## Articles

## Effect of low-cost kitchen with improved cookstove on birthweight of neonates in Shahjadpur, Bangladesh: a cluster-randomised controlled trial

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## Summary

Background Smoke from biomass fuels used for cooking in traditional cookstoves contains a variety of healthdamaging pollutants. Inhalation of these pollutants by pregnant women has been linked to abnormal foetal development and adverse pregnancy outcomes, including low birthweight (LBW). There is a dearth of data on environmental interventions that have the potential to reduce exposure to biomass fuel during pregnancy and improve birth outcomes. International Centre for Diarrheal Disease Research, Bangladesh (icddr,b) therefore, designed a low-cost kitchen with an improved cookstove and examined the impact of this intervention on the birthweight of neonates.

Methods icddr,b conducted a cluster-randomised controlled trial of a 'low-cost kitchen with improved cookstove' intervention among 1,267 pregnant women who used traditional cookstoves in a rural sub-district of Bangladesh. All participants were enrolled during the first trimester of pregnancy among 104 randomly selected clusters after obtaining informed consent. The model kitchens were installed in 628 participants' households of the intervention group, and 639 participants continued to use traditional cookstoves as the control group. The primary outcome was the proportion of LBW neonates between the intervention and control groups. The study also examined if the intervention would reduce CO exposure, measured by the differences in maternal blood carbon monoxide saturation (SpCO) levels and prevalence of LBW in neonates. We performed a generalized structural equation model for jointly assessing the simultaneous relationships of biomass fuel exposure to LBW of neonates and the relationships of LBW of neonates to maternal blood SpCO level. This trial was registered with ClinicalTrials.gov (NCT02923882).

Findings We found that in the intervention group using 'low-cost kitchen with improved cookstove', the risk of LBW reduced by 37% (adjusted risk ratio: 0.63, 95% CI [0.45, 0.89]). Between the second and third trimester, the mean maternal blood SpCO level was significantly reduced from 10.4% to 8.9% (p-value <0.01) in the intervention group but remained unchanged in the control group (11.6% and 11.5%). Of the total effects of the intervention on the risk of LBW, 48.3% was mediated through maternal blood SpCO level.

Interpretation The risk of LBW among rural neonates was reduced in the intervention group using 'low-cost kitchen with improved cookstove', which may be attributed to the reduction in maternal blood SpCO level. Additional research is needed to identify other mechanisms through which biomass fuel exposure might lead to adverse pregnancy outcomes.

Funding Grand Challenges Canada: Rising Stars in Global Health Programme.

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The Lancet Regional Health - Southeast Asia 2024;25: 100342 Published Online 3 January 2024 https://doi.org/10. 1016/j.lansea.2023. 100342

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Keywords: Low birthweight; Carbon monoxide; SpCO; Cluster randomised controlled trial; Low-cost kitchen; Improved cookstove

## Research in context

#### Evidence before this study

We conducted a systematic searching to determine the efficacy of a community-based improved cookstove intervention on adverse pregnancy outcomes (including low birthweight [LBW] neonates) in rural communities. In PubMed, we used the search string (birth weight OR low birth weight OR LBW) AND (indoor air OR biomass OR cooking fuel OR wood smoke). We found five papers published between 2000 and 2012<sup>1-5</sup> appropriate for household air pollution and about adverse pregnancy outcomes, including LBW in lowincome and middle-income countries (LMICs). We found that biomass fuel exposure significantly increases the risk of LBW. The evidence demonstrates the need for a well-designed intervention trial with observational assessment across all the trimesters. During the systematic searching, we found another paper<sup>6</sup> that did a meta-analysis on the effect of biomass fuel exposure on birthweight and infant mortality. We emphasised further randomised control intervention trials to strengthen the evidence on the effect of biomass fuel exposure on pregnancy outcomes.

## Added value of this study

Before our 'low-cost kitchen with improved cookstove' intervention, the only RESPIRE study<sup>4</sup> was a chimney stove trial among pregnant women at different trimesters and identified the relationship between maternal exposure and

## Introduction

Globally, an estimated 20.5 million infants are born each year with low birthweight (LBW), defined as weight at birth of less than 2,500 g.<sup>7</sup> The LBW neonate, usually caused by preterm births or born small for gestational age (SGA), account for approximately 15.9% of global neonatal deaths.<sup>8</sup> The LBW neonates also contribute to infant mortality as well as mortality in adulthood and those who survive, grow with a higher risk of impaired neurodevelopment and learning disabilities.<sup>9,10</sup>

In Bangladesh, the rate of LBW is 23%, which causes Bangladesh to top the world ranking in terms of having the prevalence of LBW neonates.<sup>11,12</sup> Household air pollution (HAP) exposure during pregnancy is increasingly recognized as an important but underexplored risk factor for LBW neonates.<sup>1-3,13-17</sup> Pregnant women in Bangladesh, especially in rural areas, also have high levels of air pollution exposure, primarily due to the use of traditional cookstoves with poor ventilation systems inside the houses.<sup>18</sup> These traditional cookstoves burn biomass fuels such as wood, crop residue, and animal dung and emit a complex mixture of air pollutants, including gases such as carbon monoxide (CO), sulphur birthweight of the neonates among the sub-sample based on the use of cookstove during the observation period at pregnancy and not based on randomisation and found 36.0% reduction of LBW prevalence among the sub-sample. The relationship between maternal exposure and birth outcomes is not straightforward. Our study implemented the intervention 'low-cost kitchen with improved cookstove' among the intervention group at a similar period of gestational age of 8–12 weeks and measured the concurrent associations of the intervention and prevalence of LBW neonate, maternal blood carbon monoxide saturation (SpCO) level and relationship of prevalence of LBW neonate and maternal blood SpCO levels among the whole sample.

#### Implications of all the available evidence

Our study shows that reducing biomass fuel exposure during pregnancy through the use of a low-cost healthier kitchen with improved cookstove reduces adverse pregnancy outcomes, such as LBW prevalence among rural neonates. Moreover, maternal blood SpCO level has been detected as an important factor for controlling adverse pregnancy outcomes and neonate's birthweight. Additional and larger studies can contribute to the global knowledge gaps around the interventions for reducing household air pollution levels and improving pregnancy outcomes in LMICs.

dioxide (SO<sub>2</sub>), and nitrogen dioxide (NO<sub>2</sub>) as well as different sized particulate matter (PM) due to incomplete combustion.<sup>19–21</sup> Two studies conducted in Nepal documented high HAP concentrations in kitchens using biomass fuel, 13.7 and 741  $\mu$ g/m<sup>3</sup> parts per million (ppm) for CO and PM<sub>2.5</sub> respectively.<sup>22,23</sup> Another study done in Bangladesh during 2016–2019 found that the average PM<sub>2.5</sub> and Black Carbon concentration was 141.0  $\mu$ gm<sup>-3</sup> and 13.8  $\mu$ gm<sup>-3</sup> for females, and 91.7  $\mu$ gm<sup>-3</sup> and 10.1  $\mu$ gm<sup>-3</sup> for males in 24-h span, respectively.<sup>24</sup> The exposure to this high amount of air pollutants is associated with a distinct range of comorbidities.<sup>24–26</sup>

Household air pollution increases airway inflammation, and inflammatory mediators are absorbed into the bloodstream, leading to placental inflammation.<sup>26</sup> Household air pollution exposure during the first and third trimesters has been closely linked to LBW neonates,<sup>6,14,15</sup> presumably because the placenta is formed during the first trimester and the majority of foetal nutrient transfer occurs during the third trimester.<sup>27</sup> Exposure to high levels of CO, in particular, has been directly related to LBW neonates.<sup>28</sup> CO binds to haemoglobin to form carboxyhaemoglobin, which reduces the oxygen-carrying capacity of the blood. CO can cross the placenta, and because foetal haemoglobin has 10 times more affinity for binding CO than adult haemoglobin a developing foetus exposed to CO can be deprived of adequate oxygen supply, leading to intrauterine growth restriction and increased risk of LBW.29,30 Recently few studies explored association between HAP and neonatal outcomes. A study conducted in Ghana recently found out 1 PPM increase in prenatal CO exposure in women during pregnancy is associated with reduced birthweight, and length.<sup>31</sup> Another multi-country study the Household Air Pollution Intervention Network (HAPIN) trial also found out that replacing solid fuel based cookstove with liquefied petroleum gas based cookstove has positive impact on healthy birthweight of neonate, and low incidence of blood pressure and acute lower respiratory infections.32

Despite growing literature linking air pollutants from cookstoves to LBW, very few interventions have been tested through well-designed trials to offer a locally produced low-cost solution to reduce the risk associated with biomass fuel exposure during cooking for mothers and their neonates.<sup>33</sup> Therefore, we have undertaken an evaluation of this 'low-cost kitchen with improved cookstove' (Supplementary Figure S1) intervention in rural Bangladesh.

According to prior research, assessing effectiveness of any intervention at cluster level is required to carry out the cluster-randomised controlled trial (cluster-RCT).4,33 We chose cluster-RCT over individual RCT since the phenomenon of interest (LBW outcome) affects individuals but many determinants of LBW outcome such as exposure to HAP occur in the community level. The other reason for using the cluster randomisation is to avoid the effects of individual level contamination. Hence, in this paper we presented the results obtained from a cluster-RCT to assess the prevalence of LBW neonate in pregnant women who used traditional cookstoves versus those who used the 'lowcost kitchen with improved cookstove'. Non-invasive maternal blood carbon monoxide saturation (SpCO) level in intervention and control groups as a secondary outcome has been reported in this paper. We also assessed the mediational role of maternal blood SpCO level on risk of having LBW neonate.

## Methods

#### Trial design

Over a 15-months period, from April 2013 to June 2014, we enrolled 1,267 pregnant women into a clusterrandomised controlled trial of the 'low-cost kitchen with improved cookstove', and followed them up to 42days postpartum in rural Bangladesh. The allocation ratio was 1:1. We measured the pregnancy profiles of women and observed their birth outcomes. The study was conducted in Shahjadpur sub-district of Sirajganj district, which is about 180 km northwest of Dhaka, the capital city of Bangladesh. Shahjadpur is predominately a rural area, and in almost all households' women are primarily responsible for cooking and use biomass fuels in traditional cookstoves.

#### Ethical review and approval

Ethical approval for this study was obtained from the Research Review Committee (RRC) and Ethical Review Committee (ERC) of the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b), a multidisciplinary international research institution situated in Dhaka, Bangladesh. Informed written consent was received from all the participants. The study had no more than minimal risk to the study participants. The field research team routinely visited the intervention households to assess the performance of the improved cookstove and identify any chance of operational hazard. This trial was registered with ClinicalTrials.gov, NCT02923882.

## Enrolment and eligibility criteria

We enrolled 1,267 women in the study, and of them, 628 and 639 were assigned in intervention and control groups, respectively. Women were eligible to participate if they were pregnant with a gestational age of 8–12 weeks and were using a traditional cookstove before the enrolment. Pregnant women with more than 12 weeks of gestation were excluded from the study. We obtained the verbal and written consent of the women and the household head before we started the study.

## Randomisation and masking

A single-stage cluster sampling was followed for randomisation. All the 'mouzas' (revenue villages) in eight unions of Shahjadpur sub-district were divided into clusters so that each cluster contained a population of about 2,000, which generated 188 clusters. Then, 104 of the 188 clusters were randomised to get the required number of participants using a computer-generated random sequence; 52 clusters received the intervention, and 52 clusters served as control.

Randomisation was done independently by a statistician, who had no engagement with the study site. Clusters were assigned numbers to blind the name of the village in the randomisation process by the statistician. All eligible pregnant women in each cluster were identified by door-to-door visits and invited to enrol in the study. The study health workers, with the assistance of the government community health workers invited the women. Throughout this process, they line-listed 1,695 and 1,587 pregnant women at any gestational ages in intervention and control groups, respectively for 5 months. Then, we allocated a total of 637 eligible pregnant women in the intervention group and a total of 659 eligible pregnant women in the control group. Only nine women in the intervention clusters and 20 in the control clusters declined to participate. Finally, 628 eligible pregnant women in the intervention group and 639 eligible pregnant women in the control group participated in the study (Fig. 1).

In each selected cluster during the door-to-door visits, all women of reproductive age who missed at least two menstrual periods and perceived themselves to be pregnant were identified by eight study female health workers (FHWs). After obtaining verbal consent, the female health workers used an early detection qualitative urine strip ["Diaspot"<sup>®</sup> hCG Urine Card, DiaSpot Diagnostics, USA; overall accuracy: >90%, sensitivity: 100% (95%–100%), and specificity: 100% (95%–100%) (95% confidence interval)] to assess the women for pregnancy. Once the health workers confirmed the participants' pregnancy and obtained informed written

consent, they assigned a unique identification number and recorded age, household address, parents' home address, last date of menstrual period (LMP), expected date of delivery according to LMP, and number and date of visits for each participant. Parent's home address was also recorded to assist in obtaining the birthweight of neonates because women in Bangladesh often go to their parental home to give birth.

#### Intervention

A team of researchers from icddr,b designed a prefabricated model kitchen. This model kitchen has a movable reinforced 36 square feet cement concrete floor, a concrete pillar, a single door, three windows, and a wooden roof-frame (Supplementary Figure S1). The walls and roof are made of locally-sourced, inexpensive bamboo with ample ventilation.<sup>34</sup> The model kitchen

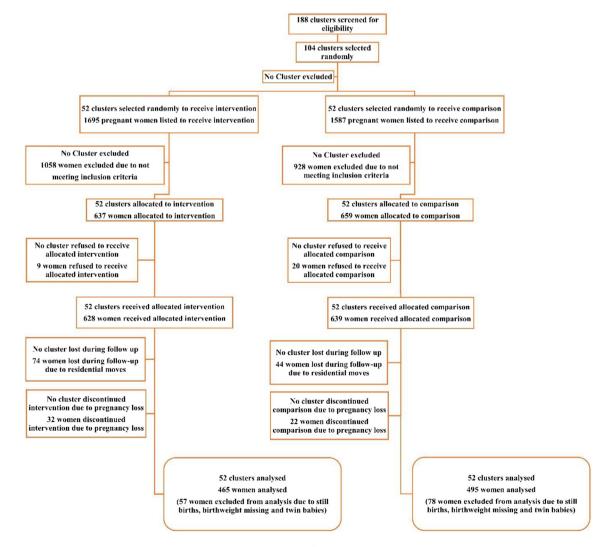


Fig. 1: Trial profile of clusters.

includes an improved cookstove with three important pieces to the cookstove's design. First, biomass fuels are placed on a grate, allowing for the wood, dung, leaves, jute sticks, or other materials to completely burn. The grate maintains the optimal distance (10 inches) required for guiding the flames to heat the bottom of the cookware while allowing air to pass underneath to allow complete burning of the fuels. Second, the design of the cookstove allows for smoke to be combusted in controlled conditions. Third, a chimney positioned on the cookstove allows for polluted smoke to rise out of the kitchen, away from pregnant women and their children, decreasing the amount of inhaled air pollutants. The model kitchen with improved cookstove costs about US\$100 (range: US\$ 95-110), including, model kitchen installation and maintenance (US\$65), improved cookstove (US\$12), distribution (US\$5-20), and labour cost (US \$13).

## Model kitchen installation and follow-up visits

All the low-cost model kitchen with improved cookstoves were installed outside the participants' homes in the intervention group within 1-2 days of the participant enrolment, and the old smoky kitchen and traditional cookstoves were removed. In a few households (n = 21), we modified the walls and roof of their existing kitchens and installed the improved cookstove. We installed more than one improved cookstove in a few households (n = 14) also where more than one family cooked their food at the same kitchen premise. The assumption was to protect the pregnant woman from inhaling polluted smoke from the other traditional cookstoves even if she was cooking on the improved cookstove. In the control group, all the enrolled pregnant women cooked their foods, as usual, using their regular traditional cookstoves in their existing kitchens.

The study FHWs visited each participant's home for five times including three times during pregnancy and once during the 72-h of childbirth and at the postpartum period immediately after 42 days (Supplementary Table S1). At each follow-up visit, the FHWs obtained weight (adult weight-scale with standardization), height (length-measuring scale), mid-upper arm circumference, and each participant's blood pressure. The FHWs used a structured questionnaire to record cooking fuel types, cooking area infrastructure, cooking frequency and duration, and participants' staying time in the kitchen. They also recorded maternal age, educational attainment, any pregnancy complications, and iron supplementation at each visit. At the second and third trimester visits, all participants were measured for total oxygen saturation, total haemoglobin, and carbon monoxide saturation (SpCO) level via the non-invasive Masimo rainbow<sup>®</sup> SET Pulse CO-Oximetric analysis (Model: Radical-7 Colour (9086) with RDS-3 (9023) Docking Station. Manufacturer: Masimo Corporation, USA).29

One family member from each household in both intervention and control groups was assigned to contact the study FHWs via mobile phone when the birth occurred. The FHWs in each group, blinded to the study objectives, visited the subject's home within 72 h of the delivery to measure the neonate's birthweight (using a Seca scale [10 g intervals] with standardisation) and length (measured using the length-measuring tape at supine position). If the delivery was in a facility, the study FHWs weighed the neonate's birthweight using the same scale within 72 h. The FHWs could not measure the birthweight of a few enrolled neonates within 72 h of delivery due to several reasons including perinatal deaths and a delay in being informed by the family members.

At 42 days post-birth, the participants were interviewed by the FHWs using a structured questionnaire (concerning their post-pregnancy care and background characteristics). The questionnaire included sociodemographic data e.g., household assets, reproductive history including gravida, parity, any maternal and neonatal complications during the antepartum, intrapartum, and postpartum periods, along with their care-seeking behaviours, and the neonatal status. The husband's smoking patterns were also recorded. Ownership of various assets by any member of the household was also recorded. The FHWs again ascertained types of fuel use, choices of fuels, cooking area infrastructure, cooking frequency, and duration, and duration of the participant's stay in the model or traditional kitchen in detail.

## Outcome

The outcomes of the study were measuring (a) the proportion of neonates with LBW between the intervention and control groups; (b) maternal blood carbon monoxide saturation (SpCO) level during the second and third trimester between the intervention and control groups.

## Statistical analysis

#### Sample size calculation

A sample size for cluster RCT had been calculated<sup>35</sup> to test a reduction of LBW from 37% to 24%<sup>1,6,36</sup> with 95% CI and 90% power, and 10% intra-cluster correlation. Therefore, we required at least 520 eligible participants from each intervention and control groups (104 clusters with 10 eligible participants from each cluster). To account for potential loss to follow-up due to residential moves (7.5%) and pregnancy loss (5.9%),<sup>36</sup> and unable to measure the birthweight of neonates (10.0%), we increased the sample size by 23.4%, bringing the total to 641 participants in each group. Thus, a minimum of 650 pregnant women was targeted for each intervention and control groups. As these 104 clusters were randomly divided into intervention and control groups and then, we were enrolled all the eligible pregnant

women in each cluster, so there was no obvious selection bias, except that the pregnant women in the intervention groups used the model kitchen. As the crude birth rate was 22.6 per 1000 population in Bangladesh,<sup>37</sup> we were able to enrol the required number of pregnant women from 104 clusters.

## Data analysis

In this paper, we included the participants who had only singleton neonate (n = 465 in intervention and n = 495 in control groups). We measured birthweight of the neonates within 72 h of the deliveries in the data analysis due to avoid biases related to LBW prevalence. Therefore, the study included the analysis of 960 births that meet the eligibility criteria, which reduced the statistical power to 88%.

Descriptive analysis to compare maternal and neonatal characteristics between the intervention and control groups was done using the survey data module of Stata (version 16.0, Stata Corp, College Station, TX, USA) by employing weighted and cluster (n = 104) adjusted analysis techniques. We used principal component analysis to create a household wealth index, which we used as a covariate in these analyses. The assets included durable consumption goods (e.g., table, chair, watch, television, bicycle), housing facilities (e.g., types of toilet, sources of drinking water), housing materials (e.g., types of wall, floor, and roof), and land ownership. The wealth index was categorized into five ordinal categories: least wealthy, less wealthy, wealthy, wealthier, and most wealthy.

We conducted the intention-to-treat analysis with all clusters. We used the log-binomial model which gives a good estimate of risk ratios (RR) of LBW (<2,500 g) among the intervention versus the control group. The log-binomial model is more easily interpretable in cluster-RCT to correct the clustering effect.<sup>38</sup> Moreover, linear regression model has been fitted to determine the reduction of maternal blood SpCO level from second trimester to third trimester between the intervention and control group. Additionally, the difference in the prevalence of LBW among intervention and control clusters has been calculated in the propensity score matched sample.

We hypothesised that the 'low-cost kitchen with improved cookstove' intervention would both, directly and indirectly, affect adverse pregnancy outcomes like LBW neonates (through maternal blood SpCO level). For modelling all the relationships simultaneously, we used generalized structural equation modelling (GSEM) with maximum likelihood estimation to test structural pathways between intervention and LBW that jointly fits three individual regression models: each arrow in the box shows the relationship between an outcome and a key regressor, adjusted for potential confounding covariates (e.g., demographic characteristics). So, we fitted the models with GSEM, where the equation with LBW neonate outcome was fitted with generalized linear model (GLM) specification of a logistic regression model, where family was specified as Bernoulli and link function as logit. All mediational model specifications were specified as simple linear models (with gaussian family and identity link).

All the crude and adjusted effects with 95% CI of neonates' birthweight and maternal blood SpCO levels were adjusted by using robust sandwich covariance estimate to account for the clustering. All the multivariable models were also adjusted by other maternal covariates, including maternal age (in years), education (in years), parity (in number), body mass index (BMI) (kg/m<sup>2</sup>), gestational age during delivery (in weeks), cooking time (in hours), and husband smoking status (yes/no). The p-value <0.05 was considered as statistically significant.

## Role of the funding source

The funding source had no role in the study design, data collection, data analysis, data interpretation, and manuscript writing. The corresponding author had final responsibility for the decision to submit for publication.

## Results

Fig. 1 shows the results of different stages of study sample selection based on the CONSORT flow diagram. We enrolled 1,267 eligible pregnant women in both the intervention and control groups. Of 1,267 women, 172 (13.6%) were lost to follow-up due to pregnancy loss, including miscarriage (4.3%) and residential moves (9.3%) both in the intervention and control groups. We observed 1,102 birth outcomes from 1,095 women due to seven women who had twin births in the intervention and control groups. There was a total of 41 stillbirths in both groups. Among the live births, we measured the birthweight of 968 (91.2%) neonates within 72 h of childbirth. Among the rest (7.8%), birthweight was measured in 77 neonates after 72 h of childbirth. Birthweight could not be measured in 16 neonates due to perinatal death. Ultimately, we included all the information of 960 singleton live birth outcomes measured birthweight within 72 h of birth, excluding the twin births in the analysis.

#### Maternal and neonatal characteristics

Table 1 presents the participants' characteristics averaged at cluster level across intervention and control groups. The data showed differences between the two groups in several key characteristics. Specifically, participants in the intervention group had a slightly lower mean age (p < 0.001), mean parity (p < 0.010), and mean BMI (p < 0.001) than those in the control group. The mean gestational age was similar for both groups (p = 0.27). As there are statistically significant differences among the background characteristics including

| Intervention mean (95% CI) | Control mean (95% CI)   |  |
|----------------------------|---|--|
| 23.1 (22.7–23.5)           | 23.9 (23.5–24.3)  |  |
| 1.9 (1.8–2.0)              | 2.1 (2.0-2.2)   |  |
| 21.5 (21.2–21.9)           | 22.3 (21.9–22.5)  |  |
| 37.2 (36.9-37.5)           | 37.5 (37.3–37.7)  |  |
| 4.4 (4.2-4.6)              | 4.2 (3.9-4.6)   |  |
| Proportion (95% CI)        | Proportion (95% CI)   |  |
| 0.46 (0.41, 0.50)          | 0.61 (0.56, 0.65)   |  |
|                            |   |  |
| 0.20 (0.17, 0.24)          | 0.18 (0.15, 0.22)   |  |
| 0.19 (0.16, 0.23)          | 0.20 (0.17, 0.24)   |  |
| 0.20 (0.17, 0.24)          | 0.20 (0.16, 0.23)   |  |
| 0.22 (0.18, 0.26)          | 0.20 (0.17, 0.24)   |  |
| 0.23 (0.19, 0.27)          | 0.21 (0.18, 0.26)   |  |
| 2.41 (2.31, 2.52)          | 2.34 (2.28, 2.41)   |  |
|                            | 23.1 (22.7-23.5)<br>1.9 (1.8-2.0)<br>21.5 (21.2-21.9)<br>37.2 (36.9-37.5)<br>4.4 (4.2-4.6)<br>Proportion (95% Cl)<br>0.46 (0.41, 0.50)<br>0.20 (0.17, 0.24)<br>0.19 (0.16, 0.23)<br>0.20 (0.17, 0.24)<br>0.22 (0.18, 0.26)<br>0.23 (0.19, 0.27) |  |

maternal age, parity, BMI, and smoking status of husband of the intervention and control groups, we have adjusted our multivariable analysis for all these variables.

Table 2 presents the neonatal outcomes across the intervention and control groups. In the intervention group, 23.0% of the neonates had LBW and in the control group, 35.8% of the neonates had LBW. Among the LBW neonates, the mean birthweight was 2,190 g in the intervention group and 2,076 g in the control group.

Table 3 shows the risk ratio of LBW neonates (<2,500 g) using the log-binomial regression model. Both crude and adjusted risk ratio has been presented. Participants of the intervention group had 37.0% (adjusted RR: 0.63, 95% CI (0.45–0.89)) lower risk of having a neonate with LBW compared to participants in the control group.

# Maternal blood carbon monoxide saturation (SpCO) level

In the intervention group, the mean maternal blood SpCO level decreased from 10.4% to 8.9% between the second to third trimester; whereas, in the control group, the mean maternal blood SpCO level remained unchanged between the trimesters (11.6% and 11.5%) (Table 4). The rate of change of mean maternal blood SpCO level in the intervention group had association with the background characteristics of the participants (Table 4). The linear regression model shows that the blood SpCO level among the pregnant women in the intervention group was significantly reduced compared to the control group (Supplementary Table S2). In the intervention group, the mothers who delivered neonates with birthweight more than 2,500 g had significantly reduced blood SpCO level from second to third trimester (10.4% versus 8.8%). Also, mother who delivered neonates with birthweight less than 2,500 g had significantly reduced SpCO level from second to third trimester (10.4% versus 9.3%) (Table 4). Adjusting the other covariates in the linear regression model, we found that the birthweight had been reduced 0.063 g for increasing of each unit of percentage of maternal blood SpCO level (Supplementary Table S3).

# Decomposition effect using generalised structural equation model

The decomposition of the effects of the intervention on LBW neonate prevalence is shown in Fig. 2. The direct effect of the intervention was –0.331; the value of 0.786 (0.674–0.914) suggests that the risk ratio of prevalence of LBW neonate was 21.4% lower as compared to the control group (Supplementary Tables S4 and S5). Indirectly, lower maternal blood SpCO level mediated 22.6% (RR: 0.774 (0.537–1.087)) reduction of prevalence of LBW neonate due to low-cost kitchen with improved cookstove. The total effect of the intervention was –0.640, i.e., LBW neonate prevalence reduced by 36%. The direct effect contributed to 51.7% of the total effect of the intervention on LBW neonate prevalence, and 48.3% was mediated through the reduction of maternal blood SpCO level.

|                                 | Intervention (95% CI)                    | Control (95% CI)              |  |
|---------------------------------|--|-------------------------------|--|
| Neonates birthweight (%)        |  |                               |  |
| Normal birthweight              | 77.0 (72.6-68.3)                         | 64.2 (60.0-68.3)              |  |
| Low birthweight                 | 23.0 (19.1-27.5)                         | 35.8 (31.7-40.0)              |  |
| Neonates birthweight (mean [g]) |  |                               |  |
| Normal birthweight              | 3207.0 (3155.2-3258.7) 2986.2 (2945.1-30 |                               |  |
| Low birthweight                 | 2190.6 (2126.6-2254.7)                   | 254.7) 2076.0 (2025.2–2126.8) |  |
|                                 |  |                               |  |

Table 2: Distribution of neonates' birthweight by intervention and control group.

|   | Crude risk ratio<br>(95% CI) | Adjusted risk ratio<br>(95% CI)ª |  |  |  |  |
|---|------------------------------|----------------------------------|--|--|--|--|
| Intervention (ref: control)   | 0.64 (0.47-0.89)             | 0.63 (0.45–0.89)                 |  |  |  |  |
| Age (years)   | 0.99 (0.97-1.02)             | 0.99 (0.97-1.02)                 |  |  |  |  |
| Parity (number)   | 0.97 (0.88-1.06)             | 0.96 (0.87-1.05)                 |  |  |  |  |
| BMI (kg/m <sup>2</sup> )  | 0.98 (0.95-1.01)             | 0.97 (0.94-1.00)                 |  |  |  |  |
| Gestational age (weeks)   | 0.97 (0.94-1.01)             | 0.96 (0.93-0.99)                 |  |  |  |  |
| Education (years)   | 1.01 (0.97-1.04)             | 1.01 (0.98–1.05)                 |  |  |  |  |
| Husband smoking (ref: no)   | 1.28 (1.05–1.56)             | 1.27 (1.07–1.51)                 |  |  |  |  |
| Wealth index (ref: Least wealthy)   |                              |                                  |  |  |  |  |
| Less wealthy  | 0.95 (0.74-1.22)             | 0.90 (0.70-1.16)                 |  |  |  |  |
| Wealthy   | 0.82 (0.56-1.19)             | 0.79 (0.55-1.15)                 |  |  |  |  |
| Wealthier   | 0.99 (0.74-1.33)             | 0.97 (0.74-1.27)                 |  |  |  |  |
| Most wealthy  | 1.01 (0.76-1.34)             | 0.93 (0.70-1.23)                 |  |  |  |  |
| Cooking time/day (hours)  | 0.93 (0.81-1.06)             | 0.94 (0.80-1.11)                 |  |  |  |  |
| <sup>a</sup> Adjusted by maternal age, education, parity, BMI, gestational age, cooking time, husband smoking, wealth |                              |                                  |  |  |  |  |

index.

Table 3: Risk ratio of low birthweight neonates (<2,500 g) using log-binomial regression model.

## Discussion

Our cluster-randomised controlled trial has shown that prenatal use of the low-cost kitchen with improved cookstove resulted in a statistically significant reduction in the prevalence of LBW neonate (37.0%, 95% CI (23.7–47.5)) within communities who received the intervention compared to the control communities in rural Bangladesh. Controlling for other maternal covariates that may affect risk of LBW, we found a reduction in the risk of LBW in the intervention group (adjusted RR: 0.63, 95% CI [0.45, 0.89]) compared to the control group communities that used traditional cookstoves.

Our findings were similar to the results of systematic reviews conducted in 2010, 2014, and 2022.<sup>6,16,17</sup> After exploring similar studies, the review concluded that indoor air pollution from solid fuel use increase the risk of LBW, stillbirth, and reduced mean birthweight. Further, our findings continued to show similarities with the study by Siddiqui and colleagues,<sup>1</sup> who showed that

|   | Mean blood SpCO l        | evel                          |                          |                               |
|---|--------------------------|-------------------------------|--------------------------|-------------------------------|
|   | Second trimester         |                               | Third trimester          |                               |
|   | Control mean<br>(95% CI) | Intervention mean<br>(95% CI) | Control mean<br>(95% Cl) | Intervention mean<br>(95% CI) |
| Overall                                 | 11.6 (11.4-11.8)         | 10.4 (10.2–10.7)              | 11.5 (11.4–11.6)         | 8.9 (8.7-9.1)                 |
| Background characteristics              |                          |                               |                          |                               |
| Age (years)                             |                          |                               |                          |                               |
| <20                                     | 11.5 (11.1–11.9)         | 10.1 (9.5–10.7)               | 11.6 (11.3–11.9)         | 8.5 (8.0-9.0)                 |
| 20–24                                   | 11.6 (11.3–11.9)         | 10.4 (10.0–10.8)              | 11.4 (11.2–11.5)         | 8.8 (8.5-9.1)                 |
| 25-30                                   | 11.8 (11.5–12.1)         | 10.3 (9.8–10.8)               | 11.5 (11.4–11.7)         | 9.1 (8.7-9.6)                 |
| >30                                     | 11.3 (10.8–11.9)         | 11.5 (10.3-12.6)              | 11.5 (11.1–11.8)         | 9.7 (9.1-10.3)                |
| Parity (number)                         |                          |                               |                          |                               |
| 1                                       | 11.3 (11.0-11.7)         | 10.2 (9.8–10.7)               | 11.4 (11.1–11.6)         | 8.8 (8.5-9.2)                 |
| 2                                       | 11.9 (11.6–12.2)         | 10.5 (10.2-10.9)              | 11.6 (11.4-11.7)         | 8.9 (8.6-9.3)                 |
| ≥3                                      | 11.5 (11.2–11.8)         | 10.5 (9.8-11.4)               | 11.4 (11.3-11.6)         | 9.0 (8.6-9.5)                 |
| BMI (kg/m <sup>2</sup> )                |                          |                               |                          |                               |
| Underweight                             | 11.0 (10.2–11.8)         | 10.2 (9.6–10.9)               | 11.0 (10.5–11.6)         | 8.9 (8.4-9.4)                 |
| Healthy weight                          | 11.7 (11.5–11.9)         | 10.5 (10.2–10.8)              | 11.5 (11.4-11.65)        | 9.0 (8.8-9.3)                 |
| Overweight                              | 11.6 (11.2–12.0)         | 10.0 (9.0-10.9)               | 11.4 (11.2–11.6)         | 8.4 (7.8-9.0)                 |
| Education (years)                       |                          |                               |                          |                               |
| No schooling                            | 11.6 (11.3-11.9)         | 10.9 (9.5-12.3)               | 11.5 (11.3-11.7)         | 9.3 (8.5-10.0)                |
| 1–5                                     | 11.7 (11.3-12.1)         | 10.5 (10.1-10.8)              | 11.5 (11.3-11.7)         | 8.9 (8.7-9.2)                 |
| 6-8                                     | 11.7 (11.3-12.0)         | 10.2 (9.7-10.7)               | 11.5 (11.3-11.7)         | 8.9 (8.5-9.4)                 |
| ≥9                                      | 11.4 (10.8–11.9)         | 10.3 (9.5-11.2)               | 11.4 (11.1-11.7)         | 8.5 (7.8-9.2)                 |
| Wealth Index                            |                          |                               |                          |                               |
| Least wealthy                           | 11.3 (10.8–11.8)         | 10.7 (10.0-11.4)              | 11.4 (11.1-11.7)         | 9.1 (8.6-9.6)                 |
| Less wealthy                            | 11.5 (11.0–11.9)         | 10.6 (10.0–11.2)              | 11.4 (11.2–11.6)         | 9.1 (8.7-9.6)                 |
| Wealthy                                 | 11.8 (11.4–12.1)         | 9.8 (9.3-10.4)                | 11.7 (11.5–11.9)         | 8.6 (8.2-9.0)                 |
| Wealthier                               | 11.8 (11.4–12.2)         | 10.6 (10.1-11.1)              | 11.5 (11.3-11.7)         | 8.9 (8.5-9.3)                 |
| Most Wealthy                            | 11.7 (11.3-12.1)         | 10.4 (9.8–11.0)               | 11.3 (11.1–11.6)         | 8.9 (8.4–9.5)                 |
| Neonates' birthweight                   | , , , ,                  |                               |                          |                               |
| Mother with normal birthweight neonates | 11.4 (11.2–11.7)         | 10.4 (10.1-10.8)              | 11.4 (11.2–11.5)         | 8.8 (8.6-9.1)                 |
| Mother with Low birthweight neonates    | 11.9 (11.6–12.2)         | 10.4 (9.8–10.9)               | 11.7 (11.5-11.8)         | 9.3 (8.9–9.7)                 |
| SpCO: carbon monoxide saturation.       |                          |                               |                          |                               |
|   |                          |                               |                          |                               |

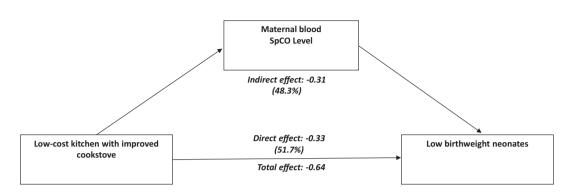


Fig. 2: Effects size in risk ratio showing the relationships between low-cost kitchen with improved cookstove and prevalence of low birthweight (LBW) neonates due to direct and indirect effects of maternal blood SpCO level.

cooking with natural gas could prevent pregnant women from inhaling CO, and reduce LBW prevalence (33.9% reduction) compared with using biomass fuels in the traditional cookstove for cooking. This study also reported that the risk of LBW was 86.0% higher among the biomass fuel users than natural gas users.<sup>1</sup> In another study conducted among the wood or dung users in the traditional cookstove and gas or kerosene users in Tamil Nadu, India in 2009 found similar results; 18.6% of infants born to gas or kerosene users were LBW compared to 34.1% of infants born to wood or dung users.5 Moreover, our results are consistent with a previous work that has established that exposure to indoor air pollution from incomplete combustion of biomass fuels during cooking by pregnant women is associated with reduced birthweights among neonates.16,17 We found that the infants born to the mothers using traditional cookstoves in an open or traditional kitchen had mean birthweights of 2.7 kg (95% CI: 2.61-2.71), whereas mean birthweights among infants born to mothers using the 'low-cost kitchen with improved cookstove' from the first trimester of their pregnancies were 3.0 kg (95% CI: 2.91-3.02). Therefore, after adjustment, neonates in the households with the model kitchen were an average 320 g more at birth than those in the control group, and the difference was statistically significant. A similar estimate is also observed in a follow-up RESPIRE study found that neonates born to mothers using a chimney cookstove weighed 328 g more compared to neonates born to mothers using open fires that would have exposed them to greater biomass fuels, though after adjustment, the mean difference of birthweight between the two arms found to be not significant.<sup>4</sup> Another study from Nigeria reported that, after adjusting for other covariates, infants born to mothers who used ethanol stove weighed more on average than infants randomised to a kerosene or a firewood stove (p = 0.020).<sup>39</sup> Though observational studies from Zimbabwe and Guatemala reported that infants born in households using liquefied petroleum gas, natural gas, or electricity for cooking were significantly weighty on average at birth than those born in the household using biomass fuels, the estimates were not similar to our study.<sup>2,3</sup> There might be heterogeneity among the types of fuel users in respect to socioeconomic index due to residence of living area. Although not RCTs, the previous studies generated a greater amount of evidence to establish relationship with biofuel exposure during gestation and possibilities to give birth of LBW.

Our study also found statistically significant differences between the intervention and control groups with respect to mean SpCO levels in maternal blood. Smoke-polluted environments include CO, have an influence on blood SpCO levels in human body. Higher SpCO levels are associated with negative effects from oxidative stress, hypoxaemia, haemolysis.40,41 A retrospective cohort study conducted in Brazil reached the same result as ours, namely that the exposure of the mother to air pollution (PM2.5 and CO from biomass fuel) during the second and third trimesters of pregnancy was associated with LBW neonates.42 Another study conducted in India confirmed that biomass fuel has adverse respiratory impact e.g., dyspnoea and airway inflammation on pregnant women.43 A recent study conducted in Ghana also found a positive association between inhalation of CO discharged from burning biomass fuel and prolonged coughing, wheezing, phlegm, and other respiratory infection<sup>44</sup> Similarly, one more study in Ghana observed effects of CO on birthweight, birth length, and gestational age.31 The findings from the study suggested for the neonates born to mothers without reported placental malaria, each 1 ppm increase in CO was associated with reduced gestational age (-0.5 days [95% CI: -1.3, 0.2 days]), birthweight (-38.7 g [95% CI: -66.2, -11.1 g]), birth length (-0.3 cm [95% CI: -0.5, -0.02 cm]).31 Another study carried out in Ghana found that the use of liquefied petroleum gas interventions resulted in a significant reduction in the exposure to air pollution compared to the use of threestone fires.<sup>25</sup> However, this is the first study of its kind to investigate the effect of 'low-cost kitchen with

improved cookstove' intervention on maternal blood SpCO level and examine its mediational role on birthweight. In our study, the low-cost kitchen with improved cookstove intervention provided a wellventilated atmosphere and was designed to prevent pregnant women from inhaling carbon monoxide during cooking. As a result, we observed lower SpCO levels among pregnant women in their third trimester in the intervention group (8.9%) compared to the control group (11.5%). We found evidence that maternal blood SpCO levels indirectly affect pregnancy outcomes. The direct effect contributed to 51.6% of the total effect of the intervention on birthweight of neonates and the rest 48.4% of the total effect was mediated through reduction of maternal blood SpCO level. We also observed lower SpCO level (8.7%) among the women experienced less complications during delivery in the intervention group and higher SpCO levels (11.6%) among the women experienced more complications during delivery in the control group.

Our study has several strengths. We tested the intervention using a cluster-RCT, which is considered a gold standard in assessing the effectiveness of drugs, vaccines, and other public health interventions at the population level.4,33 Therefore, this study designed to test the efficacy of the intervention plays an important role in strengthening the evidence for the contribution of biomass fuels on adverse pregnancy outcomes. The population of Bangladesh is highly exposed to smoke from biomass fuel use.15 One of the goals of our study was to implement safer kitchens with clean improved cookstoves across rural communities to the households of pregnant women which would initiate changes in cooking practices and improve maternal and neonatal health. We found considerable uptake and behaviour change among the pregnant women involved in the study, and evidence to support further consideration of such kitchens and cookstoves.

Our study had a few important limitations. There are statistically significant differences between some of the background characteristics of the intervention and the control group. These imbalances are referred as chance bias which occurred by chance in randomisation and might be due to sample size. So, we have adjusted those variables in multivariate analysis to account for this difference. Moreover, we have applied propensity score matching technique to identify the matched cases between intervention and control groups based on their background characteristics including maternal age, parity, BMI, gestational age, wealth index, and smoking status of husband. We found the findings are similar in terms of statistical significance and direction of association (Supplementary Table S6). Additionally, the main analysis was included all the term and preterm births. For more clarification, we have excluded all the preterm births and found similar differences regarding prevalence of LBW neonate between the intervention and

control groups (Supplementary Figure S2). The mediating pathways between using the proposed model kitchen and LBW is understood using GSEM. However, there is a lack of appropriate post-estimation techniques that could give further understanding.45 Moreover, we lacked environmental exposure measurement, and therefore, there was a dearth of data related to what extent the model kitchen decreased CO emissions in the household. Instead, we relied on an indirect physiologic measurement in pregnant women (maternal blood SpCO level). We also did not analyse any blood-based biomarkers that would reflect oxidative stress or inflammation which may mediate the association between improved ventilation and higher birthweights.40,46,47 We also were limited in our ability to investigate biological pathways through which biomass fuel exposure might lead to adverse pregnancy outcomes and any maternal complications. Last, we did not look for the effect of seasonality or sex on the findings.

Women are mainly responsible for cooking in Bangladesh and very little is required in their kitchens. They primarily require a smoke-free environment and a hygienic place to keep their washed utensils. The newly developed model kitchen has addressed all the above needs of the rural mothers. Therefore, our findings support the implementation of safer cooking alternatives than open biomass cookstoves. This finding could stimulate the local level commercial production of such a model kitchen. Moreover, local capacity building could be enhanced by providing extensive training including training of disadvantaged women on improved cookstove construction, enterprise development, leadership and management, and kitchen improvement. Thus, the low-cost kitchen with improved cookstove are scalable, and affordable options that could improve health outcomes in lowincome and middle-income countries (LMICs) where biomass fuel cooking is the norm. Understanding the physiochemical changes in pregnant women and their foetuses in response to biomass fuel exposure is critical to motivating health policies and health spending priorities in LMICs, including Bangladesh. We recommend such interventions, which may translate to improved maternal and neonatal health in countries with low resource settings.

#### Contributors

All authors were involved in the study design and tools development, intervention design, data analysis, and all aspects of writing the manuscript. AA was the principal investigator of the study and conceptualised the study theme and designed the intervention and research method, and involved in data analysis, and first author of the manuscript. SA, SEA, LR, and AER are senior epidemiologists and health system experts and were involved in data analysis plan and writing of the manuscript. Moreover, FR and AS were also involved in the literature review, writing and reviewing of the manuscript. FA, ATH, and HMS are statisticians and were directly involved in the data analysis. MAQ, SH, and NLH were senior investigators with responsibility in all technical aspects of the study design, intervention design, and development of study tools.

#### Data sharing statement

Anonymised participant data and study protocol will be shared by the corresponding author after corresponding author's institutional approval and following a reasonable submitted request.

#### Declaration of interests

This research study was funded by Grand Challenges Canada: Rising Stars in Global Health Programme, grant no. RS1\_0129-01 provided to icddr,b. Authors declare no other conflicts of interest.

#### Acknowledgements

icddr,b acknowledges with gratitude the commitment of Grand Challenges Canada to its research efforts. icddr,b is also grateful to the Governments of Bangladesh and Canada for providing core and unrestricted support. We acknowledge Sirin Construction and Pillar House, a local entrepreneur of Shahjadpur sub-district for their technical assistance in the installation of the model kitchen at the households of pregnant women enrolled in the study. We also acknowledge two local NGOs named 'Grameen Shakti' and 'Manob Shiksha Sangstha' in the sub-district for their technical assistance in the installation of the Improved Cookstoves in the model kitchens. The study is also very grateful to the mothers who participated in this study. We acknowledge Heather H. Burris, Neonatologist, Children's Hospital of Philadelphia, University of Pennsylvania, Perelman School of Medicine, Philadelphia, USA for her involvement in the writing of the manuscript. We also acknowledge Md. Mehedi Hasan, Senior Research Investigator, icddr,b and K. M. Tanvir, Research Officer, icddr,b for their statistical review and inputs in the data analysis. We thank Jocalyn Clark, Adjunct Professor of Medicine at the University of Toronto, Honorary Associate Professor at the Institute for Global Health, University College London, and International Editor of the British Medical Journal for copyediting this manuscript.

#### Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lansea.2023.100342.

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