

Effects of a Water, Sanitation and Hygiene Mobile Health Program on Respiratory Illness in Bangladesh: A Cluster-Randomized Controlled Trial of the CHoBI7 Mobile Health Program

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Abstract. Acute respiratory infections are a leading cause of morbidity and mortality among young children globally. The objective of this study was to evaluate the impact of the Cholera-Hospital-Based-Intervention-for-7-days (CHoBI7) handwashing with soap and water treatment mobile health (mHealth) program on respiratory illness among diarrhea patients and their household members in urban Dhaka, Bangladesh. A cluster-randomized controlled trial of the CHoBI7 mHealth program was conducted among diarrhea patient households in Dhaka, Bangladesh. Patients were randomized to three arms: standard recommendation on oral rehydration solution use, health facility delivery of CHoBI7 plus mHealth (weekly voice and text messages for 12 months) (no home visits), and health facility delivery of CHoBI7 plus two home visits and mHealth. Respiratory symptoms were assessed during monthly clinical surveillance over the 12-month surveillance period. Respiratory illness was defined as rapid breathing, difficulty breathing, wheezing, or coughing. Two thousand six hundred twenty-six participants in 769 households were randomly allocated to three arms: 849 participants to the standard message arm, 886 to the mHealth with no home visits arm, and 891 to the mHealth with two home visits arm. Compared with the standard message arm, participants in the mHealth with no home visits arm (Prevalence Ratio [PR]: 0.89 [95% CI: 0.80, 0.98]), and the mHealth with two home visits arm (PR: 0.89 [95% CI: 0.81, 0.99]) had significantly lower respiratory illness prevalence over the 12-month program period. Our findings demonstrate that the CHoBI7 mHealth program is effective in reducing respiratory illness among diarrhea patient households.

INTRODUCTION

Acute respiratory infections are a leading cause of morbidity and mortality globally among children under 5 years of age, resulting in over 600,000 deaths annually.¹ Over 95% of these acute respiratory infection-related deaths occur in lower- and middle-income countries (LMICs). In Southeast Asia, there are estimated to be over 30 million acute respiratory infection episodes annually, resulting in 200,000 deaths.¹ Previous studies have identified risk factors for acute respiratory infections including severe malnutrition, indoor air pollution, maternal education, socioeconomic status, and household crowding.^{2,3} Poor water, sanitation, and hygiene (WASH) infrastructure can also make young children more susceptible to respiratory infections.^{4,5}

WASH interventions focused on handwashing with soap have the potential to significantly reduce acute respiratory infections.^{4,5} Most previous studies evaluating the impact of WASH on respiratory illness have focused on WASH in schools and childcare centers. In Mali, a matched case control study of a rural and urban school-based WASH program found a 25% reduction in respiratory symptoms.⁶ In Kenya, a prospective study of a rural school-based WASH program observed a significant reduction in respiratory illness.⁷ In Laos and Kenya, however, randomized controlled trials (RCTs) of rural and urban school-based WASH programs observed no significant impact on respiratory infections or symptoms.^{8,9}

There are only a few RCTs that have investigated the impact of household and community-based WASH on respiratory illnesses in LMIC settings. In urban squatter settlements in Pakistan, an RCT of a WASH program focused on handwashing with soap reduced pneumonia incidence by 50%.¹⁰ In an RCT in urban Dhaka, Bangladesh, there was no impact on respiratory illness for those receiving a WASH and cholera vaccine intervention, though respiratory illness was lower for individuals that had soap and water present at a handwashing station.¹¹ Most recently, there were two RCTs of large-scale rural community WASH interventions in Bangladesh and Kenya.^{12,13} These WASH interventions included delivery of modules on water treatment, handwashing with soap, safe child feces disposal, and the provision of improved latrines. In Bangladesh, delivery of this WASH program reduced respiratory illness in the handwashing with soap arm by 32%; however, there was no significant improvement in child respiratory symptoms in Kenya.

In this study, we aimed to investigate whether delivery of the Cholera-Hospital-Based-Intervention-for-7-days (CHoBI7) mobile health (mHealth) program, a household WASH program that sends mobile messages and conducts in-person visits with diarrhea patient households on handwashing with soap and water treatment, can significantly reduce respiratory illness among diarrhea patients and their household members.

METHODS

Study design. This study was a three-arm cluster RCT conducted in urban Dhaka, Bangladesh from December 4, 2016–April 26, 2019. A cluster was a diarrhea patient and their corresponding household members. Patients were recruited from two health facilities, Mugda Hospital (government hospital) and the International Center for Diarrheal

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Disease Research, Bangladesh (icddr,b) Dhaka Hospital (private hospital). In this RCT, the standard message arm, which received the standard recommendation given in Bangladesh to diarrhea patients from health facility staff on oral rehydration solution use for dehydration, was compared with the CHoBI7 mHealth program with either a single in-person visit for health facility delivery of the program (mHealth with **no** home visits arm) or health facility delivery of the program plus two home visits (mHealth with two home visits arm). This study protocol was approved by the Institutional Review Board of the Johns Hopkins Bloomberg School of Public Health (6,785) and the Research and Ethical Review Committees at icddr,b (PR-15133).

Participants. The eligibility criteria for diarrhea patients were as follows: (1) have had three or more loose stools over the past 24 hours; (2) plan to reside in Dhaka for the next 12 months; (3) have no basin for running water in their home (mostly slum areas of Dhaka); (4) have a child under 5 years of age in their household (including themselves) that produced a stool sample at baseline (used to determine the etiology of diarrhea); and (5) have a working mobile phone in the household. The eligibility criteria for household members of the diarrhea patient were if (1) they shared the same cooking pot and resided in the same home with the diarrhea patient for the last 3 days; and (2) planned to reside with the diarrhea patient for the next 12 months. Recruitment of diarrhea patients at Dhaka icddr,b and Mugda hospitals was conducted Saturday to Thursday from 7:30 AM to 4 PM from December 2016–April 2018.

Randomization and masking. Block randomization of patients to study arms was conducted based on the date of health facility admission, stratified by health facility, and the ward where patients received treatment using a random number generator. This scheme limited the likelihood of seasonal variations in study arm assignment and selection bias. There were two health facilities: Mugda Hospital (four wards) and icddr,b Dhaka Hospital (four wards). The study biostatistician (JP) assigned randomization using the software R version 3.3.0. JP did not have involvement in data collection activities for the trial. Randomization was performed after the baseline enrollment of the diarrhea patient. The study arm assignment was revealed to the study coordinator in a digital database set up by the study manager (SIB). Masking was not possible because the intervention had visible components. To minimize bias, we used two separate teams for intervention and evaluation activities.

CHoBI7 program. During the time a diarrhea patient presents at a health facility for treatment, their household members are at a much higher risk of developing diarrheal diseases (> 100 times for cholera) than the general population.^{14,15} This risk is highest during the 7 days after the diarrhea patient is admitted to the health facility. To develop a standard of care to reduce diarrhea among household members of diarrhea patients, our research group developed the CHoBI7 program.¹⁶ Chobi means “picture” in Bengali for the pictorial modules delivered as part of the program. This targeted WASH program promotes handwashing with soap and water treatment (using chlorine tablets and boiling water) to diarrhea patients and their household members through health facility and home visits by a promoter during the 7-day high-risk period. The CHoBI7 program was developed through a theory-based approach informed by the

Integrated Behavioral Model for WASH (IBM-WASH) and the Risks, Attitudes, Norms, Abilities, and Self-regulation (RANAS) Model.¹⁷ The initial RCT of the CHoBI7 program found the intervention was effective in significantly reducing cholera,¹⁶ and led to sustained improvements in stored drinking water quality and observed handwashing with soap practices 12 months postintervention.¹⁸

CHoBI7 mHealth program. Building on this work, we partnered with the Bangladesh Ministry of Health and Family Welfare to develop and evaluate scalable approaches for CHoBI7 program delivery across Bangladesh. This led to the development of the current CHoBI7 mHealth program, which uses mobile messages (voice and text messages) to deliver WASH program content to remove the need for frequent in-person visits.¹⁷ The CHoBI7 mHealth program is first delivered during a health facility visit by a health promoter bedside to a diarrhea patient and their accompanying household members during the time of treatment. The health promoter delivers a pictorial CHoBI7 module on how diarrhea can spread to others and instructions on how and when to wash hands with soap and treat stored household drinking water. A diarrhea prevention package is also provided with the following items: a soapy water bottle containing water and detergent powder (a low-cost alternative to bar soap), a handwashing station, a 1-month supply of chlorine tablets for water treatment (33 mg sodium dichloroisocyanurate; Aquatabs; Medentech, [Wexford, Ireland, UK]), and a water vessel with a lid and tap to ensure safe water storage. Households are encouraged to make more soapy water for handwashing after their provided bottle is finished. After health facility delivery of the program, diarrhea patient households receive weekly voice and text messages from the CHoBI7 mHealth program over a 12-month period.

Evaluation procedure. Respiratory symptoms were assessed during monthly household visits for clinical surveillance through participant report over the 12-month surveillance period. Participants reported whether they had experienced difficulty breathing, wheezing, rapid breathing, or coughing in the past 2 weeks. For participants under 12 years of age, caregiver reports were obtained.

Outcomes. Our outcome of respiratory illness was defined as a surveillance visit with at least one of the following: rapid breathing, difficulty breathing, wheezing, or coughing, based on previous studies.^{12,13} Respiratory illness was not a prespecified outcome for this trial.

Power calculation. The sample size calculation was based on the primary outcome of the RCT, which was diarrhea prevalence in the past 2 weeks. The findings for this primary outcome are reported elsewhere.¹⁹ Diarrhea prevalence for the standard recommendation arm was estimated to be 8% for children under 5 years based on an urban cohort in Dhaka, Bangladesh (Personal Communication: Dr. ASG Faruque) and a minimum detectable difference between study arms of 25% based on the 2015 Cochrane review.²⁰ The calculations assumed a two-sided type I error α of 0.05, a power ($1-\beta$) of 0.80, a within household correlation of 0.1 for diarrhea prevalence over time, and monthly clinical surveillance visits (12 visits total). The sample size calculation indicated 250 diarrhea patient households per study arm with a cluster size of four household members, assuming a 20% loss to follow-up.

Statistical analysis. We analyzed participants according to their randomized assignment (intention-to-treat). Log binomial regression was performed to estimate the PR for respiratory illness using generalized estimating equations (GEE) to account for clustering at the individual and household level and to approximate 95% CI. Analyses were performed in SAS (version 9.4). This RCT is registered at ClinicalTrials.gov (NCT04008134).

RESULTS

A total of 2,626 participants from 769 diarrhea patient households were enrolled between December 2016 and April 2018 and randomly allocated to the standard recommendation (849), mHealth with no home visits (886), or mHealth with two home visits (891) arms (Figure 1). At the 12-month time point, 25% (189) of households were lost to follow-up. During the study period, six children died. The baseline characteristics were similar across study arms (Table 1). The median baseline age was 20 years (SD: 15 [range: 0.08–75]). Fifty-five percent (1,443/2,626) of participants were female. At baseline, 30% (780/2,625) of participants had respiratory illness, 28% (739/2,626) had coughing, 3% (84/2,625) had difficulty breathing, 2% (41/2,625) had rapid breathing, and 3% (90/2,624) had wheezing. The trial achieved high adherence to handwashing with soap behavioral recommendations (assessed by 5-hour structured observation of handwashing behavior) and high stored drinking water quality was observed (relative to *Escherichia coli*) in both mHealth arms compared with the standard message arm up to the 12-month follow-up.¹⁹

Compared with the standard message arm, participants (adults and children) had significantly lower respiratory

illness prevalence over the 12-month program period in the mHealth with no home visits arm (PR: 0.89 [95% CI: 0.80, 0.98]) and the mHealth with two home visits arm (PR: 0.89 [95% CI: 0.81, 0.99]) (Table 2). For children under 5 years of age, participants in the mHealth with no home visits arm (PR: 0.88 [95% CI: 0.79, 0.97]) and the mHealth with two home visits arm (PR: 0.91 [95% CI: 0.82, 0.99]) had significantly lower respiratory illness prevalence over the 12-month program period compared with the standard message arm. Compared with the standard message arm, participants (adults and children) had significantly higher coughing over the 12-month program period in the mHealth with no home visits arm (PR: 0.89 [95% CI: 0.80, 0.99]) and the mHealth with two home visits arm (PR: 0.88 [95% CI: 0.78, 0.98]) (Supplemental Table 1).

There was no statistically significant difference between the mHealth with two homes visits arm compared with the mHealth with no home visits arm on respiratory illness or any individual respiratory outcome (Supplemental Table 1).

DISCUSSION

Respiratory illness was significantly lower among children and adults in households receiving the CHOB17 mHealth program during the 12-month study period. Furthermore, there was no substantial added benefit of the two homes visits versus no home visits for intervention delivery. This result suggests that a single in-person visit for CHOB17 program delivery in combination with WASH mobile messages is sufficient to reduce respiratory illness over the 12-month program period. These findings complement our previous findings from the RCT of the CHOB17 mHealth program that found that this intervention significantly reduced diarrhea

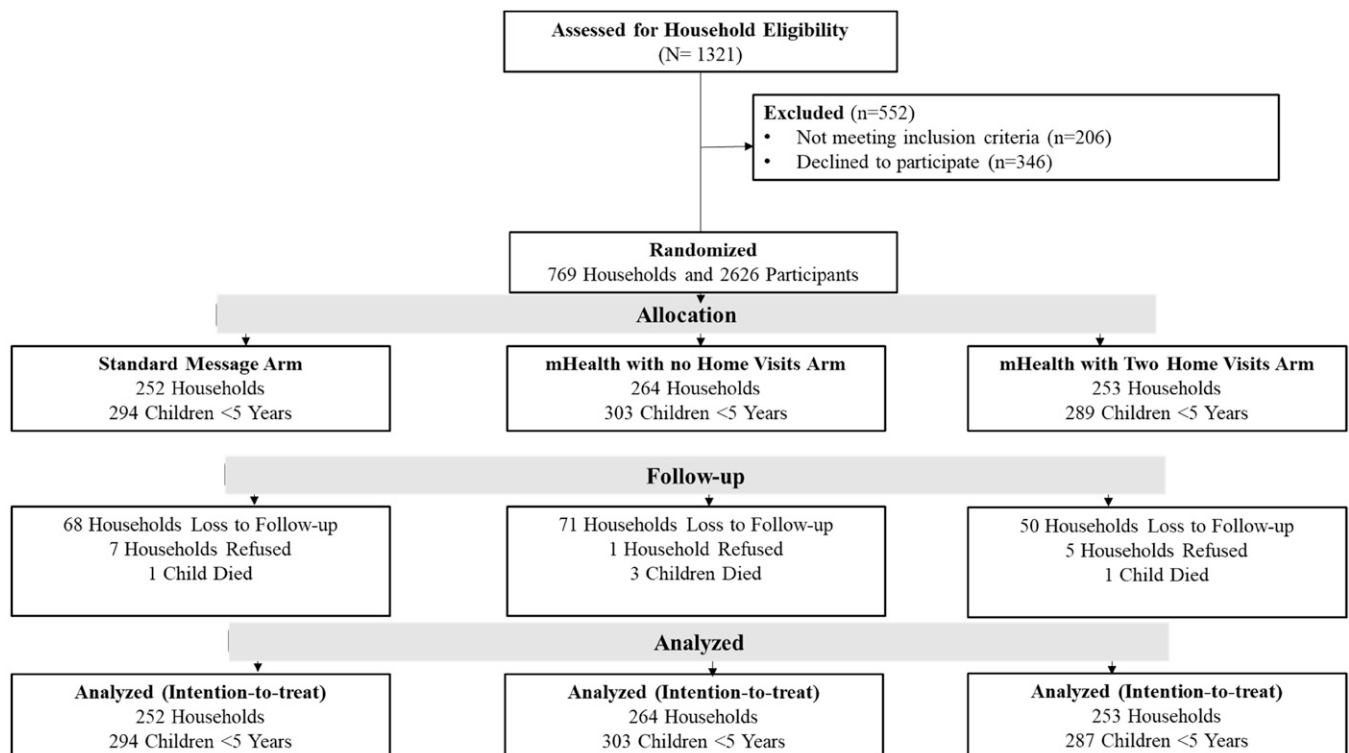


FIGURE 1. Trial profile and analysis populations for primary outcomes.

TABLE 1
Baseline population characteristics by study arm

	Standard message arm	mHealth with <u>no</u> home visits arm	mHealth with two home visits arm
Study participants	849	886	891
Children under 5 Years	294	303	287
Baseline household member age Median $\pm$ SD (Min–Max) (years)	0.9 $\pm$ 1.3 (0.08–4.8)	1 $\pm$ 1.3 (0.08–4.9)	0.9 $\pm$ 1.2 (0.08–4.8)
Gender			
% Female	42%	45%	42%
Household roof type			
Tin	33%	28%	28%
Concrete	66%	71%	72%
Other	1%	< 1%	0%
Household wall type			
Concrete	73%	71%	71%
Mud	4%	3%	4%
Tin	22%	26%	25%
Other	< 1%	0%	< 1%
Household floor type			
Concrete	96%	97%	96%
Other	4%	3%	4%
Electricity	94%	93%	92%
Refrigerator ownership	41%	45%	43%
At least one household member can read and write	92%	95%	93%
Improved sanitation	91%	93%	92%
Respiratory illness	30%	27%	33%
Coughing	28%	26%	31%
Difficulty breathing	4%	3%	3%
Rapid breathing	2%	1%	2%
Wheezing	3%	4%	3%

Acute respiratory illness was defined as caregiver-reported coughing, rapid breathing, and difficulty breathing within the past 2 weeks.

prevalence and stunting among young children, and led to sustained increases in handwashing with soap and stored drinking water quality.¹⁹

There is a growing literature showing that hand hygiene interventions can reduce respiratory illness.²¹ The soapy water promoted in the CHoBI7 mHealth program presents a low-cost alternative to bar soap that has been shown to have similar efficacy in terms of removal of *E. coli* from hands.¹¹ The handwashing station given provided a place for both soap and water to be present, which has been shown previously to be associated with hand cleanliness.²² Our findings are consistent with those from a recent RCT of a large-scale community WASH intervention in Bangladesh, which also promoted a handwashing station and soapy water and showed a significant reduction in respiratory illness.¹² This RCT evaluated a much more intensive WASH program than the CHoBI7 mHealth program, delivering an average of six household visits monthly for 2 years; however,

yielded a similar absolute reduction in respiratory illness prevalence to the RCT of the CHoBI7 mHealth program. The results from our study demonstrate that reductions in respiratory illness are possible without the need for frequent home visits by a promoter for WASH program delivery. The present study findings are in contrast to a recent RCT of a large-scale community WASH intervention in Kenya.¹³ This study, however, observed lower than expected adherence to the WASH recommendations provided. Future intervention studies are needed to establish the reproducibility of our findings in other LMIC settings.

The prevalence of respiratory illness among young children in our study setting in slum areas of Dhaka, Bangladesh is much higher than that observed previously in rural Bangladesh (43% versus 10%).¹² These findings highlight the need for interventions to reduce respiratory illness in this high-risk setting. Mobile health presents a promising scalable approach to deliver public health information, given that it

TABLE 2
Effects of the Cholera-Hospital-Based-Intervention-for-7-days (CHoBI7) mobile health program on 12-month respiratory illness prevalence

Study arm	%	Respiratory illness prevalence ¹ (coefficient [95% CI])	P value
All age groups (N = 2,626)			
Standard recommendation	26	Reference	–
mHealth with no home visits	23	0.88 (0.79 , 0.97)	0.01
mHealth with two home visits	23	0.91 (0.82, 0.99)	0.04
mHealth with two home visits vs. mHealth with no home visits		1.00 (0.90, 1.12)	0.98
Under 5 years (N = 884)			
Standard recommendation	43	Reference	–
mHealth with no home visits	38	0.89 (0.80 , 0.98)	0.02
mHealth with two home visits	39	0.89 (0.81, 0.99)	0.03
mHealth with two home visits vs. mHealth with no home visits		1.01 (0.90, 1.12)	0.93

* Percentages are the percent of surveillance visits with respiratory symptoms. CIs estimated with generalized estimating equations accounting for clustering within households. Significant findings are bolded. 1. Respiratory illness was defined as caregiver-reported rapid breathing, difficulty breathing, and coughing within the past 2 weeks.

can be sent to a large population at a low cost, and can serve as valuable reminders for facilitating behavior change.¹⁹ There is a growing body of literature demonstrating the effectiveness of mHealth in improving disease prevention practices.^{23,24} Globally, mobile phone subscriptions have doubled over the past 10 years.²⁵ In Bangladesh, 174 million phone numbers are registered with the government.²⁶ Furthermore, mHealth presents a valuable tool to reach transient populations such as those residing in slum areas of Bangladesh. Our recent mHealth survey found that over 90% of those residing in slum areas of Dhaka, Bangladesh reported active mobile phone ownership.¹⁷ This RCT of the CHOB17 mHealth program is the first to evaluate the use of a WASH mHealth program to reduce respiratory illness. There are a few studies that have used mHealth to train community health workers on pneumonia case identification and management.²⁷ Future studies are needed to develop and evaluate mHealth approaches to reduce respiratory illness among young children globally.²⁷

The findings from the qualitative formative research and RCTs of the CHOB17 program have been used as the evidence-base to take this WASH program to scale across Bangladesh.^{16,17,19,28} We are currently partnering with the Bangladesh Ministry of Health and Family Welfare to design the scaling plan for the CHOB17 program. This program will be delivered to millions across Bangladesh. The mHealth approach for program delivery allows the program to be scaled at the low cost of 4 USD per household. This cost is much lower than typical community-based WASH approaches for program delivery that can cost upward of 60 USD per household.^{29,30} The development and evaluation of the CHOB17 program presents a theory-driven and evidence-based approach for WASH intervention development that can be used in other LMIC settings globally.

This study has some limitations. First is using participant-reported respiratory symptoms rather than clinical diagnosis. Participant-reported behavior may be prone to courtesy bias; however, if courtesy bias was present, it would have likely impacted all respiratory outcomes equally, and there was no significant differences in any of our respiratory outcomes other than coughing. In addition, the link between WASH and respiratory illness was not explained as part of our health promotion program, which was conducted before the COVID-19 pandemic. Second is using difficulty breathing, fast breathing, wheezing, and coughing as respiratory outcomes that may not be specific to respiratory infections and may be indicative of other conditions, such as allergic airway disease.^{31,32} Third is focusing our intervention on diarrhea patient households that limits the generalizability of our findings to other populations. However, there are estimated to be 29 million individuals living in slum areas in Bangladesh, and 1.2 billion individuals globally.^{33–35} Therefore the study findings could be directly generalizable to this large population at high risk of diarrheal diseases. Future studies should assess the efficacy of this intervention for other populations at high risk for respiratory illness.

This study has several strengths. First is the 12-month study duration that allowed us to account for seasonal variations in respiratory illness. Second is the monthly clinical surveillance that allowed us to determine a PR over the 12-month study period. This builds on previous WASH intervention studies that collected data at two or three timepoints

for assessing respiratory illness.^{12,13} Third is including the second mHealth arm that allowed us to investigate the added benefit of home visits to the CHOB17 mHealth program. Fourth is our clinical surveillance of both child and adult respiratory illness. Most studies focus on respiratory illness in children only.

The CHOB17 mHealth program significantly lowered respiratory illness over a 12-month period. The same benefit was observed when no home visits were conducted for WASH mHealth program delivery. Our findings suggest that the CHOB17 mHealth program can be used in our study setting to reduce respiratory illness, diarrhea, and improve child growth. We are currently partnering with the Bangladesh Ministry of Health and Family Welfare to scale the CHOB17 mHealth program across Bangladesh. Future studies should investigate the efficacy of delivering CHOB17 in other settings globally.

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