.8). An even higher odds ratio was found when the child was carried on the mother's back during cooking (OR and 95% CI: 3.1 (1.8-5.3)).[20] A later systematic review of the literature including newer observational studies and the results from infants taking part in the first randomised controlled trial on IAP (RESPIRE) concluded that the risk of pneumonia in young children was increased by exposure to solid fuels by a factor of 1.79 (95%CI: 1.46-2.21).[23] Results from the RESPIRE study on child health have shown than a reduction of 1 ppm exposure to carbon monoxide (CO) was associated with a 22% lower (95% CI: -38%, -2%) risk of ALRI. The association was stronger for more severe ALRI with hypoxemia (29% reduction; 95% CI: -47%, -6%).[24]

II. Chronic pulmonary disease

II.1 Chronic obstructive pulmonary disease (COPD)

COPD is a preventable pulmonary disease characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases.[25] According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD), a clinical diagnosis of COPD should be considered in any patient who has dyspnoea, chronic cough or sputum production, and/or a history of exposure to risk factors for the disease. The diagnosis should be confirmed by spirometry with reversibility testing.[25] Although the study of COPD has been difficult because of limited resources in countries outside

Europe and the United States of America, its prevalence has now been studied in some countries in Latin America, where the crude rates of COPD ranged from 7.8% (95% CI: 5.9–9.7) in Mexico City to 19.7% (95% CI: 17.2–22.2) in Montevideo.[26]

Historically, there has been a significantly greater prevalence and mortality of COPD among men compared with women, and COPD has mainly been attributed to tobacco smoke. Although smoking is the main risk factor for development of COPD globally, only about 49% and 38% of the total burden of COPD for men and women respectively is attributable to tobacco.[20] Both the increase in prevalence of advanced stages of COPD in individuals who had never smoked, and the increased risk of COPD in women detected by several international studies conducted during the last years, raise important questions about the role of other exposures, and possibly of a greater genetic susceptibility in women.[26-28] Results from studies on cigarette smoke support also the hypothesis that women might be more susceptible to the effect of the smoke than men.[29-31]

A growing body of literature implicates IAP from biomass fuel as an important risk factor for the development of COPD.[5, 26, 32-39] Patients with chronic lung disease have been reported in communities heavily exposed to indoor biomass smoke pollution all over the world.[4, 9, 17, 20] In a meta-analysis to assess the burden of disease caused by IAP from household use of solid fuels, Smith et al. estimated the overall risk of COPD among women over 30 years of age exposed to IAP as 3.2 (95% CI: 2.3-4.8).[20]

COPD is the cause of two percent of the entire global burden of disease, and unless action is taken to reduce smoking and IAP, it is projected to be the third cause of death among women in the world by 2015.[40] Indeed, 85 percent of the 2.7 million deaths that occurred as a consequence of COPD in 2000 happened in developing countries.[41, 42] People in poorer countries tend to develop disease at younger ages, suffer longer and die sooner than those in high-income countries.[43] Because people suffering from advanced stages of COPD have reduced work capacity compared to healthy subjects, COPD is a hidden cause of poverty that hinders the economic development of many countries, and contributes to the poverty that makes it difficult for the affected poor to afford cleaner fuels.

A summarizing table of the studies of Chronic Bronchitis or COPD and exposure to biomass smoke published since 2000 is provided in Table 2. We found six cross-sectional studies, five case-control studies, one retrospective cohort study and one case series study. Although an increasing number of studies are adopting the use of spirometry to measure lung function, quality control of spirometry technique at the field site is not assessed in any of the studies to date. Only three studies measured exposure, two of them as particulate matter measured in the kitchen, as opposed to personal exposure measurements. The other studies relied on proxies for exposure assessed by questionnaire.

Table 2: Studies of Chronic Bronchitis (CB) or COPD and exposure to biomass smoke since 2000

Study and Location	Design, numbers and ages	Measure of exposure	Measure of health outcome	Findings	Comments
Liu, 2007 Guangdong-China	Cross-sectional M+F>40y	CO PM10 SO2, NO2	Spirometry	Prevalence COPD 9.4% higher in rural population*	IAP important risk factor for COPD
Akhtar, 2007 Pakistan	Case- biomass (1426) vs. control- LPG (1131) F non-smokers All ages	Questionnaire	Questionnaire CB (phlegm most days last 3months, 2 successive years)	CB case/controls: OR 2.51 (1.65-3.83) CB-use of wood: OR 2.38 (2.12-3.01)	COPD more prevalent among women > 30 years
Sezer, 2006 Turkey	Case (74)-control (74, hospital visitors) F mean age 57	Questionnaire	Questionnaire Diagnose COPD for cases	OR for COPD in women exposed to biomass for >30 years 6.61 (2.17-20.18)	OR for COPD-smoking 4.96 (1.65-14.86)
Rinne, 2006 Ecuador	Cross-sectional (80 households) F+M>7y Female >16y	Questionnaire	Spirometry	No difference in women's lung function*	Children in biomass houses had lower FVC and FEV1 (p= 0.05)
Regalado, 2006 Mexico (2600m) (data from 1994-1995)	Cross-sectional (841) Non-smoking women >38y	PM kitchen	Questionnaire Spirometry	Biomass associated with phlegm (27% vs 9%) and reduced FEV1/FVC (79.9% vs 82.8%)*	FEV1 81ml lower and cough more common (OR 1.7 (1.0-2.8) in biomass group
Ramírez-Venegas, 2006 Mexico (2240m)	Cross-sectional (520 patients diagnosed COPD) Women (mean age 68y)	Questionnaire	Spirometry Questionnaire	Women exposed to biomass develop COPD with clinical characteristics, quality of life, and increased mortality similar in degree to smokers.*	
Orozco-Levi, 2006 Spain	Case (60)-control (68) F>50y	Questionnaire	Spirometry	OR 4.5 (1.4-14.2) for COPD in women using wood and charcoal*	The association length of exposure-COPD suggested a dose–response pattern
Sherstha, 2005 Nepal (1400m)	Cross-sectional 168 women. Mean age 36.1y Biomass compared to cleaner fuels	PM10 in kitchen CO Gastec	Questionnaire PEF	Associations between biomass and respiratory symptoms (wheezing OR 5.39 (1.6-18.5) and chronic respiratory diseases (COPD/asthma OR 3.85 (1.1-13.4))*	

Ekici, 2005 Turkey	Cross-sectional (528) W>40 y	Questionnaire	Questionnaire Spirometry CAD: either Chronic Airway Obstruction (CAO), chronic bronchitis or chronic bronchitis with CAO	CAD was associated with exposure (OR 1.4, 1.2-1.7)* Significant adverse effect of exposure on lung function*	Fraction of CAD attributed to exposure to biomass: 23.1% (13.4–33.2) Acute dyspnoea (OR 3.4) and acute wheezing (OR 3.3) due to biomass, best acute predictors for CAD*
Chapman, 2005 Xuanwei, China	Retrospective cohort study (20453)	Questionnaire	Questionnaire	COPD for people using a chimney: Risk ratio 0.58 (0.49- 0.70) in men and 0.75 (0.62-0.92) in women*	The reduction in risk became unequivocal about 10 years after stove improvement
Sümer, 2004 Turkey	Cross-sectional (265) Non-smokers M+W Age 17-70y	Questionnaire	Questionnaire Spirometry	12.4% (7.0-17.7%) (0.382 liter) reduction in FVC (0.396 liter reduction for FEV1) in biomass users*	
Kiraz, 2003 Turkey	Case (300 rural)- control (150 urban) W>25y	Questionnaire	Questionnaire Spirometry	Women with CB were more likely than women without CB to have exposure to biomass (OR 28.9, 8.7-95.9)*	Pulmonary function tests within normal limits; FEV, values in rural women were relatively low compared with urban women ($p < 0.05$)
Kara, 2003 Turkey	Case-control Total: 92 non-smoking women. Mean age 49.3y	Questionnaire	High resolution computer tomography (HRCT)	Exposure to biomass fuels was the cause or predisposing factor for many pulmonary diseases, ranging from chronic bronchitis to diffuse lung diseases.	Incidence of bronchiectatic changes: 26% in symptomatic women, 6.3% in asymptomatic, and 3.3% in controls.
Özbay, 2001 Turkey	Case series study, 30 female patients Mean age 59y (SD 11y)	Questionnaire	HCRT Spirometry	Spirometry: severe obstruction. HRCT: increased lung volume, emphysema, focal thickening septae,emphysematous areas, increased cardiothoracic ratio.	Biomass leads to both obstructive and restrictive pathologies.

M=males; F=females; CB=chronic bronchitis

* Results adjusted for different variables

II.2 Hut lung

The term "hut lung" or domestically acquired particulate lung disease, has been used to describe a wide spectrum of clinical manifestations including chronic bronchitis (CB), chronic obstructive pulmonary disease (COPD), and interstitial lung disease associated with high level exposures to biomass smoke.[44] Grobbelaar and Bateman introduced the term in 1991.[45] Two years later, in a study of 30 non-smoking women with lung disease previously exposed to IAP, Sandoval et al. described a diffuse, bilateral, reticulonodular pattern, combined with normalized or hyperinflated lungs, as well as indirect signs of pulmonary arterial hypertension. This wood-smoke inhalation-associated lung disease appeared to be more severe than other forms of interstitial lung disease and tobacco-related COPD. On the pulmonary function test the patients showed a mixed restrictive-obstructive pattern with severe hypoxemia and variable degrees of hypercapnia.[46] The most common high resolution computer tomography findings described among female patients exposed to long-term biomass smoke are increased lung volume or diffuse emphysema, thickening of interlobular septae, focal emphysematous areas, increased cardiothoracic ratio, and increased bronchovascular arborisation. Pulmonary function tests of the same patients revealed severe obstruction. [47] Recognition of this syndrome and removal of the patient from the environment is the only treatment to date.[48]

II.3 Asthma

The predominant feature of the clinical history of asthma is episodic shortness of breath, particularly at night, often accompanied by cough. Wheezing appreciated on auscultation is the most common physical finding.[49] The relationship between air pollution and asthma remains controversial, partly because of the low reported prevalence of asthma in many developing countries. Later studies including countries in Latin America, however, report a prevalence of asthma similar to that from developed countries.[50]

There is consistent evidence that air pollution triggers asthma in sensitised individuals,[17, 51] but there are few studies on the association between IAP and adult asthma, and their results are contradictory.[9, 52] Some reports find a positive association between cooking smoke and asthma,[36, 53-56] while others fail to find any relationship.[57] The relative risk for asthma in children between 5-14 years has been estimated to be 1.6 (95% CI: 1.0-2.5). Similarly, the relative risk for asthma in adults over 15 years of age was estimated to be 1.2 (95% CI: 1.0-1.5).[5]

II.4. Pulmonary tuberculosis

The incidence of tuberculosis is increasing worldwide, mostly because of the HIV-epidemic, but also because of the spreading of drug-resistant tuberculosis.[58] A link between tuberculosis and solid fuel use is suggested both by animal studies[13] and by surveys of human populations. Two Indian studies found statistically significant relationships between biomass fuel use and tuberculosis in both adult men and women who were exposed to smoke from dung or wood.[5, 59] Although these two studies in India did not address smoking as a possible confounder, one study in Mexico City did take smoking into account and still found an association between exposure to wood smoke and tuberculosis.[60] A later study on IAP and tuberculosis, however, did not report a positive association between biomass use and tuberculosis disease after adjustment.[61] The finding that biomass fuel combustion increases risk of tuberculosis is in accordance with animal studies, that show that repeated inhalation of woodsmoke can compromise pulmonary immune mechanisms that are critical for host protection against infectious lung pathogens.[4] This eventual relationship should be clarified with larger studies in the future. [62, 63]

II.5 Lung cancer

In developing countries, non-smokers, especially women, form a larger proportion of patients with lung cancer than in industrialised countries. [39] A meta-analysis of several Chinese studies found a relative risk for lung cancer (from exposure to coal smoke) in women over 30 years of age of 1.94 (95%CI: 1.09-3.47). [5] In India, the risk of development of lung cancer was highest for women using biomass fuels, with an odds ratio of 3.59 (95% CI: 1.07-11.97) after adjusting for smoking and passive smoking.[64] In Mexico, a case control study supported the hypothesis that long-term exposure to wood smoke from cooking may contribute to the development of lung cancer, despite the controls being women suffering from other respiratory diseases as tuberculosis or interstitial lung disease, that could also be related to IAP.[11, 65]

III. Adverse pregnancy outcomes

Adverse pregnancy outcomes, such as stillbirth, low birth weight and perinatal death have been linked to IAP from solid fuel use. One study in India reported an association between perinatal mortality and exposure to IAP, with an odds ratio of 1.5 (95% CI: 1.0-

2.1) for still births after adjustment.[39] In rural Guatemala, babies born to women using wood fuel were 63 grams lighter ($p<0.05$) than those born to women using gas and electricity, after adjustment for socioeconomic and maternal factors.[66] In Zimbabwe, babies born to mothers cooking with wood, dung, or straw were 175 grams lighter (95% CI: -300, -50), on average, compared with babies born to mothers using LPG, natural gas, or electricity.[67] Low birth weight is an important risk factor for infant and child morbidity and mortality from several diseases, and it has also been linked to ill health later in life. Although it is likely that there is a substantial health impact from adverse pregnancy outcomes later in the life of a child, at present it is difficult to quantify this burden.[5]

IV. Cataract

Cataract is the leading cause of blindness worldwide. In one study on blindness in India, Mishra et al. concluded that 18% of partial and complete blindness among persons age 30 and older might be attributed to biomass fuel use, suggesting that smoke exposure from the use of biomass fuels for cooking substantially increased the risk of partial blindness.[68] A later case-control study in Nepal confirmed that use of solid fuel in unflued indoor stoves was associated with increased risk of cataract in women who did the cooking.[69] The relative risk for cataracts in adults over 15 years of age was estimated to be 1.3 (95% CI: 1.0-1.7). [5] In addition to cataracts, IAP from solid fuels may also be linked to blindness through trachoma.

V. Blood pressure and heart disease

Several studies from developed countries have shown increased risk of heart disease for exposure to tobacco smoke and outdoor air pollution at much lower levels than IAP levels seen in developing countries. There are, however, no studies from developing countries on the relationship between IAP and heart disease yet.[4, 70] The only exception comes from results from the RESPIRE study on elderly women (38-65 years). McCracken et al.[71] investigated de effect of IAP on blood pressure, concluding that older women using improved stoves had 3.7 mm Hg (95% CI: -8.1 to -0.6) lower systolic blood pressure and 3.0 mm Hg (95% CI: –5.7 to –0.4) lower diastolic blood pressure compared with women using open fires, in adjusted analysis.[71] More studies on this topic are needed.

VI. Nasopharyngeal and laryngeal cancer

Two studies in Brazil[5] have shown a relationship between exposure to wood smoke and upper aero-digestive tract cancers, with adjusted relative risks of 2.5 and 2.7. One of the studies also found an association between exposure to wood smoke and nasopharyngeal cancer, but this result contrasted with detailed studies in Asia that found no evidence for such a link.

VII. Bites, violence, and other risks linked to household energy

A number of other health consequences is directly associated with household energy although not directly related to IAP. In most developing countries, it is women's responsibility to provide biomass fuel. Women typically use from two to twenty hours a week collecting fuel, and the distances covered over difficult terrain can be considerable.[3] This work does not only reduce the time that women can use in other activities, but it contributes to different threats to health such as back problems from carrying heavy loads, injuries, animal bites, and increased risk of violence, such as rape. In addition, girls are often removed from school to assist their mothers in these tasks. Burns represent other health consequence of the use of open fires. Infants and young children can become severely burned because the cooking area is on the floor and, while crawling or sleeping near the flame, their clothing is ignited. Women often get burnt while cooking for the family.[72, 73]

5. 3 From open fire to improved stoves: women's opinion

Despite some major program successes, [74] many developing-country households fail to adopt improved stoves. Attempts have been made to learn from past experiences.[75, 76] Reasons are complex, and often locally specific, but the lack of involvement of women in the project cycle has been identified as one major factor contributing to poor uptake and sustainability.[77] Yet, there are few published studies that incorporate women's perspectives on the introduction of improved stoves in populations previously using open fires. In the available studies, [78, 79] most of the women reported that the primary advantage of the stoves was the reduction of smoke in the kitchen. In addition, women using stoves reported reduction of symptoms like dry cough (OR and 95% CI: 0.61 (0.26–1.41)), sneezing (OR and 95% CI: 0.54 (0.22–1.30)) and tears while cooking (OR and 95% CI: 0.51 (0.21–1.21)). The authors attribute the non-signifficancy of the results to the small number of participants.[78] Other frequently mentioned advantages were the ability for a person to cook in a standing position on an elevated surface, the constant availability of hot water and the aesthetic qualities of the stove.

There have been, however, several negative aspects linked to some types of improved stoves. For example, in Guatemala the Lorena type stove was unable to provide adequate space heating. By contrast, the open fire had traditionally been a source of warmth, especially for smaller children and for the elderly. When given the choice, many of the more conservative Guatemalan Indians decided that they would rather enjoy the heat of the open fire than economize on firewood or reduce smoke. These and other unexplored negative perceptions of the stoves are likely to contribute to the abandonment of the stoves in many households. Thus, it is important to understand women's perceptions regarding advantages and disadvantages of different methods proposed for cooking and heating. Only in this way adequate alternatives to the open fires will be developed and hopefully adopted.

6. GUATEMALA

The context of the work described in this thesis is the high levels of indoor air pollution that affect most of the rural women living in the Department of San Marcos in Guatemala.

6.1 Geography, demographics, literacy and language

Located in the Central America subtropics, the Republic of Guatemala borders Mexico and Belize to the north and El Salvador and Honduras to the south. It covers a total land area of 108889 km^2, and has a population of nearly 13 million.[80] Guatemala is a relatively little urbanized country. Almost 60% of the population live in rural areas, and 81% of rural people are indigenous.[81] Our study was carried out in San Marcos, one of Guatemala's departments, located in the Western part of Guatemala.

The official language in Guatemala is Spanish. Indigenous communities speak a wide range of languages and dialects, and many do not speak Spanish. Mam is one of the most important indigenous languages, spoken by more than a million people in the country,[82] and it is the main language spoken in San Marcos Department.

Although the situation has changed over the past decade with the growth of a considerable commercial middle class, implementation of democratic elections, and the end of a 30-year long civil war, Guatemala remains a highly stratified society in which a small elite controls much of the land and economy, and retains political power. [83] The population is divided into two ethnic groups of approximately equal size: the indigenous population, who are descendants of Mayas and other pre-conquest groups, and Ladinos, who, regardless of ethnic origin, speak Spanish, wear European clothes, and view themselves as part of the mainstream Guatemalan culture.[83] Most of the indigenous people living in San Marcos have Mayan ancestors.

Poverty in Guatemala is widespread, but mostly concentrated in rural areas and among indigenous communities.[81] According to the most recent estimates, 51% of Guatemalan families live below the poverty line [80], which is defined as having insufficient resources to purchase a basic basket of goods and services ($1.52 per person per day in 2000)[84]. The poverty rate is even higher for the indigenous Mayan population: in 2000, 76% of indigenous people were poor.[82] Poverty is higher in the North and Northwest regions, as well as in the Department of San Marcos, which were largely affected by the country's three-decades long civil war. [85] San Marcos has a poverty rate of 87% and an extreme poverty rate ($ 0.67 per person per day in 2000) of 61%.[86]

Illiteracy and lack of education are key factors that perpetuate poverty in Guatemala. Although access to primary education in Guatemala has increased in recent years, levels of educational attainment and literacy remain among the lowest in Latin America. Adult illiteracy is estimated to be 30% in Guatemala. Furthermore, inequalities in school access and grade attainment linked to ethnicity, gender, poverty, and residence remain, and Mayan females are the least likely to ever enrol school.[84] Therefore, under 40% of 15-64 year old Mayan women are literate, and just two-thirds of 10-19-year-old Mayan females are literate.[84] The overall literacy rate in San Marcos is 66%.[86]

Unlike many other countries in Latin America, Guatemala is only at the beginning of the demographic and epidemiological transition. The population is young, is growing rapidly, and is still primarily rural. The median age for the Guatemalan population in 2000 was only 18.0 years, compared to the 24.4 years average for the Latin America and Caribbean region. Guatemala had a total fertility rate of 5.0 in 1998, practically unchanged from 1995. The fertility rate among indigenous Mam women is 7.8.[82]

6.2 Health in Guatemala

Guatemala ranks among the worst countries in Latin America for several health outcomes. Life expectancy at birth is 65 years, the lowest in Central America. The infant mortality rate, considered to be one of the most sensitive measures of a population's health, was still 45 deaths per 1000 live births in 1998.[82] Maternal mortality was 2 per

1000 live births in 2000. The patterns of health also suggest worse conditions for the poor, rural and indigenous populations.[85]

As a typical pre-transition stage country, Guatemala still has a high proportion of communicable diseases as causes of death (61%) compared with Mexico (22%),[42] and the country has the highest prevalence of chronically malnourished children in Latin America (44%).[82] However, the proportion of deaths represented by chronic diseases and injuries has increased to over 30% in Guatemala, and a continuous increment in non communicable diseases (like COPD) is expected for the next decades in all the countries in Latin America.[42]

Adequate access to health facilities is defined by the World Health Organization (WHO) as living no more than one hour of travel from a health care facility. Using this standard, only 41% of all children in Guatemala have access to health facilities. As expected, access is more limited for children in rural areas (only 36%), and among the poorest families (34%).[82] Additionally, because of cultural and linguistic barriers, most indigenous people still explain ill health in terms of the humoral theory of disease. The existence of germs is not well known, and *cold* (enfrío in Spanish, chew in Mam) is probably the most important etiological agent. Most of the indigenous people explain respiratory illnesses as caused by the imbalance of body temperature. A lay aetiology of chronic cough is also linked to a life history of prolonged exposure to the sun followed by exposure to the night cold.[87] Thus, indigenous people tend to rely more often than non-indigenous people on the help of other members of their households, on self-medication, and on non-medically trained practitioners.[82] Consequently, doctors treat 44% of non-indigenous people, but only 24% of indigenous people in Guatemala.

6.3 Indoor air pollution in Guatemala

Solid fuels (predominantly wood, but also crop residues and coal) are used by 62 to 73% of the population in Guatemala for daily heating and cooking. [5, 88] Traditionally burned over three-stone fires or simple stoves on the floor, the use of solid fuels in the kitchen represents the main source of air pollution exposure for Guatemalan women and their children. Most cooking is done by women, who spend 2–3 hours daily on cooking.[89] One-quarter of the country's population lives in households that cook with firewood inside their house in a room that is not a partitioned kitchen. More than half of the population cooks with firewood in a partitioned kitchen or in a separate building. The poor are overrepresented among firewood users cooking inside without partition. IAP, however, is encountered in most income groups in both rural and urban areas.[89] According to WHO, the deaths of 1570 children under 5 years and of 1690 adults were attributable to solid fuel use in Guatemala in 2002.[90]

Due to economic, geographic, and cultural factors, domestic exposure to IAP is a particularly severe problem in the Western highland of Guatemala. Indigenous women have used open fires for many centuries, and the open fire has a traditional social and cultural role. Besides, very few families can afford to purchase improved wood-burning stoves (approximate US$100 price) or gas stoves. The high altitude creates a relatively cold climate that causes people to keep their windows/shutters and doors closed, especially between the months of December and April, when temperatures can reach zero degrees Celsius.[91]

Table 3 shows indoor pollution levels recorded in Guatemalan homes with open wood fires[92, 93] compared to WHO air quality guidelines [1, 19] The values from Guatemala were obtained during the pilot work for RESPIRE. The reference values for carbon monoxide (CO) are, however, occupational standards, hence the maximum exposure is only eight hours. As far as we know, no guidelines exist for longer-term exposures, as we do not know the health impacts of being chronically exposed to levels at/just below the eight hour guideline every day from infancy.

Table 3: Indoor pollutant levels in households using open fires in Guatemala compared to WHO guidelines

	Guatemala	**WHO**	**Number of times in excess of guidelines**
24-h average PM_{10} ($\mu g/m^3$)	700-1200	50	14-24
24-h average $PM_{2.5}$ ($\mu g/m^3$)	500-850	25	20-34
24-h average CO (ppm)	2-50	n.a.	?
CO (ppm) during cooking	10-500	10	1- 50

$PM_{2.5}$: particles with diameter below 2.5 microns

PM_{10}: particles with diameter below 10 microns

CO: carbon monoxide; ppm: parts per million

7. RESPIRE: Randomised Exposure Study of Pollution Indoors and Respiratory Effects

7.1 Rationale for an intervention study

There is a very large body of evidence on the effects of air pollution (principally outdoor pollution and from tobacco smoke) on health, and, accordingly, most of the developed countries in the world have implemented increasingly restrictive laws to prevent people being exposed to air pollution. However, in countries where not even basic needs like vaccines and clean water can be met with the available resources, any intervention to promote health has to be rigorously proven to be highly effective.[94]

Several observational studies published during the last few years,[32, 33, 36-38, 95-97] suggest that exposure to wood smoke is a risk factor for the development of COPD in women. These studies have, however, some important limitations. First, none of them were randomised intervention studies and could not exclude the possibility of residual confounding by overcrowding, poor nutrition, prior respiratory infections, and other poverty-related factors. Second, few of the studies included measurements of lung function by spirometry, which is the gold standard method for the diagnosis of COPD. Third, very few studies have included direct measurements of exposure, relying instead on surrogates such as fuel and/or stove type, or time spent near the fire.[32, 33, 37, 38, 95, 96] Hence there was a need for better risk estimates and for quantification of the health effects obtained by the introduction of improved stoves to reduce IAP.[98]

7.2 Aims of RESPIRE

RESPIRE was an international collaboration between University of California Berkeley, USA, Del Valle de Guatemala University, Guatemala, Liverpool University, UK, and University of Bergen, Norway. In close collaboration, investigators in these countries had main responsibility for the study of different health outcomes. (Fig. 1)

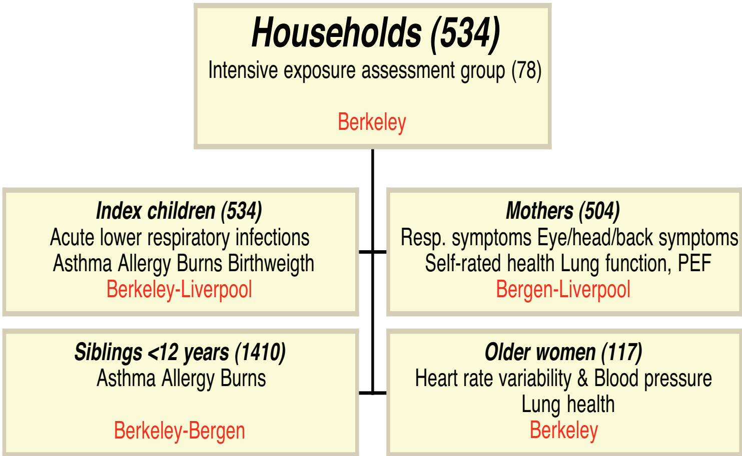


Fig. 1 Study groups taking part in RESPIRE and main responsible Universities.

The main aim of the randomised controlled trial was to determine the impact of using improved wood stoves with chimneys (intervention) on acute lower respiratory infection incidence in children aged <18 months, compared with continuing the use of traditional open fires (control).[99] Other health outcomes were: [98]

1. Index children:
    a. Prevalence of low birth weight
    b. Burns
    c. Diarrhoea (though in part included as 'control' outcome which was not expected to change if only IAP was reduced)

2. Mother of the study children:
    a. Lung health: lung function, peak expiratory flow, prevalence of chronic respiratory symptoms, incidence of acute respiratory symptoms
    b. Other symptoms (headache, eye discomfort, back pain, skin rash, etc)
    c. Self-rated health and self-assessed change in health
3. Siblings under 12 years of age:
    a. Prevalence of asthma and allergies
    b. Burns
4. Older women (older than 40 years):
    a. Heart rate variability and blood pressure
    b. Lung function

In addition to personal exposure measurements on mother and children taking part in the study, intensive exposure measurements from a group of 78 households were carried out. These will provide valuable data on IAP levels, measured both as particulates and as carbon monoxide, that will be used to validate the different methods used for exposure measurement in RESPIRE. Results from this analysis will allow exposure-response investigations, which in turn can contribute to cost-effectiveness and cost-benefit analysis of the *planchas*.

7.3 Previous history and pilot studies for RESPIRE

The planning of an intervention trial started in 1984, when an international group of scientists met to explore the research implications of the first published assessment of household cooking exposures, done in India in 1981.[100] After some unsuccessful proposals to conduct the trial in Nepal, in 1991 an international committee was established by WHO (Working Group on Childhood Pneumonia and Household Air Pollution in Developing Countries)[101] to locate a suitable site for a randomised controlled trial. The requirements were: a place where biomass was the main fuel and led to high levels of IAP, infant mortality higher than 80 per 1000 births, high incidence of respiratory infections, an existing program of acute respiratory infections surveillance that could reach the standard required for the study, and an area with reasonable security and access where the appropriate interventions were available.[101] San Marcos Department in Guatemala met these requirements for site selection. Extensive pilot work was carried out in the 1990s to ensure the suitability of the study area and community support,[87] acceptability and effectiveness of the stove,[91, 102, 103] and methods used for exposure assessment.[92, 104-108] The trial was launched in 2001.

7.4 Funding

The National Institutes of Health in the US funded the major part of the study by a 1.8 million USD grant, and approximately 150.000 USD was donated from private foundations. Much of the pilot work in Guatemala was funded by resources from IDRC (Canada) and WHO, which also helped support parts of the child health study (WHO funding of 61,900 USD for the trial). The Norwegian Research Council funded the study of lung health in women and asthma/allergies in children with 1 million NOK.[98]

8. AIMS OF THE THESIS

The aim of this thesis was to explore health benefits of reducing indoor air pollution by means of improved stoves in a group of Mayan women previously using open fires for daily cooking and heating. The work is part of the RESPIRE study, the first randomised intervention study ever performed on indoor air pollution.

The aims of the four papers included in this thesis research were:
Among non-smoking young Mayan women exposed to high levels of indoor air pollution since birth

a) To describe the methods used and the practical difficulties associated with assessing respiratory health in this poor, rural, mainly illiterate population, as well as to describe the pre-intervention prevalence of respiratory symptoms and lung function values, and the associations between pre-intervention exposure levels and symptoms/lung function.
b) To examine whether reducing indoor air pollution with improved stoves diminishes the burden of respiratory symptoms, and to investigate the possible benefit of the stoves on lung function.
c) To examine whether reducing indoor air pollution with improved stoves reduces the burden of eye discomfort and headache. Also, to investigate the possible benefit of the stoves in back pain by changing the working posture to the upright position.
d) To compare self-rated health and self-assessed change in health between intervention and control women; to describe the impact of the stoves on their daily life, and to explore women's perception of a link between indoor air pollution and their own health and that of their young children.

9. MATERIAL AND METHODS

9.1 Study site and study population

The study area comprises approximately 20 poor, rural indigenous Mayan-Indian communities living in the San Marcos region of highland Guatemala (altitude 2200–3000 m). The department is five hours drive from the national capital and poorly covered by roads. This region has rough terrain and during the rainy season of June through October can be difficult to access. The study field headquarters was located in the town of San Lorenzo (altitude 2600m).[2] In the Highlands, the altitude creates a relatively cold climate, especially between the months of December and April. Most of the population earn their livings from their own land, growing corn, wheat, potatoes, other vegetables and fruits.[86] Many of the households have farm animals, mainly poultry (89%), pigs (65%) and cattle or sheep (34% each). Nevertheless, the families are poor, and around half of the young women migrate to the coast to work for some weeks during the year.

Households in this community are dependent on wood fuel, and women in this area spend, on average, 5 hours a day in a room with a lit fire.[107] In addition, most of the Mam people use the *temascal*, a local sauna heated by a wood fire in poorly ventilated conditions. Extremely high levels of wood smoke can be reached inside these *temascales*.[109] Smoking is uncommon among Mam women, and, although 23.4% of men smoke, most of them consume only one to two cigarettes a day. No other significant pollution sources were found locally. Motor vehicle traffic along most roads in the area was confined to a few per day and many households are far from a road. Homes are generally enclosed with doors and shutters, although open eaves spaces are common. The typical study home was made of adobe mud walls, a dirt floor and a galvanized-iron roof and had an enclosed kitchen separate from the main house, that consisted of one room. Mean kitchen volume was 45 m^3. Eighty percent of the study population had a latrine, 75% had electricity – used for illumination purposes – and over 50% had access to piped water.[110]

The main language in San Marcos is Mam, and many women speak little Spanish. Illiteracy is common, especially among women. Ninety-six percent of the mothers and 84% of the fathers have a primary school education or less.[110] Women taking part in the study had, on average, 3.7 (SD1.9) children older than one year of age. Nearly one third of them were pregnant at the time they were recruited for the trial.

9.2 Study design

The women in this study were mothers of children recruited to the RESPIRE study. Based on a rapid assessment of the area (5365 households), an initial census identified 777 families fulfilling the household eligibility criteria; i.e. exclusive use of an open fire for cooking and heating, and having a pregnant woman or an infant of less than 4 months of age. In order to avoid extending the recruitment area, families were recruited in two rounds. After informed consent was obtained for 534 study children, randomisation of households into intervention and control groups was carried out in blocks of ten. 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* on completion of follow-up, when the child reached 18 months. Advice and training on safe, efficient use and maintenance of the *plancha* were given. Poorly operating stoves were identified and repaired throughout the project.

When invited to participate in the adult part of RESPIRE, thirty mothers declined. Thus, a total of 504 women (mean age 27.7 years, SD 7.2), mothers of the study children, were recruited. Recruitment Group A (RGA) (300 women, 153 receiving a *plancha*) occurred between October and November 2002 and Recruitment Group B (RGB)(204 women, 106 receiving a *plancha*) between April and May 2003. The fieldwork was conducted between October 2002 and December 2004.

9.3 The intervention: improved stove (*plancha mejorada*)

The improved stove (Fig.2), called *plancha mejorada* is a locally designed and constructed wood burning chimney stove used in Guatemala. Evolved over the last 20 years, the *plancha* is a popular stove and if well made, installed and mantained can be relatively durable.

Fig 2. (i) Open fire (Anaité Díaz) and (ii) *Plancha* (Nigel Bruce)

Its central feature is a thick metal heating surface through which three or four removable concentric rings for pots are cut, allowing the holes to fit a range of pot sizes. When the pot-holes are covered with the complete set of rings, the stove top becomes a flat plate. The Guatemalan *plancha mejorada* was named for its ability to grill (planchar) tortillas on the flat, iron surface above the firebox. The body of the stove is made up of cinder blocks and red bricks. The firebox has a length and width of 98cm and 45cm, respectively, and a height ranging from 19cm in the front half the firebox to 7cm in the back due to a baffle at the midpoint. A door at the front of the firebox can be used to control airflow. A metal tube flue allows for removal of smoke from the kitchen.[91, 111]

The steel plate itself must be manufactured industrially in Guatemala City from imported metal, but cutting of the potholes and rings, and all other aspects of manufacture and installation, are carried out locally. The cost of the stove, including installation, is between 100 and 150 USD depending on the design, materials and contribution of labour by the household. *Planchas* are not easily affordable by poor rural people.[102]

Pilot work carried out in Guatemala had shown that, under experimental conditions, the typical levels of pollution (24h mean PM_{10} levels) in houses using an open fire were around 700-1200 $\mu g/m^3$.[106] Under real life working conditions, over a five months period, the kitchens with open fires had 24-hour average $PM_{2.5}$ (particles less than 2.5 microns in diameter) concentrations of 1102 $\mu g/m^3$, while the households with the *plancha mejorada* had average concentrations of 180 $\mu g/m^3$.[91] Other feasibility studies carried out comparing the *plancha* with the open fire demonstrated that the *plancha* could reduce $PM_{2.5}$ levels from a mean of 520 $\mu g/m^3$ in homes with open fires to around 90$\mu g/m^3$.[102] A study of stoves that had been in use for some time showed a higher mean $PM_{2.5}$ of 152 $\mu g/m^3$, although this was still very substantially lower than the value of 868 $\mu g/m^3$ $PM_{2.5}$ for the comparison group of homes using open fires.[92]

The thermal efficiency of the traditional three-stone fire was not found to be significantly different to the efficiency of the *plancha mejorada*, suggesting that the use of the *plancha* did not save fuel. The *plancha* also required more time to perform the cooking tests, but it emitted 87% less suspended particles less than 2.5 μg in diameter ($PM_{2.5}$) and 91% less carbon monoxide per kJ of useful heat delivered compared to the open fore during water boiling tests.[108]

9.4 Health outcomes assessment

The fieldwork took place through home visits by locally recruited, bilingual (Mam and Spanish) fieldworkers. All the questionnaires were prepared in English, then translated into Spanish and back translated. Afterwards, the Spanish version was translated into Mam, and piloted in focus groups of local women.

Baseline information was gathered using three interviewer-led questionnaires (Fig 3), conducted in each participant's home, enquiring about social, demographic and economic factors. Due to an unforeseen overload of work early in the study, the third questionnaire, covering health outcomes in women (respiratory symptoms, eye irritation, headache and backache) and spirometry, had to be delayed by four months in Recruitment Group A. By then, intervention households in this Recruitment Group had already been using the *plancha* for a month, thus information on pre-intervention symptoms and spirometry is only available from Recruitment Group B.

Figure 3. Information assessment at baseline for Recruitment Groups A and B

**** First visit (Group A October-November 2002, Group B April-May 2003)***

- Consent for the study child (and mothers in recruitment Group B)
- Baseline Questionnaire-1:
  - Information about household members
  - Household structure
  - Fuel use
  - Socioeconomic status
  - Tobacco use
- Placement of CO tubes for personal IAP measurement

RANDOMISATION

* ***Second visit*** (48 hours after first visit)

- Information to the family about which randomising group the household belongs to
- Consent for the mother (Recruitment Group A)
- Baseline Questionnaire-2:
  - Household structural characteristics
  - Energy use
  - Cooking information
  - Local sauna *(Temascal)* use
- Collection of CO tubes

**** Third visit (Group A- March-June 2003-after installation of planchas in intervention households-, Group B- April-June 2003-before installation of planchas)***

- Baseline Questionnaire-3: Chronic health symptoms
  - Respiratory symptoms
  - Asthma, Rhinitis, Eczema
  - Sore eyes, Headache, Backache
- Spirometry
- Measurement of Carbon Monoxide in exhaled breath

After baseline, the women were assessed 6-monthly with interviewer-administered questionnaires and spirometry, until their children reached 18 months of age (up to 12 months in RGA and 18 months in RGB). The main reason loss to follow-up was migration for seasonal work (Figure 4).

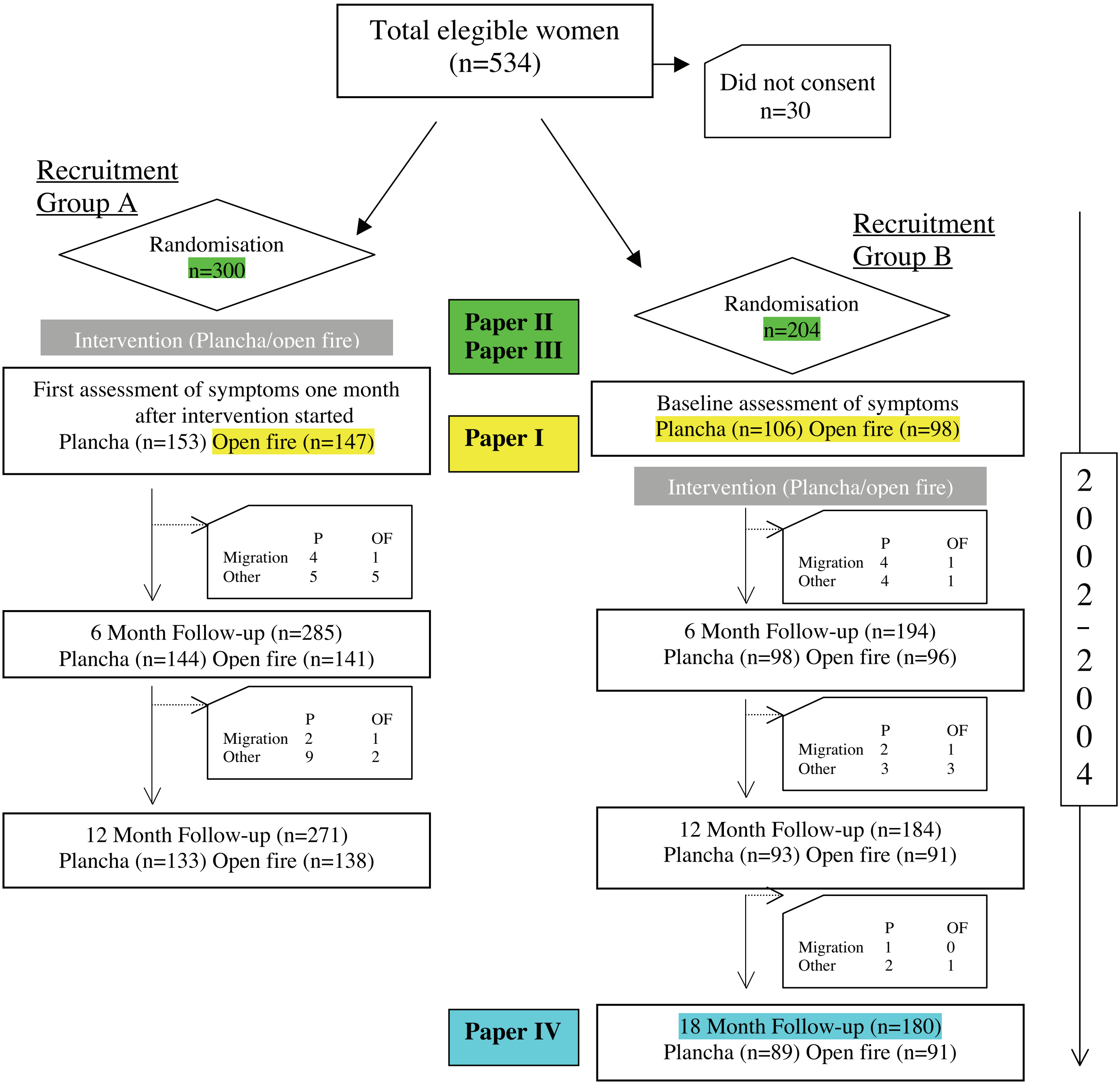
Also, between September and November 2004, a final interview was carried out in

Recruitment Group B (180 women), to collect information on self-rated health, and self-assessed change in health after the study, and to explore the impact of the stoves on daily life.

For the children, surveillance began after 5 weeks when *planchas* were ready for use. Pneumonia case-finding was carried out at four levels:[112]

1. Weekly household visits by fieldworkers.
2. Clinical assessment of children referred by fieldworkers, or self-referred, by study physicians, working in local community centres to maintain blindness.
3. Extraction of information from hospital records.
4. Investigation by verbal autopsy of all deaths.

Figure 4: Flowchart of the adult study population in RESPIRE from baseline to follow-up. OF: open fire, P: plancha



9.4.1 Respiratory symptoms

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 (MRC/IUATLD) and asthma (ISAAC),[113-116] translated from English to Spanish, and then to Mam, with back-translation. Translations were modified through extensive local piloting to versions with both health terminology and time patterns of symptoms that were adequate and understandable for the local women. There were, however, considerable difficulties in finding the translations appropriate to this population, for three reasons. First, women found it hard to comprehend the time duration patterns that standard questionnaires enquired about. Second, seasons are different from temperate countries, for which questionnaires were designed. Third, identifying the correct local terms for symptoms proved difficult, especially terms for wheeze. The same questions were used at baseline and every six months until the women left the study. (Appendix A)

9.4.2 Lung function measurements

Lung function was measured on completion of interviews. Standing height and weight were measured. Spirometry was performed in accordance with the American Thoracic Society (ATS) guidelines[117] using a Micro Medical Microloop spirometer (Micro Medical Ltd, Rochester, UK), but no reversibility tests were performed. For spirometry, participants were seated without nose clips, and measurements were classified as acceptable if the woman had at least three good blows, and if best and second best values of Forced Expiratory Vital Capacity (FVC) and Forced Expiratory Volume in 1 second

(FEV_1) respectively did not differ by more than 0.20 litres. No more than eight blows per session were attempted.

The proportion of women who fulfilled ATS criteria for spirometry increased with experience, 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 (only Recruitment Group B). Likewise, FVC values increased from baseline to 12 month assessment in both intervention and control groups, probably because the women continued to blow for a longer time. FEV_1 values remained quite stable during the first year (average increase of 42 ml for the same women). As the improvement was more evident in FVC values, the ratio FEV_1/FVC declined over time.

A study of the variation in spirometry values depending on the fieldworker using Bland and Altman plots[118] confirmed that the mean differences between the two observers were under 0.20 litres throughout the range of measurements for FEV1 and for FVC $\geq$ 3 litres. Mean differences between observers were 0.04 litres (SD 0.10) for FEV1, and 0.18 litres (SD 0.13) for FVC.

9.4.3 Other symptoms

Together with the assessment of respiratory symptoms, other symptoms were evaluated on the basis of reported experience during the previous month: sore eyes, headache and back pain. The frequency and severity of these symptoms were reported at baseline and every six months.

9.4.4 Self-rated health

Eighteen months after the beginning of the study, a final interview was carried out in Recruitment Group B (180 women). The interview was designed to collect information on self-rated health (*"Generally speaking, how is your health: good, average or poor?"*) and change in health during the study (*"How is your health now compared to the beginning of the study: better, the same or worse?")*. Intervention women were also asked in which way, for better or worse, the *plancha* had changed their life, if there had been any change at all. Those who mentioned "reduction of smoke in the kitchen" in the previous question were also asked whether they thought that the smoke reduction had influenced their own health or their children's health in any way, and how.

9.4.5 Peak expiratory flow (PEF)

All women in Recruitment Group B who reported asthma-like symptoms at baseline (wheeze or tightness in the chest during the last year, n=103) were invited to participate in a Peak Expiratory Flow (PEF) variability study conducted in July-September 2004. Participants received a mini-Wright peak flow meter and were instructed to perform three PEF measurements every morning on rising, and again in the evening at bedtime, for a period of 1 week. They marked the result from each blow on a scale that was identical to the scale on the PEF meter. During the week of recording, the women had a particle pollution monitor placed in their kitchen, and respiratory symptoms were assessed. Results from this study are not included in this thesis report.

9.5 Exposure assessment

9.5.1 Carbon monoxide

Carbon monoxide (CO) is a colourless, odourless and tasteless gas that is poorly soluble in water, and it is the most abundant constituent of the products of incomplete combustion emitted from the fire.[110] In the human body it has a high affinity to haemoglobin and reacts with it to form carboxyhaemoglobin (COHb). The most important variables determining the COHb level are CO concentration in inhaled air, duration of exposure and alveolar ventilation. During an exposure to a fixed concentration of carbon monoxide, the COHb concentration increases rapidly at the onset of exposure, starts to level off after 3 hours, and reaches a steady state after 6–8 hours. The formation of COHb is a reversible process, but the elimination half-life while breathing room air is 2–6.5 hours depending on the initial COHb level.[119]

In healthy subjects, small amounts of CO are also formed endogenously from the catabolism of haemoglobin and other haem proteins. This endogenous production of CO results in COHb levels of 0.4–0.7%. The COHb levels in non-smoking general populations are usually 0.5–1.5%, owing to endogenous production and environmental exposures. Non-smokers in certain occupations (car drivers, policemen, traffic wardens, garage and tunnel workers, firemen, etc.) can have long-term COHb levels of up to 5%, and heavy cigarette smokers have COHb levels of up to 10%.[119] During pregnancy, the endogenous production of CO can be elevated, the concentration of maternal haemoglobin is often reduced, and the mothers have physiological hyperventilation. As a result of these changes, maternal COHb levels of 0.7–2.5% have been reported.[119]

Carbon monoxide itself does not cause pulmonary damage, but it is well known that severe hypoxia due to acute carbon monoxide poisoning may cause both reversible, short-lasting neurological deficits and severe, often delayed, neurological damage. At a COHb level of about 10%, CO is likely to cause headache, and at somewhat higher levels there will be also dizziness, nausea and vomiting. At a COHb level of about 40%, carbon monoxide starts to cause coma and collapse, and at 50–60% the toxic effects are often lethal.[119]

The following WHO guideline values and periods of time-weighted average exposures for CO have been determined in such a way that the COHb level of 2.5% is not exceeded.[19]

- 100 μg/m^3 (90 ppm) for 15 minutes
- 60 μg/m^3 (50 ppm) for 30 minutes
- 30 μg/m^3 (25 ppm) for 1 hour
- 10 μg/m^3 (9 ppm) for 8 hours

Global background concentrations of CO range between 0.06 and 0.14 μg/m^3 (0.05–0.12 ppm)[1]. In the streets of large European cities, 8-hour average CO concentrations are generally lower than 20 μg/m^3 (17 ppm) with short peaks below 60 μg/m3 (53 ppm).[19] Pilot work previous to RESPIRE reported 22-hour average CO levels in Guatemalan kitchens of 0.46 μg/m^3 (0.4 ppm) under background conditions and 6.84 μg/m^3 (5.9 ppm)

[1] The conversion from ppm to μg/m^3 depends on the molecular weight of the gas involved. For CO, the molecular weight is 28. This means that ppm values must be multiplied by 28/24.15 or 1.16 to find μg/m^3 values.

for open fire conditions. Average personal CO level (10-12 hours) for the mothers taking part in the same study was 7.8 μg/m^3 (6.7 ppm).[92]

9.5.2 Particulate matter

Particulate matter, also known as particle pollution or PM, is a complex mixture of extremely small particles and liquid droplets. Particle pollution is made up of a number of components, including acids (such as nitrates and sulphates), organic chemicals, metals, and soil or dust particles.[120] The size of particles is directly linked to their potential for causing health problems. Particles that are 10 micrometers in diameter or smaller (PM_{10}) pass generally through the throat and nose and enter the lungs and can cause serious health effects.

The United States Environmental Protection Agency (USEPA) groups particle pollution into two categories:

1. *Coarse particles*, such as those found near roadways and dusty industries, are larger than 2.5 micrometers and smaller than 10 micrometers in diameter (PM_{10}). Health effects associated with short-term exposure to coarse particles include premature death in people with heart or lung disease, increased hospital admissions for heart and respiratory disease, increased respiratory symptoms in children, and decreased lung function. The health risk associated with short-term exposure to PM_{10} produce an increase in mortality of around 0.5% for each 10 μg/m^3 increment in the daily concentration.[1] The available evidence generally does not suggest a link between long-term exposure to coarse particles and

health problems.

2. *Fine particles*, such as those found in smoke and haze, are 2.5 micrometers in diameter and smaller ($PM_{2.5}$). These particles can be directly emitted from sources such as open fires, or they can form when gases emitted from power plants, industries and automobiles react in the air. Wood smoke particles are generally smaller than 1 μm, with a peak in the size distribution between 0.15 and 0.4 μm. Fresh wood smoke contains a large number of *ultrafine* particles, less than 0.1 μm, which condense rapidly as they cool and age. Fine particles in this size range efficiently evade the mucociliary defence system and are deposited in the peripheral airways, where they may exert toxic effects.[4] Health effects associated with short-term exposure to fine particles include premature death in people with heart and lung disease, non-fatal heart attacks, increased hospital admissions for respiratory and cardiovascular diseases, increased respiratory symptoms such as coughing, wheezing and shortness of breath, lung function changes, especially in children and people with lung diseases such as asthma, changes in heart rate variability, and irregular heartbeat. Health effects associated with long-term exposure to $PM_{2.5}$ include premature death in people with heart and lung diseases, reduced lung function and development of chronic respiratory disease in children.[120]

The WHO air quality guidelines from 2005 for PM are:[8]

- $PM_{2.5}$: 10 μg/m^3 averaged over a one-year period or 25 μg/m^3 averaged over 24 hours
- PM_{10}: 20μg/m^3 annual mean or 50 μg/m^3 24-hour mean

In both the United States and Western Europe, the background concentrations for PM_{10} and $PM_{2.5}$ have been estimated to be 6-10 μg/$m^3$and at 3-5 μg/m^3 respectively. In contrast, pilot studies in Highland Guatemala reported 22-hours average $PM_{2.5}$ background levels of 56 μg/m^3 in the kitchens, and of 528 μg/m^3 under the use of open fires.[92]

9.5.3 Types of exposure measurement

Small particles are thought to be the best indicator of the health risk of combustion pollutants. However, because of the practical difficulties of using burdensome and noisy air sampling pumps or other PM monitoring devices, particularly in very young children, the RESPIRE study measured CO exposure as a reliable surrogate for $PM_{2.5}$ exposure.[2] Personal measurements of exposure were chosen, as they allow better estimation of exposure-response relationships and give a more comprehensible picture of exposure rather than ambient pollution levels.

RESPIRE exposure assessment included both main (extensive) and validation (intensive) components. In the extensive portion of the study, personal monitoring was conducted in every house at baseline and approximately every three months thereafter until either the child reached 18 months or otherwise withdrew. Because of tube costs, mothers' exposures were measured in most, but not all, rounds. In addition, sixty-five homes were randomly selected for intensive monitoring, which included a range of simultaneous CO and PM measurements, both time-integrated and continuous, at different fixed locations (personal, kitchen, bedroom, outside) and a detailed time-activity questionnaire. [110]

Drawing on earlier validation work,[92, 104] two types of personal measurements were employed for the work reported in this thesis, to assess exposure to biomass smoke:

a) Exhaled CO was measured with Micro CO (Micro Medical Ltd), at baseline and follow up, after spirometry was completed. Exhaled CO is a non-invasive procedure, and the Micro CO set is portable, cheap, quick, and requires no specialist technical back-up in the field.[121] The level of CO in exhaled breath reflects exposure to CO over the previous 5-15 hours from the time of measurement and indicates the degree to which the haemoglobin in the blood has taken up CO, thereby depriving the body of oxygen-carrying capacity. [122]

b) Forty-eight hour personal CO was measured with Gastec 1DL CO passive diffusion tubes (Gastec Corp., Japan) in all women at baseline and every six months. Although designed for industrial hygiene applications, the passive and relatively inexpensive (approximately 8 USD) colour-stain diffusion tubes are sensitive to typical ranges of CO found in households using biomass for cooking and are sufficiently small, light and safe.[110] The CO tubes were attached to the woman's clothes on the upper chest. To reduce variation between measurements in the same house, a 48-hour rather than the more commonly used 24-hour measurement period was used. All tubes were read blind to intervention status by two research staff.[110]

9.6 Statistical methods

Sample size for RESPIRE was driven primarily by requirements to detect a reduction in the incidence of child pneumonia. A sample size of 500 households was judged sufficient (with 80% power) to detect a reduction in adult respiratory symptom prevalence from 25% to 15%, and a difference in Forced Expiratory Volume in 1 second (FEV_1) of 0.09 litres if a significance level of 5% and two-sided tests were used. The calculation used an estimated population mean FEV_1 of 2.70 litres and a standard deviation of 0.35 litres.

The balancing effect of randomisation on baseline measurements was studied using appropriate hypothesis testing; chi-squared test for categorical variables, t-test for comparison of means and Mann-Whitney U-Test for comparison of medians of carbon monoxide.

Multiple linear regression was used to study the associations between lung function and respiratory symptoms, and between lung function and exposure in Paper I, and logistic regression was used to study the relationship between symptoms and exposure.

Longitudinal analyses of the effect of the intervention on respiratory symptoms (Paper II) (binomial data) and an assessment of possible change in the effect over time were conducted with tests of effects and estimation of relative risk in log binomial Generalized Estimating Equations analyses (GEE). Also, analysis of the effect of the intervention on the number of respiratory symptoms in each woman was performed using ordinal logistic regression, as explained in Paper II.

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

In Paper III, cross-sectional analyses for the 6, 12 and 18-month follow-up assessments were conducted checking for significant differences between *plancha* and open fire groups. The Mann-Whitney U test was used to compare CO levels from *plancha* and open fire groups. Differences in symptoms between women using *plancha* and open fire and a possible change over time were estimated in logistic random intercept models.

In Paper IV, Chi-squared tests were used for the analysis of the first two closed questions. A binary logistic regression model was used to study the independent effect of reporting symptoms at the 18 months health assessment on self-rated health.

Analyses were performed with SPSS v. 16.0[123] and STATA v.9.[124]

9.7 Quality assurance

Three local female fieldworkers were recruited at baseline for the conduction of the adult part of RESPIRE. None had previous experience with spirometry, although two of them had been health workers before. The fieldworkers were carefully instructed in the use of the Mam terms written in the questionnaires, received training on diffusion tube use by the project air pollution team, and were also trained in spirometry technique over one month, with additional training before recruitment of Recruitment Group B. From this time (April 2003) only two of the fieldworkers continued in the adult study. Fieldworkers were randomly assigned to intervention and control houses.

All lung function data were daily checked by the study physician. Calibration checks of the Micro Medical spirometers were undertaken weekly. Instrument comparisons of the Gastec tubes were regularly conducted in the field office. After the study, CO monitors were returned to UC Berkeley for comparison against calibration gas, and found to be accurate. Validation tests posterior to the RESPIRE study comfirmed that, under specified conditions and with care, such tubes can also be used for personal exposure assessment in future studies.[110]

Data forms were checked daily for errors and missing information. Double data entry and cross checking took place at study headquarters on an on going basis. A random sample of data entry operations was routinely checked against paper versions.

9.8 Ethics

The adult component of RESPIRE was approved by the Research Ethics Committees at the Universities of Bergen, Liverpool and Del Valle de Guatemala.

9.9 Benefits to the participants

Although *planchas* are available in the study area, they are too expensive for most of the impoverished families living in rural Guatemala. The study provided a *plancha* to each household that participated in the study; the intervention households received them at the start of the follow-up period and the control households at the end. Also control households that withdrew from the project received the *plancha* at the time they had been scheduled to exit the study.

10. RESULTS (SYNOPSIS OF THE PAPERS)

10.1 Paper I

Lung function and symptoms among indigenous Mayan women exposed to high levels of indoor air pollution.

Díaz E, Bruce NG, Pope D, Lie RT, Díaz A, Arana B, Smith KR, Smith-Sivertsen T (2007). *International Journal for Tuberculosis and Lung Diseases* 11(12); 1372-1379.

This paper describes the pre-intervention prevalence of respiratory symptoms and lung function values in 350 non-smoking young women exposed to high levels of indoor air pollution since birth. Women reported a relatively high prevalence of chronic respiratory symptoms (cough (22.6%), phlegm (15.1%), wheeze (25.1%) and tightness in the chest (31.4%)), but lung function measurements were within the normal limits. Respiratory symptoms were positively associated with exposure levels. In addition, we describe the methods used and the practical difficulties associated with assessing respiratory health in this poor, rural, mainly illiterate population that are relevant to the interpretation of our findings and are pertinent to the development and comparability of future field studies of respiratory health in developing countries.

10.2 Paper II

Effect of reducing indoor air pollution on women's respiratory symptoms and lung function: RESPIRE Guatemala randomised trial.

Smith-Sivertsen T, Díaz E, Pope D, Lie RT, Díaz A, McCracken J, Bakke P, Arana B, Smith KR, Bruce NG. *Submitted 2008*

This paper presents the main effects of the intervention on women's respiratory symptoms and lung function, over a period of 12 to 18 months use of the *plancha* in the intervention group, compared to continued use of open fires in the control group. Among 504 rural indigenous Mayan women, the *plancha* significantly reduced exposure to CO by 61.6% as measured by diffusion tubes. For all symptoms, a consistent reduction in risk was observed in the *plancha* group for the follow-up period as a whole, the reduction being statistically significant only for wheeze (RR and 95% CI: 0.42 (0.25-0.70)). The number of symptoms in a woman at each follow-up time was also significantly reduced by the *plancha* (OR and 95% CI: 0.7 (0.50-0.97)). No significant effects were, however, found on lung function measurements within the 18 months follow-up.

10.3 Paper III

Eye discomfort, headache and back pain among Mayan Guatemalan women taking part in a randomised stove intervention trial.

Díaz E, Smith-Sivertsen T, Pope D, Lie RT, Díaz A, McCracken J, Arana B, Smith KR, Bruce NG. (2007) *Journal of Epidemiology and Community Health* 61; 74-79.

The aim of this paper was to examine whether reducing indoor air pollution with new stoves (*planchas*) diminishes the burden from eye discomfort and headache among poor rural women in Guatemala. We also investigated the possible benefit of the *plancha* through changing working posture to the upright position. Marked improvement in such symptoms may represent one of the more immediate positive aspects of the stove experienced by women, and contribute substantially to acceptability and hence opportunities for wider dissemination. Our study confirmed that the use of the *plancha* in this population significantly reduced the prevalence of sore eyes (OR and 95% CI: 0.18 (0.11-0.29)) and headache (OR and 95% CI: 0.63 (0.42-0.94)) over an 18 months period. The prevalence of back pain was non-significantly reduced.

10.4 Paper IV

Self-rated health among Mayan women participating in a randomised intervention trial reducing indoor air pollution in Guatemala.

Díaz E, Bruce NG, Pope D, Díaz A, Smith KR, Smith-Sivertsen T (2008) *BMC International Health and Human Rights* 8;7.

This paper compares self-rated health and self-assessed change in health among 89 intervention and 80 control women who had participated in the RESPIRE study for 18 months. We describe the impacts of the stoves on women's daily lives and explore their perceptions of how reduced kitchen smoke affects their own and their children's health. On intention-to-treat analysis, 52.8% of intervention women reported improvement in health, compared to 23.8% of control women ($p<0.001$). Among 84 intervention women who reported reduced kitchen smoke as an important change, 88% linked this to improvement in their own health, particularly to non-respiratory symptoms (mainly eye discomfort and headache); 57% linked reduced smoke to improvement in their children's health, particularly sore eyes. We conclude that women's perception of their health was improved, and that smoke reduction was appreciated. However, this was linked mainly with alleviation of non-respiratory symptoms like eye discomfort and headache. More focus on such symptoms may help in promoting demand for improved stoves and cleaner fuels, but education about more severe consequences of indoor air pollution exposure is also required.

11. DISCUSSION

11. 1 Methodological considerations

RESPIRE is the first randomised controlled trial ever performed on IAP. For the adult part of the study, over 500 women living in the Highlands of Guatemala were enrolled. The inclusion criteria were two: using an open fire for cooking and heating and either having a child under four months of age or being pregnant. No exclusion criteria were applied.

Intervention studies, if well conducted, yield the strongest and most direct epidemiologic evidence on which to judge whether an observed association is one of cause and effect. There are, however, methodological challenges in performing such a study,[125] especially when conducted in a rural and remote area of a developing country, which should be discussed.

11.1.1 Ethical considerations: the choice of the intervention

In every intervention study there is an active assignment of participants to a particular procedure. In our case, the intervention was a stove, the *plancha*, which had been shown to reduce the levels of pollution in the kitchens of women previously using open fires.[92, 103] According to the Declaration of Helsinki,[126] however, in any medical study, every patient should be assured of the best proven therapeutic/preventing method. Thus, from an ethical point of view, the choice of the *plancha* as an appropriate intervention could be raised.

The use of biomass fuel is tightly related to poverty, and it has been postulated that poor households would go up the *energy ladder* as their income increased. The *energy ladder* is a scale that rates the quality of household fuels. At the lower end of the ladder are traditional biomass fuels: dried animal dung, crop residues, wood and charcoal. Moving up the ladder, coal is next, followed by kerosene, bottled and piped gas, biogas (from animal dung) and electricity.[3] In general, as households climb the ladder there is an associated increase in the sophistication of the cooking technology, its cleanliness, efficiency and its cost.

In developed countries, modernization has been accompanied by a shift from biofuel use to use of petroleum products (e.g., kerosene, gas) and electric stoves. In developing countries, however, even where cleaner fuels are available, many households continue to rely on biomass fuels for cooking and heating. Indeed, the adoption of modern fuels often results in multiple fuel use (and greater total energy demand), resulting in houses consuming different energy sources at different points of the energy ladder. Data from Guatemala in 2000 show that firewood use only declines to a very limited extent at the top end of the rural income distribution, with a large percentage of households over the minimum income using both wood and liquefied petroleum gas, and the poorest using only wood.[89] Also, in an assessment of a program for the promotion of household stoves in China,[74] multiple fuels were used in the majority of the houses.

There are reasons that may help understand the use of energy in developing countries. In many low-income households, an important portion of women's economic contribution (like fuel gathering and cooking) is unpaid, unrecognized and undervalued, resulting in less attention to technology development and to investment in improving women's work than men's work.[127] Especially where income is low, many households invest in other articles and needs before their attention is given to the cooking process, as new technology and alternative fuels are beyond their economic capacity.[128]

The transition to cleaner fuels is further hindered by a number of socio-cultural factors and practical considerations. The flavour of foods cooked with biomass is sometimes preferred to that cooked with commercial fuels. Biomass fuels are also often used for space heating and drying of food, fuel, and house building materials.[103] Also, the fire is associated with ritual practices in different periods of life, as it is the case with the *dieta* (post-partum period where mother and child are exposed to high levels of IAP) or the *temascal* (local sauna used for bathing and ritual purposes)[109] in Guatemala. Also, the lack of awareness of a link between IAP and health might be a reason for not changing the open fire, a cooking tradition that has been a part of the culture for centuries.

Thus, while switching to a cleaner fuel would be the most effective way of reducing IAP, the vast majority of the 3 billion people exposed,[129] will have no possibility to abandon biomass fuel for a very long time to come. They will have no choice but to use biomass as their primary fuel. It is critical, therefore, to find an alternative to the open fire in the interim that not only significantly reduces pollutant concentrations but is economically feasible and culturally acceptable.[103] Therefore, we believe that the conduct of this study is ethically defensible, as it will give us more knowledge on one of the real alternatives for nearly a half of the population of the world.

11.1.2 Design and conduct of RESPIRE

Internal validity refers to the extent to which differences identified between randomised groups are a result of the intervention being tested. *External validity* (or generalisability) refers to the extent to which study results can be applied to other individuals or settings.[130] A number of issues have to be considered in the design and conduct of clinical trials to ensure that valid results are obtained. These include selection of the study population, allocation of the intervention, maintenance and assessment of compliance, and quality of ascertainment of outcomes, among others.[125]

I. Selection of the study population

The San Marcos district in Guatemala was selected because the area met the criteria explained earlier in this work. The local reference population, over 5000 households living in 23 communities in the area, was exposed to high levels of IAP, with an infant mortality > 80 per 1000 births, and high incidence of respiratory infections.

To avoid extending the study area and to improve feasibility, the study population was recruited in two rounds a few months apart. Despite several months preparatory work with the communities to gain acceptance for the study, the response for Recruitment Group A was only 55%, presumably due to residual fears about the intentions of groups such as ours working for a relatively short period in the area. A higher response was obtained in Recruitment Group B (90%), probably reflecting a gradually increased trust between the community and the study team.

There were significant differences between Recruitment Groups, especially regarding pregnancy and prevalence of symptoms at baseline. The percentage of pregnant women was higher in Recruitment Group B, as many women at the end of their pregnancy or with young infants were already recruited to Recruitment Group A. Respiratory symptoms for Recruitment Group A were assessed during the dry, colder season, and for Recruitment Group B during the wet, warmer season, which would influence their prevalence. Recruitment Group was nevertheless included in the longitudinal models as a controlling variable, and proved not to alter the results regarding differences between the intervention group and the control group.

There was otherwise no evidence that the households who accepted to take part in the study were different from the rest of the eligible population, although it is known that those willing to participate in clinical trials tend to experience lower morbidity and mortality rates than those who do not. Thus, we believe that volunteerism has not essentially affected the generalisability of our results to similar populations.

Most of the women in the study were of Mayan origin. Very little is known about respiratory health for American Indians,[131-133] but living at high altitudes has been associated with higher than predicted lung function. [26, 134, 135] Also, increased pulmonary function associated with body complexion has been reported in Quechuan natives in Bolivia[136] and Ecuador[33]. Thus, we should be cautious when comparing lung function values from our study to other populations. There is, nevertheless, no theoretical background that indicates that the reduction of IAP should have a different effect in any ethnic group. Hence, any effect of the *planchas* on lung health found in this study should be generalisable to other women in the same age range in developing countries who are exposed to high levels of IAP.

II. Allocation of the planchas

We conducted a randomised study, but it was not a blind one, as it was obviously not practically feasible to avoid that the families would find out if they were using a *plancha* or an open fire. As the fieldworkers interviewed the families at their homes, they too knew if the woman they were interviewing belonged to the intervention or the control group. The random list of assignments, however, was kept at del Valle de Guatemala University, and was administered by the study project manager, who could not identify the families at that time. Also, the study investigators in the different countries did not obtain the key to decode the households into intervention and controls until the fieldwork was completed. Consequently, nobody involved in deciding whether a participant was eligible, participated in the assignation of treatment group.

The success of the randomisation was tested after the fieldwork was finished. The intervention and control groups were found to be comparable with respect to all variables except for the intervention, which reduces the risk for known *confounders* and, even more crucially, reduces the risk of unsuspected potential confounders.

The main health outcome of RESPIRE was pneumonia in children. Consent for the study child was obtained after information about the study was given to the family during the first visit to the house. Two days afterwards, the fieldworkers informed the family about the randomisation group they have been assigned to. For Recruitment Group B, the consent for the participation of the mother in the adult study was obtained together with the child consent. For Recruitment Group A, however, the mothers themselves were asked for consent after information on randomisation group was given, i.e. during the second visit to the house. As a consequence, concealment of allocation was not achieved for the women taking part in Recruitment Group A of RESPIRE, which might theoretically have introduced a *post-randomisation selection bias*.[130] The balance of randomisation, however, does not indicate that this occurred.

III. Maintenance and assessment of compliance

The adult part of RESPIRE took advantage of the study of children's health, for which fieldworkers made weekly visits to the families. In this way, the actual use and working conditions of the *planchas* were regularly checked. Problems detected regarding the use of the *planchas* were solved and correct use reinforced. Occasional use of open fires was observed in intervention households, but all the intervention households used the *plancha* for cooking on a daily basis. It is difficult to know to which extent the intervention would be accepted and used correctly in the real world, without the fieldworkers' observation and help, but it is probable that at least some of the *planchas* would have deteriorated or would have been abandoned after some period of use. In this case, the *external validity* of our study would be reduced.

IV. Ascertainment of outcome

Observation bias is an especially important potential problem in a study that is not double-blinded. Knowledge of a participant's intervention status might influence the identification or reporting of symptoms or relevant information. The likelihood of such bias is directly related to the subjectivity of the outcomes under study. In the papers reported in this thesis, different possibilities for observation bias can be identified. First, pollution exposure assessment and lung function measurement should not be subject to observation bias, as there are procedures and instruments that measure these outcomes independently of the observers. Second, the assessment of symptoms (both respiratory and non-respiratory) could be modified by the fieldworkers' knowledge of the intervention status of the participant, although the margin for such a bias should be small, as the questionnaires were the same for the two groups and close-ended questions were used. Third, and probably more susceptible to this kind of bias, is the study of self-rated health and self-assessed changes in health, especially the open questions regarding the connection between smoke and health. However, two reasons can be argued to defend the validity of the results of Paper IV: (i) internal coherence was proven between the answers obtained in this study and those obtained a few weeks earlier using close-ended questions; (ii) the exposure was objectively reduced (as measured by carbon monoxide levels) in the intervention households, which support the reported reduction of smoke obtained from an open question.

Another well-documented effect related to the observation bias is the *placebo effect*, or the tendency for individuals to report a favourable response to any intervention regardless of the physiologic efficacy of what they receive. If the placebo effect is substantial, it might falsely increase the estimate effect of the intervention. The placebo effect might be, in our study, difficult to distinguish from the desire to please the study investigators giving the "right" answers, which is probably more characteristic among Mam women than in European populations. Although this is probably the case for some participants, it might be argued that the control women, who were still waiting to get their *planchas*, would be at least as inclined to please the study personnel by giving the "right" answers. In fact, the prevalence of all symptoms was reduced during the course of the study in both the intervention and the control groups. However, the objective reduction of IAP detected by carbon monoxide measurements, supports the reported greater reduction of symptoms detected in the intervention households.

Study of COPD

Among the problems with performing epidemiological studies of COPD in developing countries are (i) the lack of validated questionnaires adapted to local language, seasonal patterns and cultural circumstances, (ii) the limited availability of local personnel trained in performing high-quality spirometry, and (iii) the lack of appropriate reference population data. The first of these three challenges also applies for other outcomes in the study.

(i) Questionnaires

To be able to communicate with the local women in their own language, we translated and adapted validated questions on respiratory symptoms from standard questions on COPD and asthma.[113, 115] The questionnaires were translated from English to Spanish, and then to Mam, with back-translation. To address this challenge, a local anthropologist helped us identify the correct local Mam expressions and terminology for both symptoms and time patterns, using discussion groups of local women and field staff. The Mam term identified for wheeze, which was the most difficult to interpret, was supported by a subsequent study conducted by Thompsom et al.[137] among the same population after RESPIRE was over. As explained in Paper I, although the internal consistency in our study for respiratory symptoms suggests that modified questions were useful, it was not possible to verify whether their sensitivity and specificity for COPD and asthma are comparable to the original standard instruments.

Self-perceived health is influenced by culture and tradition. Among the alternatives for studying self-perceived health in the study, questions from self-rated health studies were chosen.[138-143] Two objections can be raised regarding this choice. First, the women had been asked about symptoms many times before this last questionnaire was conducted. Although open questions were used, any symptom that had not been mentioned at all in the previous interviews was probably not so likely to be mentioned at this point. Second, we could also have asked the same questions on self-rated health at the beginning of the study. In that way, we could have verified the significant improvement in health status among the participants that we found when asking about *changes* in health. However, these two objections would be applicable to both the intervention and control groups, and our results regarding differences between them would not have been changed. In addition to the self-rated health study presented in this work, focus groups were conducted among some local women, confirming and expanding the results from the questionnaire presented in this thesis. Results from these focus groups will be published.

(ii) Spirometry

Spirometry is an effort-dependent procedure that requires understanding, coordination, and cooperation by the subject, who must be carefully instructed.[117] Quality control of this procedure is often encouraged, but results from fieldwork are seldom available in the literature. An inter-observer variation between fieldworkers was identified, but only of potential clinical importance for FVC measurements under 3 litres. In addition, an improvement in technique (longer FVC) over time among the participants was detected. For these reasons, although we still rely on our crude data, we chose not to rely on FEV_1/FEV ratios, as their decrease over time was probably an artefact due to increasing FVC values.

(iii) Reference population

There are few published spirometry references for American Indians, with most applying to older women.[131-133] As previously explained, the lung function data from our population were higher than the predicted values from the most relevant source identified, i. e. Mexican-American women from the USA,[132] making it difficult to use such values to classify COPD. It is of vital importance to define appropriate reference values to be able to study respiratory health among different populations in developing countries.

11.1.3 Sample size considerations: statistical power

The statistical power of a trial to detect a postulated difference between treatment groups depends on the sample size, but more specifically on two factors: the total number of end points experienced by the study population, and the difference in compliance between the treatment groups.

In our study, the population chosen consisted of young mothers. These women had a relatively high prevalence of symptoms, which made them an ideal population for our study. Their young age was, however, an obstacle for the study of COPD, as this disease develops over the years, and rarely affects young people. On the one hand, the ideal way of overcoming this problem would have been to extend the study for some more years, but that was not a feasible option, as the sample size was determined by the child health study design. On the other hand, very little was known about women in this age range, and the study of children in RESPIRE opened for a unique opportunity to study the effect of IAP in this young female population exposed to high levels of air pollution.

Non-compliance has previously been described in this chapter. Few women were lost to follow-up in our study, and most of them did so because of temporary internal migration for working. There was a slightly higher tendency to abandon the study in the *plancha* group.

11.1.4 Analysis and interpretation of results

One important early step in the analysis of any trial is to compare the relevant characteristics of the randomised intervention and control groups to assure that the balance is achieved. As illustrated in Table 4, randomisation was effective in establishing two study groups that were similar with respect to socio economical and other factors that could independently affect the outcomes under study.

In Papers II and III, Random Effects Models and Generalised Estimating Equations (GEE) were used for the longitudinal analysis of the data (symptoms and lung function). Generally speaking, standard regression analyses do not account for the correlation between repeated measurements in the same subject. Random Effect Models and GEE account for this correlation, and also for the order of the observations. With the first of these two methods we obtain odd ratios (OR), which would be the adequate parameter if the prevalence of a symptom was low. In Paper III, differences in headache, eye discomfort and back pain between women using *plancha* and open fire and a possible change over time were estimated in logistic random intercept models. Further development of the analysis for Paper II, however, showed that relative risk (RR) should have been the estimate of choice, as the prevalence was high for all the three symptoms. The RR that had been obtained using GEE would be slightly higher than the OR from Random Effect Models, but still significant for both sore eyes and headache (Table 5).

Table 4. Baseline characteristics of *Plancha* and open fire groups. Recruitment Groups A&B.

	Recruitment group A (300)		**Recruitment group B (204)**	
	Plancha	Open fire	Plancha	Open fire
Number of women	153	147	106	98
Characteristics of the women				
Mean age in years (SD)	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 <12y (SD)	3.7 (1.7)	3.8 (1.7)	3.6 (1.8)	3.8 (1.6)
Ever smoked (%)	1 (0.7)	1 (0.7)	0	0
Household characteristics				
Relative smokes inside (%)	32 (20.9)	42 (28.6)	20 (18.9)	24 (24.5)
Mean no cigarettes husband (SD)	1.04 (0.2)	1.06 (0.2)	1.20 (0.4)	1.05 (0.2)
Have Temascal[‡] (%)	124 (81.0)	115 (78.2)	101 (95.3)	91 (92.9)
Temascal > once a week (%)	55 (35.9)	55 (37.4)	45 (42.4)	41 (41.8)
Kitchen separate from bedroom (%)	128 (83.7)	126 (85.7)	87 (82.1)	85 (86.7)
Economic indicators				
Owns TV (%)	28 (18.3)	25 (17.8)	25 (23.6)	18 (18.4)
Owns bicycle (%)	29 (19.0)	30 (20.4)	30 (28.3)	21 (21.4)
Have pigs (%)	107 (69.9)	102 (69.4)	62 (58.5)	60 (61.2)
Symptoms from cooking at first survey				
Eyes always irritated[1] (%)	101 (66.0)	96 (65.3)	59 (55.7)	54 (55.1)
Headache always[2] (%)	53 (34.6)	43 (29.3)	37 (34.9)	32 (32.7)
Back pain always[3] (%)	22 (14.4)	31 (21.1)	31 (29.2)	29 (29.6)
Lung function				
Mean FEV1 (l) (SD)	2.64 (0.4)	2.69 (0.4)	2.65 (0.3)	2.62 (0.3)
Mean FVC (l) (SD)	3.05 (0.4)	3.11 (0.5)	3.08 (0.4)	3.09 (0.4)
Climate and exposure				
Median 48-hr CO (tubes)(ppm)	3.3 (1.9)	3.5 (2.7)	3.3 (3.1)	3.4 (3.2)
Mean rainfall (mm/day) (SD)	0.22 (0.4)	0.23 (0.5)	3.66 (0.4)	3.87 (0.4)
Mean temperature (C^o) (SD)	11.8 (1.4)	11.8 (1.3)	13.5 (0.7)	13.3 (0.8)

[1] When you are cooking, do your eyes get irritated? [2]When you are cooking or immediately after, do you get a headache? [3]When you are cooking or immediately after, does your back hurt?
* % of the total number of women
[‡]Local sauna

Another advantage from using these models is that both can deal with missing data from follow-up. In this way, we could include in the longitudinal analysis women for whom information from one or more assessment was missing.

Table 5. Relative risk (RR) and 95% confidence intervals (CI) and Odds ratio (OR) and 95% confidence intervals (CI) from longitudinal analyses for the period 6 to 18 months after the intervention for sore eyes, headache and back pain.

	GEE		**Random effect model**	
	RR	95% CI	OR	95% CI
Sore eyes	0.37	0.28-0.49	0.18	0.11-0.29
Headache	0.82	0.70-0.97	0.63	0.42-0.94
Back pain	0.93	0.74-1.18	0.85	0.52-1.39

11.2 Discussion of main results

11.2.1 Exposure

The RESPIRE study measured personal exposures in young children and their mothers, and kitchen concentrations of carbon monoxide (CO) as an indicator of wood smoke. Analysis including all the participants in RESPIRE, conducted by Smith et al.[110] found all three metrics, as measured by diffusion tubes, significantly lower after intervention: from approximately 10.2, 3.4, and 3.3 ppm at baseline, levels were reduced by 90%, 61% and 52% for kitchens, mothers, and babies respectively. Accordingly, our analysis of the 504 women who gave consent to the adult part of the study confirmed that the *plancha* significantly reduced their CO exposure by 61.6% measured by diffusion tubes. These figures seem to be in accordance, or even better, than those reported in 2007 for stove fuel performance in India and Mexico, where kitchen levels of carbon monoxide were reduced from 30 to 70%.[144-147] The relationship between levels of personal exposure and kitchen levels of exposure, however, is still subject of study. That personal exposures were not reduced as much as kitchen levels is consistent both with daily time-activity patterns, and the presence of other sources of CO exposure that were not affected by the intervention, particularly the use of open fires for non-cooking purposes and preparation of the *temascal*. [110]

The *temascal* is a local sauna bath traditionally used between two and four times per month, and it represents an important source of air pollution in Highland Guatemala. As there was no difference in the use of the *temascal* between the intervention and control groups, this exposure represents non-differential misclassification, and has probably decreased our ability to detect differences between groups. Although this source of exposure would have not been detected completely by the diffusion tubes, it would affect women's exhaled CO, that was measured at baseline and follow up every six months. CO in exhaled breath was significantly reduced (p=0.0001) in the *plancha* group compared to the open fire group at all follow-up examinations, declining from a median of 8.0 ppm at baseline, to 5.0 ppm in women using *planchas*. This 32.5% reduction is lower than the reduction measured by CO tubes. While the use of the *temascal* might account for part of this difference, further analyses and validation work will be carried out to try to better understand this discrepancy.

The average personal CO levels measured in RESPIRE were not highly elevated as compared to WHO guideline values.[19] The range of measurements at baseline, however, was broad, 29 ppm for CO in exhaled breath, and 20ppm for CO measured by diffusion tubes. There were, therefore, many women exposed to CO levels well above WHO guidelines.

11.2.2 Burden of symptoms at baseline

A woman who uses solid fuels in Guatemala has usually been exposed to IAP since her own mother was pregnant. She has probably been exposed to high levels of pollution during her first days of life (*dieta*, a period right after birth when the mother should rest beside an open fire), then been carried at the back of her mother during the first year of life, and kept in the nearby afterwards while her mother doing household cooking. Being a girl, she typically begins to help in the kitchen from a young age, so that she becomes more exposed to IAP than her brothers during infancy. Finally, as soon as she gets married, she is responsible for cooking for her growing family until she becomes substituted by her daughter/daughter in law.

I. Respiratory symptoms

Early exposure to IAP has been proven to affect children's respiratory health, mainly, but not only, as acute lower respiratory infections.[10] The lung function attained in early adulthood is, together with smoking, one of the strongest predictors of COPD.[148] Thus, there is good reason to ask how the respiratory health of Guatemalan's women is affected.

The GOLD guidelines described in 2001 a Stage 0 (“At risk”) for developing COPD. People exposed to air pollution who reported chronic symptoms (cough, sputum production) but with normal spirometry would be included in this group.[149] In 2006, however, this stage disappeared from the new GOLD guidelines,[150] as it seemed to be incomplete evidence that the individuals who met the definition of “At risk” necessarily progressed on to Stage I.[25] According to the most recent review on risk factors for COPD,[151] though, it is likely that as much as 50% of those with long-term exposure to smoke develop COPD, a percentage which is higher than the approximately 15% previously stated.

The prevalence of COPD among women in developing countries has been principally studied among subjects older than 40 years, with few exceptions.[96, 152] Among non-smoking women the prevalence of COPD was 7.2% in rural Yunyan (Guancon),[34] and 13.5% in Mexico.[153] For women taking part in the PLATINO study[26] COPD prevalence ranged from 6.5% in Mexico City, to 14% in Sao Paulo, where individuals over 60 years were three times more likely to have COPD than those aged 40-49, and 19.7% in Montevideo.[154] In the same study, the prevalence of chronic cough and phlegm with normal spirometry values (Stage 0) ranged from 20% in Montevideo to 33% in Santiago. The authors of this international study concluded that COPD is a greater health problem in Latin America than previously realized.[26]

Our questions about respiratory symptoms included cough, phlegm, wheeze and tightness in the chest. Wheeze (25.1%) was the second respiratory symptom in prevalence, after tightness in the chest (31.4%); 16.6% of the women reported wheeze during the last year (22.7% in the wet season). Wheeze is usually thought of as a symptom of asthma, but it has also been identified as the most potent predictor of having airflow limitation in COPD patients.[155] Similar prevalence of current wheezing (16.2%) is described in a young female Mexican population, of which 20% were smokers.[30] Also, 24.8% of Nepalese women using unprocessed fuels reported having breathlessness and wheezing.[36] In comparison, among Norwegian women aged 20 to 44 years, the prevalence of wheezing during the last 12 months was 7.7% among non-smokers, but the prevalence increased significantly to 9.8% among ex-smokers and 15.9% among smokers.[29]

The relatively high prevalence of respiratory symptoms, both typical symptoms of COPD (chronic cough >3 months (16.0%), chronic phlegm > 3 months (10.3%)) and symptoms often, but not exclusively, related to asthma (wheeze, tightness in the chest) among the young, non-smoking females participating in RESPIRE, suggest that these women might be beginning to develop chronic respiratory disease, even though their lung function values are still normal.

II. Non-respiratory symptoms and self-rated health

More than a half of the women reported sore eyes during the last month, and nearly three quarter of them had suffered from headache during the same period. These symptoms have been described in the literature as related to wood smoke before,[9, 79, 156, 157] and tears while cooking have been proposed as a rough indicator of IAP and related health effects in developing countries.[158] Back pain, although not a consequence of exposure, has also been related to cooking position and reported to be alleviated by the use of other cooking devices that change position from squatting to standing.[79]

Non-respiratory reported symptoms were not confirmed by medical certification or diagnostic test. Thus, it is not possible to assess either sensitivity or specificity of the questions. They were, however, the same symptoms that women, unprompted, related to reduction of smoke both in RESPIRE and in previous studies.

Women in Guatemala, and in many developing countries, do not only cook for the family, clean the house and take care of the children, but they are also responsible for collecting fuel, water hauling, animal care activities and agricultural operations such as transplanting, weeding and harvesting.[159] It is therefore essential to understand that the relief of common and uncomfortable symptoms can be of central importance in the everyday life of these women and their families.

11.2.3 Effect of the **plancha** *on health*

The *plancha* confirmed to decrease exposure levels inside the kitchen and in personal CO measurements over an18 months period. Among young women, it significantly reduced the prevalence of both respiratory (wheeze and number of symptoms) and non-respiratory symptoms (headache and eye discomfort). The *plancha* was also linked to a significant improvement in self-rated health, and the study women related it to comfort, an easier everyday work, and to improved social status. Also, some disadvantages of the *plancha* were detected, such as difficulty cooking with special clay pots or food for the animals, and a reduction of light and warmth compared to open fire.

There is a gap in knowledge about IAP and respiratory health in the age group that we have studied. Relatively more is known about the effect of IAP on children and older women. Our study women had a mean age of 27.8 years. This is probably one of the reasons why none of them had COPD as defined by lung function (which needs some years to full development) and why our results do not show any significant effect on lung function. In community studies (as opposed to hospital based studies) the reported differences in lung function associated with wood smoke exposure have usually been relatively small (from no significant differences to a 3% decrease in FEV1/FVC in Regalado[153]). The other probable likely explanation for our inability to detect any differences on lung function is the relatively short follow-up period, 18 months. A cohort study conducted in China[37] published after the fieldwork in RESPIRE was over, indicated that the reduction in reported COPD became unequivocal first about 10 years after stove improvement. The evidence on IAP and COPD in this age group should not be evaluated on its own, but together with the evidence on other age groups.

11.3 Summary of limitations

Our study had several limitations that have been discussed through this introduction and in each paper. First, although the study was randomised and controlled, it was not blinded, which implies a potential source of bias. Although there is no evidence that the intervention and control groups were different in any way, we cannot know whether membership in either group could, in itself, have changed the habits of that group regarding exposure compared to the other one, which would have introduced eventual post-randomisation confounding in the study. Second, we did not have baseline information on either symptoms or carbon monoxide in exhaled breath for one of the recruitment groups. Third, the questionnaires generally used to study COPD proved to be unusable in our population, so that the final questions used are not validated for the study of COPD, which was the main purpose of the adult part of RESPIRE. The study of non-respiratory symptoms was not obtained by medical certification or diagnostic test, but relied on reported symptoms. Also, the questions regarding self-rated health could have been leaded by previous interviews, and subject to observation bias. Fourth, reference values for spirometry for this population have not been described before, and there was probably a learning effect in the performance of spirometry; thus, we should be cautious when comparing our results with other populations. Fifth, the methods used to measure exposure have not been widespread for the study of IAP; although validation studies have been conducted on diffusion tubes, similar work is still to be done for carbon monoxide in exhaled breath. Last, the relatively short follow-up of the study is probably one of the reasons why we do not find any effect of the intervention on lung function. Under ideal circumstances we would have followed the women for many years, but this option was not feasible and probably not ethically acceptable.

12. CONCLUSIONS

12. 1 Main conclusions

Among young women previously using open fires in Highland Guatemala, the *plancha* proved to significantly reduce the number of respiratory symptoms, especially the prevalence of wheeze, as well as the prevalence of headache and eye discomfort. The use of the *plancha* was also connected, after 18 months of use, with significantly better self-rated health.

The evidence from the adult part of RESPIRE presented in this work supports and strengthens the case for the *plancha* as a feasible option for many families in the world to gain a better health and a better daily life. That this empowerment is achieved mainly through women's (and their children's) health, is an important remark, as 70% of the approximately 1.3 billion people living in poverty in the world are women. We should not forget, however, other outcomes not presented in this work, for both women (cataracts, tuberculosis, lung cancer) and children (ALRI), for which there is evidence for a causal association with IAP. The effect of the *plancha* that we report here should be analysed together with the other parts of RESPIRE, and with other studies covering effects that could not be studied in San Marcos.

12.2 Implications and further research

Non-communicable diseases, like COPD, are increasing in developing countries, where they double the burden of infective diseases. Eighty-five percent of the 2.7 million deaths occurred as a consequence of COPD in 2000 happened in developing countries, most of them due to IAP. There is a close interrelationship between poverty and dependence on polluting fuels. Because of the intense competition for limited resources, the evidence required to support measures to improve health in developing countries has to be at least as rigorous than in other countries. These measures will, unfortunately, have to compete with clean water, antibiotics or vaccines. Analysis on cost-benefit and cost-effectiveness including the results of RESPIRE should be, therefore, conducted, to be able to priority different measures to improve health appropriately.

The study of chronic respiratory diseases in developing countries implies some challenges that the scientific community should be aware of. It is vital to remark that the validated questionnaire instruments for the study of COPD and asthma used in developed countries will probably not be usable in many populations in developing countries. Neither will be the available reference values. For these reasons, for nearly all future studies on respiratory health in developing countries, external validity will be compromised, unless these issues are addressed. If the scientific community has a real interest in studying respiratory health among the populations exposed to highest levels of IAP, an effort should be made, and the necessary resources should be invested, to adapt and validate questionnaires, and to develop adequate reference values. In addition, the quality control of spirometry techniques in the field should be given due attention in the future.

Although the results of the study show improvement in health with the *plancha*, more information on respiratory health is needed. The question of whether it would be ethically acceptable to continue a randomised controlled trial for a longer period has been raised. Instead, the CRECER (Chronic respiratory effects of early childhood exposure to respirable particulate matter) study is now following the cohort of children who participated in the RESPIRE Guatemala, and some of their mothers, longitudinally for a 5-year period to elicit the chronic effects of inhaled PM on respiratory health.

Exposure-response analyses, although fundamental to compare populations throughout the world, have not been presented in this thesis. They will, however, be conducted on a short time and presented to the scientific community.

Last, the *plancha* was chosen for RESPIRE because of its ability to reduce IAP over time together with the long successful history in Guatemala, local production, and high acceptance in the study area. Although these characteristics remain important, new generations of improved woodstove technologies that appear in the market should also be explored. Also, due attention should be given to educational programs running parallel to promoting programs. Through education, local people could attain a higher level of knowledge about the relationships between fuel use and health that could, in turn, facilitate the demand and promotion of stoves.

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Appendix I

Appendix I: Baseline Questionnaire-3 (BLQ3) ENGLISH VERSION

BLQ3: STUDY OF ADULT HEALTH, ASTHMA AND ALLERGIES

HOME VISIT

A. INTRODUCTION AND CONSENT:

Question		Answer	Code
A1	Group	GROUP A (00-12) GROUP B (00-18)	
A2	ID (home)		
A3	ID (woman)		
A4	ID Interviewer		
A5	Date	dd /mm /yy	
A6	Consent	No = 1 Yes = 2	

CHRONIC RESPIRATORY SYMPTOMS

B. COUGH: (SJO'L)

Question		Answer	Code
B1	Do you cough or have you coughed a lot? *¿Tzun n-sjolin mo o sjolin ma nintz mouj?* **If "NO", go to section C (Phlegm)**	No = 1 Yes = 2	
B2	Do you cough or have you coughed when getting up in the morning? *¿Tzun n-sjolin mo o sjolin aj tjawey janjin qlexje?*	No = 1 Yes = 2	
B3	**IF, Yes:** Since how long ago have you been coughing when getting in the morning? *¿Jtexe q'ij toknin ten sjo'l tija aj tjawey tzen qlexje?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	
B4	**If, Yes:** During this time, how often do you cough when getting up in the morning? *¿Chq'al n-tzaj sjol aj tjawey?*	Frequently = 1 Once in a while = 2	
B5	Do you cough or have you coughed during the day? *¿Tzun n-sjolin mo o sjolin tzen q'ijl?*	No = 1 Yes = 2	
B6	**If, Yes:** Since how long ago have you been coughing during the day? *¿Jtexe q'ij toknin ten sjo'l tija a-qijtl?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	
B7	**If, Yes:** During this time, how often do you cough during the day? *¿Chq'al n-tzaj sjol tija tzen q'ijl?*	Frequently = 1 Once in a while = 2	
B8	Do you cough or have you coughed during the night? *¿Tzun n-sjolin mo o sjolin tzen qnik'in?*	No = 1 Yes = 2	
B9	**If, Yes:** Since how long ago have you been coughing during the night? *¿jtexe q'ij toknin ten sjol tija tzen qnik'en?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	

B10		**If, Yes:** During this time, how often do you cough during the night? *¿Chq'al n-tzaj sjol tija tzen qnik'en?*	Frequently = 1 Once in a while = 2	

C. FLEMA: (XLOQ)

Question		Answer	Code
C1	Do you produce or have you produced a lot of phlegm? *¿Tzun njatz xloq mo o jatz nim xloq tun?* **_ If "NO" go to section D (Periods of Cough with Phlegm)**	No = 1 Yes = 2	
C2	Do you produce or have you produced phlegm when getting up in the morning? *¿Tzun njatz mo o jatz xloq tu'n aj tjawey?*	No = 1 Yes = 2	
C3	**If, Yes:** For how long have you been producing phlegm when getting up in the morning? *¿Jtexe q'ij toklin ten n-jatz txloqa tzen qlexje?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	
C4	**If, Yes:** During this time, how often do you produce phlegm when getting u in the morning? *¿chqaltzin njatz txloqa tzen njawey qlexje?*	Frequently = 1 Once in a while = 2	
C5	Do you produce or have you produced phlegm during the day? *¿Tzun njatz mo o jatz txloqa tzen q'ijl?*	No = 1 Yes = 2	
C6	**If, Yes:** Since how long ago have you been producing phlegm during the day? *¿Jtexa q'ij toklen ten xloq a njatz tzen q'ij?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	
C7	**If, Yes:** During this time, how often do you produce phlegm during the day? *¿Chq'al njatz txloqa tzen q'ijl?*	Frequently = 1 Once in a while = 2	
C8	Do you produce or have you produced phlegm during the night? *¿Tzun njatz mo o jatz txloqa txloqa tzen qnikén?*	No = 1 Yes = 2	
C9	**If, Yes:** Since how long ago have you been producing phlegm during the night? *¿Jtexa q'ij toklen ten njatz txloqa tzen qnik'en?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	
C10	**If, Yes:** During this time, how often do you produce phlegm during the night? *¿Chq'al njatz txloqa tzen qnik'en?*	Frequently = 1 Once in a while = 2	

If the answer is "No" for the questions B.1 and C.1: GO TO Section E (Asthma, Rhinitis and Eczema).

If the answer is "Yes" for the questions B.1 and/or C.1: CONTINUE with Section D (Periods in which cough and phlegm get worse).

D. PERIODS IN WHICH THE COUGH (SJO'L) AND PHLEGM (XLOQ) GET WORSE:

Question		Answer	Code
D1	During the past 12 months, have you had periods in which the cough and phlegm **GETS WORSE**? *¿Toja ab'q'e xjawel b'aj at q'ij n-xiy to il tu'n sjol tuk'a xloq?* **_If NO, go to section E (Asthma, Rhinitis and Eczema)**	No = 1 Yes = 2	
D2	**If, Yes:** How long has it been since you had periods in which the cough and phlegm **GETS WORSE**? *¿Jte maj' o txiy tun il tun sjol tuj'a xloq?*	A few days =1 One to two weeks =2 Three weeks or more =3	

D3	**If, Yes:** During the last 12 months, have you had more than one of these periods in which the cough and phlegm **GETS WORSE**? *¿Toja abq'e xjawel b'aj jte maj xiy taj il tun sjol ex xloq ?*	No = 1 Yes = 2	
D4	Have you had difficulty breathing during the periods in which the cough or phlegm **GET WORSE**? *¿At junjen maj penex njatza txewa te txiy tojil tun sjol ex xloq?*	No = 1 Yes = 2	

E. ASTHMA, RHINITIS AND ECZEMA:

Question		Answer	Code
E1	Has your neck ever whistled? *¿At jun maj o tzolen tqula?* **_If the answer is NO, go to E3**	No = 1 Yes = 2	
E2	During the past 12 months, have you once had attacks in which your neck whistles? *¿Toja abq'e xjawel-b'aj at jun maj oklen tzol qul tija?*	No = 1 Yes = 2	
E3	During the past 12 months, have you once woken up in the morning with the sensation of a pressure on your chest? *¿Toja abq'e xjawel b'aj o ja sak'pajxiy jun maj qlixje penix njatza txewa?*	No = 1 Yes = 2	
E4	Has the doctor or nurse ever diagnosed you with Asthma? *¿At jun maj o tza q'man tey tun Doctor o Enfermera qa at asma tija?*	No = 1 Yes = 2	
E5	Have you ever had on your skin an itchy rash that appeared and disappeared for periods that lasted a total of at least 6 months? *¿At jun maj o-tzaj xjo's tija (n-spufen) n-mtzen tija n-tzajxe n-elxe naj a nwe qaq xjaw?* **_If the answer is "NO", go to question E8**	No = 1 Yes = 2	
E6	Have you had this itchy rash at any moment <u>during the last 12 months</u>? *¿At jun majtoja abq'e xjawel o-tzaj xjo's tija a-tzunxex n-metzen?*	No = 1 Yes = 2	
E7	Have you ever had this itchy rash in any of the following places? **(a)**Fold of your elbow, **(b)**Behind your knee, **(c)**Fold of your ankle, **(d)**Below your buttocks, **(e)**or Around your neck, ears and eyes *¿At jun maj o-tzaj xjos a-nmetzen tija plaj?* **(a)**Tcheky tq'ob'a **(b)**Txpaq'ch tqan, **(c)**Twonsi tqan, **(d)**Tij t-xopa, **(e)**Tij tqula txquin ex twutza.	No = 1 Yes = 2	
E8	Have you ever had problems with sneezing, mucus or blocked nose when you **DID NOT** have a cold or flu? *¿Atjun maj o tzaj metzin loj t-txan mo xpon t-tzan tzen nti' chon-wi'tija?* **_If the answer is "NO", go to question F1**	No = 1 Yes = 2	
E9	<u>During the past 12 months</u>, have you had problems with sneezing, mucus or blocked nose when you **DID NOT** have a cold or flu? *¿Toja ab'qe xjawel-baj o xpet jun maj te t-txan te n-ti chon-wi' tija?*	No = 1 Yes = 2	

F. HEADACHE AND BURNING EYES:

Question	Answer	Code

Question		Answer	Code
F1	During the past month, have you had headaches? *¿Toja xjaw xbaj tzaj te tchon twi' ?*	No = 1 Yes = 2	
F2	**If, Yes:** How often have you had headaches during this time? *¿ Cha'al n-tzaj tchon twiy?*	Every day = 1 Most days of the week =2 A few days per week = 3 Once per week = 4 Less than once per week = 5	
F3	**If, Yes:** How strong are the headaches? *¿Tzentzn tchon twiy?*	Very strong = 0 Average = 1 Mild = 2	
F4	During <u>the past month</u>, have you had burning eyes, **watery eyes?** *¿Toja xjaw xb'aj ma chi julin twutza mo nchi talinj?*	No = 1 Yes = 2	
F5	**If, Yes:** During this time, how often have you had burning eyes or **watery eyes**? *¿Chq'al nchi julin mo nchi talin twutza?*	Every day = 1 Most days of the week =2 A few days per week = 3 Once per week = 4 Less than once per week = 5	
F6	<u>Ask and observe:</u> If your eyes water, what is the secretion like? *<u>Qaninxa ex kayinka:</u>* *¿Qa ntalin twutz ¿tzen kayin tal twutz?*	Clear, aqueous = 1 Yellow, green, sticky = 2	
F7	**If the answer = 2:** the secretion is yellow or greenish and sticky, Does it make it so you cannot open your eyes when you wake up? ***If, Yes =2:*** *¿Q'an o txax kayin txa twutza minjqet aj tja wey?* **_ If, Yes*: Refer to Health Center***	No = 1 Yes = 2	

G. BACK PAIN:

Question		Answer	Code
G1	Have you had back pain during the past month? *¿Toja xjaw xbaj o chon tzkeltija?* **If the answer is "No", go to section H**	No = 1 Yes = 2	
G2	**If, Yes:** *During this time, how often have you had back pain?* *¿Chq'altzin n-tzaj tchon tzkeltija?*	Every day = 1 Most days of the week =2 A few days per week = 3 Once per week = 4 Less than once per week = 5	
G3	**If, Yes:** *What things make your back hurt more?* *¿Ti n-kub' tb'inchin tzen n-oqkten tija chol?*	Carrying Wood = 1 Washing Clothes= 2 Cooking = 3 Other (specify) = 4	
G4	**If, Yes:** *Have the back pain been so strong that that you have stopped doing your duties?* *¿Aj t-tzaj tchon tija mi n-aq'nila tun?*	No = 1 Yes =2 (specify in the following box)	

Question		Answer	Code
G5	Describe how the pain affects your duties:		

H. TRAFFIC:

Question		Answer	Code
H1	From Mondays to Fridays, how frequently do trucks pass by the roads where you live? *¿T'kiaqil q'in nchi b'et car ja tkub'a tjay?*	Never = 1 Almost never =2 A few times during the day = 3 Almost all day = 4	

ASTHMA, RHINITIS Y ECZEMA (FATHER): (IF SINGLE MOTHER, GO ON TO SECTION J)
If possible, interview father of the child under study. If he is not found, then ask the child's mother:

Question		Answer	Code
I1	Has your neck ever whistled? *¿At jun maj o tzolen tqula?* **_If the answer is NO, go to I3**	No = 1 Yes = 2	
I2	During <u>the past 12 months</u>, have you once had attacks in which your neck whistles? *¿Toja abq'e xjawel-b'aj at jun maj oklen tzol qul tija?*	No = 1 Yes = 2	
I3	During <u>the past 12 months</u>, have you once woken up in the morning with the sensation of a pressure on your chest? *¿Toja abq'e xjawel b'aj o ja sak'pajxiy jun maj qlixje penix njatza txewa?*	No = 1 Yes = 2	
I4	Has the doctor or nurse ever diagnosed you with Asthma? *¿At jun maj o tza q'man tey tun Doctor o Enfermera qa at asma tija?*	No = 1 Yes = 2	
I5	Have you ever had on your skin an itchy rash that appeared and disappeared for periods that lasted a total of at least 6 months? *¿At jun maj o-tzaj xjo's tija (n-spufen) n-mtzen tija n-tzajxe n-elxe naj a nwe qaq xjaw?* **_If the answer is "NO", go to question I8**	No = 1 Yes = 2	
I6	Have you had this itchy rash at any moment <u>during the last 12 months</u>? *¿At jun majtoja abq'e xjawel o-tzaj xjo's tija a-tzunxex n-metzen?*	No = 1 Yes = 2	
I7	Have you <u>ever</u> had this itchy rash in any of the following places? **(a)**Fold of your elbow, **(b)**Behind your knee, **(c)**Fold of your ankle, **(d)**Below your buttocks, **(e)**or Around your neck, ears and eyes *<u>¿At jun maj o-tzaj xjos a-nmetzen tija plaj?</u>* **(a)**Tcheky tq'ob'a **(b)**Txpaq'ch tqan, **(c)**Twonsi tqan, **(d)**Tij t-xopa, **(e)**Tij tqula txquin ex twutza.	No = 1 Yes = 2	
I8	Have you ever had problems with sneezing, mucus or blocked nose when you **DID NOT** have a cold or flu? *¿Atjun maj o tzaj metzin loj t-txan mo xpon t-tzan tzen nti' chon-wi'tija?* **_If the answer is "NO", go to question J1**	No = 1 Yes = 2	
I9	<u>During the past 12 months</u>, have you had problems with sneezing, mucus or blocked nose when you **DID NOT** have a cold or flu? *¿Toja ab'qe xjawel-baj o xpet jun maj te t-txan te n-ti chon-wi' tija?*	No = 1 Yes = 2	

J. QUESTIONS RELATED TO THE CHILD IN THE STUDY: (IF MOTHER IS PREGNANT, GO ON TO SECTION K)

Question		Answer	Code
J1	Has your child's neck ever whistled? *¿At jun maj o tzolin tqulja tala?* **_If the answer is"NO," please go to question J3**	No = 1 Yes = 2	
J2	**If, Yes:** How many attacks in which their neck has whistled has your child had in their life? *¿Jtexe maj n tzaj tzolin qul tija tala tuk'a tanq'len?*	None = 0 1-3 = 1 4-12 = 2 More than 12 = 3	
J3	How often do you bath your child, be it with a sponge or in a tub? *¿Chq'al n-okx tala chujel mo noq n-ichin?*	Rarely = 1 Once per month = 2 Once or twice per week = 3 Daily =4	

K. QUESTIONS THAT SHOULD BE REPEATED FOR EACH OF THE SIBLINGS < 15 YEARS: (IF THE MOTHER DOES NOT HAVE ANY MORE CHILDREN IN THE STUDY, GO TO SECTION M)

K1 BROTHER/SISTER ID:

Child ID	Age in Years (as of last birthday)	Code

K2 ADDITIONAL ENVIRONMENTAL QUESTIONS:

Question		Answer	Code
K2.1	Has your child lived in the same house for all his/her life? *¿Antza najlen tala tuk-a titzja?*	No = 1 Yes = 2	
K2.2	During the <u>first 12 months</u> of your child's life, did you usually give him/her acetaminophen to reduce his/her fever? *¿A-te tel ab'q'e tala xi tq'on acetaminofen tun tkub' kyaq tij?* **_ If the answer is "NO," please go to question K2.4**	No = 1 Yes = 2	
K2.3	During the <u>past 12 months</u>, more or less, how often did you give acetaminophen to your child? *¿Toja ab'q'e xbaj chq'al xi tq'on acetaminofen te?*	Never = 1 At least once per year =2 At least once per month =3	
K2.4	Did you give antibiotics to your child during the <u>first 12 months</u> of your child's life? *¿Te s-el ab'q'e tala xi tq'on antibiotico te tala?*	No = 1 Yes = 2	

K3 "MEDULARES" QUESTIONS ABOUT ASTHMA:

Question		Answer	Code
K3.1	Has your child's neck ever whistled in the past? *¿At jun maj tzolin tqul tala?* **_ If the answer is "NO," please go to question K3.6**	No = 1 Yes = 2	

Question		Answer	Code
K3.2	Has your child's neck whistled <u>during the past 12 months</u>? *¿Toja ab'q'e xbaj tzolin tqulja tala ?* **_If the answer is"NO," please go to question K3.6**	No = 1 Yes = 2	
K3.3	How many attacks in which their neck has whistled has your child had <u>during the past 12 months</u>? *¿Toja ab'q'e xb'aj jte maj tzaj tzolin qul tij tala?*	None = 1 1-3 = 2 4-12 = 3 > 12 = 4	
K3.4	<u>During the past 12 months</u>, how frequently, more or less, has your child's sleep been interrupted due to his/her neck whistling? *¿Toja ab'q'e xb'aj jte maj el twatlja tala tun tzolin qul?*	He/she has never woken up with whistling in the neck = 1 Less than one night per week = 2 One or more nights per week = 3	
K3.5	<u>During the past 12 months</u>, have the whistles in you're your child's neck been so bad that he/she cannot say more than one or two words in a row without taking a breath? *¿Toja ab'q'e xb'aj a tala penix nb'anta tyolin tun tzolin qul?*	No = 1 Yes = 2	
K3.6	Has the doctor or nurse ever diagnosed your child with Asthma? *¿At jun maj o tzaj q'man tun Doctor o Enfermera qa at asma tij tala?*	No = 1 Yes = 2	
K3.7	<u>During the past 12 months</u>, has your child's neck ever whistled during or after doing exercise? *¿Toja ab'q'e xb'aj n-tzaj tzolin qul tijtala tzen n-rinen?*	No = 1 Yes = 2	
K3.8	<u>During the past 12 months</u>, has your child had dry cough during the night, without having had a cold or respiratory infection at the same time? *¿Toja ab'q'e xb'aj o tzaj tzqij sjol tij tala qnik'en exsin nti chon-wi tij?*	No = 1 Yes = 2	

K4 "MEDULARES" QUESTIONS ABOUT RHINITIS:

Question		Answer	Code
K4.1	Has your child ever had problems with sneezing or blocked nose and mucus WITHOUT having a cold or flu? *¿At jun maj o-tzaj ti tala xpon t-txan a nti chon-wi' tij?* **_If the answer is "NO," please go to section K5**	No = 1 Yes = 2	
K4.2	<u>During the past 12 months</u>, has your child had problems with sneezing or blocked nose and mucus WITHOUT having a cold or flu? *¿Toja ab'q'e xb'aj xpet t-txan tala te ntitaq chon-wi tij?* **_If the answer is "NO," please go to section K5**	No = 1 Yes = 2	
K4.3	<u>In the past 12 months</u>, have you seen the nose problem accompanied by burning eyes or tearing eyes? *¿Toja ab'q'e ab'aj tzen n-xpet t-txan tzun njulin twutz monchi talin twutz?* **_If the answer is "NO," please go to section K5**	No = 1 Yes = 2	

Question		Answer	Code
K4.4	During which of the past 12 months did he/she have this problem? ***(Underline the answer and note code number)*** *¿Alky xjaw te' ab'q'e xb'aj te t-tzaj tij?* January =1 | May =5 | September =9 February =2 | June =6 | October =10 March =3 | July =7 | November =11 April =4 | August =8 | December =12		

K5 "MEDULARES" QUESTIONS ABOUT ECZEMA:

Question		Answer	Code
K5.1	Has your child ever had on his/her skin an itchy rash that appeared and disappeared for periods that lasted a total of at least 6 months? *¿Atjun maj tij tala O-tzaj xjo's (n-spulen) n-metzen n-tzajxe n-elxe nai a nwe qaq xjaw?* **_If the answer is "NO," please go to section L**	No = 1 Yes = 2	
K5.2	Has your child had this itchy rash at any moment during the last 12 months? *¿ At jun maj toja ab'q'e xbaj o tzaj xjos tija tala a-tzunxex n-metzen?* **_If the answer is "NO," please go to section L**	No = 1 Yes = 2	
K5.3	Has your child ever had this itchy rash in any of the following places? **(a)**Fold of the elbow, **(b)**Behind the knee, **(c)**Fold of the ankle, **(d)**Below the buttocks, **(e)**or Around the neck, ears and eyes *¿Atjun maj o-tzaj xjos a-nmetzen tija plaj?* **(a)**Tcheky tq'ob'a, **(b)**txpaq'ch tqan, **(c)**twonsl tqan, **(d)**Tij t-xopa, **(e)**tijtqul txquin ex twutza.	No = 1 Yes = 2	
K5.4	How was old was your child when he/she first got this itchy rash? *¿Jtetaq ab'q'e tala te tzaj xjos taj a-tzunx n-metzen tnejel maj?*	Less than 2 years = 1 From 2-4 years = 2 5 years or more = 3	
K5.5	During the past 12 months, has the rash disappeared completely? *¿Toja ab'q'e xjawel o-naja xjos tij te-junmajx?*	No = 1 Yes = 2	

L. QUESTIONS THAT SHOULD BE REPEATED FOR EACH ONE OF THE SIBLINGS LESS THAN 9 YEARS:

L1. ID OF SIBLING:

Child ID	Age in years (as of last birthday)	Code

L2. BURNS AND SCALDINGS:

Question		Answer	Code
L2.1	During the past 6 months, has your child suffered a burn (with a hot object or liquid)? *¿Toja tqaqen xjaw o tzey jun maj tala tuk'a kyqa mojqa tuk'a q'aq'?*	No = 1 Yes = 2 **_If the answer is "NO," please go to question L2.4**	

Question		Answer	Code
L2.2	*If **YES**, how serious?* *¿Jni tzey?*	Light (there is no scar) = 1 Moderate (scar smaller than a Q1 coin) = 2 Serious (scar larger than a Q1 coin) = 3 ***‡ If it is serious (3) measure the size of the scar and note its dimensions:*** ***____ x _____ cms.***	
L2.3	*And how did he/she get burned?* *Y, ¿Tzen tzeya?*	He/she fell in the fire = 1 He/she was burned with a hot object = 2 A container with hot water was spilled = 3 Other (specify) = 4	
L2.4	At any time before your child reached 6 months, was s/he burned? *¿Toja tqaqen xjaw o-tzey tala jun maj?*	No = 0 Light (there is no scar) = 1 Moderate (scar smaller than a Q1 coin) = 2 Serious (scar larger than a Q1 coin) = 3 ***‡ If it is serious (3) measure the size of the scar and note its dimensions:*** ***____ x _____ cms.***	
L2.5	*If it was serious **(code = 3),** how old was he/she when burned?* *¿qa nim tzey te jtetaq tb'q'e te t-tzey?*	Age (years)	
L2.6	How was he/she burned*?* *¿Tzen tzeya?*	He/she fell in the fire = 1 He/she was burned with a hot object = 2 A container with hot water was spilled = 3 Other (specify) = 4	

M. SPIROMETRY: (To the mother of study child)

		Answer	Code
M1	Operator ID		
M2	Spirometer ID		
M3	Date of Birth	dd / mm / yy	
M4	Height of woman	cm	
M5	Weight of woman	kg	
M6	Is the mother pregnant?	No = 1 Yes = 2	
M7	Date spirometry performed	dd / mm / yy	
M8	Time spirometry performed	hh mm	
M9	Supervisor was present	No = 1 Yes = 2	

M1. RECENT COLD WITH COUGH:

Question	Answer	Code

Question		Answer	Code
M1.1	Have you had a cold with cough in recent days?	No = 1 Yes, during the past two weeks = 2 Yes, for more than two weeks = 3	

M2. SPIROMETRY RESULTS: (With a maximum of 8 blows)

Blow #	Good blow = 1 Slow start = 2 Little force = 3 Abrupt ending = 4 Cough = 5 Bad technique = 6 Short blow = 7		FEV1		FVC	
	Operator	Microloop Apparatus	Result	Best = 1 2^{nd} best = 2	Result	Best = 1 2^{nd} best = 2
1						
2						
3						
4						
5						
6						
7						
8						
Calculate the difference between the first and second best attempts **ONLY**			LITERS		LITERS	

M2. SPIROMETRY QUALITY CONTROL:

		Answer	Code
M2.1	At least three good blows	No = 1 Yes = 2	
M2.2	FEV1: Is the difference between the best and second best less than **0.20** liters?	No = 1 Yes = 2	
M2.3	FVC: Is the difference between the best and second best less than **0.20** liters?	No = 1 Yes = 2	
M2.4	If it is not possible to achieve a good blow describe the reason?		
M2.5	If the woman did not perform the spirometry, describe the reason:		

N. BREATH CARBON MONOXIDE:

	Answer	Code

		Answer	Code
N1	How long has it been since you last cooked?	Date dd/mm/yy	
		Time hh:mm	
N2	CO Monitor ID		
N3	Measurement Start Time	Time hh:mm	
N4	Measurement Results	PPM	
		PPM	
		PPM	

O. MOTHER'S REFERRAL:

		Answer	Code
O1	Referral	No = 1 Study Doctor = 2 Health Center = 3	
O2	Reason for referral (Describe)		

THANK INTERVIEWEE FOR HER PARTICIPATION – END OF INTERVIEW

Interview

Interviewer Initials: ________________ Interviewer Signature: _________________

Interview Check

Supervisor Signature:______________________ Date of check: __________________

Measurement Supervision

Supervisor Signature:______________________ Date of revision: __________________

Data Entry

Data Enterer #1 Signature: __________________ Data Enterer #2 Signature: __________________

Data Entry Check

Supervisor Signature:______________________ Date of check: __________________

OBSERVATIONS:

Appendix II

Appendix II: 6 Month Assessment Follow-up Questionnaire "AAA" English

STUDY OF ADULT HEALTH, ASHMA AND ALLERGIES
Six monthly assessment

A. INTRODUCTION AND CONSENT:

Question		Answer	Code
A1	Group	GROUP A (00-12) GROUP B (00-18)	
A2	ID (home)		
A3	ID (woman)		
A4	ID Interviewer		
A5	Date	dd /mm /yy	

CHRONIC RESPIRATORY SYMPTOMS

Notes for the interviewer: when you ask the fallowing questions it is very important that you remind the woman that these questions refer to the symptoms/ complaints that she and/or her family may have had since the last time you visited the house.

B. COUGH: (SJO'L)

Question		Answer	Code
B1	During the past 6 months, Do you cough or have you coughed a lot? *¿Tzun n-sjolin mo o sjolin ma nintz mouj?* **If "NO", go to section C (Phlegm)**	No = 1 Yes = 2	
B2	Do you cough or have you coughed when getting up in the morning? *¿Tzun n-sjolin mo o sjolin aj tjawey janjin qlexje?*	No = 1 Yes = 2	
B3	**IF, Yes:** Since how long ago have you been coughing when getting in the morning? *¿Jtexe q'ij toknin ten sjo'l tija aj tjawey tzen qlexje?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	
B4	**If, Yes:** During this time, how often do you cough when getting up in the morning? *¿Chq'al n-tzaj sjol aj tjawey?*	Frequently = 1 Once in a while = 2 Occasionally = 3	
B5	Do you cough or have you coughed during the day? ¿Tzun n-sjolin mo o sjolin tzen q'ijl?	No = 1 Yes = 2	
B6	**If, Yes:** Since how long ago have you been coughing during the day? *¿Jtexe q'ij toknin ten sjo'l tija a-qijtl?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	
B7	**If, Yes:** During this time, how often do you cough during the day? *¿Chq'al n-tzaj sjol tija tzen q'ijl?*	Frequently = 1 Once in a while = 2 Occasionally = 3	
B8	Do you cough or have you coughed during the night? *¿Tzun n-sjolin mo o sjolin tzen qnik'in?*	No = 1 Yes = 2	
B9	**If, Yes:** Since how long ago have you been coughing during the night? *¿jtexe q'ij toknin ten sjol tija tzen qnik'en?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	

B10	**If, Yes:** During this time, how often do you cough during the night? *¿Chq'al n-tzaj sjol tija tzen qnik'en?*	Frequently = 1 Once in a while = 2 Occasionally = 3	

C. FLEMA: (XLOQ)

Question		Answer	Code
C1	<u>*During the past 6 months*</u>, Do you produce or have you produced a lot of phlegm? *¿Tzun njatz xloq mo o jatz nim xloq tun?* **_ If "NO" go to section D (Periods of Cough with Phlegm)**	No = 1 Yes = 2	
C2	Do you produce or have you produced phlegm when getting up in the morning? *¿Tzun njatz mo o jatz xloq tu'n aj tjawey?*	No = 1 Yes = 2	
C3	**If, Yes:** Since how long ago have you been producing phlegm when getting up in the morning? *¿Jtexe q'ij toklin ten n-jatz txloqa tzen qlexje?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	
C4	**If, Yes:** During this time, how often do you produce phlegm when getting u in the morning? *¿chqaltzin njatz txloqa tzen njawey qlexje?*	Frequently = 1 Once in a while = 2 Occasionally = 3	
C5	Do you produce or have you produced phlegm during the day? *¿Tzun njatz mo o jatz txloqa tzen q'ijl?*	No = 1 Yes = 2	
C6	**If, Yes:** Since how long ago have you been producing phlegm during the day? *¿Jtexa q'ij toklen ten xloq a njatz tzen q'ij?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	
C7	**If, Yes:** During this time, how often do you produce phlegm during the day? *¿Chq'al njatz txloqa tzen q'ijl?*	Frequently = 1 Once in a while = 2 Occasionally = 3	
C8	Do you produce or have you produced phlegm during the night? *¿Tzun njatz mo o jatz txloqa txloqa tzen qnikén?*	No = 1 Yes = 2	
C9	**If, Yes:** Since how long ago have you been producing phlegm during the night? *¿Jtexa q'ij toklen ten njatz txloqa tzen qnik'en?*	Less than 3 months = 1 Around 3 months = 2 More than three months = 3	
C10	**If, Yes:** During this time, how often do you produce phlegm during the night? *¿Chq'al njatz txloqa tzen qnik'en?*	Frequently = 1 Once in a while = 2 Occasionally = 3	

If the answer is "No" for all the questions: B1 and, GO TO a la Section E.

If the answer is "Yes", for the questions: B.1, and/or C.1 CONTINUE with Section D.

D. PERIODS IN WHICH THE COUGH (SJO'L) AND PHLEGM (XLOQ) GET WORSE:

Question		Answer	Code
D1	<u>*During the past 6 months*</u>, have you had periods in which the cough and phlegm **GETS WORSE**? *¿Toja ab'q'e xjawel b'aj at q'ij n-xiy to il tu'n sjol tuk'a xloq?* **_If NO, go to section E (Asthma, Rhinitis and Eczema)**	No = 1 Yes = 2	

D2	**If, Yes:** How long has it been since you had periods in which the cough and phlegm **GETS WORSE**? *¿Jte maj' o txiy tun il tun sjol tuj'a xloq?*	A few days =1 One to two weeks =2 Three weeks or more =3	
D3	**If, Yes:** During the last 12 months, have you had more than one of these periods in which the cough and phlegm **GETS WORSE**? *¿Toja abq'e xjawel b'aj jte maj xiy taj il tun sjol ex xloq ?*	No = 1 Yes = 2	
D4	Have you had difficulty breathing during the periods in which the cough or phlegm **GET WORSE**? *¿At junjen maj penex njatza txewa te txiy tojil tun sjol ex xloq?*	No = 1 Yes = 2	

E. ASTHMA, RHINITIS AND ECZEMA:

Question		Answer	Code
E1	*During the past 6 months,* have you once had attacks in which your neck whistles? *¿Toja abq'e xjawel-b'aj at jun maj oklen tzol qul tija?*	No = 1 Yes = 2	
E2	*During the past 6 months*, have you once woken up in the morning with the sensation of a pressure on your chest? *¿Toja abq'e xjawel b'aj o ja sak'pajxiy jun maj qlixje penix njatza txewa?*	No = 1 Yes = 2	
E3	*During the past 6 months* ,Has the doctor or nurse ever diagnosed you with Asthma? *¿At jun maj o tza q'man tey tun Doctor o Enfermera qa at asma tija?*	No = 1 Yes = 2	
E4	Have you had itchy rash at any moment during the last 6 months? *¿At jun majtoja abq'e xjawel o-tzaj xjo's tija a-tzunxex n-metzen?*	No = 1 Yes = 2	
E5	Have you ever had this itchy rash in any of the following places? **(a)**Fold of your elbow, **(b)** Behind your knee, **(c)**Fold of your ankle, **(d)**Below your buttocks, **(e)**or Around your neck, ears and eyes *¿At jun maj o-tzaj xjos a-nmetzen tija plaj?* **(a)**Tcheky tq'ob'a **(b)**Txpaq'ch tqan, **(c)**Twonsi tqan, **(d)**Tij t-xopa, **(e)**Tij tqula txquin ex twutza.	No = 1 Yes = 2	
E6	During the past 6 months, have you had problems with sneezing, runny or blocked nose when you **DID NOT** have a cold or flu? *¿Toja ab'qe xjawel-baj o xpet jun maj te t-txan te n-ti chon-wi' tija?*	No = 1 Yes = 2	

F. HEADACHE AND BURNING EYES:

Question		Answer	Code
F1	During the past month, have you had headaches? *¿Toja xjaw xbaj tzaj te tchon twi' ?*	No = 1 Yes = 2	
F2	**If, Yes:** How often have you had headaches during this time? *¿ Cha'al n-tzaj tchon twiy?*	Every day = 1 Most days of the week =2 A few days per week = 3 Once per week = 4 Less than once per week = 5	
F3	**If, Yes:** How strong are the headaches? *¿Tzentzn tchon twiy?*	Very strong = 0 Average = 1 Mild = 2	

Question		Answer	Code
F4	During <u>the past month</u>, have you had burning eyes, **watery eyes?** *¿Toja xjaw xb'aj ma chi julin twutza mo nchi talinj?*	No = 1 Yes = 2	
F5	**If, Yes:** During this time, how often have you had burning eyes or **watery eyes**? *¿Chq'al nchi julin mo nchi talin twutza?*	Every day = 1 Most days of the week =2 A few days per week = 3 Once per week = 4 Less than once per week = 5	
F6	<u>Ask and observe:</u> If your eyes water, what is the secretion like? <u>Qaninxa ex kayinka:</u> *¿Qa* ntalin twutz *¿tzen kayin tal twutz?* **_ If, the answer is 1, go to section G**	Clear, aqueous = 1 Yellow, sticky = 2	
F7	**If the answer = 2:** the secretion is yellow or greenish and sticky, Does it **make it so you cannot open your eyes when you wake up?** ***Si, respuesta =2:*** *¿Q'an o txax kayin txa twutza minjqet aj tja wey?* **_ If, Yes*: Refer to study doctor***	No = 1 Yes = 2	

G. BACK PAIN:

Question		Answer	Code
G1	<u>Have you had back pain during the past month?</u> <u>*¿Toja xjaw xbaj o chon tzkeltija?*</u>	No = 1 Yes = 2	
G2	**If, Yes:** *During this time, how often have you had back pain?* *¿Chq'altzin n-tzaj tchon tzkeltija?*	Every day = 1 Most days of the week =2 A few days per week = 3 Once per week = 4 Less than once per week = 5	
G3	**If, Yes:** *What things make your back hurt more?* *¿Ti n-kub' tb'inchin tzen n-oqkten tija chol?*	Carrying Wood = 1 Washing Clothes= 2 Cooking = 3 Other (specify) = 4	
G4	**If, Yes:** *Have the back pains been so strong that that you have stopped doing your duties?* *¿Aj t-tzaj tchon tija mi n-aq'nila tun?*	No = 1 Yes =2 (specify in the following box)	
G5	Describe how the pain affects your duties:		

H. TOBACCO SMOKING:

Question		Answer	Code
H1	Have you smoked cigarettes <u>*during the past 6 months*</u>? *Tojja' qaq xjaw o tziky' o bajxa' sich' tu'n?*	No = 1 Yes = 2	
H2	**If, Yes**: *How many cigarettes per day do you usually smoke?* *Jte sich' nbaj tu'n junjun q'ij?*	# Cigarettes/day	

Question		Answer	Code
H3	There are someone else that smoke **inside** the house and/or the kitchen? *Tzun nsichin junxil xjal toj tjay?*	No = 1 Yes = 2	
H4	**If, Yes**: *How many cigarettes per day do they usually smoke?* *How many cigarettes per day do you usually smoke?*	# Cigarettes/day	

I. ASTHMA, RHINITIS Y ECZEMA (FATHER):

If possible, interview father of the child under study. If he is not found, then ask the child's mother:

Question		Answer	Code
I1	*During the past 6 months,* have you once had attacks in which your neck whistles? *¿Toja abq'e xjawel-b'aj at jun maj oklen tzol qul tija?*	No = 1 Yes = 2	
I2	*During the past 6 months*, have you once woken up in the morning with the sensation of a pressure on your chest? *¿Toja abq'e xjawel b'aj o ja sak'pajxiy jun maj qlixje penix njatza txewa?*	No = 1 Yes = 2	
I3	*During the past 6 months,* Has the doctor or nurse diagnosed you with Asthma? *¿At jun maj o tza q'man tey tun Doctor o Enfermera qa at asma tija?*	No = 1 Yes = 2	
I4	Have you had itchy rash at any moment during the last 6 months? *¿At jun majtoja abq'e xjawel o-tzaj xjo's tija a-tzunxex n-metzen?*	No = 1 Yes = 2	
I5	Have you ever had this itchy rash in any of the following places? **(a)**Fold of your elbow, **(b)**Behind your knee, **(c)**Fold of your ankle, **(d)**Below your buttocks, **(e)**or Around your neck, ears and eyes *¿At jun maj o-tzaj xjos a-nmetzen tija plaj?* **(a)**Tcheky tq'ob'a **(b)**Txpaq'ch tqan, **(c)**Twonsi tqan, **(d)**Tij t-xopa, **(e)**Tij tqula txquin ex twutza.	No = 1 Yes = 2	
I6	During the past 6 months, have you had problems with sneezing, mucus or blocked nose when you **DID NOT** have a cold or flu? *¿Toja ab'qe xjawel-baj o xpet jun maj te t-txan te n-ti chon-wi' tija?*	No = 1 Yes = 2	

J. PREGUNTAS RELACIONADAS CON EL NIÑO DEL ESTUDIO:

Question		Answer	Code
J1	*During the past 6 months,* Has your child's neck ever whistled? *¿At jun maj o tzolin tqulja tala?* **_If the answer is"NO," please go to question J3**	No = 1 Yes = 2	
J2	**If, Yes:** How many attacks in which their neck has whistled has your child had in their life? *¿Jtexe maj n tzaj tzolin qul tija tala tuk'a tanq'len?*	**None = 0** 1-3 = 1 4-12 = 2 More than 12 = 3	

Question		Answer	Code
J3	How often do you bath your child, be it with a sponge or in a tub? *¿Chq'al n-okx tala chujel mo noq n-ichin?*	Rarely = 1 **Once per month = 2** Once per week = 3 Daily =4	

K. QUESTIONS THAT SHOULD BE REPEATED FOR EACH OF THE BROTHERS < 15 AÑOS:

K1 BROTHER/SISTER ID:

Child ID	Age in Years (as of last birthday)	Code

K2 ADDITIONAL ENVIRONMENTAL QUESTIONS:

Question		Answer	Code
K2.1	*During the past 6 months*, how often did you give acetaminophen to your child? *¿Toja ab'q'e xbaj chq'al xi tq'on acetaminofen te?*	Never = 1 At least once per year =2 At least once per month =3	

K3 MAIN QUESTIONS ABOUT ASTHMA:

Question		Answer	Code
K3.1	Has your child's neck whistled during the past 6 months? *¿Toja ab'q'e xbaj tzolin tqulja tala ?* **_If the answer is"NO," please go to question K3.5**	No = 1 Yes = 2	
K3.2	How many attacks in which their neck has whistled has your child had during the past 6 months? *¿Toja ab'q'e xb'aj jte maj tzaj tzolin qul tij tala?*	None = 0 1-3 = 1 4-12 = 2 > 12 = 3	
K3.3	During the past 6 months, how frequently, more or less, has your child's sleep been interrupted due to his/her neck whistling? *¿Toja ab'q'e xb'aj jte maj el twatlja tala tun tzolin qul?*	He/she has never woken up with whistling in the neck = 0 Less than one night per week = 1 One or more nights per week = 2	
K3.4	During the past 6 months, have the whistles in you're your child's neck been so bad that he/she cannot say more than one or two words in a row without taking a breath? *¿Toja ab'q'e xb'aj a tala penix nb'anta tyolin tun tzolin qul?*	No = 1 Yes = 2	
K3.5	Has the doctor or nurse ever diagnosed your child with Asthma? *¿At jun maj o tzaj q'man tun Doctor o Enfermera qa at asma tij tala?*	No = 1 Yes = 2	
K3.6	*During the past 6 months*, has your child's neck ever whistled during or after doing exercise? *¿Toja ab'q'e xb'aj n-tzaj tzolin qul tijtala tzen n-rinen?*	No = 1 Yes = 2	

K4 MAIN QUESTIONS ABOUT RHINITIS:

Question	Answer	Code

Question		Answer	Code
K4.1	<u>During the past 6 months</u>, has your child had problems with sneezing runny or blocked nose **WITHOUT** having a cold or flu? *¿Toja ab'q'e xb'aj xpet t-txan tala te ntitaq chon-wi tij?* **_If the answer is "NO," please go to section K5**	No = 1 Yes = 2	
K4.2	**<u>In the past 6 months</u>, have you seen the nose problem accompanied by burning eyes or tearing eyes?** ***¿Toja ab'q'e ab'aj tzen n-xpet t-txan tzun njulin twutz monchi talin twutz?***	No = 1 Yes = 2	
K4.3	During which of the <u>past 6 months</u> did he/she have this problem? ***(Underline the answer)*** *¿Alky xjaw te' ab'q'e xb'aj te t-tzaj tij?* ***(Underline the answer)*** January =1 · May =5 · September =9 February =2 · June =6 · October =10 March =3 · July =7 · November =11 April =4 · August =8 · December =12		

K5 MAIN QUESTIONS ABOUT ECZEMA:

Question		Answer	Code
K5.1	Has your child had this itchy rash at any moment <u>*during the last 6 months*</u>? *¿ At jun maj toja ab'q'e xbaj o tzaj xjos tija tala a-tzunxex n-metzen?* **_If the answer is "NO," please go to section L**	No = 1 Yes = 2	
K5.2	Has your child <u>*during the last 6 months*</u> had this itchy rash in any of the following places? **(a)**Fold of the elbow, **(b)**Behind the knee, **(c)**Fold of the ankle, **(d)**Below the buttocks, **(e)**or Around the neck, ears and eyes *¿Atjun maj o-tzaj xjos a-nmetzen tija plaj?* **(a)**Tcheky tq'ob'a, **(b)**txpaq'ch tqan, **(c)**twonsl tqan, **(d)**Tij t-xopa, **(e)**tijtqul txquin ex twutza.	No = 1 Yes = 2	
K5.3	How old was your child when he/she first got this itchy rash? *¿Jtetaq ab'q'e tala te tzaj xjos taj a-tzunx n-metzen tnejel maj?*	Less than 2 years = 1 From 2-4 years = 2 5 years or more = 3	
K5.4	**<u>During the past 6 months</u>, has the rash disappeared completely?** ***¿Toja ab'q'e xjawel o-naja xjos tij te-junmajx?***	No = 1 Yes = 2	

L. BURNS AND SCALDS: (Only for children less than 9 years)

L1. CHILD ID

Child ID	Age in years (as of last birthday)	Code

L2. BURNS AND SCALDS:

Question		Answer	Code
L2.1	<u>During the past 6 months</u>, has your child suffered a burn (with a hot object or liquid)? *¿Toja tqaqen xjaw o tzey jun maj tala tuk'a kyqa mojqa tuk'a q'aq'?*	No = 1 Yes = 2 **_If the answer is "NO," please go to section M**	
L2.2	*If **YES**, how serious?* *¿Jni tzey?*	Light (there is no scar) = 1 Moderate (scar smaller than a Q1 coin) = 2 Serious (scar larger than a Q1 coin) = 3 **_If was serious (3) measure the size of the scare and write it down the surface measure:** **______ X _______ cm**	
L2.3	*And, ¿how did he/she get burned?* *Y, ¿Tzen tzeya?*	He/she fell in the fire = 1 He/she was burned by some hot object = 2 A container with a hot liquid (Ex. water) was spilled = 3 Other = 4 (specify) ___________________________________	

M. SPIROMETRY: (to the mother of the study child)

		Answer	Code
M1	Operator ID		
M2	Spirometer ID		
M3	Date of Birth	dd / mm / yy	
M4	Height of woman	cm	
M5	Weight of woman	kg	
M6	Is the mother pregnant?	No = 1 Yes = 2	
M7	Date spirometry performed	dd / mm / yy	
M8	Time spirometry performed	hh : mm	
M9	The supervisor was present	No = 1 Yes = 2	
M10	If this is a repetition: Reason why the sprirometry is been repeated	The length of the blows in the first session were < of 6 secs. = 1 The difference between FEV1 and/or FVC was ≥ 0.20 liters = 2 It couldn't be possible get at least two good blows = 3 Other reason = 4	

M1. RECENT COLD WITH COUGH:

Question	Answer	Code

Question		Answer	Code
M1.1	Have you had a cold with cough in recent days?	No = 0 Yes, during the past two weeks = 1 Yes, for more than two weeks = 2	

M2. TEMASCAL USE:

Question		Answer	Code
M2.1	Do you use the Temascal?	No = 1 Yes = 2	
M2.2	If, Yes: When was the last time you use the Temascal?	dd / mm / yy	
		hh : mm	

M3. SPIROMETRY RESULTS:
(With a maximum of 8 blows)

Blow #	Good blow = 1 Slow start = 2 Little force = 3 Abrupt ending = 4 Cough = 5 Bad technique = 6 Short blow = 7		FEV1		FVC	
	Operator	Microloop Aparatus	Result	Best = 1 2^{nd} best = 2	Result	Best = 1 2^{nd} best = 2
1						
2						
3						
4						
5						
6						
7						
8						
Calculate **ONLY** using the values of he good blows the difference between the first and second ***best***			LITERS		LITERS	

M4. SPIROMETRY QUALITY CONTROL:

		Answer	Code
M2.1	At least three good blows	No = 1 Yes = 2	
M2.2	FEV1: Is the difference between the best and second best less than **0.20** liters?	No = 1 Yes = 2	
M2.3	FVC: Is the difference between the best and second best less than **0.20** liters?	No = 1 Yes = 2	

		Answer	Code
M2.4	If it is not possible to achieve a good blow describe the reason?		

N. BREATH CARBON MONOXIDE:

		Answer	Code
N1	How long has it been since you last cooked?	Date dd/mm/yy	
		Time hh:mm	
N2	CO Monitor ID		
N3	Measurement Start Time	Time hh:mm	
N4	Measurement Results	PPM	
		PPM	
		PPM	

O. MOTHER'S REFERRAL:

		Answer	Code
O1	Referral	No = 1 Study Doctor = 2 Health Center = 3	
O2	Reason for referral (Describe)		

P. CO CONTINUOS MONITOR (HOBO):

	HOBO ID	Check Day 3	Battery (%)	File name	Graphic check	Validity	Initials
P1							
P2							

THANK INTERVIEWEE FOR THE INFORMATION – END OF INTERVIEW

Interview

Interviewer Initials: ________________ Interviewer Signature: _________________

Interview Check

Supervisor Signature:______________________ Date of check: __________________

Measurement Supervision

Supervisor Signature:______________________ Date of revision: __________________

Data Entry

Data Enterer #1 Signature: _________________ Data Enterer #2 Signature: _________________

Data Entry Check

Supervisor Signature:______________________ Date of check: __________________

OBSERVATIONS: (Please include initials, date and time)

___

___

___

Appendix III

Appendix III: Self-rated health Questionnaire

SELF-PERCEIVED HEALTH QUESTIONNAIRE
Extra questions for 18 months assessment Group B

INTRODUCTION:

Question		**Answer**	**Code**
	ID (home)	## ### ###	
	ID Interviewer	##	
	Date	dd /mm /yy	

SELF-PERCEIVED HEALTH

Question		**Answer**	**Code**
1	Generally speaking, how is your health?:	Good = 1 Average = 2 Poor =3	
2	How is your health now compared to the beginning of the study?	Better now = 1 The same = 2 Worse now = 3	
Only for *Plancha* users: In which way, for beter or worse, has the *Plancha* changed your life, if there has been any change at all? ***(Check all the answers that the lady mentions, without making any sugestión or telling the options)***:			

3	Reduction in smoke	
4	Better working posture	
5	Useful as a work surface	
6	Take less time to cook	
7	Better spaceheating	
8	Cleaner clothes	
9	Cleaner pots	
10	Cleaner children	
11	Cleaner skin	
12	Less smell incide the house	
13	Less smell from clothes	
14	Less smell from hair	
15	Saves fuel	
16	Saves money	
17	Status	
18	Pride working in the kitchen	

19	More sociable in kitchen	
20	More pleasant to work in the kitchen	
21	Less concerní about burns in children	
22	Less washing of clothes	
23	Other ***(Describe):*** 1)________________________________ 2)________________________________ 3)________________________________	
24	Poorer spaceheating	
25	Chimney cleaning	
26	Difficulty lighting	
27	Loose lighting from the flames	
28	More time in chopping wood smaller	
29	Takes more time to cook	
30	More difficult to cook with certain pots ***(specify:)*** 1) ____________________ 2) ____________________ 3) ____________________	
31	Difficulty/can't use for certain cookin tasks ***(specify:)*** 1) ____________________ 2) ____________________ 3) ____________________	
32	More insects ***(specify:)*** 1) ____________________ 2) ____________________ 3) ____________________	
33	Reduced smoke means timbres less protected	
34	Other ***(Describe):*** 1)________________________________ 2)________________________________ 3)________________________________	

If a reduction in smoke is mentioned, ask (Optionn 3)		**Answer**	**Code**
35	Would you say the reduction in smoke has influenced your health in any way ? **(If yes, explain):**	No = 1 Yes = 2	

36	Would you say the reduction in smoke has influenced the health of your children in any way ? **(If yes, explain):**	No = 1 Yes= 2	

THANK INTERVIEWEE FOR THE INFORMATION – END OF INTERVIEW

Interview

Interviewer Initials: ________________ Interviewer Signature: _________________