Environmental Research 166 (2018) 658–667

Contents lists available at ScienceDirect

Environmental Research

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

Effect on blood pressure and eye health symptoms in a climate-financed randomized cookstove intervention study in rural India

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ARTICLE INFO

Keywords:
Biomass fuel
Black carbon
Cardiovascular health
Climate financed
Particulate matter

ABSTRACT

Background: Air pollution from cooking with solid fuels is a potentially modifiable risk factor for increased blood pressure and may lead to eye irritation.
Objectives: To evaluate whether a climate motivated cookstove intervention reduced blood pressure and eye irritation symptoms in Indian women.
Methods: Households using traditional stoves were randomized to receive a rocket stove or continue using traditional stoves. Systolic (SBP) and diastolic blood pressure (DBP), and self-reported eye symptoms were measured twice, pre-intervention and at least 124 days post-intervention in women > 25 years old in control (N = 111) and intervention (N = 111) groups in rural Karnataka, India. Daily (24-h) fine particle ($PM_{2.5}$) mass and absorbance (Abs) were measured in cooking areas at each visit. Mixed-effect models were used to estimate before-and-after differences in SBP, DBP and eye symptoms.
Results: We observed a lower SBP (−2.0 (−4.5, 0.5) mmHg) and DBP (−1.1 (−2.9, 0.6) mmHg) among exclusive users of intervention stove, although confidence intervals included zero. Stacking or mixed use of intervention and traditional stoves contributed to a small increase in SBP 2.6 (−0.4, 5.7) mmHg) and DBP (1.2 (−0.9, 3.3) mmHg). Exclusive and mixed stove users experienced higher post-intervention reductions, on average, in self-reported eye irritation symptoms for burning sensation in eyes, and eyes look red often compared to control. Median air pollutant concentrations increased post-intervention in all stove groups, with the lowest median $PM_{2.5}$ increase in the exclusive intervention stove group.
Conclusions: Health benefits were limited due to stacking and lower-than-predicted efficiency of the intervention stove in the field. Stove adoption and use behavior, in addition to stove technology, affects achievement of health co-benefits. Carbon-financing schemes need to align with international guidelines that have been set based on health outcomes to maximize health co-benefits from cookstove interventions.

1. Introduction

High blood pressure (BP) is the leading global risk factor for premature deaths and disease burden (Forouzanfar et al., 2015). High BP is a recognized risk factor for chronic kidney (Jha et al., 2013) and cardiovascular diseases (CVD) including stroke and ischemic heart disease (Sesso et al., 2003; Glynn et al., 2002), which are among the leading causes of death and disease burden worldwide (Feigin et al., 2015; Roth et al., 2015).

High BP has many contributing risk factors, including diet, tobacco use, physical inactivity, excess body weight or body mass index (BMI), genetics, family history, stress, and alcohol (Chobanian et al., 2003; Shanthirani et al., 2003; Whelton et al., 2002). In addition, a 2010 review found moderate epidemiological evidence of an effect of short-

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https://doi.org/10.1016/j.envres.2018.06.044
Received 1 August 2017; Received in revised form 14 June 2018; Accepted 21 June 2018
Available online 13 July 2018
0013-9351/

term (~ days) exposure to ambient fine particulate matter ($PM_{2.5}$) and increased BP (Brook et al., 2010). Both short- and long-term exposure to ambient $PM_{2.5}$ is associated with adverse fatal and non-fatal cardiovascular events (Miller et al., 2007; Mustafic et al., 2012; Shah et al., 2015, 2013).

Whereas associations between air pollution and cardiovascular events are well-established, the majority of this evidence comes from urban and traffic-related air pollution exposures. A substantial segment of the world's population (2.7 billion, mainly in rural areas) is exposed to household biomass combustion from burning of wood, cow dung, and crop residues in inefficient traditional stoves (International Energy Agency, 2011; World Energy Outlook/International Energy Agency, 2015). Exposures in these indoor settings are typically substantially higher (Bruce et al., 2006) and differing in particle chemical composition (Naeher et al., 2007) compared with urban exposures to outdoor air pollution (Brauer et al., 2012).

Several cross-sectional studies in Asia, Latin America, and Africa suggest associations between biomass derived or household air pollution (HAP) and BP (Baumgartner et al., 2011; Burroughs Peña et al., 2015; Clark et al., 2011; Neupane et al., 2015; Painschab et al., 2013), and CVD related biomarkers (Clark et al., 2009; Quinn et al., 2016; Ruiz-Vera et al., 2015; Shan et al., 2014). Only a limited number of longitudinal studies have examined effects of air pollution or cookstove interventions on BP (Alexander et al., 2017, 2015; Clark et al., 2013a; Hanna et al., 2012; McCracken et al., 2007) and indicated mixed findings with regards to the effect of PM reductions on BP with only two of these studies including a randomized population with a control group (Alexander et al., 2017; McCracken et al., 2007). A review concluded that additional evidence from longitudinal studies was needed to confirm the role of HAP on BP (Giorgini et al., 2015).

Eye irritation is a frequently reported symptom amongst traditional cookstove users. Systematic reviews indicate an association between HAP exposure and cataracts (Smith et al., 2014) and links to other measures of eye health have also been suggested (West et al., 2013). Cross-sectional studies found reduced reporting of eye irritation symptoms among users of natural gas (compared to wood fuel) and chimney clay stoves (compared to traditional stoves) (Khushk et al., 2005; Siddiqui et al., 2005). A longitudinal study in Guatemala assessed the effectiveness of a chimney wood stove intervention on eye irritation symptoms and found reduced odds of reporting sore eyes in the intervention group that corresponded with lowered blood carbon monoxide in exhaled breath (Díaz et al., 2007).

In this study, we evaluated whether a climate motivated cookstove intervention implemented by a local non-governmental organization (NGO) in rural India resulted in blood pressure and eye health benefits for women. The intervention is approved under the Clean Development Mechanism, a carbon financing scheme established under the United Nations Framework Convention on Climate Change (Chiquet, 2015). This allows greenhouse gas (GHG) emission reductions from use of higher efficiency cookstoves to be sold as carbon credits to investors to offset existing GHG emissions. Carbon financed cookstove interventions are increasing worldwide (Ecosystem Marketplace and Global Alliance for Clean Cookstoves, 2014; Lambe et al., 2015; Putti et al., 2015), and while their overarching aim is to reduce GHG emissions (Sanford and Burney, 2015), they have the potential to provide public health benefits. However, the extent of the health benefits from climate financed cookstove intervention has not been previously investigated.

Our aim was to evaluate the potential health benefits of a stove intervention that was not primarily motivated by health considerations and which was already underway (Aung et al., 2016). India is an important setting to evaluate the potential for health co-benefits as it has the largest population in the world using biomass fuels (841 million) (International Energy Agency, 2015). Hypertension and HAP are the first and fourth-highest-ranking health risk factors for mortality in India (Forouzanfar et al., 2015). Results of this study could guide intervention programs to address these two major modifiable risk factors for CVD, a leading cause of mortality and morbidity in India, and in low- and middle-income countries (Feigin et al., 2015; Institute for Health Metrics and Evaluation (IHME), 2016).

2. Methods

2.1. Setting

A carbon-financed cookstove intervention was initiated by an Indian NGO in northern Karnataka, India as part of an approved United Nations' CDM cookstove program. Details of the program are described elsewhere (Aung et al., 2016). Briefly, the NGO planned to distribute 40,000 biomass “rocket-style” cookstoves across 110 rural villages (21,500 households). As a CDM-approved program, the intervention was intended to generate saleable carbon credits attributed to carbon emission reductions; the calculated quantity of carbon emission reduction attributed to stove use was derived from laboratory-based fuel consumption measurements (where the intervention cookstoves must demonstrate reduced fuelwood use) and available estimates of the proportion of biomass burned that would have been harvested non-renewably. Sale of the carbon credits subsidized the cost of the intervention stoves.

Prior to the launch of the full CDM program across Karnataka, the partner NGO planned a pilot intervention in Hire Waddarkal (HW) Village in Koppal District, Karnataka. Of the 300 households in the HW Village, 202 met the CDM eligibility criteria (Aung et al., 2016) to participate in the intervention program.

2.2. Study design

We partnered with the local NGO prior to the start of the pilot intervention in HW Village. This allowed us to randomize distribution of the intervention cookstoves to the CDM eligible households. Of the 202 CDM eligible households, 187 homes were eligible to participate in the study (Aung et al., 2016) and were randomly assigned to either the control (n = 91) or intervention (n = 96) groups.

Baseline (pre-intervention) measurements were collected over a period of 3 months from end September to December 2011 (post-monsoon to winter season). Intervention homes received two “rocket-style” cookstoves after baseline measurements. Identical follow-up measurements were conducted in control and intervention groups over a period of 4 months from end of March to July 2012 (summer to pre-monsoon season) with a minimum of 124 days (average of 194 days) between pre- and post-intervention measurements. Control households were given the option to receive the intervention stoves at the end of the one-year study period.

2.3. Study population

Participation of eligible participants was restricted to women above age 25 years who were non-smokers and not pregnant at time of enrollment. From the 187 households, total of 247 women were eligible to participate. Upon obtaining oral informed consent, we recruited 222 women into the study who were randomized to control (n = 111) and intervention (n = 111) groups.

2.4. Intervention

Intervention stoves were single-pot “rocket-style” biomass cookstoves, with an elbow-shape insulated combustion chamber made of lightweight ceramic (See Supplemental material, Fig. S1). The stoves used the same locally available fuelwood as traditional cookstoves. Laboratory tests indicated that the intervention stoves had thermal efficiency of 30.8% – three times more than a traditional stove – and reduced fuelwood consumption by 67% relative to a traditional stove (The Gold Standard, 2011). Each household received two intervention stoves in exchange for a participation registration fee of 200 Rupees (approximately US$3) equal to the cost of constructing two traditional stoves.

To improve users' acceptance of the intervention cookstoves, the NGO conducted extensive prototyping and in-village testing, and used the stoves in its local field office where the type of fuel and foods prepared were similar to those in the intervention communities. Before and during the intervention in HW Village and elsewhere, the NGO obtained community feedback on the cookstove design, ease of use, and quality issues, which were incorporated into the development of the final stove model. The NGO also made daily visits to intervention homes during the pilot study to ensure proper use of the stoves and to answer user questions.

2.5. Blood pressure

Systolic (SBP) and diastolic blood pressure (DBP) measurements were taken at participants' homes prior to the start of morning cooking events using an oscillometric device (Omron 705 IT, Omron Healthcare Europe BV, Hoofddorp, The Netherlands) that was maintained and calibrated in the 6 months prior to data collection. The device has been validated against mercury sphygmomanometers in adults and is recommended for professional and home-use in adult populations (Coleman et al., 2006). Recent guidelines recommend home rather than in-clinic BP measurements as a convenient method to avoid spurious increases in BP caused by measurement in a clinical setting (Pickering et al., 2005).

Prior to BP measurement, participants were encouraged to relax, and following at least 5 min of rest in a quiet room, SBP and DBP was measured in the supported right arm (at heart level) of a seated participant following the American Heart Association's recommendations (Pickering et al., 2005). Three repeat measures were taken at intervals of at least 1 min during a total period of 10 min of continued rest for each study participant. The second and third BP measurements were used for analysis as the first measurement tends to be elevated (Pickering et al., 2005). BP measurement was repeated over the next two consecutive days to allow for averaging of readings over a 3-day period, similar to the protocol used in a previous cookstove intervention study (McCracken et al., 2007). Field staff recorded the day of the week and time of day during each visit, and whether any caffeine beverages or betel nut were consumed prior to BP measurement. Betel nut is a seed of the areca palm that has been associated with elevated blood pressure (Heck et al., 2012; Javed et al., 2010; Tseng, 2008).

2.6. Eye health symptoms

Preliminary discussions with the NGO indicated that participants were concerned about eye irritation from smoke. Self-reported eye-health symptoms were collected via questionnaires on the same participants in the BP monitoring group. The questions asked whether participants felt the following symptoms: 1) burning sensation in the eyes before, after, during cooking or at times other than cooking; 2) discharge on eye lids in the mornings; 3) eyes look red often; and 4) watering of the eyes often. Whereas previous studies (Díaz et al., 2007; Saha et al., 2005; Siddiqui et al., 2005) obtained self-reported symptoms on broad eye health outcomes, such as "eye irritation", "eye congestion", "sore eyes", and "eye symptoms", our study probed specific symptoms by asking about burning sensation, discharge, and redness. We are not aware of any studies that have validated self-reported questionnaires on eye irritation symptoms from HAP exposures. One prior study found that self-reported symptoms such as "Tears while Cooking" provided a simple and immediate indicator for assessing effects of cookstove interventions (Ellegård, 1997).

2.7. Covariates

Each subject's weight (kilogram), height (centimeters), and waist circumference (centimeters) was measured with a scale and tape measure at baseline and follow-up visits. Weight and height were used to calculate body-mass index (BMI). We measured 24-h salt use for cooking by asking cooks to collect the same amount of salt they would use for the next 24-h period into a plastic container, and to only use the salt from the container. The container was weighed before and after the 24-hr period; difference in weight indicates 24-h household salt consumption. We employed age- and gender-specific adult equivalence factors for fuelwood consumption measured at the household unit weighted by household demographics (Bailis, 2007). We consider this method to be reasonable as it is likely to reflect proportional intake of food (and salt) consumption within a household based on age and gender. The adult equivalence factors give men between the ages of 15–59 years a weight of 1, for women over the age of 14 years and men over the age of 59 years a weight of 0.8, and children younger than 14 years a weight of 0.5. We are not aware of a validated method in literature for adjusting individual salt consumption measured at a household unit. Other demographics, previous health conditions, and exposures were obtained from questionnaires administered to each subject about previous diabetes and hypertension diagnoses and related medications, coffee and betel consumption, and presence of smokers in the household, age, occupation, monthly income, education, caste, housing conditions, and household assets. Household assets were converted into asset scores representing the sum of binary indicators for owning the following assets: chair, mobile phone, radio, television, bicycle, motorcycle, mixer, land ownership (irrigated and dry), livestock, and roof, floor and wall materials (natural/unimproved versus finished/improved quality). Questionnaires were translated (and, during pilot-testing, back-translated) between English and Kannada and pilot tested in a nearby village. Questions that did not pilot test well were modified or removed to ensure that they were appropriate to the local social and cultural context. Ambient temperature data was obtained from a central weather station located approximately in the center of the study village. Given the size of the village and estimates from a Google map (Fig. S3), all homes in the village are less than 500 m from the weather station.

2.8. Air pollution measurements

Household air pollution was assessed in the cooking area using integrated gravimetric measurement of fine particulate matter ($PM_{2.5}$) and absorbance (Abs; an optical measure of black carbon), using methods described in detail elsewhere (Aung et al., 2016). Briefly, baseline and post-intervention measurements took place in the same location based on kitchen layout diagrams drawn by field staff and as verified by participating household members. $PM_{2.5}$ samples were collected on 37 mm Teflon filters placed downstream of a cyclone with a 2.5 μm aerodynamic-diameter cut point connected to a battery-operated pump. Teflon filters were pre- and post-weighed and blank-corrected by subtracting the mean mass of field blanks from each phase from the sample mass. Absorbance was measured by filter reflectance analysis using a Smoke Stain Reflectometer (International Organization for Standardization, 1993).

2.9. Statistical analysis

Baseline characteristics of intervention and control households were compared to assess differences between the two groups using either the *t*-test (for normally-distributed data) or the Mann-Whitney-Wilcoxon Test (for skewed distribution data) for continuous variables; the chi-square test was used for categorical variables. Mixed-effect models with random intercepts at the individual and household levels were used to evaluate the impact of stove use on BP and eye symptoms. Variables that were statistically significantly different between the two groups (intervention households; control households) at baseline and potential risk factors for our health outcomes were evaluated separately in univariate analyses for BP and eye symptom outcomes, including age, BMI, ambient temperature, education, family size, caste, socio-economic indicators (house type, room number, asset score, land ownership), rating of one's health compared to others of same age, occupation, cooking years, self-reported time spent near stove during cooking events, betel use, salt consumption, and presence of smokers, chimney and windows. Variables found to be significant at or below $p = 0.10$, and which were not collinear (variance inflation factor < 2) were included in regression analyses.

Age and BMI were first entered as linear terms and then dichotomized into groups. Age was dichotomized at below or above the median age of study's population, 40 years, following the approach of (Clark et al., 2013a). BMI was categorized as $< 18.5\,kg/m^2$ (underweight); $18.5\,kg/m^2 \geq BMI < 23\,kg/m^2$ (normal); and $BMI \geq 23\,kg/m^2$ (overweight). The BMI cut off for overweight was in accordance with Indian guidelines which have a lower threshold than WHO standards ($BMI \geq 25\,kg/m^2$) (Misra et al., 2009).

Change in BP between baseline and post-intervention phases was assessed using the model:

$$BP_{ik} = \beta_0 + \beta_1\, group_{ik} + \beta_2\, BP\ baseline_{ik} + \beta_3\, time + \beta_4\, group_{ik} * time\ (baseline/post{-}intervention) + \beta_5\, Age_i + \beta_6\, BMI_i \ldots + b_{0ik} + \varepsilon_{ik}$$

where i denotes individual, and k denotes household. β1 is the effect estimate for the stove group as either the randomized “intent-to-treat” (ITT) (control versus intervention), as per our primary analysis plan, or the actual use “per-protocol” (PP) where intervention households were divided into those following / not following the protocol (i.e., exclusive use of the intervention stove versus mixed use of intervention plus traditional stove (see Figs. S1 and S2). Intent-to-treat evaluates the effectiveness of the intervention to provide health benefits while per-protocol assesses efficacy. Per-protocol status or stove use was identified by field staff in participants’ homes at the end of a 24-h kitchen area air quality measurement period. The field staff returning to homes to remove air quality instruments asked the main cooks about the type and number of cookstoves used during the air measurement period; the information was recorded in the field data collection questionnaire.

An interaction term between stove group and phase (baseline/post-intervention) was included to reflect an intervention in the post-intervention phase. The interaction term tests whether change is blood pressure from baseline to post-intervention change is greater for the intervention group than for the control group. Least-squares means (‘*lsmeans*’ and ‘*contrast*’ in R package) was used to obtain the mean differences (change) in BP between baseline and post-intervention phase by stove groups.

We adjusted for covariates that were known predictors of BP, such as BMI (Tesfaye et al., 2006), age (Franklin et al., 1997; Martins et al., 2001), and ambient temperature (Barnett et al., 2007), which were fitted as linear terms. Other covariates in the regression models included categorical variables: betel user (current, past, never), and self-reported health condition (excellent, good, fair, poor, don’t know). Separate regression analyses were conducted for SBP and DBP. We performed a sensitivity analysis by removing individuals who reported treatment for hypertension and/or diabetes ($N = 9$) to test robustness of the findings.

We assessed effect modification by age and BMI due to a priori knowledge. An interaction term was included between these two variables (for both group and continuous data) and the randomized groups or per-protocol groups in the model. If the interaction tested significant at $p < 0.05$ level, post-hoc testing was conducted with least-squares means (‘lsmeans’ in R package) to estimate mean differences between the comparison groups for age and BMI groups.

Model assumptions were verified using quantile plots to inspect normality of random effect, and residuals of the mixed effect model. We conducted visual inspection of graphs by plotting residuals of the regression model against the fitted model to check for heteroscedasticity.

Self-reported eye health symptoms were analyzed using a mixed-effects binomial logistic regression model for specific eye symptoms. The generalized linear model (glmer) function in R software (R Core Team, 2014) was used to model the odds of reporting an eye irritation symptom using the model:

$$Eye\ symptom_{ik} = \beta_0 + \beta_1\, group_{ik} + \beta_2\, time + \beta_3\, group_{ik} * time\ (baseline/post{-}intervention) + \beta_4\, Age_i + \beta_5\, Chimney + \varepsilon_{ik}$$

where i denotes individual, k denotes household. β_1 is effect estimate for stove group as either randomized (ITT) or actual use (PP), i.e. exclusive intervention stove users or mixed stove users. Similar to the BP model, variables that were statistically significantly different between the two groups (intervention households; control households) at baseline and potential risk factors for eye irritation symptoms based on plausibility and prior knowledge were evaluated separately in univariate analyses. Covariates considered in the analyses included age, BMI, education, family size, caste, socio-economic indicators (house type, room number, asset score, land ownership), rating of one's health compared to others of same age, occupation, cooking years, self-reported time spent near stove during cooking events, and presence of smokers, chimney and windows. Variables found to be significant at or below $p = 0.10$, and which were not collinear (variance inflation factor < 2) were included in regression analyses. Separate analyses were conducted for each of four eye irritation symptoms: burning sensation in the eyes, discharge on eyelids in the mornings, red eye, and watering of the eye. Odds ratios were obtained by exponentiating the coefficient estimates on the logit scale.

3. Results

Of the 222 female participants from 187 households that initially consented to participate in the study, 23 participants from 21 households dropped out of the study after baseline, with 199 participants (i.e., 90%) remaining for post-intervention measurements. Participant drop out was related to their unavailability for follow-up ($n = 4$ control households; $n = 3$ intervention households), or no longer wanting the intervention ($n = 14$ intervention households). Participant drop-out rates in the control and intervention groups were 3.6% ($n = 4$ individuals) and 17% ($n = 19$ individuals), respectively.

Household characteristics (asset score, presence of smokers, windows) were similar for intervention and control groups, suggesting successful randomization at the household level (Table 1). Other household characteristics (house type, number of rooms, family size) and assets were also similar for control and intervention groups (Aung et al., 2016). However, households that dropped out from the study were 3.5 times more likely to be from the caste group, Other Backward Class (OBC). Thus, caste was included in BP regression models.

A majority of participants were underweight (52%). Over a third (36%) were of normal BMI, and a smaller percentage (12%) were overweight. Participants in the intervention group had marginally higher BMI (mean (SD): 19.3 (3.4)) compared with the control group (18.5 (3.3)) (Table 1); we therefore adjusted for this difference in BP regression models.

At baseline, mean (SD) of SBP and DBP were slightly higher in the intervention group compared to the control group (SBP: 111.8 (17.2) vs. 107.3 (17.7) mmHg; DBP: 73.7 (10.3) vs. 70.2 (10.2) mmHg) (Table 1). We adjusted for the baseline value of the outcome variable (BP) to take into account regression to the mean (Twisk et al., 2018). Consumption of caffeine or betel prior to taking BP measurements was associated with higher systolic and diastolic BP in univariate analyses.

Table 1
Baseline characteristics of households and female participants.

Household characteristics	Control	Intervention	p-value[a]	Loss to follow up	p-value[b]
Number of households	91	96	–	21	–
Caste (%)			0.89		**0.10**
Scheduled Castes and Tribes	41	39	–	22	–
Other Backward Class (I, II, III)	59	61	–	78	–
Asset Score	6.8 (2.7)	6.8 (2.4)	0.93	6.8 (2.7)	0.93
Smokers present in home (%)	36	36	1.0	35	1.0
$PM_{2.5}$ (μg/m^3) *(79 control, 83 intervention)*	357 ± 379	396 ± 434	0.62	447 ± 581	0.81
Absorbance (× 10^{-6}/m) *(79 control, 84 intervention)*	29 ± 16	31 ± 22	0.95	33 ± 38	0.28
Personal characteristics	**Control**	**Intervention**	**p-value[a]**	**Drop-outs**	**p-value[b]**
Number of women	111	111	–	23	–
Age (years)	43.1 ± 13.0	43.9 ± 11.9	0.42	41.9 ± 10.3	0.72
Education (years)	0.78 ± 2.2	0.56 ± 1.7	0.66	0.09 ± 0.42	0.16
BMI (kg/m^2)	18.5 ± 3.3	19.3 ± 3.4	**0.06**	18.2 ± 3.6	0.21
Waist circumference (cm)	72.3 ± 8.4	72.5 ± 12.9	0.36	69.2 ± 12.7	0.20
Salt intake (g/day/person)	17.3 ± 10.4	18.3 ± 10.2	0.39	18.2 ± 10.2	0.77
Betel nut use (%)			0.18		0.64
Current	67	56	–	67	–
Never	29	41	–	33	–
Overall Health					
Self-reported health compared with others of similar age (%)			0.57		0.49
Excellent/Good	55	58	–	48	
Fair	43	41	–	52	
Poor	3	1	–	0	
Difficulty carrying out work/daily activities due to illness in past 3 months (%)	48	56	0.42	61	0.58
Blood Pressure (baseline)					
Systolic BP (mmHg)	107.3 (17.7)	111.8 (17.2)	**0.01**	108.8 (17.4)	0.86
Diastolic BP (mmHg)	70.2 (10.2)	73.7 (10.3)	**0.003**	72.5 (10.5)	0.82
Eye Health (baseline)					
Burning sensation in eye often (%)	60	53	0.44	70	0.35
Discharge on eyelids in morning (%)	21	20	1	30	0.44
Eyes look red often (%)	44	38	0.46	57	0.22
Watering of the eyes often (%)	61	43	**0.02**	65	0.32

[a] Statistical test of difference between control and intervention group as randomized.
[b] Statistical test of difference between those who remained in the study and loss to follow up. Data are mean ± SD or number (%). Wilcoxon tests for continuous variables; chi-square tests for categorical variables.

Thus, we included these two covariates in the regression models. At baseline, prevalence of symptom for watering of the eyes was higher in the control group (61%) than in the intervention group (46%) (Table 1); we controlled for these differences by including random effects for subject and household in the mixed effect models.

Based on intent-to-treat analyses, there was no change in the intervention group in SBP (−0.1 mmHg; 95% CI: −2.1, 2.1) or DBP (−0.2 mmHg; 95% CI: −1.5, 1.2) compared to its baseline (Table 2). The control group was associated with higher DBP (1.7 mmHg; 95% CI: 0.4, 3.0) compared to its baseline (Table 2).

Per-protocol analysis categorizes the intervention group into an exclusive intervention stove group, and mixed stove group, with some households in the latter using three stoves instead of two stoves typically used in this community. Exclusive use of intervention stoves was associated with lower SBP (−2.0 mmHg; 95% CI: −4.5, 0.5), and DBP (−1.1 mmHg; 95% CI: −2.9, 0.6) compared to baseline, though the pre-post changes were not significant (Table 2). Mixed stove was associated with a small increase in SBP (2.6 (−0.4, 5.7) mmHg) and DBP (1.2 (−0.9, 3.3) mmHg) (Table 2). Though the confidence intervals included zero, in general, the control group and mixed stove groups experienced higher BP, while the exclusive intervention stove group had lower BP compared to their respective baselines (Fig. 1).

Table 2
Adjusted before-and-after mean differences (post vs. pre) in systolic and diastolic BP (mmHg) in stove groups.

	Control (ITT)	Intervention (ITT)	Exclusive intervention stove (per-protocol)	Mixed stove (per-protocol)
	Estimate[a] (95% CI)			
	N = 92	N = 77	N = 46	N = 31
SBP	0.4 (−1.5, 2.4)	−0.1 (−2.1, 1.9)	−2.0 (−4.5, 0.5)	2.6 (−0.4, 5.7)
DBP	1.7 (0.4, 3.0)	−0.2 (−1.5, 1.2)	−1.1 (−2.9, 0.6)	1.2 (−0.9, 3.3)

[a] Represents adjusted mean differences between baseline and post-intervention change; ITT = Intent-to-treat; CI = confidence interval; N = sample size; adjusted for BMI, age, temperature, betel user, socio-economic status, and self-rating of own health.

Sub-analysis on effect modification did not result in interactions between stove use groups, and age or BMI, though age as a continuous variable was found to have a significant interaction with mixed stove group (N = 31) (Table S2). Approximately 10% of the participants reported being told by a health professional of having hypertension (7%) or diabetes (3%). Of this 10%, only 5% reported being treated for either of these diagnoses. Removing participants who reported treatment for hypertension or diabetes did not affect the analyses (Table S1).

All stove groups reported reduced odds of reporting two eye irritation symptoms (burning sensation in eyes, and watering of eyes) (Table 3). The odds of having burning sensation in eyes in the past three months in the post-intervention were 94% (95% CI: 62–99%) lower in the mixed stove users, 78% (39–92%) in the exclusive intervention stove user and 52% (4–76%) in the control group. For red eye symptom, the odds were significantly lower in the post-intervention in the exclusive (84% (53–94%)) and mixed stove users (80% (9–96%) (Table 3). Prevalence of eye irritation symptoms in baseline and post-intervention by stove use groups is provided in Table S4.

The baseline median (interquartile range) of air pollutant concentrations for $PM_{2.5}$ and Abs were 258 (117–458) μg/m^3 and 33 (16–40) 10^{-6}/m for the control group and 221 (124–491) μg/m^3 and

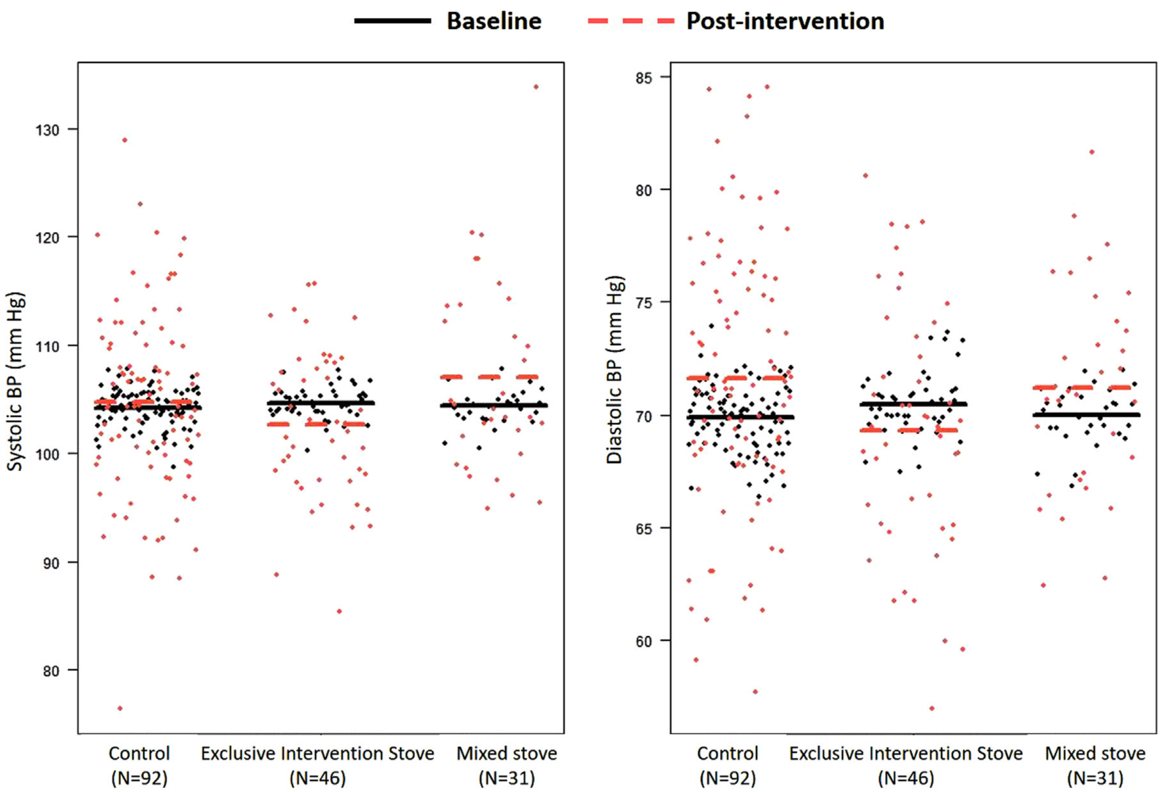

Fig. 1. Adjusted baseline and post-intervention systolic and diastolic BP (mmHg) by stove groups.

Table 3
Adjusted eye irritation symptoms within groups (post vs. pre-intervention phases).

Symptoms	Control	Exclusive intervention stove	Mixed stove
	Odds ratio (95% CI)		
Burning sensation in eyes often	0.48 (0.24, 0.96)	0.22 (0.08, 0.61)	0.06 (0.01,0.38)
Discharge on eyelids in morning	0.87 (0.38, 1.96)	1.05 (0.37, 3.00)	1.84 (0.37, 9.20)
Eyes look red often	0.55 (0.29, 1.04)	0.16 (0.06, 0.47)	0.20 (0.04, 0.91)
Watering of the eyes often	0.35 (0.18, 0.65)	0.38 (0.16, 0.93)	0.23 (0.07, 0.79)

Burning sensation adjusted for chimney, and room numbers in household; discharge on eyelids adjusted for chimney, and age; red eyes adjusted for caste and BMI; and watering of eyes adjusted for chimney, caste, age, and BMI.

30 (17–40) 10^{-6}/m for the intervention group. The $PM_{2.5}$ concentrations increased in the post-intervention phase for all stove use groups though the increase was significant only in the control group (Table S4). The control group was associated with the highest median (95% CI) increase in $PM_{2.5}$ concentrations of 126 (47, 212) μg/m^3. For the exclusive intervention stove and mixed stove group, the median (95% CI) pre-post-intervention change in $PM_{2.5}$ was 51 (−58, 161) μg/m^3, and 90 (−18, 281) μg/m^3, respectively (Table S5). The post-intervention increases in Abs and Abs/$PM_{2.5}$ ratios were significant in all stove groups.

4. Discussion

We evaluated potential health co-benefits associated with a climate-financed randomized stove intervention, including measurement of household air pollutant concentrations over a period of one year. Intent-to-treat analysis suggest no significant change in BP between baseline and post-intervention phase in the intervention group. This may be partly a result of a large number of households in the intervention group who were stacking stove technologies (i.e. households using both traditional and intervention stoves). Though the results were not significant, per-protocol analysis suggests a trend towards reduced BP among exclusive intervention stove users, and increased BP in the mixed stove users in the post-intervention phase when compared to their baselines.

The reduced BP trend in the exclusive intervention stove group is encouraging though the limited sample size (N = 46) in the group precludes definitive conclusions. The exclusive intervention stove group had higher $PM_{2.5}$ and Abs concentrations in the post-intervention phase, however, the increases were lower than in the control or the mixed stove groups with some households experiencing reduced $PM_{2.5}$ concentrations. Previous analyses (Aung et al., 2016) also indicated that households exclusively using intervention stove had 26% lower (95% CI: −53%, 18%) indoor $PM_{2.5}$ concentrations compared to control in the post-intervention phase. Air pollutants measured in this study were kitchen concentrations, which represent surrogate exposures for women cooks. The measured concentrations may not represent actual individual exposures especially for women not involved in cooking or are otherwise typically away from the kitchen during cooking activities.

Our findings are generally in line with previous studies that reported lower BP where interventions reduced air pollutant exposures. A randomized trial of chimney stoves in Guatemala reduced mean personal $PM_{2.5}$ exposure from 273 to 174 μg/m^3, which was associated with decreases in SBP (−3.7 mmHg (95% CI: −8.1, 0.6)) and DBP (−1.9 mmHg (95% CI: -3.5, -0.4) (McCracken et al., 2007). Another chimney intervention in Bolivia reduced mean ± SD kitchen carbon monoxide (CO) concentrations by 80% from 240 ± 210 to 48 ± 41 μg/m^3, which was associated with steep reductions in SBP from 114.5 ± 13.0 mmHg to 109.0 ± 10.4 mmHg. That study had a small sample size (N = 28), did not adjust for covariates, and lacked a control group (Alexander et al., 2015). An intervention study in Nicaragua, however, found that despite significant reduction in mean ± SD in kitchen $PM_{2.5}$ concentrations from 1801 ± 1587 μg/m^3 to 416 ± 523 μg/m^3, BP was not reduced in the study population (Clark et al., 2013a). The authors attributed the lack of change to a non-linear relationship between HAP and certain health risks, including BP, that is steep at low exposures and flattens out at higher levels (Baumgartner et al., 2011; Burnett et al., 2014; Pope et al., 2009), meaning that interventions must achieve lower exposure levels for health benefits. A recent intervention study in Nigeria randomized 324 pregnant women who used kerosene or firewood into an intervention group (ethanol stove) or control group (Alexander et al., 2017). The study found a significant decrease in DBP, but not in SBP, in the intervention group compared to control. The DBP decrease was driven by kerosene users who switched to ethanol whereas fuelwood users who switched to ethanol did not experience significant changes in BP (Alexander et al., 2017).

It is important to note that previous studies on the effect of cookstove interventions on BP have been primarily from Latin America (Alexander et al., 2014; Clark et al., 2013a; McCracken et al., 2007), and Africa (Alexander et al., 2017), where population characteristics and the prevalence of cardiovascular risk factors may be different than in our study location (Ahmed and El-Menyar, 2014; Joshi et al., 2007; Reddy, 2002). Those differences may affect how a cookstove intervention influences BP outcomes. For example, half of our study population was underweight; mean ± SD of BMI was 19.0 ± 3.3 kg/m^2, which was considerably lower than study populations in Nicaragua (27.8 ± 7.1 kg/m^2) (Clark et al., 2013a), Bolivia (23.0 ± 4.0 kg/m^2), Guatemala (24.6 kg/m^2) (McCracken et al., 2007), and Nigeria (24.0 kg/m^2) (Alexander et al., 2017). In Nicaragua, over a third (38%) of the population was overweight compared with only 12% in our study. Having a large susceptible population who are underweight may contribute to unpredictable changes in BP. Clark et al. concluded in the Nicaragua study that susceptible population, such as overweight and older women > 40 years of age are more likely to experience reductions in BP compared to the general population (Clark et al., 2013a). Further studies are needed to investigate how cookstove intervention influences BP in populations at the other end of the susceptibility spectrum, such as underweight females. Other differences, beyond BMI, may also play a role (e.g., diet, exercise, presence of smokers in household, genetics, or other health conditions not evaluated in our study).

The mixed stove group experienced a slight increase in BP compared to its baseline. The mixed stove group behaved differently (i.e. stacking) from the other group that adopted the intervention as-per-protocol. There was also a wide variability in $PM_{2.5}$ change in the mixed stove homes. Stacking stove technologies is common in many intervention programs but evaluation of health outcomes resulting from this behavior is limited. Though the sample size in per-protocol analyses were smaller than the initially intended randomized groups, and precludes definitive conclusion, the findings can inform future studies to assess health outcomes from stacking behavior.

In addition, there may be non-air pollution related mechanisms responsible for the increased SBP in mixed stove homes. Dietary changes may have occurred because of the increased number of stoves in the households, especially in the mixed stove homes, which were known to use more than two stoves (both traditional and intervention stoves). Though the study did not directly measure food consumption, an earlier study (Aung et al., 2016) reported higher fuelwood consumption in the mixed stove group compared to control group, which potentially suggests a "rebound effect" (Nepal et al., 2011; Sorrell et al., 2009). It is possible that having more efficient stoves or more stoves may have motivated households to cook more frequently or different types and larger quantities of food thus changing their diet, which may ultimately affect BP levels. A cross-sectional study in India found higher food and diet diversity in homes using biogas stoves compared with similarly matched homes using traditional stoves (Anderman et al., 2015). The authors noted this may be partly attributable to households which avoid or reduce frequency of preparing dishes with long cooking times to conserve fuelwood. In other words, the Anderman et al. (2015) study suggests that households may alter cooking behavior and diet in response to changes in stoves' fuel efficiency. Similarly, a few studies have suggested how fuelwood scarcity can reduce diet diversity (Brouwer et al., 1996, 1989). Longitudinal studies are needed to evaluate how cookstove interventions may impact diet, and subsequently, health.

The BP changes across groups were not likely to be attributable to key participant characteristics known to affect BP since we controlled for known predictors of BP (e.g., age, BMI, temperature). We note seasonality effects based on comparison of indoor $PM_{2.5}$ concentrations and emission factors in our study area. Emission factor (EF) measurement in a subset of homes in this study found reduced $PM_{2.5}$ EF in control homes in the post-intervention phase compared to baseline, possibly due to decreased fuel moisture in the post-intervention phase (Grieshop et al., 2017). However, in the larger sample of control homes, indoor $PM_{2.5}$ concentrations were higher compared to the baseline phase, suggesting seasonality effects. Variable air exchange rates across phases (baseline to post-intervention) may have played a role in increasing indoor concentrations despite lower EF. Although we cannot rule out an impact of seasonal changes in the intervention – blood pressure relationship, because this study included a control population, the role of seasonality was likely accounted for since seasonal or time-varying factors would be expected to influence the measured health outcomes on both the intervention and control groups in a similar manner.

While the study was conducted over a one-year period, a reasonable time to evaluate health outcomes like BP, the sustained long-term benefits of the intervention are still unknown. Short and long-term exposures to particle pollution can affect BP via several mechanisms. Short-term exposures have been shown to immediately increase BP by triggering autonomic nervous system imbalance (Brook and Rajagopalan, 2009). Long-term exposures are associated with chronic hypertension via initiation of systemic oxidative and pro-inflammatory responses that consequently cause vascular endothelial dysfunction (Brook and Rajagopalan, 2009). Long-term particle pollution exposure can also have a direct impact on cardiovascular tissues and epigenetic pathways (Giorgini et al., 2015). The various mechanisms and long-term impacts suggest that further studies may be needed to evaluate health benefits from HAP interventions over a longer-term period in chronically exposed populations.

Further, emissions from biomass combustion consist of a mixture of constituents, including organic compounds, polycyclic aromatic hydrocarbons, and volatile organic compounds (Morawska and Zhang, 2002). An intervention may alter the composition of these constituents and affect health outcomes differently. Currently, evidence on BP impacts from other air pollution constituents, such as metals, organic compounds, gases, and mixed air pollution exposures, is limited (Baumgartner et al., 2014; Giorgini et al., 2015).

Several eye irritation symptoms were lower in the post-intervention phase in all stove groups, though the odds of having burning sensations and red eyes were much lower among the intervention stove users compared to the control group. Emissions from biomass combustion can consist of thousands of chemical constituents (Naeher et al., 2007). Despite significant lack of reductions in particle concentrations, it is possible that the intervention stove reduced air pollution components that were not measured by the study, and which may be responsible for irritation, such as aldehydes (Claeson and Lind, 2016; Dwivedi et al., 2015).

Studies on eye health from cookstove interventions are limited and are often obtained from self-reported symptoms. Bias in self-reporting of health symptom has been reported in other intervention studies. A study in Ghana found significant reductions in self-reported eye and respiratory symptoms despite lack of detectable reductions in CO exposure, which the authors attributed to "courtesy bias" (i.e., study participants' working relationship with the NGO implementing the intervention) (Burwen and Levine, 2012). In our study, efforts were made to inform participants that the study was independent of the NGO implementing the intervention but collaboration necessary at the field level, i.e. introduction of the study to village committees by the NGO, may have fostered perceptions of association for the participants. Mixed stove users may have felt a need to report benefits as they were not complying with the NGO requirement to exclusively use the intervention stoves. This result suggests that self-reported questionnaires may be unreliable. A randomized controlled trial in Guatemala attributed a decline in self-reported symptoms in the control group to respondent fatigue with survey questions (Díaz et al., 2007).

Our questionnaire on eye health has not been validated previously. We are unable to discern how sensitive these questionnaires are in capturing differences in eye health outcomes attributable to changes in exposures or the clinical implications of the results found in our study. Future intervention studies should consider objective eye heath measures as eye irritations represent one of the key concerns for cooks (Person et al., 2012; Pine et al., 2011), and would assist in quantification of eye health benefits from interventions.

Use of the intervention stoves was not associated with significant reductions in air pollutant concentrations; all groups experienced higher $PM_{2.5}$ and Abs concentrations in the post-intervention phase. However, median $PM_{2.5}$ increases were lower in households using the intervention stoves than in control households. Households using intervention stoves exclusively or mixed with traditional stoves had slightly higher Abs/$PM_{2.5}$ ratios (Aung et al., 2016) (Table S4) suggesting proportionally higher black carbon content in the particle emissions from intervention stoves. This has been corroborated by laboratory-based measurements of the intervention stove (Just et al., 2013)

Though we did not see significant reductions in air pollutants from the intervention, it was important to evaluate health outcomes. There could have been a change in blood pressure related to the intervention that was not mediated by pollution (for example, the intervention may have led to changes in diet). On the other hand, if intervention was ineffective with regards to pollution reduction but led to increased pollution there could have been an increase in blood pressure (via a pollution-related mechanism). Finally, many cookstove intervention programs tout co-benefits for health and climate, and we provide empirical evidence that the health benefits were limited from the climate motivated intervention program.

The natural draft rocket stove evaluated in this study was the preferred technology choice for the implementing organization because it could be locally manufactured and modified based on user preferences. The CDM approval of the technology also meant that the intervention could be scaled up to a wider community through sale of carbon credits. However, the stove's lower field performance compared to laboratory-based results, and behavioral factors (stove stacking) limited the expected health benefits. While more advanced biomass cookstoves can significantly reduce HAP concentrations in the field (Kar et al., 2012; Muralidharan et al., 2015; Pennise et al., 2009), no solid-fuel stove intervention programs to date have reduced exposures to below the WHO guidelines (Clark et al., 2013b). Health benefits from cookstove intervention programs remain inconclusive due to limited HAP reductions provided by the intervention technology as well as behavioral practices, including low adoption and stacking (Clark et al., 2017; Mortimer et al., 2017; Quansah et al., 2017). Modern fuel stoves, such as LPG and electric can significantly reduce indoor concentrations and exposures (Still et al., 2015) though their health benefits would depend on the extent to which traditional inefficient stoves are actually dis-adopted by users (Johnson and Chiang, 2015).

5. Conclusions

To our knowledge, this was the first study to independently evaluate the health impacts from an ongoing climate financed stove intervention program using robust randomized controlled study designs and methods. We did not find significant reductions in BP in homes exclusively using the intervention stoves. This, together with the increased BP associated with the mixed stove users suggests stove adoption and use behavior, in addition to stove technology, can potentially complicate achievement of health co-benefits from cookstove interventions. Significant reductions in self-reported eye irritation symptoms in homes using intervention stoves suggest potential benefits from changes in HAP constituents, or a reporting bias. Climate-financed cookstove interventions need to align with international guidelines and standards that have been set based on health outcomes to maximize health co-benefits. Additional studies are needed to investigate relationships between BP and cookstove interventions given that HAP is a potentially modifiable risk factor for high BP, which in turn is a modifiable risk factor for cardiovascular diseases. Eye irritation symptoms are some of the most commonly reported concerns by solid fuel users but one of the least investigated outcomes. Future studies should consider objective eye health measures to assess impacts from cookstove intervention.

Acknowledgments

The authors would like to thank the people of Hire Waddarkal Village, especially the women who participated in the study, the Karnataka field team who carried out field measurements, and partner NGO and its staff for their field support. We also wish to thank Dr. Megha Shenoy, and project advisors at the University of Minnesota: Profs. Ramachandran, Alexander, Millet, and Cox.

Funding sources

The study was funded by the Initiative for Renewable Energy and the Environment in the Institute on the Environment at University of Minnesota (DG-0007-11). TWA was supported by the UBC Bridge (Canadian Institutes of Health Research (CIHR) Strategic Training Initiative in Health Research) Program and the CIHR Training Grant in Population Intervention for Chronic Disease Prevention: A Pan-Canadian Program (Grant #: 53893).

Conflict of interest

The authors declare they have no actual or potential competing financial interests.

Ethics

The study protocol was approved by institutional review boards at the University of Minnesota (IRB code #1104S97992), St. John's Medical College (IERB Study Ref No. 103/2011) in India, and The University of British Columbia (CREB #H14-03012).

Appendix A. Supplementary material

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.envres.2018.06.044.

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