

Contents lists available at ScienceDirect

Environment International



Full length article

Fidelity and adherence to a liquefied petroleum gas stove and fuel intervention: The multi-country Household Air Pollution Intervention Network (HAPIN) trial



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https://doi.org/10.1016/j.envint.2023.108160

Received 21 May 2023; Received in revised form 24 July 2023; Accepted 17 August 2023 Available online 19 August 2023

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Abbreviations: Intvn, Intervention group; Cntrl, Control group; HAP, Household Air Pollution; HAPIN, Household Air Pollution Intervention Network trial; LPG, Liquefied petroleum gas; K-S, Kolmogorov-Smirnov test; Preg, Follow-up that occurred during the pregnancy period, from delivery of the LPG stove through birth of the child; Infcy, Follow-up that occurred during the post-birth or "infancy" period, from birth through the child's first birthday; Pre-COVID-19, Period of follow-up occurring prior to the onset of the global COVID-19 pandemic, between May 7, 2018 and March 16, 2020; Post-COVID-19, Period of follow-up occurring after the onset of the global COVID-19 pandemic, between March 17, 2020 and the end of the trial (September 22, 2021); PM2.5, Fine particulate matter; SUMs, Stove use monitors; TS, Traditional stove; TSU, Traditional stove use; WHO, World Health Organization.

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ARTICLE INFO

Handling Editor: Xavier Querol

Keywords: Liquefied petroleum gas Intervention fidelity Adherence Household air pollution Clean cooking Health behavior change

ABSTRACT

Background: Reducing household air pollution (HAP) to levels associated with health benefits requires nearly exclusive use of clean cooking fuels and abandonment of traditional biomass fuels.

Methods: The Household Air Pollution Intervention Network (HAPIN) trial randomized 3,195 pregnant women in Guatemala, India, Peru, and Rwanda to receive a liquefied petroleum gas (LPG) stove intervention (n = 1,590), with controls expected to continue cooking with biomass fuels (n = 1,605). We assessed fidelity to intervention implementation and participant adherence to the intervention starting in pregnancy through the infant's first birthday using fuel delivery and repair records, surveys, observations, and temperature-logging stove use monitors (SUMs).

Results: Fidelity and adherence to the HAPIN intervention were high. Median time required to refill LPG cylinders was 1 day (interquartile range 0–2). Although 26% (n = 410) of intervention participants reported running out of LPG at some point, the number of times was low (median: 1 day [Q1, Q3: 1, 2]) and mostly limited to the first four months of the COVID-19 pandemic. Most repairs were completed on the same day as problems were reported. Traditional stove use was observed in only 3% of observation visits, and 89% of these observations were followed up with behavioral reinforcement. According to SUMs data, intervention households used their traditional stove a median of 0.4% of all monitored days, and 81% used the traditional stove < 1 day per month. Traditional stove use was slightly higher post-COVID-19 (detected on a median [Q1, Q3] of 0.0% [0.0%, 3.4%] of days) than pre-COVID-19 (0.0% [0.0%, 1.6%] of days). There was no significant difference in intervention adherence pre- and post-birth.

Conclusion: Free stoves and an unlimited supply of LPG fuel delivered to participating homes combined with timely repairs, behavioral messaging, and comprehensive stove use monitoring contributed to high intervention fidelity and near-exclusive LPG use within the HAPIN trial.

1. Introduction

Household air pollution (HAP), caused by the inefficient combustion of polluting fuels such as wood, dung, coal, charcoal, crop residue, and kerosene for household energy needs, was responsible for an estimated 3.2 million premature deaths and 82 million healthy life years lost in 2019 (IEA, Irena, UNSD, World Bank, WHO, 2022). Transitioning to energy sources that are cleaner at the point of use, such as liquefied petroleum gas (LPG), electricity, natural gas, or ethanol, can significantly reduce exposure to HAP (Fandiño-Del-Rio et al., 2022; Chillrud et al., 2021). Exposure to HAP is associated with an array of poor health outcomes, including diabetes, kidney diseases, chronic respiratory diseases, cardiovascular diseases, maternal and neonatal disorders, respiratory infections, and tuberculosis (GBD, 2019; Lee et al., 2020). However, there is a lack of evidence from randomized controlled trials on whether switching to cleaner fuels improves health.

Although some stove intervention trials have found substantial exposure-response relationships between specific air pollutants and health outcomes (Balakrishnan et al., 2023; Smith et al., 2011), most have not demonstrated significant health impacts of the interventions in intention-to-treat analyses (Katz et al., 2020; Jack et al., 2021; Alexander et al., 2018; Clasen et al., 2022). These null findings, however, have largely been ascribed to a lack of exclusive use of the clean fuel stove and HAP exposure levels that remained above both interim target and guideline levels of PM2.5 recommended by the World Health Organization (WHO) (Bruce et al., 2015). Recently, a small (n = 180) randomized controlled trial of an LPG intervention in Peru was able to achieve near exclusive LPG stove use (>98% of total cooking minutes across all stoves in the household were done with LPG) and an average personal exposure to PM2.5 below the WHO interim target 1 in intervention participants (mean of 30 μ g/m³ compared to 98 μ g/m³ in control participants). However, the study found no impact of the stove intervention on blood pressure, lung function, or respiratory symptoms among non-pregnant adult women (Checkley et al., 2021).

The Household Air Pollution Intervention Network (HAPIN) randomized controlled trial sought to assess the effects of an LPG stove and fuel intervention in populations relying chiefly on solid biomass fuels (wood, charcoal, dung, agricultural residue) on four primary outcomes: infant birth weight, stunting at one year of age, and severe pneumonia in children under one year of age, and blood pressure in non-pregnant adult women living in the same household (Clasen et al., 2020). The research questions raised by the trial required high levels of intervention fidelity and adherence in order to reach the levels of HAP believed necessary to achieve health benefits (Johnson and Chiang, 2015). Stoves and an unlimited supply of LPG were accompanied by behavior change approaches to attain as close to exclusive LPG use as possible (Williams et al., 2020b).

We previously reported high levels of intervention fidelity and adherence during pregnancy in the HAPIN trial as part of an assessment of pregnancy and birth outcomes (Quinn et al., 2021). Here, we report on fidelity and adherence during the child's first year of life and over the entire trial period, from LPG stove delivery through the child's first birthday, as well as adherence in the subset of households in which a second non-pregnant adult woman was enrolled (to understand adherence in relation to the blood pressure primary outcome). We also explore the impact of the COVID-19 pandemic on intervention fidelity and adherence.

2. Methods

2.1. Study setting and design

Details on the HAPIN study design have been published separately (Clasen et al., 2020; Williams et al., 2020b). Briefly, we enrolled approximately 800 pregnant women between 9 and 19 weeks of gestation who primarily used biomass fuels for cooking in each of four countries: Jalapa, Guatemala; Puno, Peru; Kayonza, Rwanda; and Tamil Nadu, India. Participants who were randomly assigned to the intervention arm received an LPG stove, free LPG replacement cylinders delivered as needed, behavioral reinforcement to promote exclusive LPG use, and free stove repairs, if required. Control participants were expected to continue relying primarily on biomass cooking fuels. We also enrolled a subset of non-pregnant adult women (aged 40–79 years) living in the same household as the pregnant woman (n = 417).

2.2. Intervention and delivery

Intervention participants received an LPG stove with at least two burners (see Quinn et al., 2021 for details on stove models) together with a continuous supply of free LPG fuel from two exchangeable cylinders (Quinn et al., 2021). Households were instructed to request an LPG refill from the HAPIN study team when the first cylinder in their household ran out, thus, under typical consumption patterns, enabling them to continue cooking using their second cylinder and allowing HAPIN staff up to seven days to complete the refill request. At every LPG delivery visit in Guatemala, Peru, and Rwanda, and at every SUMs download visit in India, HAPIN field staff checked the functionality of the LPG stove and cylinders and recorded their observations in a survey. If a problem was identified, field staff either fixed it immediately or returned as soon as possible to resolve the issue. In between visits, participants were instructed to inform study staff if they had any problems with the LPG equipment. Dates of repair requests and repair completion, including actions taken to complete the repair, were recorded.

Upon LPG stove delivery, all intervention participants received the following behavioral support package: 1) a pledge by which they agreed to cook exclusively with the LPG stove during the trial, 2) training on how to safely operate the LPG equipment, and 3) behavioral messaging and materials to motivate exclusive LPG use and discourage biomass stove use. The messaging on exclusive LPG use was reinforced for any participants who showed evidence of traditional stove use during the trial. During reinforcement visits, participants were asked about their reasons for using the traditional stove and fieldworkers offered suggestions for alternatives.

2.3. Stove use monitoring

We used a combination of stove use monitors (SUMs - data logging temperature sensors), surveys, and visual observations to assess stove use in our trial. Our SUMs monitoring efforts focused on ensuring that traditional stoves in intervention households were not used. This decision was driven by the evidence that traditional stove use must be nearly eliminated (<1 h per week) to achieve clinically significant reductions in HAP (Johnson and Chiang, 2015). As such, we installed SUMs on all traditional stoves in intervention households. The SUMs recorded temperature readings every five minutes throughout the duration of the trial and were downloaded every two weeks. Temperature readings were used to flag cooking events based on temperature increases above identified thresholds that lasted at least five minutes (details on the algorithm are available in Quinn et al. 2021) (Quinn et al., 2021). In the event of device malfunction, we eliminated data that occurred after the error until the faulty SUM was repaired or replaced. We included only households that had at least two weeks of continuous SUMs data during pregnancy and/or the post-birth period (n = 1,095 out of 1,584). We also installed SUMs in a subset of LPG stoves in intervention homes (n = 276) and a subset of traditional stoves in control homes (n = 214).

Surveys asking participants to report which stoves they had used in the prior 24 h were administered with both intervention and control participants, twice during pregnancy (24–28 and 32–36 weeks of gestation) and three times post-birth (when the infant was approximately 3, 6, and 12 months old). Field staff conducted visual observations for evidence of traditional stove use at SUMs download visits in India, Peru, and Rwanda and at all visits in Guatemala. Any signs of recent traditional stove use (i.e., traditional stove being used during the visit, warm to the touch, or with fresh ashes) were recorded, in addition to whether the traditional stove in use had a SUMs installed in it.

2.4. Data analysis

Table 1 shows the indicators and metrics we used to evaluate fidelity and adherence to the intervention. We define fidelity (i.e., the extent to which the intervention was implemented as planned) as fulfillment of continuous LPG fuel delivery, timely repairs to LPG equipment, and behavioral reinforcement of exclusive LPG use. We define adherence as abandonment of traditional biomass stoves and adoption of the LPG stove among intervention participants, continued biomass stove use by control participants, and the extent to which these practices continued during temporary or permanent moves.

For each metric, we calculated the value during pregnancy, during

Table 1

Indicators and metrics used to measure intervention fidelity and adherence.

Measure	Indicator	Metrics of assessment	Data source		
Intervention Fidelity	Continuous LPG fuel delivery	# days between request for refill (or	Surveys		
		identification of refill need by fieldworkers)			
		and LPG cylinder			
		delivery			
		% intervention participants reporting			
		traditional stove use			
		because they ran out of LPG			
	Timeliness of	# and types of repairs	Surveys		
	repairs	made			
		# days between problem identification			
		and successful repair			
		# repairs per intervention			
		participant			
	Behavioral	% intervention	Surveys		
	reinforcement of exclusive LPG use	participants who reported using			
		traditional stove due to			
		problems or concerns with LPG			
		# times intervention			
		participants reported			
		concerns with LPG % intervention			
		participants with			
		observed traditional stove use who later			
		received behavioral			
		reinforcement			
		# days between observation of			
		traditional stove use			
	Discos	and reinforcement visit	CUDA-		
Intervention Adherence	Disuse of traditional stoves	% of days with traditional stove use	SUMs		
	in intervention	% intervention			
	households*	households with no traditional stove use			
		% intervention			
		households with < 1			
		day of traditional stove use per month			
		# days with traditional			
		stove use per month Average minutes of			
		traditional stove use			
		per day	Observations		
		% intervention households where	Observations of traditional stove		
		traditional stove use	use		
		was ever observed # observations of			
		traditional stove use			
		per intervention household			
		% observations			
		indicating traditional			
	LPG stove use by	stove use % intervention	Surveys		
	intervention	participants who			
	participants	reported exclusive LPG use across the study			
		visits			
		% days with LPG stove	SUMs		
		use # days with LPG stove			
		use per month			
		Minutes of LPG stove use per day			

Table 1 (continued)

Measure	Indicator	Metrics of assessment	Data source		
	Biomass stove use by control participants	% control participants who reported exclusive biomass use, mixed use of biomass and LPG, or exclusive LPG use across the study visits	Surveys		
		% days with biomass stove use Minutes of biomass stove use per day	SUMs		
	Impact of temporary or permanent moves on adherence	% intervention participants who used biomass stoves in a new permanent home or temporary home % control participants who used exclusively clean fuel in new permanent or temporary home # days in the new permanent or temporary home	Surveys		

* Note that we refer to intervention adherence at the household level given that the SUMs data do not distinguish which household member(s) are using the stove during flagged use events.

the 12 months of follow-up after birth (infancy period), and across the full trial, by country and overall. We also calculated values for the follow-up that occurred before the onset of the global COVID-19 pandemic ('pre-COVID,' defined here as before March 17, 2020, which was the date across our study regions that best approximates the onset of major disruptions associated with local and national COVID-19 mitigation measures) and 'post-COVID' (March 17, 2020 or later) to assess any potential impact of COVID-19 mitigation strategies on our results. We additionally divided the post-COVID period into early (March 17-July 17, 2020) and late (after July 17, 2020) to assess for any differences between the initial months after the start of the COVID-19 pandemic (when nationally mandated lockdowns were instituted and new operating procedures were being developed) and later months after new routines were established. We used the Kolmogorov-Smirnov (K-S) test to compare differences by COVID-19 period and generalized estimating equations (GEE) in a logistic regression model with repeated measures, and accounting for overdispersion, to compare differences by birth period controlling for COVID-19 period.

Survey data were analyzed using StataSE version 15. SUMs data were analyzed using SAS version 9.4 and R version 4.2.2 (2022–10-31) – "Innocent and Trusting".

3. Results

3.1. Study population

A total of 3,195 participants were enrolled and randomized between May 7, 2018 and February 29, 2020, 1,590 in the intervention group and 1,605 in the control group (see Supplemental Table S12 for demographic characteristics). Follow-up during pregnancy occurred between May 16, 2018 and September 17, 2020. Post-birth follow-up (the infancy period) occurred between September 21, 2018 and September 22, 2021. For the purposes of our analysis, we excluded six intervention participants who exited the study prior to receiving their LPG stove. Intervention participants were followed for nearly twice as many days in the infancy period compared to the pregnancy period, with similar follow-up times across countries (Table 2). Follow-up time was similar for control households (data not shown). Only 224 participants (14%) were still pregnant at the start of the global COVID-19 pandemic on March 17, 2020, with a remaining gestational period of a median 40.5 days (Q1, Q3: 14, 79) after March 17, 2020. A total of 1,324 participants (87%) contributed post-birth follow-up time for a median 237 days (Q1, Q3: 139.5, 345.5) after March 17, 2020.

3.2. Intervention fidelity

3.2.1. Continuous LPG fuel delivery

Across settings, a total of 42,852 visits were made to deliver LPG to households (10,623 during pregnancy and 32,229 post-birth) (Table 2). The median (Q1, Q3) time between request for or identification of the need for a refill and delivery of the LPG cylinder(s) was 1 day (0, 2). Median [Q1, Q3] time between refill request and delivery was highest in India (4 [3, 6] days), where local LPG distributors delivered LPG to households in coordination with the HAPIN team. Overall, 95.6% of LPG deliveries were completed within the 7-day target specified in the protocol. Time between refill request and delivery was lowest in Peru (median [Q1, Q3]: 0 [0, 0]), where fieldworkers often observed that cylinders were empty at SUMs download visits and installed a replacement cylinder at the same visit. Median (Q1, Q3) delivery times were similar during pregnancy (1 day; 0, 2) and post-birth (1 day; 0, 2) (Table 2), as well as pre-COVID (1 day; 0, 3) and post-COVID (1 day; 0, 2) (data not shown).

Overall, 26% of participants reported ever using their traditional stove because they ran out of LPG before a refill was delivered (Supplemental Table S1); however, despite this seemingly large percentage, the median (Q1, Q3) number of times these participants reported running out was low: 1 (1, 2). The percent of participants reporting running out of LPG was highest in Rwanda (67%), followed by Peru (27%) and Guatemala (11%). In India, no participants reported running out of LPG prior to a refill being delivered. Reports of running out of LPG were higher in the post-birth compared to the pre-birth period; however, this is likely due to the COVID-19 pandemic, which started when most participants were in the post-birth period. Fig. 1 indicates that most reports of running out of LPG occurred in the first four months following the COVID-19 shutdowns in March 2020 (mostly from Peru and Rwanda). Instances of running out of LPG were less frequent in the later months of the COVID-19 pandemic once permissions were obtained and/or new operating procedures were established.

3.2.2. Timely repairs and assurance of LPG equipment functionality

Over the course of the study, a total of 1,586 repair visits were made to repair the LPG equipment, with most done the same day as the need for repair was identified (Table 2). Overall, 53% of participants required repairs, with a median (Q1, Q3) of 2 (1, 2) repairs per participant among those who ever received a repair (see Supplemental Table S2 for types of repairs). The need for repairs was lowest in India (11%), followed by Guatemala (46%), Peru (73%), and Rwanda (84%). There were no clear trends in the frequency of stove repairs over time (Supplemental Figure S1).

3.2.3. Behavioral reinforcement of exclusive LPG use

Overall, 43% of intervention participants reported problems, difficulties, or concerns with the LPG stove (including both equipment problems and user perceptions) at any behavioral reinforcement visit (Supplemental Table S1). Issues were more frequently reported in Rwanda (77% of participants ever reported a problem or difficulty), followed by Peru (54%), Guatemala (42%), and India (1%). The percent of participants reporting problems or difficulties was higher in the postbirth period compared to the pre-birth period in Guatemala (38% vs. 15%) and Rwanda (78% vs. 17%), but similar between periods in Peru (37% vs. 37%) and India (0% vs. 1%). Although nearly half of participants reported ever experiencing a problem, difficulty, or concern with the LPG stove, the median (Q1, Q3) number of reports per participant (among those with any reports) was low: 2 (1, 3). The most commonly reported reasons for traditional stove use by country across the full trial are shown in Fig. 2.

Table 2

Average time in the study, stove repairs, and LPG deliveries for intervention participants during pregnancy ("preg"), the post-birth or infancy period ("infcy"), and total across the full trial ("full").

Study period in relation to the baby's birth	Guatemala			India			Peru			Rwanda			Total		
	Preg	Infcy	Full												
N Intervention Participants	400	382	400	398	384	398	394	379	394	392	372	392	1584	1517	1584
Median number of days in study period, (Q1, Q3)	150 (130, 167)	394 (383, 408)	545 (521, 562)	139 (120, 157)	373 (366, 384)	514 (494, 534)	153 (133, 176)	386 (377, 394)	541 (517, 564)	153 (135, 170)	395 (377, 421)	549 (522, 580)	149 (129, 168)	386 (374, 401)	536 (511, 560)
# (%) of intervention participants who ever received a stove repair	46 (12)	166 (43)	182 (46)	22 (6)	25 (7)	45 (11)	56 (14)	274 (72)	286 (73)	68 (17)	317 (85)	330 (84)	192 (12)	782 (52)	843 (53)
Median (Q1, Q3) # of stove repairs received per participant, among those with any repair	1 (1,1)	1 (1,2)	1 (1,2)	1 (1,1)	1 (1,1)	1 (1,1)	1 (1,1)	1 (1,2)	2 (1, 2)	1 (1,1)	2 (1,2)	2 (1,3)	1 (1,1)	1 (1,2)	2 (1,2)
Total repair visits made	58	290	348	22	28	50	64	483	547	74	567	641	218	1368	1586
Median (Q1, Q3) days between repair identification/ request and successful repair	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)	0 (0, 0.5)	0 (0,0)									
Total LPG delivery visits made*	4950	14673	19623	846	3423	4269	3293	9032	12325	1534	5101	6635	10623	32229	42852
Median (Q1, Q3) days between delivery identification/ request and successful delivery	2 (1,3)	2 (1,3)	2 (1,3)	5 (3,8)	4 (3,6)	4 (3,6)	0 (0,0)	0 (0,0)	0 (0,0)	1 (0,2)	1 (0,3)	1 (0,2)	1 (0,2)	1 (0,2)	1 (0,2)

* Note that LPG cylinder sizes differed by country: 11.3 kg in Guatemala, 14.2 kg in India, 10 kg in Peru, and 12 or 15 kg in Rwanda.

Eighty-nine percent (n = 1,346) of observations of traditional stove use were followed up with a behavioral reinforcement visit (Supplemental Table S3). The median (Q1, Q3) number of days between observation of traditional stove use and the reinforcement visit was 9 (0, 56).

3.3. Intervention adherence

3.3.1. Disuse of traditional stoves in intervention households

Traditional stoves were successfully monitored by a SUM in 96% (n = 1,039) and 86% (n = 877) of intervention households with a traditional stove during pregnancy and post-birth, respectively (Supplemental Table S4). A total of 218 participants had SUMs data only in pregnancy, 56 only post-birth, and 821 in both pregnancy and post-birth, for a total of 1,095 intervention households with traditional stoves monitored by SUMs at some point during the trial. In households with SUMs installed, the SUMs successfully recorded data for the majority of follow-up time: 84.3% of days between each participant's date of LPG stove delivery and their exit date were monitored by SUMs was lower in Guatemala because many participants destroyed their traditional stove and thus only had SUMs data from a small percentage of their total time in the study.

Over the full trial, intervention households with SUMs installed rarely used their traditional stove, for a median (Q1, Q3) of 0.4% (0.0%,

2.3%) of monitored days (Table 3, Supplemental Table S5). The median percent of days in which the traditional stove was used was slightly higher in Peru (0.8%) and Rwanda (0.8%) than in Guatemala (0.0%) and India (0.0%), but consistently low overall. Although a few intervention households used their traditional stoves more frequently (Fig. 3; Supplemental Figures S2, S3), 85% either removed their traditional stove (29%), never used their traditional stove (29%), or used their traditional stove on less than one day out of every 30 days (27%) (Supplemental Figure S4). Households with SUMs had a median (Q1, Q3) of 0.1 (0.0, 0.7) days with TSU per 30 days of monitoring (Table 3). On days with any traditional stove use, intervention participants spent a median (Q1, Q3) of 105.3 (55.8, 168.1) minutes cooking with the traditional stove. Results were similar in the subset of households with a non-pregnant adult woman enrolled (aged 40–79 years; n = 143 with SUMs monitoring): traditional stove use was detected on a median (Q1, Q3) of 0.4% (0.0%, 3.6%) of monitored days and 0.1 days (0.0, 1.1) per 30 days of monitoring (Supplemental Table S6).

After controlling for COVID-19, there were no statistically significant differences in traditional stove use during the pregnancy period (median 0.0% [Q1, Q3: 0.0%, 1.6%]) as compared to the infancy period (median 0.3% [Q1, Q3: 0.0%, 2.3%]) (odds ratio = 1.11 [CI: 0.95–1.30], p = 0.1866) (Table 3, Fig. 4). The onset of the COVID-19 pandemic was associated with a statistically significant increase in traditional stove use among some users, but medians remained the same at 0.0% during the pre-COVID-19 period (Q1, Q3: 0.0%, 1.6%) and 0.0% during the post-

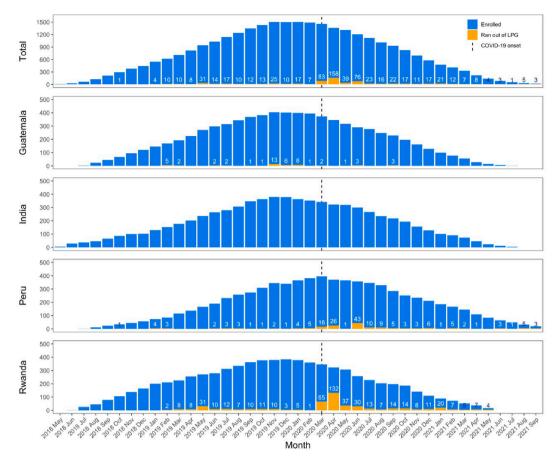


Fig. 1. Number of participants reporting running out of LPG out of all enrolled intervention participants by month. Dashed line indicates onset of the global COVID-19 pandemic (March 17, 2020).

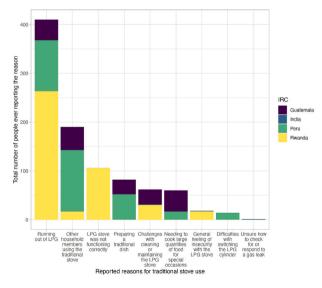


Fig. 2. Top reasons for traditional stove use (including the top five reported reasons from each country), showing the total number of people who ever reported each reason by country. Bars for India are very small given that very few people ever reported a problem or concern about LPG (n = 3).

COVID-19 period (Q1, Q3: 0.0%, 3.4%) (Supplemental Table S7) (KS test D = 0.12, p < 0.001). More people had a significantly greater proportion of days with traditional stove use in the first four months after the start of the COVID-19 pandemic (median: 0.0%; Q1, Q3: 0.0%, 3.5%) compared to later months of the COVID-19 period (median: 0.0%; Q1,

Q3: 0.0%, 1.5%) (Fig. 4, Supplemental Table S8) (KS test D = 0.12, p = 0.001).

Nearly all intervention participants (1,575/1,584 or 99%) received at least one visit in which fieldworkers looked for signs of any traditional stove use, with a median (Q1, Q3) of 29 (23, 34) observation visits per participant over the course of the trial (Supplemental Table S9). A total of 55,241 observation visits were made, of which only 1,506 (3%) indicated recent traditional stove use (Supplemental Table S3). Observations indicating traditional stove use were rare in India (only 5 participants [1.3%] were ever observed to have used their traditional stove recently) (Supplemental Table S9). Although more participants were observed to have ever used their traditional stove in Guatemala (n = 224; 56%), Peru (n = 202; 51%), and Rwanda (n = 229; 58%), the median (Q1, Q3) number of traditional stove use observations per participant among those with any observed use was low: 2 (1, 3) observations per participant (excluding India). Overall, among participants with any observations of traditional stove use, traditional stove use was only observed in a median (Q1, Q3) of 4.5% (3%, 9%) of observation visits.

Most traditional stoves that were observed to have been recently used had a SUMs installed (64%) (Supplemental Table S3), suggesting that most traditional stove use events were captured and reflected in the SUMs data. For households with no SUMs data, traditional stove use was rarely observed, for a median (Q1, Q3) of 0 (0, 0) times out of a median of 10 observations in pregnancy and 22 in the post-birth period (Supplemental Table S10).

3.3.2. Use of the LPG stove in intervention households

In the subset of 276 intervention households who had SUMs installed on their LPG stoves, LPG use was detected on a median (Q1, Q3) of

Table 3

Traditional stove use (TSU) by intervention participants based on SUMs data during pregnancy ("preg"), the post-birth or infancy period ("infcy"), and total across the full trial ("full").

Study period in relation to the baby's birth	Guatemala			India			Peru			Rwanda			Total		
	Preg	Infcy	Full	Preg	Infcy	Full	Preg	Infcy	Full	Preg	Infcy	Full	Preg	Infcy	Full
Total households with valid SUMs data	133	102	164	182	139	184	385	304	387	339	332	360	1039	877	1095
Proportion of follow-up time	69.5 (21.5, 100)	92.3 (40.6, 99.5)	35.5 (8.7, 95.4)	100 (81.7, 100)	99.5 (87.6, 99.7)	95.8 (43.2, 99.8)	100 (98.1, 100)	99.0 (56.7, 99.7)	94.6 (40.9, 99.8)	100 (69, 100)	86.6 (64.1, 99.5)	84.0 (65.4, 96.1)	100 (76.7, 100)	95.8 (61.4, 99.7)	84.3 (42.2, 99.5)
monitored by SUMs: median (Q1, Q3)		,												,	
Percent of	0.0	0.5	0.0	0.0	0.0	0.0	0.6	0.5	0.8	0.0	0.8	0.8	0.0	0.3	0.4
monitored	(0.0,	(0.0,	(0.0,	(0.0,	(0.0,	(0.0,	(0.0,	(0.0,	(0.0,	(0.0,	(0.0,	(0.0,	(0.0,	(0.0,	(0.0,
days with TSU detected: median (Q1, Q3)	0.0)	3.9)	2.0)	0.0)	0.0)	0.2)	3.4)	3.3)	4.2)	1.3)	2.3)	2.1)	1.6)	2.3)	2.3)
Avg # days	0.0	0.1	0.0	0.0	0.0	0.0	0.2	0.1	0.2	0.0	0.2	0.2	0.0	0.1	0.1
with TSU per 30 days of monitoring: median (Q1, Q3)	(0.0, 0.0)	(0.0, 1.2)	(0.0, 0.6)	(0.0, 0.0)	(0.0, 0.0)	(0.0, 0.1)	(0.0, 1.0)	(0.0, 1.0)	(0.0, 1.3)	(0.0, 0.4)	(0.0, 0.7)	(0.0, 0.6)	(0.0, 0.5)	(0.0, 0.7)	(0.0, 0.7)
Traditional	143.5	139.0	142.0	85.0	42.5	78.1	93.7	103	101.5	82.2	115.0	113.6	90.8	109.2	105.3
stove cooking minutes per day among those with TSU: median	(44.4, 380.2)	(523.5, 218.2)	(52.5, 244.1)	(48.9, 121.5)	(18.1, 135.6)	(30.7, 123.5)	(54.0, 131.7)	(61.0, 156.2)	(65.0, 144.5)	(45.0, 153.3)	(58.8, 189.1)	(57.1, 182.5)	(47.5, 141.9)	(53.0, 184.0)	(55.8, 168.1)

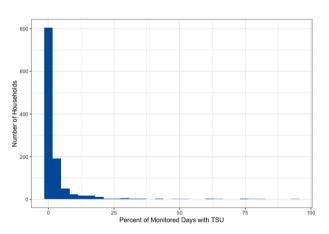


Fig. 3. Frequency of the percent of stove-use-monitored days in which traditional stove use (TSU) was detected via stove use monitors (SUMs) in intervention households over the full trial period.

95.2% (87.8%, 98.6%) of all monitored days. The LPG stove was used for a median (Q1, Q3) of 28.6 (26.3, 29.6) days per 30 days of monitoring and 260.9 (204.2, 325.4) minutes of use per day. Self-reported data showed that intervention participants reported using LPG exclusively the preceding day in the majority of pregnancy and post-birth survey visits (96.6%) (Fig. 5). Nearly 90% of participants reported using LPG exclusively in all survey visits, and 99.3% of participants reported exclusive LPG use in 75% or more of survey visits.

3.3.3. Use of biomass and LPG stoves in control households

Across all study visits in pregnancy and post-birth, control participants in Guatemala, India, and Rwanda reported exclusive use of biomass (97.9%) or a mix of LPG and biomass (0.3%) (Fig. 5). In Peru, control participants reported some use of biomass in 76% of all visits (42% exclusive and 34% mixed); although 24% of all visits indicated exclusive LPG use, only 17 participants (4.5%) reported exclusive LPG use at every survey visit. Across all countries, approximately 84% of control participants reported using biomass in all survey visits, and 91.1% reported using biomass in 75% or more of survey visits. In the subset of control households with SUMs installed in traditional stoves (n = 214), traditional stove use was recorded on a median (Q1, Q3) of 69.3% (43.4%, 87.8%) of monitored days and used for 245.7 (165.5, 334.4) minutes per day of use.

3.3.4. Impact of temporary or permanent moves on adherence

Overall, 22% of intervention participants and 23% of control participants moved to either a temporary or permanent home during the trial (Supplemental Table S11). Most intervention participants continued using LPG exclusively in their new or temporary home (95%), and most control participants continued using biomass either primarily or secondarily in their new or temporary home (96.5%).

4. Discussion

The research questions that the HAPIN trial sought to answer required an understanding of the intervention fidelity and adherence. To achieve the highest possible adherence, special steps were undertaken, including free LPG stoves and fuel delivered directly to the home, timely repairs, locally tailored behavioral messaging, and comprehensive stove

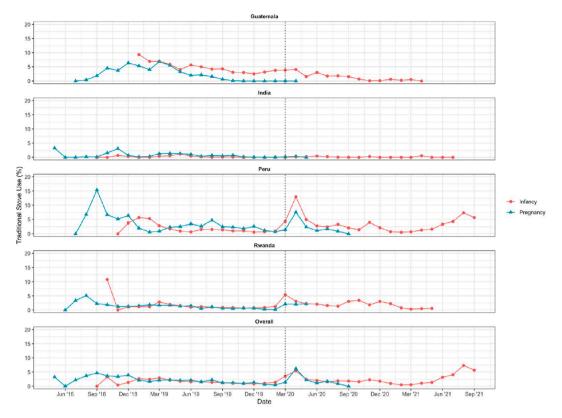


Fig. 4. Percent of monitored days with traditional stove use as recorded by SUMs by calendar month during pregnancy and post-birth ("infancy") periods, by country and overall among intervention participants. The dashed line indicates the onset of the COVID-19 pandemic, which began March 17, 2020 (shown at the March'20 position given that all March data was aggregated into one point).

use monitoring. The trial achieved high fidelity to implementation of these intervention components, which were successful in contributing to high intervention adherence by intervention participants throughout the 18-month trial period, while most control participants continued to use primarily biomass fuels for cooking. The level of adherence to LPG stove use achieved among the intervention participants in the HAPIN trial aligns with that observed in a smaller scale randomized controlled LPG intervention in Peru (Checkley et al., 2021), and is much higher than has been reported in other clean cooking trials (Katz et al., 2020; Carrión et al., 2020; Aung et al., 2018).

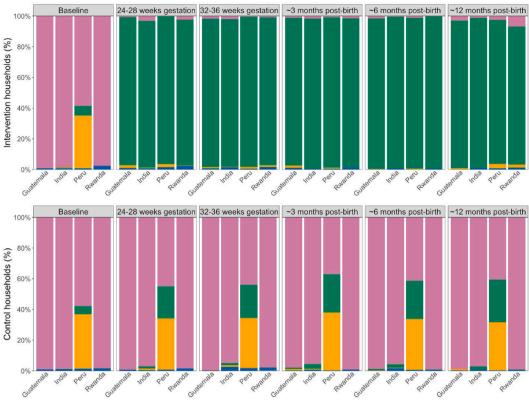
Our study did not find that adherence to exclusive LPG use was significantly different during pregnancy compared to post-birth. This contrasts with Carrión et al. (2020), who found that LPG stove use was higher during pregnancy compared to during the infant's first year of life in a randomized controlled trial in Ghana (95.4% reported using the LPG stove for the main meal the previous day during pregnancy, compared to 82.8% over one year post-birth) (Carrión et al., 2020). Although we found that traditional stove use was slightly higher post-birth compared to during pregnancy, this was likely an effect of COVID-19 given that most participants were already in or near the post-birth follow-up period when the COVID-19 shutdown began. Indeed, after controlling for the COVID-19 pandemic, differences in adherence between pregnancy and post-birth periods were non-significant.

Notably, we found that participants in India had higher adherence (both in terms of traditional stove use flagged by SUMs and by observations), fewer reports of problems or concerns with LPG, and fewer documented stove repairs than in Peru, Guatemala, or Rwanda. Greater exclusivity of LPG use in India may have been driven by enhanced awareness of and motivation to use LPG in the country due to national policies, such as the Pradhan Mantri Ujjwala Yojana (PMUY) LPG subsidization program for households below the poverty line (Gill-Wiehl et al., 2022; Ravindra et al., 2021). Additionally, because LPG was delivered by local distributors in India, they may have made simple stove or tank repairs or addressed small concerns that were not reported to the study team, thus resulting in a lower number of documented repairs and reported problems in India compared to other countries where study staff made LPG deliveries.

Our results indicate that the COVID-19 pandemic temporarily impacted the timely delivery of LPG (mainly in Peru and Rwanda), contributing to slightly higher traditional stove use during this period. Nonetheless, traditional stove use remained extremely low overall. Our findings suggest that the impacts of the COVID-19 pandemic were mainly limited to the first four months of the pandemic, and that this did not jeopardize the high rate of fidelity and adherence achieved.

Our field teams' frequent observations for traditional stove use aligned with the adherence data obtained from the SUMs. Across over 55,000 observations made, only 3% indicated any traditional stove use and only 1% indicated use of a traditional stove that did not have a SUMs installed. Additionally, in households lacking SUMs data either due to removal of the traditional stove or missing data, observations rarely indicated any traditional stove use. Also, our tracking of household moves showed that most participants continued to use the stove indicated by their assigned randomization group.

Factors driving the high rates of adherence to LPG use observed among our intervention participants may include the study's rapid delivery of free LPG in response to refill needs (with deliveries completed in a median of 1 day from the time of request), provision of behavioral reinforcement to participants who used their traditional stove (89% of traditional stove use events were followed up with behavioral reinforcement), and timely completion of repairs to LPG equipment (with repairs completed in a median of 0 days from the time that the need for a repair was identified). Additionally, the extensive training and education provided to participants at the beginning of the study and the participants' completion of pledges to use the LPG stove for all



Biomass LPG Biomass + LPG No cooking Other clean

Fig. 5. Self-reported stove use in the 24-hours preceding the survey at baseline, 24–28 and 32–36 weeks gestation, and 3, 6, and 12 months post-birth among intervention and control participants. Pink represents exclusive biomass use; green, exclusive LPG use; orange, mixed use of biomass and LPG; dark blue, no cooking; and light blue, cooking with other clean technologies such as electric stoves. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

household cooking needs may have also motivated high adherence, as reported in Quinn et al. (2021) (Quinn et al., 2021). Another research trial in Peru that also reported high adoption of LPG similarly found that behavioral training and reinforcement, as well as support from field-workers, motivated LPG use (Williams et al., 2020a).

Overall, we found that occasional traditional stove use was mainly driven by factors outside of the participants' control (i.e. running out of LPG, other household members using the traditional stove, or problems with the LPG stove); cultural traditions and taste preferences were less commonly cited as reasons for using the traditional stove, suggesting that such factors, which have been previously believed to influence adoption decisions (Puzzolo et al., 2016), are no longer significant when financial and structural barriers to LPG use are removed. Our study found that other household members using the traditional stove was among the top five reasons for traditional stove use across all four countries. This indicates that a large portion of the traditional stove use flagged in our study may have been done by someone else in the household other than the pregnant woman/mother. Thus, our adherence estimates may overestimate the extent to which the pregnant women/mothers were using and directly exposed to the emissions of the traditional stoves. Additionally, as similarly reported by Williams et al. (2020) (Williams et al., 2020a), LPG delivery delays, resulting in participants running out of LPG, also triggered some traditional stove use. Problems with the LPG stove also resulted in some traditional stove use while waiting for repairs or behavioral support on specific issues.

We found a fairly consistent need for stove and equipment repairs over time, despite the fact that stove models selected were all expected to be of high quality, durable, and compatible with local cooking needs based on formative research and pilot results (Liao et al., 2021; Williams et al., 2020b). This indicates that programs seeking to distribute or promote LPG stoves must ensure the infrastructure is available and affordable for continued repair and maintenance to ensure continued stove functionality, as highlighted by Gould et al. (2018) (Gould et al., 2018). However, the need for complete stove replacement was rare, suggesting that with continuous maintenance and small repairs, the stoves were sufficiently durable to last throughout the trial.

Strengths of our study include use of multiple sources of adherence data to assess consistency (i.e., direct-reading instruments, self-report, and observations), bi-weekly visits to households to verify placement and download SUMs data to limit any data loss, checking LPG stoves twice monthly to ensure functionality, and systematic tracking of intervention implementation (i.e., LPG delivery, repairs, and behavioral reinforcement). However, several limitations to our fidelity and adherence data should be noted. First, although we deployed high quality SUMs with continuous tracking through an online dashboard (Wilson et al., 2020), it is possible that some traditional stove use events may have been missed or that some non-events may have been erroneously flagged as use. Additionally, some participants may have used unmonitored traditional stoves not observed by fieldworkers. Observations and stove use surveys typically occurred on weekdays, meaning weekend use may have been less likely to be captured through these methods (although SUMs were continuously in place and thus captured both weekday and weekend use). Our extensive follow-up and examination of multiple adherence data sources suggests that unmonitored traditional stove use was infrequent. Second, national shutdowns due to the COVID-19 pandemic, which began partway through our trial, necessitated some adjustments and adaptations to trial implementation. Although we adapted study procedures and data collection methods to align with global safety protocols as described in Simkovich et al. (2021) (Simkovich et al., 2021), there were some delays and interruptions to fidelity as new procedures were established. Despite these, however, overall fidelity and adherence remained high.

5. Conclusion

In contrast to previous studies where uptake and use of clean cooking was sub-optimal, we show that LMIC householders adopt and use LPG fuels almost exclusively with behavior change and programmatic support when they do not face the challenges of affordability and access. This laid the groundwork for other HAPIN research to show that such levels of uptake can deliver exposure reductions that meet WHO targets (Johnson et al., 2022). In this way, our research indicates the importance of addressing issues related to affordability and access as key for enhancing exclusivity of LPG use within real-world clean fuel interventions.

Institutional Review Board Statement

The study protocol was reviewed and approved by institutional review boards (IRBs) or Ethics Committees at Emory University (00089799), Johns Hopkins University (00007403), Sri Ramachandra Institute of Higher Education and Research (IEC-N1/16/JUL/54/49) and the Indian Council of Medical Research – Health Ministry Screening Committee (5/8/4-30/(Env)/Indo-US/2016-NCD-I), Universidad del Valle de Guatemala (146-08-2016) and Guatemalan Ministry of Health National Ethics Committee (11-2016), Asociación Beneficia PRISMA (CE2981.17), the London School of Hygiene and Tropical Medicine (11664-5) and the Rwandan National Ethics Committee (No.357/ RNEC/2018), and Washington University in St. Louis (201611159). The study was registered with ClinicalTrials.gov (Identifier NCT02944682). Informed consent was obtained from all participants.

CRediT authorship contribution statement

Kendra N. Williams: Conceptualization, Methodology, Formal analysis, Data curation, Supervision, Writing - original draft. Ashlinn Quinn: Conceptualization, Methodology, Formal analysis, Data curation, Writing - review & editing, Visualization. Hayley North: Formal analysis, Data curation, Writing - review & editing, Visualization. Jiantong Wang: Formal analysis, Data curation, Writing - review & editing, Visualization. Ajay Pillarisetti: Conceptualization, Methodology, Formal analysis, Data curation, Writing - review & editing, Visualization. Lisa M. Thompson: Conceptualization, Methodology, Writing - review & editing, Supervision. Anaité Díaz-Artiga: Conceptualization, Methodology, Writing - review & editing, Supervision, Kalpana Balakrishnan: Conceptualization, Methodology, Writing - review & editing, Supervision. Gurusamy Thangavel: Conceptualization, Methodology, Writing - review & editing, Supervision. Ghislaine Rosa: Conceptualization, Methodology, Writing - review & editing, Supervision. Florien Ndagijimana: Investigation, Project administration. Lindsay J. Underhill: Writing - review & editing. Miles A. Kirby: Writing - review & editing. Elisa Puzzolo: Conceptualization, Methodology, Writing - review & editing, Supervision. Shakir Hossen: Formal analysis, Data curation, Writing - review & editing, Visualization. Lance A. Waller: Conceptualization, Methodology, Writing - review & editing, Supervision. Jennifer L. Peel: Conceptualization, Methodology, Writing - review & editing, Supervision, Project administration, Funding acquisition. Joshua P. Rosenthal: Conceptualization, Methodology, Writing - review & editing, Supervision. Thomas F. Clasen: Conceptualization, Methodology, Writing - review & editing, Supervision, Project administration, Funding acquisition. Steven A. Harvey: Conceptualization, Methodology, Writing - review & editing, Supervision. William Checkley: Conceptualization, Methodology, Writing - review & editing, Supervision, Project administration, Funding acquisition.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

Acknowledgements

The HAPIN trial was funded by the U.S. National Institutes of Health (NIH; cooperative agreement 1UM1HL134590) in collaboration with the Bill & Melinda Gates Foundation (OPP1131279). A multidisciplinary, independent Data and Safety Monitoring Board (DSMB) appointed by the National Heart, Lung, and Blood Institute (NHLBI) monitored the quality of the data and protected the safety of patients enrolled in the HAPIN trial. NHLBI DSMB: Catherine Karr (Chair), Nancy R. Cook, Stephen Hecht, Joseph Millum, Nalini Sathiakumar, Paul K. Whelton, Gail Weinmann, and Thomas Croxton (Executive Secretaries). Program Coordination: Gail Rodgers, Bill & Melinda Gates Foundation; Claudia L. Thompson, National Institute of Environmental Health Science; Mark J. Parascandola, National Cancer Institute; Marion Koso-Thomas, Eunice Kennedy Shriver National Institute of Child Health and Human Development; Joshua P. Rosenthal, Fogarty International Center; Concepcion R. Nierras, NIH Office of Strategic Coordination Common Fund; Katherine Kavounis, Dong- Yun Kim, Antonello Punturieri, and Barry S. Schmetter, NHLBI. The investigators would like to thank the Drs. Patrick Breysse, Donna Spiegelman, and Joel Kaufman (members of the advisory committee) for their valuable insight and guidance throughout the implementation of the trial. We also wish to acknowledge all the research staff and study participants for their dedication to and participation in this important trial. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the US National Institutes of Health or Department of Health and Human Services. Under the grant conditions of the Bill & Melinda Gates Foundation, a Creative Commons Attribution 4.0 Generic License has already been assigned to the Author Accepted Manuscript version that might arise from this submission. The data that support the findings of this study are available from the corresponding author upon reasonable request.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.envint.2023.108160.

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