

Impact of the Wood-Burning *Justa* Cookstove on Glycated Hemoglobin (HbA1c): A Stepped-Wedge Randomized Trial in Rural Honduras

Bonnie N. Young,¹ Jennifer L. Peel,¹ Sarah Rajkumar,¹ Kayleigh P. Keller,² Megan L. Benka-Coker,³ Nicholas Good,¹ Ethan S. Walker,⁴ Robert D. Brook,⁵ Tracy L. Nelson,⁶ John Volckens,^{1,7} Christian L'Orange,⁷ Casey Quinn,¹ Sebastian Africano,⁸ Anibal B. Osorto Pinel,^{8,9} and Maggie L. Clark¹

¹Department of Environmental and Radiological Health Sciences, Colorado State University, Fort Collins, Colorado, USA

²Department of Statistics, Colorado State University, Fort Collins, Colorado, USA

³Department of Health Sciences, Gettysburg College, Gettysburg, Pennsylvania, USA

⁴Center for Population Health Research, School of Public and Community Health Sciences, University of Montana, Missoula, Montana, USA

⁵Division of Cardiology, School of Medicine, Wayne State University, Detroit, Michigan, USA

⁶Department of Health and Exercise Science, Colorado State University, Fort Collins, Colorado, USA

⁷Department of Mechanical Engineering, Colorado State University, Fort Collins, Colorado, USA

⁸Trees, Water & People, Fort Collins, Colorado, USA

⁹Asociación Hondureña para el Desarrollo, Tegucigalpa, Honduras

BACKGROUND: Type 2 diabetes is a rapidly growing global health challenge in low- and middle-income countries (LMICs), and evidence suggests that air pollution exposure contributes. Household air pollution from burning solid fuels for cooking is a major burden in LMICs, but studies demonstrating associations between reductions in household air pollution and improvements in HbA1c, a biomarker of diabetes risk, are lacking. We previously reported substantial reductions in fine particulate matter with an aerodynamic diameter $\leq 2.5 \mu\text{m}$ ($\text{PM}_{2.5}$) and black carbon concentrations following an intervention in rural Honduras with the *Justa* cookstove, a wood-burning stove with an engineered combustion chamber and chimney.

OBJECTIVE: In a stepped-wedge randomized controlled trial among 230 Honduran women using traditional wood-burning stoves at baseline, we evaluated the effect of the *Justa* intervention on HbA1c and characterized the longitudinal associations between air pollution exposures and HbA1c.

METHODS: At each of six visits over 3 y, we measured 24-h $\text{PM}_{2.5}$ and black carbon concentrations, and finger-stick HbA1c levels. We used linear mixed models in intent-to-treat (condition by assigned stove type), exposure–response (using 24-h measures and modeled estimates of long-term exposures), and “per protocol” self-reported stove use analyses.

RESULTS: HbA1c was reduced for the *Justa* condition in comparison with the traditional stove condition, but estimates were small and not statistically significant [−0.03 percentage points, 95% confidence interval (CI): −0.13, 0.07, $n = 1,208$ observations]. A slightly stronger effect was observed when using self-reported stove use in per protocol analyses. Exposure–response analyses demonstrated positive associations between HbA1c and air pollution [e.g., HbA1c was 0.22 percentage points higher (95% CI: 0.13, 0.30) per log-unit higher long-term average personal $\text{PM}_{2.5}$].

DISCUSSION: Our study provides novel evidence of exposure–response associations between household air pollution and HbA1c within a randomized cookstove trial, contributing to the evidence base necessary to support clean cooking policy initiatives. <https://doi.org/10.1289/EHP15095>

Background

Household air pollution is a major risk to human health and the second leading environmental risk factor for premature deaths

worldwide, following ambient air pollution.^{1,2} The primary sources of household air pollution in low- and middle-income countries (LMICs) come from residential burning of solid fuels (e.g., biomass, animal dung, crop residue, charcoal) and kerosene for cooking, heating, and lighting homes.³ Forty-eight percent of the world relied on solid fuels for cooking in 2019,⁴ and the resulting exposure was responsible for an estimated 2.3 million premature deaths and 91.5 million disability-adjusted life years (i.e., lost years of “healthy” life).²

Household air pollution exposure can lead to harmful health impacts in all stages of life and on nearly every system in the body.^{3,5,6} Adverse cardiometabolic effects, notably risk of type 2 diabetes and prediabetes, are increasingly linked with air pollution exposure.^{7–13} In 2019, it was estimated that one-fifth of the global burden for type 2 diabetes was attributable to exposure to $\text{PM}_{2.5}$ (particulate matter with diameter $\leq 2.5 \mu\text{m}$) from both ambient and household sources.¹⁴ Diabetes is rising rapidly worldwide and is labeled as one of the fastest-growing health challenges of the 21st century.¹⁵ From 2010 to 2021, the age-adjusted years lived with disability due to diabetes rose by 25.9%, with increases in every country.¹⁶ The same biological responses to air pollution exposure that trigger cardiovascular events can also promote insulin resistance through an air pollutant-associated diabetic cascade.^{7,12,17,18} Studies of possible biological pathways suggest that exposures to $\text{PM}_{2.5}$ and other pollutants lead to systemic oxidative stress, chronic inflammation, autonomic nervous system imbalance, impaired endothelial function, and decreased skeletal muscle microvascular flow, thus deteriorating glucose metabolism and insulin action and dysregulating glucose homeostasis.^{7,18,19} Glycated hemoglobin (HbA1c, also called glycosylated hemoglobin), which represents the average percentage of blood glucose attached to hemoglobin

Address correspondence to Maggie L. Clark, 1681 Campus Delivery, Colorado State University, Fort Collins, CO 80523-1681 USA. Telephone: (970) 491-2891. Email: Maggie.Clark@colostate.edu

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Two of the authors, S.A. of Trees, Water & People, and A.B.O.P. of Asociación Hondureña para el Desarrollo (AHDESA), are members of the implementing nongovernmental organizations that deploy the cookstove technology presented in this manuscript. Publications like this are often used to support their cookstove technology in Trees, Water & People and AHDESA blogs, articles, and grant proposals, which may lead to future funding of these initiatives by individual and/or institutional supporters of the respective organizations. As such, we disclose this information. All other authors declare they have no conflicts of interest related to this work to disclose.

Conclusions and opinions are those of the individual authors and do not necessarily reflect the policies or views of EHP Publishing or the National Institute of Environmental Health Sciences.

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over the past 2 to 3 months, is used to diagnose diabetes (HbA1c $\geq 6.5\%$).^{20,21} Previous research supports associations between HbA1c levels and intermediate- and long-term ambient air pollution exposure among children and adults.^{9,22–24} Although most evidence linking air pollution and diabetes comes from studies of ambient exposure and high-income countries, the evidence from household air pollution investigations is limited and based on cross-sectional studies with mixed results. Overall, evidence from controlled intervention studies demonstrating reductions in household air pollution is needed.

Reducing household air pollution is possible with the use of engineered solid-fuel stoves that are less polluting or with the use of cleaner energy sources, such as liquified petroleum gas, biogas, alcohol fuels, or electricity. Although the aspirational goal is for all households to use 100% renewable, clean energy for cooking, the existing literature describing exposure reductions and health-related benefits following cooking-related interventions is inconsistent.^{25,26} The Household Air Pollution Intervention Network (HAPIN) Trial demonstrated that households participating in an ~ 18 -month free gas stove and fuel trial with intensive ongoing encouragement and monitoring of behavior changes can achieve reduced personal exposures to PM_{2.5} at levels previously not observed at such a scale (i.e., median, 24 $\mu\text{g}/\text{m}^3$; conducted among 3,195 households in four rural locations in Guatemala, Peru, Rwanda, and India).²⁷ However, most interventions or large-scale observational studies of households using different stove types have produced mixed results. We conducted a community-engaged, stepped-wedge trial of a wood-burning *Justa* cookstove with an engineered combustion chamber and chimney among 230 women over 3 y in rural Honduras; fuel was not provided as part of the intervention.²⁸ Our previously published exposure paper reported median 24-h average personal PM_{2.5} exposures were 81 $\mu\text{g}/\text{m}^3$ (25th–75th percentile: 50–141 $\mu\text{g}/\text{m}^3$; geometric mean, 87 $\mu\text{g}/\text{m}^3$) for the traditional stove condition ($n = 622$ observations) and 43 $\mu\text{g}/\text{m}^3$ (25th–75th percentile: 27–73 $\mu\text{g}/\text{m}^3$; geometric mean, 45 $\mu\text{g}/\text{m}^3$) for the *Justa* stove condition ($n = 585$ observations).²⁹ These postintervention exposures were lower than those reported in previous studies of biomass stoves with chimneys (but without engineered combustion chambers) in Latin America and substantially lower than the calculated pooled estimate from four biomass stove interventions presented in a systematic review (mean, 100 $\mu\text{g}/\text{m}^3$).^{30,31} Further, the personal exposures we measured in Honduras among those in the *Justa* stove condition were similar to those observed in the Prospective Urban and Rural Epidemiological (PURE-Air) study (conducted in 120 rural communities in eight countries) among female participants using gas as a primary fuel (geometric mean, 48 $\mu\text{g}/\text{m}^3$).^{25,32} These types of inconsistencies in

exposures measured across various cooking fuel types are often attributed to differences in adoption of the new stove and discontinuance of use of traditional stoves, sustained use and functioning of the new stove, effective financing and market development, and other behavioral complications related to transitioning to a new technology.^{33–36} As scientists and global leaders rightfully advocate for approaches to overcome these challenges and make clean energy available and affordable for all, reducing household air pollution via changes in cooking behaviors that are currently sustainable (such as those observed by introducing the *Justa* stove) can be a promising solution for the short term and the midterm.

Given the plausible biological mechanisms linking household air pollution exposure to increased risk for diabetes^{7,19} and to address the gap in knowledge on the impacts of household air pollution exposure on diabetes risk, we evaluated HbA1c outcomes following the wood-burning *Justa* cookstove intervention among women in rural Honduras. We hypothesized that an engineered combustion stove intervention would lead to reduced HbA1c.^{28,29} Within a community-engaged framework that involved stove selection and ongoing community input and problem-solving centered on the conduct of the trial, we pursued three study aims: *a*) in an intent-to-treat analysis, we evaluated the impact of the *Justa* cookstove intervention on HbA1c; *b*) in an exposure–response analysis, we characterized the independent associations between household air pollution and HbA1c; and *c*) using “per protocol” self-reported cookstove use as the exposure in an exposure–response analysis, we evaluated the impact of stove use, including stove stacking, on HbA1c.

Exploring the impact of the *Justa* stove intervention on HbA1c can offer insights into cardiometabolic health risks from household air pollution exposure. Given the increasing prevalence of diabetes and its public health burden in LMICs, finding effective cookstove interventions that mitigate household air pollution as an environmental determinant is of high importance.

Materials and Methods

Study Population

As described in our protocol paper,²⁸ this research took place in rural Honduras in the Department of Intibucá, where nearly 90% of households relied on solid fuels with 3-stone fires and various forms of traditional stoves for cooking.³⁷ Figure 1 displays examples of typical outdoor and indoor traditional stoves used by this study population. The study area was a mountainous region with a predominately agricultural-based economy, and participants’ household elevations ranged from 1,700 to 2,200 m, based on



Figure 1. Examples of traditional solid fuel cookstoves in an outdoor setting (A) and indoors (B). Photo credits: Bonnie Young.

elevation data collected at each household using a standard GPS instrument.

Intervention Cookstove and Participant Recruitment

Wood-fuel stoves were the primary traditional cookstove type in this region. Traditional stoves typically had griddles and home-made chimneys, but did not have an engineered combustion chamber. Kitchens were mostly located inside the house or as a separate building near the house, and most secondary stoves (often typical of 3-stone fires) were located outside.

The *Justa* intervention cookstove was selected based on formative research and a feasibility study among the study population^{38,39} in addition to guidance from community partners, Trees, Water & People and the Honduran Association for Development (Asociación Hondureña para el Desarrollo, AHDESA). The *Justa* cookstove was designed by Trees, Water & People specifically for Honduran homes as a culturally appropriate, well-accepted, locally sourced, and well-functioning stove when maintained properly.⁴⁰ Previous work in this region with the *Justa* cookstove has shown anecdotally through in-person discussions and observations that it fulfills cultural needs with its sturdy griddle resting above the fire, so pots and pans are not blackened, and it has a large area for making tortillas and simultaneously cooking other meals. The *Justa* is a wood-burning cookstove with a rocket type (L-shaped) insulated, ceramic combustion chamber, a chimney, a metal griddle, and a side soot-removal compartment.^{40,41} Figure 2 displays external and internal views of the *Justa* cookstove.

We held community events at local elementary schools, where each school received two free *Justa* stoves, demonstrating for community members and participants the *Justa* cookstove construction, design, and operation process, allowing community members to ask questions and discuss its use and perceived benefits. The community-wide stove demonstrations were separate from the participant-level training, in which each participant received detailed in-person training at their home at the time of construction by AHDESA technicians and the study coordinators to review proper use and maintenance steps.²⁸ Participants received a laminated, waterproof, photo example poster that included use and maintenance information and the phone

number of our study coordinator for any problems or questions (Figure 2).

Communities were selected with guidance from the Community Advisory Board, including two local leaders per community, based on traditional cookstove use among households, accessibility from the field house in La Esperanza (within a 1-h drive), and permission from local leaders to conduct the study within their community. Community meetings were held to introduce the research team and objectives and to obtain a list of people interested in enrolling in the study. Women not in attendance at the meeting could still be enrolled if a friend or family member added their name to the list, or if they later decided they would like to be screened for eligibility. Local leaders and study coordinators visited interested households for eligibility screening and official enrollment, if a woman was interested.

Study participants ($n = 230$) were recruited from 10 rural communities within a 1-h drive from La Esperanza, Department of Intibucá. Inclusion criteria for enrollment included the following characteristics: female, 24–59 y of age, primary cook of the household, and used a wood-burning traditional stove (i.e., no evidence of an engineered combustion chamber). Exclusion criteria included self-reported pregnancy at the time of recruitment, currently smoking, or experiencing regular exposure to secondhand smoke. After enrollment into the study, participants were not visited if they became pregnant or were unavailable after two contact attempts, and then they were revisited each subsequent study visit. This research was collaborative between Colorado State University (CSU); Trees, Water & People in Fort Collins, Colorado; and AHDESA in Tegucigalpa, Honduras. All study procedures were approved by the CSU institutional review board (No. 12-3870H), permission to conduct research was granted by local community leaders for each village, and informed consent was obtained from all participants included in the study. The Community Advisory Board met approximately once a month while data collection was underway and helped guide survey development and communication with participants, including recruitment and retention strategies and compensation items.

This study was registered under the National Institutes of Health (NIH) clinical trials website (ClinicalTrials.gov Identifier



Figure 2. Examples of *Justa* cookstoves showing an external view preparing coffee (A) and an internal view with the griddle removed (B). Photo credits: Bonnie Young.

NCT02658383, Principal Investigator M.L.C.). All study procedures were approved by the CSU institutional review board (No. 12-3870H), permission to conduct research was granted by local community leaders for each village, and informed consent was obtained from all participants included in the study. All research was conducted in accordance with the principles of the Declaration of Helsinki.

Trial Design and Study Visits

This intervention study used an individual-level, stepped-wedge design, a type of a randomized controlled trial that involves a sequential rollout of the intervention.⁴² Participants were randomly assigned to study arm 1 (*n* = 115) or arm 2 (*n* = 115) by blindly drawing a number from a bag at a community meeting. Table 1 outlines our study design, showing stove types and timing of the intervention for both study arms, and a flow diagram of the sample at each visit is presented in Supplemental Figure 1. Data were collected at six repeated visits from August 2015 through May 2018, with ~6 months between each visit. All participants cooked on traditional stoves for the first two visits, and then those in study arm 1 received the *Justa* cookstove intervention after visit 2, and those in study arm 2 received the intervention after visit 4 (Table 1). This study design offered all participants the intervention in a stepped timeline to allow each study arm its own pre- and postintervention observations at different time points.⁴³ This type of randomized controlled trial is considered beneficial in human-based studies, particularly in developing countries, when the intervention is desired and expected to do more good than harm.⁴² Blinding of participants and researchers was not possible because the intervention was a new cookstove.

Study visits occurred Monday through Saturday. On setup days, we greeted the participant, installed personal and kitchen exposure monitors, and conducted questionnaires on household stoves, sociodemographics, diet, and other health-related questions. After 24 h, we returned to the household; removed exposure monitors; completed the questionnaires; conducted all health measurements, including the HbA1c collections; and explained health results from the point-of-care tests, such as HbA1c. We then gave the participant her incentive per study visit, a bag of food items worth \$5 USD. All study visits for both setups and takedowns were completed by 1200 hours (12 P.M.) each day.

Assigned Stove Condition and Exposure Assessment

Participants’ random assignment to study arms 1 or 2 determined the timing of stove interventions (*Justa* vs. traditional cookstove), which was the condition of interest (i.e., assigned stove type). Household air pollution, measured by 24-h gravimetric personal and kitchen PM_{2.5} and black carbon (BC) concentrations, were the main exposures of interest.^{29,44} Per protocol self-reported stove use was an additional type of assessment in which participants reported using the *Justa* cookstove only or by stacking it with another type of improved cookstove, the *Justa* cookstove with stacking of a traditional stove, or a traditional stove only.

Exposure monitors for personal measures were attached to a small bag or a cloth necklace, with the air intake located near the participant’s breathing zone. The participant was instructed to wear the monitors for a full 24 h, only removing them to bathe, and place them nearby when sleeping. Kitchen exposure monitors were placed within 76–127 cm above the front edge of the primary cookstove, near the participant’s breathing zone and away from direct smoke plumes and windows or doorways. Researchers collected 24-h PM_{2.5} samples for personal and kitchen concentrations on 37-mm filters [Fiberfilm (Pall Corporation) and Teflo filters (VWR)]. PM_{2.5} was sampled by drawing air through a size-selective cyclone inlet (Triplex; BGI, Inc.), with the Airchek pump (XR5000; SKC Inc.) calibrated to a flow rate of 1.5 L per minute (DryCal Lite; Mesa Labs) before collection of each sample. At study visit 5, we switched personal exposure monitors for all participants in both study arms to the Ultrasonic Personal Aerosol Sampler (UPAS; Access Sensor Technologies), which drew in air at 1.0 L per minute with a customized cyclone to capture PM_{2.5} sample on the enclosed filter. The UPAS monitors were more compact, lighter, and quieter than the original setup with the Airchek pump and therefore decreased participant burden, prompting this switch of personal monitors.^{28,45} The kitchen exposure monitors stayed the same as the original setup with the Triplex cyclone/Airchek pump. To ensure consistency between filter types (Fiberfilm and Teflo) and exposure monitors (Triplex cyclone/Airchek pump and UPAS), we conducted field tests of paired measures and observed strong Spearman correlations of 0.96 (*n* = 11 paired samples)²⁹ and 0.91 (*n* = 43 paired samples),⁴⁶ respectively. All exposure filters were stored at –20° Celsius at the field house in Honduras and then transported to CSU and stored at –80° Celsius prior to postsampling analysis. Details on field blanks, equilibration, weighing of filters to determine PM_{2.5} mass, and limits of detection are published elsewhere.^{28,29}

Full details on BC measurements and calculations have been previously published.⁴⁴ BC mass concentrations for personal and kitchen assessments were calculated from the change in 880 nm light transmission through each filter before and after sampling with the Sootscan Transmissometer (OT21; Magee Scientific).⁴⁴ Calculations used an effective filter area of 0.00071 m² (Teflo) and 0.00078 m² (Fiberfilm), the total sampled volume collected over 24 h at 1.0 or 1.5 L/min, and a mass attenuation cross-section of 12.5 m²/g.

Health End Point

HbA1c was a primary health end point of this cookstove trial, as described in our published protocol paper.²⁸ At each study visit, HbA1c was collected from a finger-stick blood drop on the middle or ring finger of the participant’s nondominant hand, after cleaning the puncture site with 70% isopropanol and wiping the first blood drop away with sterile gauze. Then, ~5 µL of blood were collected into the HbA1c sampler (A1CNow + Kit; PTS Diagnostics and Bayer Diabetes Care). The A1CNow + Kit was cleared by the US Food and Drug Administration and certified by the National Glycohemoglobin Standardization Program. The

Table 1. Study design and data collection timeline for the stepped-wedge randomized controlled cookstove intervention in rural Honduras (*n* = 230 participants).

Study visit number	1	2	3	4	5	6
Timing of data collection	Aug–Dec 2015	Jan–May 2016	Sep–Dec 2016	Feb–May 2017	Sep–Dec 2017	Feb–May 2018
Condition: Arm 1 (<i>n</i> = 115 participants)						
Assigned stove type	Traditional	Traditional	<i>Justa</i>	<i>Justa</i>	<i>Justa</i>	<i>Justa</i>
Condition: Arm 2 (<i>n</i> = 115 participants)						
Assigned stove type	Traditional	Traditional	Traditional	Traditional	<i>Justa</i>	<i>Justa</i>

HbA1c value was recorded as a continuous number. Clinical cut-offs for diabetes were as follows: <5.7% was normal, 5.7 to <6.5% was prediabetes, and 6.5% or higher was diabetes.¹⁵

Additional Data

In-person questionnaires conducted by our study interviewer gathered in-depth information on self-reported health and sociodemographic characteristics that were relevant for the HbA1c models, based on literature review of potential confounders and information that might improve model precision. Anthropometric measures were collected at each visit and included waist and hip circumference after removing shoes, any extra layers of clothing, hats, and headwraps (measuring tape in cm, waist measured at narrowest part of waist, hips measured at broadest part of hips), weight (electronic scale, kg), height (measuring tape and level against a wall, meters), and body mass index (BMI; kg/m²). Women reported any recent illnesses (during the past week, symptoms), education (years of school completed), and dietary diversity based on a 24-h dietary recall of commonly consumed Honduran food items summarized into 11 food categories [cereals (corn, grains, rice, chips), pulses (beans, nuts), potatoes, vegetables, fruit, sweets (desserts, cake, cookies, candy, sweet breads), eggs, dairy (cream, milk, cheese, butter), meat, fat (oils, lard), and sweetened drinks (coffee, soda, juice)]. Each food category was dichotomized into yes/no based on the dietary recall and then summed as a final dietary diversity score of 1–11, collected each visit.

Medication use was recorded based on participant recall of current use of any medications, herbal remedies, or vitamins, with verification by seeing the medication, which included Ibuprofen, Advil, Motrin, acetaminophen, Tylenol, vitamins, folic acid, prenatal vitamins, antibiotics, lipids, allergies, asthma, sinus, bronchitis, blood pressure control, miscellaneous pain medicine, aspirin, nonsteroidal anti-inflammatory medication, and birth control. Physical activity was estimated each visit as metabolic equivalent of tasks (MET) based on 10 lifestyle activities typical for this study population from the 2011 Compendium of Physical Activity scores: cutting wood (MET = 5.5), grinding corn (MET = 3.3), washing clothes (MET = 4), milking cow (MET = 3.5), working in the field (MET = 4.8), moderate walking (MET = 3.5), cooking (MET = 3.3), cleaning (MET = 3.3), sitting (MET = 1.3), and sleeping (MET = 0.95).⁴⁷ Each participant's MET was calculated as self-reported hours of each activity per week multiplied by the MET value for that activity, summed.⁴⁷

Household material wealth was estimated at baseline by calculating a weighted index score based on the prevalence of nine culturally relevant items per household: bicycle, car, motorbike, television, radio, refrigerator, cell phone, computer, sewing machine.²⁸ Items that were rarer (e.g., car, computer) were more heavily weighted than more common items (e.g., radio). Metabolic syndrome was defined per International Diabetes Federation guidelines,⁴⁸ modified for non-fasting triglycerides⁴⁹ with a waist circumference greater or equal to 80 cm and at least two of the following: HbA1c over 5.6%, triglycerides over 200 mg/dL, high-density lipoprotein <50 mg/dL, systolic blood pressure greater than or equal to 130 mmHg, or diastolic blood pressure greater than or equal to 85 mmHg. Further descriptions of these measures have been reported.²⁸

Cooking behaviors, such as the use of secondary stoves (i.e., “stove stacking”), hours per day spent cooking, preparing foods/drinks, or roasting performed on different stove types were self-reported at each visit. Self-reported stove stacking included the use of another improved stove, such as the metal Envirofit or Project Mirador stove (similar in design to the *Justa* stove) with rocket-elbow combustion chambers, wood-fuel, metal griddles, and chimneys. Stove stacking could also include temporary or permanent traditional stoves (most often in outdoor locations in

this setting). Stove condition and maintenance of the *Justa* stove were observed and recorded through in-person stove assessments by the field research staff at each study visit.

Statistical Analysis

Any observations missing HbA1c values or covariates included in the final models were dropped from the analysis, and observations missing exposure data were dropped from the exposure–response models. Three women who reported currently taking diabetes control medications were excluded from all analyses. We conducted descriptive analyses of exposures (medians and 25th, 75th percentiles), HbA1c, and other health and household characteristics. Data were summarized descriptively as means, standard deviations (SDs), ranges, and frequencies, per data type. Study arms were compared to assess the success of randomization by comparing key sociodemographic characteristics, such as baseline age, household wealth, and health measures. Pearson correlation coefficients were estimated for the correlations between the two household air pollution measures, PM_{2.5} and BC, across all participants at all time points. The intraclass correlation coefficient (ICC) was estimated for HbA1c for all visits with participant ID as a random effect in a mixed-effects model for the full sample. The ICC was calculated as the ratio of the between-participant variance to the total variance, obtained by dividing the square of the SD of the random effect by the sum of its square and the residual variance.

For intent-to-treat analysis (aim 1), we evaluated data from all six study visits to investigate the association between assigned stove type and HbA1c using linear mixed models with a fixed effect for the exposure variable of interest (*Justa* condition or traditional stove condition). The models included a random effect for participants to account for within-person correlations from repeated measures. A natural cubic spline for calendar date with 6 degrees of freedom (df) was included as a fixed effect to account for potential temporal confounding due to the stepped-wedge design.⁴² We chose to include the fixed effect for time (using the spline for calendar date) over a fixed effect for visit number (i.e., 1 through 6) because the spline could account for variation across calendar time within the same study visit (measurements for each visit took ~3–4 months to complete for all participants). With a goal of improving precision, secondary intent-to-treat models included adjustment for several variables [age, BMI, waist-to-hip ratio, physical activity as metabolic equivalents, dietary diversity score, and weighted index score for household assets (all continuous variables)] hypothesized to explain variability in HbA1c levels. Last, for the intent-to-treat models, we conducted a secondary analysis using a subset of the data for visits 1–4 to mimic a scenario more like a classical parallel-group trial where the control group (here, study arm 2) used only traditional stoves and never switched to the *Justa* stove condition; the fixed effect of a natural cubic spline for time used 4 df given the 4 study visits for this model.

For the exposure–response analyses (aim 2), we used linear mixed models with a random effect for participants. Personal and kitchen PM_{2.5} and BC measurements were included as exposure variables separately per model. All exposures were natural log-transformed to meet the assumptions of linear regression, and this resulted in a model that better fit the data (diagnostic plots of residuals vs. fitted values for raw and natural log-transformed personal and kitchen PM_{2.5} and BC from crude linear models with HbA1c and each exposure concentration are presented in Supplemental Figure 2). We also constructed two graphs to explore the shape of the exposure–response association using a spline with 3 df for both raw and natural log-transformed personal PM_{2.5}, showing a spline fit consistent with a linear trend on the logarithmic scale (Supplemental Figure 2). Covariates of age,

BMI, waist-to-hip ratio, physical activity as metabolic equivalents, dietary diversity score, and weighted index score for household assets (all continuous variables), were included in the models based on *a priori* importance (i.e., as confounders or variables that could improve model precision by explaining variability in HbA1c without evidence of being a mediator or collider). Although our primary intent-to-treat analysis of the stepped-wedge design requires an adjustment for time to obtain valid estimates, we did not include a spline function to adjust for time in the exposure–response models. This decision was made after fitting separate models for personal exposure with time, stove, and time and stove, and discovering that ~90% of variation in exposure explained by time was due to stove (Supplemental Table 1). Given the likely minimal temporal confounding from other sources and to avoid the potential for overadjustment, because stove type and time are correlated by design and stove type is a precursor to household air pollution, adjusting for time could mask the true exposure effects.

For additional exposure–response analyses, given our interest in characterizing longer-term impacts of exposure on health end points, we assessed predicted long-term averages of personal and kitchen PM_{2.5} and BC as alternative exposures.⁵⁰ The long-term averages were estimated from a mixed model with assigned stove status, natural cubic spline function for time with 6 df, and a random effect for participant. This approach means that the long-term averages are influenced by both the concentration averages for each household and the between-household averages for each assigned stove status. See Keller and Clark for further details.⁵⁰

For a per protocol analysis of the impact of self-reported stove use, including stove stacking, on HbA1c (aim 3), we used linear mixed models with self-reported cookstove use as the key exposure, including participant as a random effect, adjusted for the covariates listed above, including time. Three categories of exposure included *Justa* use with or without another improved secondary stove, *Justa* use with a traditional secondary stove, and traditional stove use only as the reference group. Participants were categorized based on self-reported cookstove use and behaviors at each visit. Last, for the per protocol self-reported stove use models, we ran a subset of the data as secondary analysis for only visits 1–4 to mimic a scenario more like a classical parallel-group trial where the control group never switched to intervention status; this approach was taken for the per protocol analysis to compare directly to the same approach used in the intent-to-treat analysis.

We assessed effect modification by adding the following prespecified interaction variables to all model iterations for assigned stove type, exposure–response, and per protocol self-reported stove use: age (<40 vs. ≥40 y of age), BMI (normal <25 vs. overweight/obese ≥25), waist circumference (<80 cm vs. ≥80 cm), blood pressure (normal systolic <120 and diastolic <80 vs. borderline high/high systolic ≥120 or diastolic ≥80 mmHg), and metabolic syndrome (absent vs. present) as interaction terms, with stove assignment or exposure measurement variables in separate models. Previous research suggests that people of older ages might be more susceptible to adverse health impacts from air pollution, given a decline in cardiovascular and respiratory functions, leading to negative impacts on glucose metabolism and HbA1c levels.⁵¹ There is also research to suggest that people with higher BMI levels are more susceptible to the effects of air pollution on glucose metabolism due to chronic inflammation and insulin resistance associated with overweight and obesity, which can heighten the negative impacts of air pollution from insulin signaling disruption and glucose uptake, leading to increased HbA1c. Given the connection between this and the potential for modifications of the associations between exposures and HbA1c, as has also been seen with comorbidities modifying the effects between air pollution and risk of stroke,⁵² we further

considered other cardiometabolic indicators, including blood pressure, waist circumference, and metabolic syndrome.

We evaluated numerous sensitivity analyses to assess robustness of modeling choices. For assigned cookstoves, we assessed visit 3 only, adjusted for baseline HbA1c levels. For assigned cookstoves, exposure–response, and per protocol self-reported cookstove sensitivity analyses, we further investigated models after excluding the following observations: $n = 23$ HbA1c outliers (if ≥2 SD above the mean, HbA1c ≥7.03%), $n = 30$ HbA1c values from five participants who had high variability based on the full sample SD of 0.78 (if within-person SD >0.78 for six visits), and $n = 73$ *Justa* stove users with combustion chambers and/or chimneys that were in need of repair or were absent.

All data management and analyses were conducted in R Statistical Software and RStudio (version 4.2.2; The R Foundation for Statistical Computing Platform).

Results

Three women who reported taking diabetes control medications were removed from the dataset, for a total of $n = 227$ participants with 1,208 HbA1c observations over six study visits, although baseline data included 226 participants due to one missing HbA1c value. A flow diagram of participant follow-up, exclusions, and total HbA1c results analyzed at each visit throughout the entire trial is shown in Supplemental Material (Supplemental Figure 1). Missing HbA1c results were typically due to instrument errors. Permanent exclusions from the trial were due to participants moving away or declining, and temporary exclusions were due to pregnancy or unavailability (Supplemental Figure 1). Comparing sociodemographic, health, and exposure variables between the full study sample ($n = 1,248$ total observations) and the reduced analyzed sample of participants with HbA1c observations ($n = 1,208$) showed no differences, minimizing the potential that selection bias was a factor for our results among the HbA1c subsample (Supplemental Table 2).

Baseline Characteristics

The random allocation of participants into two study arms resulted in balanced distributions of potential confounding variables (Table 2). At baseline, the 226 women with HbA1c observations were on average 38 y of age (SD 8.6), half had <6 y of school ($n = 117$, 52%), and dietary diversity was on average 6.4 (SD 1.8) out of a maximum of 11. Household characteristics showed less than a third had working electricity in the home ($n = 64$, 28%), the weighted index for household assets was on average 6.6 (SD 7.2) out of a maximum of 45, and an average of 6.1 (SD 2.5) people lived in the house (Table 2).

Women's health characteristics at baseline showed less than a third used any medication ($n = 64$, 28%), average BMI was 26.1 kg/m² (SD 4.2), waist-to-hip ratio was 0.88 (SD 0.06), and physical activity in metabolic equivalent of tasks was 302 (SD 98) (Table 2). Average baseline HbA1c was 5.5% (SD 0.6), with most women categorized as normal ($n = 160$, 71%), and 30% ($n = 66$) categorized as prediabetes/diabetes. Average systolic and diastolic blood pressures were 120.6 mmHg (SD 15.2) and ≤74.3 mmHg (SD 9.4), respectively, categorized as normal (systolic ≤120 mmHg and diastolic ≤80 mmHg; $n = 122$, 55%) or borderline high/high blood pressure (systolic >120 mmHg or diastolic >80 mmHg; $n = 99$, 45%). Metabolic syndrome was prevalent in 121 women (55%) (Table 2).

Exposure Results

Self-reported compliance and adherence to the stove assignments was high. Supplemental Table 2 displays the descriptive summaries

Table 2. Descriptive summary at baseline (visit 1, 2015) among all participants and by study arm ($n = 226$ participants not taking diabetes control medications with HbA1c measurements at baseline), stepped-wedge randomized controlled cookstove intervention in rural Honduras.

Baseline characteristics	All ($n = 226$ participants) Mean \pm SD or n (%)	Arm 1 ($n = 114$ participants) Mean \pm SD or n (%)	Arm 2 ($n = 112$ participants) Mean \pm SD or n (%)
Sociodemographic characteristics			
Age at baseline visit (y)	38.0 (8.6)	38.4 (8.0)	37.7 (9.2)
Age [(y) binary]			
<40	136 (60%)	65 (57%)	71 (63%)
≥ 40	90 (40%)	49 (43%)	41 (37%)
Education			
<6 y	117 (52%)	59 (52%)	58 (52%)
6 or more y	109 (48%)	55 (48%)	54 (48%)
Dietary diversity score (range 1–11) ^a	6.4 (1.8)	6.1 (1.8)	6.6 (1.8)
Missing observations (n)	4	3	1
Working electricity in home			
Yes	64 (28%)	29 (25%)	35 (31%)
No	162 (72%)	85 (75%)	77 (69%)
Household assets weighted sum (range 0–45) ^b	6.6 (7.2)	5.8 (6.1)	7.5 (8.1)
Number of people living in house	6.1 (2.5)	6.0 (2.5)	6.2 (2.6)
Health characteristics			
Current use of any medication (excluding diabetes medications) ^c			
Yes	64 (28%)	33 (29%)	31 (28%)
No	162 (72%)	81 (71%)	81 (72%)
BMI (kg/m ²)	26.1 (4.2)	26.2 (3.9)	25.9 (4.4)
BMI [(kg/m ²) binary]			
<25 (normal or underweight)	100 (44%)	47 (41%)	53 (47%)
≥ 25 (overweight or obese)	126 (56%)	67 (59%)	59 (53%)
Waist-to-hip ratio	0.88 (0.06)	0.88 (0.06)	0.88 (0.06)
Waist circumference			
<80 cm	80 (35%)	42 (37%)	38 (34%)
≥ 80 cm	146 (65%)	72 (63%)	74 (66%)
Physical activity (metabolic equivalents) ^d	302 (98)	306 (94)	299 (102)
HbA1c [continuous (%)]	5.5 (0.6)	5.5 (0.5)	5.4 (0.6)
HbA1c (categorized)			
<5.7% (normal)	160 (71%)	78 (68%)	82 (73%)
5.7–6.4% (prediabetes)	60 (27%)	32 (28%)	28 (25%)
≥ 6.5 % (diabetes)	6 (3%)	4 (4%)	2 (2%)
Systolic blood pressure (mmHg)	120.6 (15.2)	120.0 (13.9)	121.2 (16.4)
Missing observations (n)	6	1	5
Diastolic blood pressure (mmHg)	74.3 (9.4)	74.1 (9.1)	74.5 (9.6)
Missing observations (n)	6	1	5
Blood pressure (categorized) ^e			
Normal	121 (55%)	62 (55%)	59 (55%)
Borderline high or high	99 (45%)	51 (45%)	48 (45%)
Missing observations (n)	6	1	5
Metabolic syndrome ^f			
Metabolic syndrome	121 (55%)	61 (54%)	60 (56%)
No metabolic syndrome	99 (45%)	51 (46%)	48 (44%)
Missing observations (n)	5	1	4

Note: Descriptive analyses included summary statistics of mean (SD) or counts (n) with frequencies (%). BMI, body mass index; SD, standard deviation.

^aDietary diversity score: sum of having eaten or drank in past 24 h from up to 11 categories: cereals (corn, grains, rice, chips), pulses (beans, nuts), potatoes, vegetables, fruit, sweets (desserts, cake, cookies, candy, sweet breads), eggs, dairy (cream, milk, cheese, butter), meat, fat (oils, lard), sweetened drinks (coffee, soda, juice).

^bHousehold assets weighted sum: weighted index score based on prevalence in sample of nine items: radio, mobile phone, bicycle, television, sewing machine, refrigerator, car, motor-bike, computer.

^cMedications: Ibuprofen, Advil, Motrin, acetaminophen, Tylenol, vitamins, folic acid, prenatal vitamins, antibiotics, lipids, allergies, asthma, sinus, bronchitis, blood pressure control, miscellaneous pain medicine, aspirin, nonsteroidal anti-inflammatory, birth control.

^dMetabolic equivalents based on the 2011 Compendium of Physical Activities for 10 typical lifestyle activities, calculated as MET-adjusted hours per week: cutting wood, grinding corn, washing clothes, milking cow, working in the field, walking moderately, cooking, cleaning, sitting relaxed, sleeping.

^eBlood pressure categorized as normal: systolic blood pressure ≤ 120 mmHg and diastolic blood pressure ≤ 80 mmHg; borderline high/high: systolic blood pressure > 120 mmHg or diastolic blood pressure > 80 mmHg.

^fMetabolic syndrome defined as waist circumference ≥ 80 cm and at least two of the following: hemoglobin A1c $> 5.6\%$, triglycerides > 200 mg/dL, high-density lipoprotein < 50 mg/dL, systolic blood pressure ≥ 130 mmHg, or diastolic blood pressure ≥ 85 mmHg.

(median, 25th–75th quartiles) of all exposure concentrations. There were moderate to strong correlations between PM_{2.5} and BC measures for both personal and kitchen concentrations. Pearson correlation coefficients across all participants and study visits were 0.63 ($n = 1,136$) for log-transformed personal PM_{2.5} and BC, and 0.80 ($n = 1,132$) for log-transformed kitchen PM_{2.5} and BC. When stratifying by assigned stove type, the Pearson correlation coefficient for log-transformed personal PM_{2.5} and BC was 0.69 among traditional stove users ($n = 586$), and 0.50 among *Justa* stove users ($n = 550$). Pearson correlation coefficients for log-transformed kitchen PM_{2.5}

and BC were 0.83 among traditional stove users ($n = 589$), and 0.69 among *Justa* stove users ($n = 543$).

Figure 3 box-and-whisker plots show that the assignment of the *Justa* stoves in place of traditional stoves led to substantial exposure reductions. Intent-to-treat results for reductions in personal and kitchen PM_{2.5} and BC exposures for the *Justa* stove condition in comparison with the traditional stove condition have been published.^{29,44} Here, we present pollutant concentrations for the slightly smaller sample size of those with HbA1c measures. As expected, we observed the same patterns. Differences in *Justa*

stove condition air quality measures in comparison with traditional stove condition measures over the course of the study are as follows: Personal PM_{2.5} exposures were reduced by 48%—median 24-h average concentrations (25th, 75th percentiles) were 82 µg/m³ (51, 142 µg/m³) for traditional stoves (*n* = 605 observations) and 43 µg/m³ (27, 73 µg/m³) for *Justa* stoves (*n* = 563). Kitchen PM_{2.5} exposures were reduced by 70%: median 24-h average concentrations were 178 µg/m³ (69, 440 µg/m³) for traditional stoves (*n* = 612) and 53 µg/m³ (29, 103 µg/m³) for *Justa* stoves (*n* = 555). Personal BC exposures were reduced by 70%: median 24-h average concentrations were 11.8 µg/m³ (5.1, 28.9 µg/m³) for traditional stoves (*n* = 597) and 3.5 µg/m³ (1.5, 11.9 µg/m³) for *Justa* stoves (*n* = 559). Kitchen BC exposures were reduced by 86%: median 24-h average concentrations were 47.0 µg/m³ (11.7, 160.3 µg/m³) for traditional stoves (*n* = 595) and 6.5 µg/m³ (2.3, 25.7 µg/m³) for *Justa* stoves (*n* = 556) (Figure 3).

HbA1c Results

HbA1c concentrations by study arm, assigned stove condition, and visit number are presented as box-and-whisker plots in Figure 4. The red dashed line in Figure 4 depicts the standard cutoff for diabetes (HbA1c ≥ 6.5%), with few participants above the threshold. The corresponding numeric data for creating Figure 4 is included in Supplemental Materials (Supplemental Table 3). The ICC across all six visits was 0.66, indicating that more of the variability in HbA1c measures was between-person rather than within-person.

In the primary intent-to-treat analysis of the intervention (aim 1), participants had reduced average HbA1c when in the *Justa* condition in comparison with the traditional stove condition [−0.03 percentage points, 95% confidence interval (CI): −0.13, 0.07], but the CI included the null value (Table 3). Results were similar after adjusting for additional covariates of age, BMI, waist-to-hip ratio, physical activity as metabolic equivalent of tasks, dietary diversity score, and household socioeconomic status (HbA1c reduced in *Justa* vs. traditional stove conditions, −0.04 percentage points, 95% CI: −0.14, 0.06). When we assessed a subset of the data as a secondary analysis to more closely mimic a classical parallel-group trial design using only visits 1–4, those in the *Justa* stove condition experienced significantly reduced HbA1c (−0.09 percentage points, 95% CI: −0.18, −0.003) in comparison with those in the traditional stove condition (Table 3).

Exposure–response models, adjusted for the covariates listed above, showed significant associations between log-transformed personal and kitchen PM_{2.5} and BC and HbA1c (aim 2), as hypothesized (Table 3). For example, average HbA1c was 0.04 percentage points higher (95% CI: 0.003, 0.07) per unit increase of log-transformed personal PM_{2.5}. As a reference to understand the magnitude of this difference in exposure, 1 log unit of µg/m³ is the approximate difference between the 25th and 75th percentiles of personal exposures within each stove type. Results were nearly identical for BC, with 0.03 percentage points (95% CI: 0.01, 0.05) higher average HbA1c per unit increase of log-transformed personal BC. Stronger associations were observed when considering the estimated long-term average exposures, such as 0.22 percentage

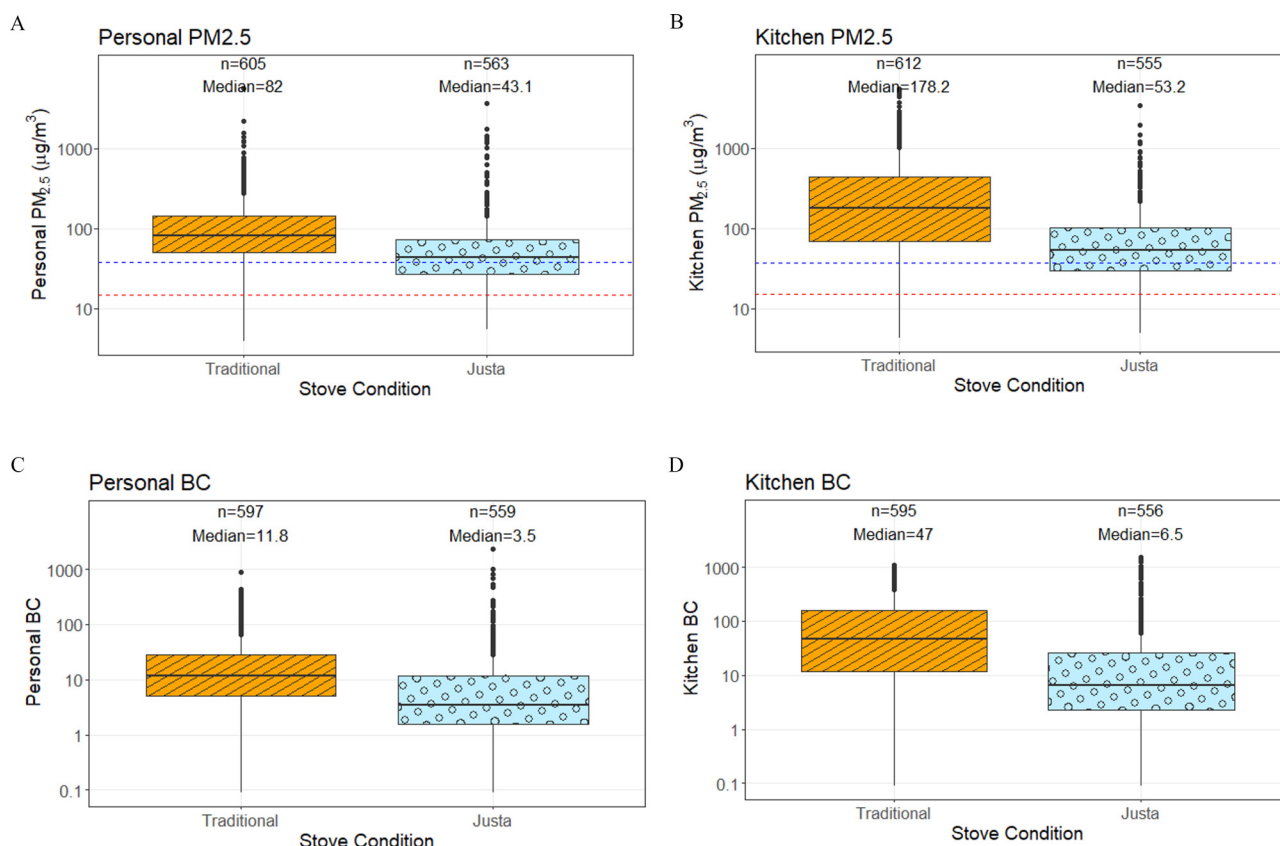


Figure 3. Box plots of 24-h household air pollution exposures of personal PM_{2.5} (A; traditional: *n* = 605; *Justa*: *n* = 563), kitchen PM_{2.5} (B; traditional: *n* = 612, *Justa*: *n* = 555), personal BC (C; traditional: *n* = 597; *Justa*: *n* = 559), and kitchen BC (D; traditional: *n* = 595, *Justa*: *n* = 556). For reference, the blue and red dashed lines for the PM_{2.5} plots represent the WHO 24-h interim-3 air quality target (37.5 µg/m³) and air quality guideline (15 µg/m³), respectively.⁵⁴ The boxes extend from lower to upper quartiles of the data, the horizontal bar is the median; whiskers extend from minimum and maximum values within 1.5 times the interquartile range; outliers are plotted as individual points. The numeric values for this figure are also described in the main text. Note: BC, black carbon; PM_{2.5}, particulate matter with an aerodynamic diameter ≤ 2.5 µm; WHO, World Health Organization.

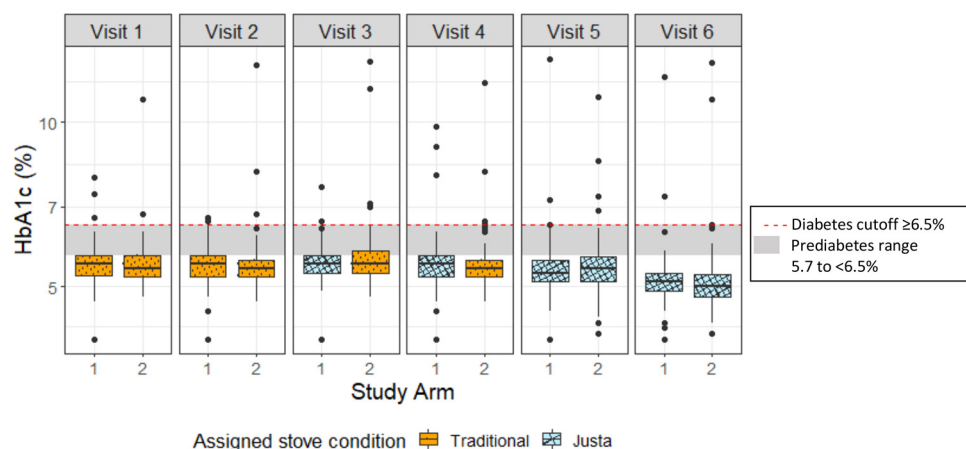


Figure 4. HbA1c by study arm, assigned stove type, and visit number ($n = 1,208$ HbA1c observations among 227 unique participants). HbA1c distribution by randomized study arm (arm 1 or arm 2), assigned stove type (traditional or *Justa*), and study visit number. The boxes extend from lower to upper quartiles of the data, the horizontal bar is the median; whiskers extend from minimum and maximum values within 1.5 times the interquartile range; outliers are plotted as individual points. For reference, the red dashed line represents the standard cutoff for diabetes (HbA1c $\geq 6.5\%$) and the gray shaded area represents the range for prediabetes (HbA1c 5.7% to $< 6.5\%$).¹⁵ The corresponding numeric data for this figure can be found in Supplemental Materials (Supplemental Table 3).

points higher average HbA1c (95% CI: 0.13, 0.30) per unit increase of log-transformed $\mu\text{g}/\text{m}^3$ long-term average personal $\text{PM}_{2.5}$ (Table 3).

Suggestive impacts (i.e., even though these effect sizes are not statistically significant, they support further exploration) on HbA1c were observed in the per protocol analysis of self-reported cookstove use (aim 3), with reductions in average HbA1c of -0.05 percentage points (95% CI: -0.16 , 0.06) among those using a

Justa stove with or without other improved secondary stoves and by -0.03 percentage points for those using a *Justa* stove plus a traditional secondary stove (95% CI: -0.13 , 0.07), in comparison with those using only traditional stoves (Table 3). In our secondary per protocol analysis where we assessed a subset of the data to mimic a classical parallel trial design for only visits 1–4, there was a greater impact from *Justa* users on HbA1c reduction with or without stove stacking in comparison with traditional stove users,

Table 3. Adjusted mixed-effects regression models for intent-to-treat analyses, based on assigned stove condition, personal and kitchen $\text{PM}_{2.5}$ and BC exposure–response analyses, and “per protocol” self-reported cookstove use analyses demonstrating effects on HbA1c values, stepped-wedge randomized controlled cookstove intervention in rural Honduras ($n = 1,208$ HbA1c observations).

	<i>n</i> Obs.	Estimate (%)	95% CI
Condition: Intent-to-treat (assigned stove type)			
Intent-to-treat ^a			
<i>Justa</i> stove	582	-0.03	-0.13 , 0.07
Traditional stove (Ref)	626	Ref	Ref
Intent-to-treat plus additional covariates ^{a,b}			
<i>Justa</i> stove	578	-0.04	-0.14 , 0.06
Traditional stove (Ref)	620	Ref	Ref
Secondary analysis: subset of visits 1–4 only ^c			
<i>Justa</i> stove	207	-0.09	-0.18 , -0.003
Traditional stove (Ref)	620	Ref	Ref
Exposure–response with 24-h $\text{PM}_{2.5}$ and BC ($\mu\text{g}/\text{m}^3$, natural log-transformed)			
Personal $\text{PM}_{2.5}$ ^b	1,158	0.04	0.003 , 0.07
Personal predicted long-term average $\text{PM}_{2.5}$ ^{b,d}	1,197	0.22	0.13 , 0.30
Kitchen $\text{PM}_{2.5}$ ^b	1,157	0.04	0.01 , 0.06
Kitchen predicted long-term average $\text{PM}_{2.5}$ ^{b,d}	1,198	0.11	0.07 , 0.16
Personal BC ^b	1,147	0.03	0.01 , 0.05
Personal predicted long-term average BC ^{b,d}	1,194	0.09	0.05 , 0.13
Kitchen BC ^b	1,141	0.03	0.01 , 0.05
Kitchen predicted long-term average BC ^{b,d}	1,196	0.07	0.04 , 0.10
Per protocol: Self-reported cookstove stove			
Self-reported cookstove use ^{a,b}			
<i>Justa</i> with or without improved secondary stove	208	-0.05	-0.16 , 0.06
<i>Justa</i> plus traditional secondary stove	369	-0.03	-0.13 , 0.07
Traditional stove only (Ref)	621	Ref	Ref
Secondary analysis: Subset of visits 1–4 only ^c			
<i>Justa</i> with or without improved secondary stove	70	-0.12	-0.24 , 0.001
<i>Justa</i> plus traditional stove	143	-0.07	-0.16 , 0.04
Traditional stove only (Ref)	614	Ref	Ref

Note: Participant ID is a random effect in all models. BC, black carbon; BMI, body mass index; CI, confidence interval; df, degrees of freedom; *n* Obs., number of observations; $\text{PM}_{2.5}$, fine particulate matter with an aerodynamic diameter ≤ 2.5 micrometers; Ref, reference.

^aFixed effect term for “time” is a spline function with 6 df.

^bAdditional covariates in model: age at baseline (continuous), BMI (continuous), waist-to-hip ratio (continuous), physical activity as metabolic equivalent of tasks (continuous), dietary diversity score (continuous), weighted index for household material assets at baseline (continuous).

^cFixed effect term for “time” is a spline function with 4 df and random effect for participant ID.

^dPredicted long-term average exposure, estimated from intercept, stove type, spline for time (6 df), and random effect for household. Two exposures per household, one for each stove type, combining stove group mean and the household random effect.

although CIs included the null value (*Justa* with or without improved secondary stove: -0.12 percentage points, 95% CI: $-0.24, 0.001$; *Justa* with traditional stove use: -0.07 percentage points, 95% CI: $-0.16, 0.04$) (Table 3).

Results from Effect Modification and Sensitivity Analyses

The Supplemental Material displays the results from the effect modification models (Supplemental Table 4). In general, we did not observe interactions between exposures and age, BMI, waist circumference, or metabolic syndrome for impacts on HbA1c (Supplemental Table 4). There was some evidence of an exposure–response effect on HbA1c from household air pollution measures interacting with blood pressure, where women with normal blood pressure (systolic blood pressure ≤ 120 mmHg and diastolic blood pressure ≤ 80 mmHg) experienced more substantial differences in HbA1c per unit increase in pollutant in comparison with women with borderline high/high blood pressure (systolic > 120 mmHg or diastolic > 80 mmHg) (Supplemental Table 4). Women with normal blood pressure also experienced greater reductions in HbA1c using a *Justa* stove (with or without other stove stacking) in comparison with women with borderline high/high blood pressure. Results from effect modification analyses should be interpreted cautiously due to the issue of multiple testing.

The sensitivity analyses are presented in the Supplemental Material (Supplemental Table 5). In the assigned cookstove sensitivity analyses, results of including only visit 3, adjusted for visit 1 HbA1c values, showed stronger effects of the intervention, with a reduction in HbA1c by 0.20 percentage points (95% CI: $-0.34, -0.05$) (Supplemental Table 5). After removing HbA1c outliers or excluding observations if the *Justa* stove was in need of repairs, results showed consistent patterns to intent-to-treat primary models with reductions in HbA1c following the *Justa* intervention, despite CIs including the null value. For example, after removing HbA1c outliers for any observations ≥ 2 SD above the mean, we observed a reduction in HbA1c by 0.02 percentage points (95% CI: $-0.08, 0.05$) among *Justa* users in comparison with traditional stove users (Supplemental Table 5).

In sensitivity analyses for exposure–response models, we observed results nearly identical to primary exposure–response models of higher average HbA1c per unit increase in household air pollution, regardless of exclusions to data by HbA1c outliers (≥ 2 SD above the mean), HbA1c variability (within-person SD > 0.78 for all visits), or *Justa* stove condition (if chimneys needed repairs or were removed by the participant) (Supplemental Table 5). Overall, the consistency in results from our sensitivity analyses in comparison with our primary analyses indicated robustness of the primary models, supporting the primary models as reliable and consistent across different subsets of data and model specifications.

Discussion

In Honduras, diabetes rates have doubled since 1980,⁵³ and although individual-level factors, such as socioeconomic, behavioral, biological, and demographic characteristics are predictors of diabetes, evidence suggests that environmental determinants, such as air pollution, also play a key role.^{8,15} Findings from our randomized cookstove intervention showed reductions in 24-h personal and kitchen PM_{2.5} and BC among assigned users of *Justa* stoves in comparison with traditional stoves.^{29,44} A notable finding is that a substantial proportion of personal PM_{2.5} exposures post intervention fell below the WHO interim-3 24-h air quality target ($37.5 \mu\text{g}/\text{m}^3$) (53% and 41% of participants during rainy and dry seasons, respectively).⁵⁴ These decreases in household air pollution measures post intervention led to reductions in HbA1c when

comparing the *Justa* to traditional stove conditions in intent-to-treat analysis, although CIs included the null value. In the secondary analysis with a subset of data that included only visits 1–4, which mimicked a classical parallel trial design, we found significant reductions in HbA1c among the assigned *Justa* users in comparison with traditional stove users. Our sensitivity analyses (e.g., removing outliers) were conducted to explore potential reasons as to why the analysis limited to visits 1–4 showed a stronger effect of the intervention in comparison with the primary analysis of all six visits; however, these sensitivity analysis results were consistent with the primary results. It is possible that increased variability in HbA1c measures at visits 5 and 6 may have increased the confidence interval width in the full analysis although clear mechanisms that might explain this pattern are unknown.

We observed positive exposure–response associations for household air pollution and HbA1c, as hypothesized. The strongest exposure–response effects were seen with the predicted long-term average exposures, consistent with those averages being less susceptible to daily variation and thus having reduced classical measurement error in comparison with the individual measurements that only incorporate concentrations over a 24-h period.⁵⁰ The per protocol self-reported stove-use analysis also showed suggested reductions in HbA1c among *Justa* stove users regardless of stove stacking with other improved stoves or traditional stoves, in comparison with traditional stove users. These findings are likely impacted by the practice of using secondary traditional stoves in outdoor locations, thus not having as much impact on personal exposures as indoor cooking. We did not observe consistent interaction effects between household air pollution and other variables on HbA1c levels, other than suggestive modification by blood pressure categories, despite a previous study reporting stronger associations between air pollution and HbA1c among women over 40 y of age.³⁸ Further exploration of sensitivity analyses generally supported the primary results, suggesting reliability of our modeling approaches.

We observed relatively small reductions or differences in HbA1c for both our intention-to-treat and our exposure–response analyses; therefore, it is important to place these results into context regarding the potential for clinical significance. An accepted cutoff for a clinically meaningful change in HbA1c is 0.5% for clinical trials and medical care approaches evaluating diabetes medications among individuals with diabetes, when diabetes control is the focus.^{55,56} Among nondiabetic populations, the guidance is less clear regarding the clinical significance for individual-level changes. However, several studies have demonstrated that population-level increases in HbA1c, over the continuum of HbA1c observed in our study, are associated with increased risk of incident coronary heart disease,⁵⁷ hypertension,⁵⁸ and mortality⁵⁹ among nondiabetic populations. For example, in the Atherosclerosis Risk in Communities Study, among nondiabetic participants that had HbA1c levels $> 4.6\%$ (representing the second percentile in our Honduran study population), higher HbA1c levels (assessed continuously) were associated with increased risk of coronary heart disease.⁵⁷ Finally, we can also draw parallels to other types of interventions typically recommended for the prevention of diabetes; for example, a systematic review and meta-analysis concluded that physical activity interventions among nondiabetic populations can reduce HbA1c levels by 0.01% to 0.22%.⁶⁰ Therefore, the changes in HbA1c observed in our study (i.e., a reduction in HbA1c by 0.03% for the intent-to-treat analysis, a reduction of 0.09% for the secondary analysis subset of visits 1–4 to mimic a parallel trial design, and the associated exposure–response increases that ranged from 0.03 to 0.22% per unit increases in PM_{2.5} and BC) could have meaningful impacts on population health, especially given the large number of people exposed to household air pollution, globally.

Because this study is the only randomized cookstove trial with longitudinal household air pollution and HbA1c data, to our knowledge, our ability to compare our results with other trials is not possible. However, results from the household air pollution and HbA1c literature from cross-sectional studies show mixed results. Our previous cross-sectional study in Honduras among 142 women found higher prevalence of pre-diabetes/diabetes in women with elevated household air pollution (e.g., prevalence ratio per 84 $\mu\text{g}/\text{m}^3$ higher in personal $\text{PM}_{2.5}$, 1.49; 95% CI: 1.11, 2.01), yet no effects by stove type.³⁸ Results for continuous HbA1c were generally in the hypothesized direction but consistent with a null association.³⁸ A recent cross-sectional study among 299 Nepali women comparing cardiovascular functions by stove types (LPG, wood-burning biomass, and biogas) observed higher prevalence of HbA1c $\geq 6.5\%$ (the standard cutoff for diabetes) among LPG users (13%, 25/195), in comparison with biogas (9%, 3/35), and biomass users (9%, 6/69) (chi-square across stove types = 0.09).⁶¹ Another recent study did not report associations between indoor $\text{PM}_{2.5}$ and carbon monoxide and HbA1c based on 617 participants living across different settings of urbanization, altitude, and biomass cookstove use in Peru.⁶² In a cross-sectional study among 58 residences (45 men, 33 women) in Copenhagen, Denmark, HbA1c was associated with indoor particle number concentrations [2% higher per interquartile range (IQR)], but not with other exposure markers.⁶³

A potential reason for the mixed results consistently observed in the household air pollution and HbA1c literature is that health impacts may not be realized when only single contributors to household air pollution are addressed.⁶⁴ Literature on ambient exposures suggests that the effect of nitrogen dioxide, which was not measured in this study, may be stronger than $\text{PM}_{2.5}$.⁸ Multipollutant models, which were not feasible to assess in this study, can help identify various sources and types of pollutants. It has also been suggested that engineered biomass stoves and cleaner fuels are not “clean enough” (i.e., do not reduce household air pollution concentrations to low enough levels) to improve health, especially with the presence of other pervasive risk factors, such as ambient pollution, and other sources of household air pollution, such as tobacco use or burning trash, and continued use of stove stacking with traditional stoves.⁶⁴ However, even small reductions in air pollution exposures may have some impact on population health, and our study achieved a substantial proportion of personal $\text{PM}_{2.5}$ exposures post intervention that were below the WHO interim-3 air quality target. There is a call for more comprehensive interventions that consider lighting, heating, cooking, and other sources of combustion (e.g., trash burning, motor vehicles) to reduce both household air pollution and ambient pollution.⁶⁴ In a similar vein, preventing cardiometabolic disease will likely require a multitude of factors, including attaining air quality standards and an improvement of social and environmental conditions.^{8,18}

Strengths

Several strengths of this study are important to note. We present novel evidence evaluating household air pollution and HbA1c with repeated, quantitative measures of personal and kitchen exposures within a randomized controlled trial. Our study relied on close collaboration with local partners to carefully choose a Honduran-made, culturally appropriate, acceptable intervention cookstove, which was installed by AHDESA-trained stove technicians to ensure consistency across households. We applied thorough steps for community stove demonstrations, in-person trainings, educational materials, and regular check-ins on proper stove maintenance and use.²⁸ Further, the stepped-wedge design is considered a more ethical study design in real-world settings

where withholding a desired intervention from a group of participants raises concerns, particularly when the intervention is highly desired, with anticipated benefits.^{42,43} Last, HbA1c was evaluated with rapid, point-of-care testing, where participants received their results within 5 min of their finger stick. HbA1c has greater stability and less variability than plasma glucose measurements, does not require fasting, and is considered more feasible in nonclinic settings.²¹ Because HbA1c reflects long-term glucose levels (2–3 months), it better aligns with chronic exposure to household air pollution as an indicator of cardiometabolic health in comparison with daily blood glucose tests, which fluctuate throughout the day. Given the approximate 6-month timing between each study visit, it was reasonable to expect to see changes in HbA1c following changes in stove type.

Challenges and Limitations

There were also challenges and limitations to this study. This research took place in real-world conditions in field settings, without ideal circumstances to evaluate the efficacy of the *Justa* stove and resulting health benefits. The occurrence of stacking with secondary stoves, whether traditional or other types of improved stoves, meant our population did not achieve near-complete displacement of traditional stoves, which may be necessary to see larger health benefits.⁶⁵ There could have been unmeasured air pollution from other sources that might have lessened any benefits from household air pollution reductions from the *Justa* stove. Our models were single-pollutant exposures, lacking multipollutant measurements that might have highlighted more complete effects than just $\text{PM}_{2.5}$ or BC as individual exposures. Residual confounding of our exposure–response analyses by unmeasured behavioral and socioeconomic factors was also a possibility, although the exposure contrasts we observed post intervention were driven, in part, by the randomized stove assignment.

The stepped-wedge study design has known statistical limitations due to its complex data structure and susceptibility to temporal confounding, because the intervention was introduced over time. This means that changes in HbA1c over time may not be solely due to the intervention, and there is reduced statistical power because each study arm had unequal time spent in control vs. intervention status. We accounted for this by including a natural cubic spline function for time as a fixed effect in the intent-to-treat models.

There are possible limitations with point-of-care tests for HbA1c monitoring, such as reduced specificity with the A1CNow + Kit in comparison with venous blood draw for laboratory methods using high-performance liquid chromatography.⁶⁶ The overall downward trajectory of HbA1c post intervention and the consistently observed positive associations between household air pollution and HbA1c suggest reductions to HbA1c from the *Justa* stove, but this 3-y study may have benefited from a longer duration, allowing for more time to see lagged effects from the chronic exposure to air pollution. Last, results may not apply to other populations who differ in their underlying characteristics that may influence susceptibility to air pollution health effects, such as age, sex, diet, obesity, smoking status, and socioeconomic status.⁶⁷

Conclusions

Reducing household air pollution may translate into high-impact population-based prevention to combat cardiometabolic diseases like diabetes, given high exposure in LMICs due to cooking with solid fuels on inefficient stoves. Although only modest impacts on HbA1c were observed in intent-to-treat analyses, the exposure–response models showed support for positive associations between HbA1c and $\text{PM}_{2.5}$ and BC concentrations, as

hypothesized. Overall, the *Justa* stove may offer a feasible intermediate step toward cleaner air in Honduran homes until clean fuels/technologies are available and can be sustainably used.

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