

Effects of a Water, Sanitation, and Hygiene Program on Diarrhea, Cholera, and Child Growth in the Democratic Republic of the Congo: A Cluster-Randomized Controlled Trial of the Preventative Intervention for Cholera for 7 Days (PICHA7 WASHmobile) Mobile Health Program

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Background. We assessed whether the Preventative Intervention for Cholera for 7 Days (PICHA7) WASHmobile program reduced diarrhea and cholera serological responses and improved child growth in the Democratic Republic of the Congo (DRC).

Methods. The PICHA7 WASHmobile cluster-randomized controlled trial enrolled diarrhea patient households in urban Bukavu, DRC. Households were randomized into 2 arms: single in-person visit for the DRC government's diarrhea patient standard message on oral rehydration solution use and a basic water, sanitation, and hygiene (WASH) message (standard arm); or this standard message and the PICHA7 program with weekly voice and text mobile health (mHealth) messages and quarterly in-person visits (PICHA7 arm). The primary outcome was diarrhea in the past 2 weeks assessed monthly for 12 months. Secondary outcomes were healthcare facility visits for diarrhea, *Vibrio cholerae* serological response, stunting, underweight, wasting, and diarrhea with rice water stool over 12 months. A *Vibrio cholerae* serological response was defined by a rise in serum *V. cholerae* O1 O-specific polysaccharide (OSP) immunoglobulin A (IgA) or immunoglobulin G (IgG) from baseline to the 1-month follow-up. Generalized estimating equations were used for regression models to account for clustering at the individual and household level.

Results. Between December 2021 and December 2022, 2334 participants were randomly allocated to 2 arms: 1138 standard arm and 1196 PICHA7 arm. Diarrhea prevalence during the 12-month surveillance period was significantly lower among PICHA7 arm participants compared to standard arm participants (prevalence ratio, 0.39 [95% confidence interval {CI}: .32–.48]). PICHA7 arm participants had lower odds of visiting a healthcare facility for diarrhea during the 12-month surveillance period (OR: 0.44 [95% CI: .25–.77]) and lower odds of diarrhea with rice water stool (OR: 0.48 [95% CI: .27–.86]). Significantly lower *V. cholerae* IgA serological responses were observed in the PICHA7 arm compared to the standard arm, defined by a change in serum IgA to *V. cholerae* O1 OSP from baseline to the 1-month follow-up (coefficient of between-arm difference from baseline to 1 month: –0.85 [95% CI: –1.60 to –.09]). PICHA7 arm children aged <5 years were significantly less likely to be stunted (52% vs 63% standard arm) (OR: 0.65 [95% CI: .43–.99]) at the 12-month follow-up. All WASH components had high adherence.

Conclusions. The PICHA7 WASHmobile program, which combines mHealth with quarterly in-person visits, lowered healthcare facility visits for diarrhea, cholera serological responses, and stunting in the DRC.

Clinical Trials Registration. NCT05166850.

Keywords. diarrhea; cholera; serosurveillance; mobile health; randomized controlled trial.

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Globally there are an estimated 2.3 billion diarrhea episodes each year [1]. The highest burden of diarrheal disease morbidity and mortality is among children aged <5 years in sub-Saharan Africa [1, 2]. Frequent enteric infections among young children can result in intestinal inflammation leading to reduced nutrient absorption, which has been associated with impaired linear growth in young children [3]. In 2025, 150 million children aged <5 years were estimated to be stunted globally [4]. Stunting has been associated with poor cognitive outcomes and a higher risk of mortality and chronic diseases later in life [5, 6]. Effective water, sanitation, and hygiene (WASH) interventions are urgently needed to reduce diarrheal disease outbreaks and improve child growth globally.

Worldwide there are an estimated 2.9 million cholera cases annually [7]. The Democratic Republic of the Congo (DRC) has one of the highest rates of cholera in Africa [8]. Individuals living in close proximity to cholera patients are at an increased risk of subsequent cholera infections [9]. A recent study in the DRC found that individuals living within 30 m of a cholera patient were at 20 times higher risk of developing cholera during the 7-day period after patient hospitalization, with studies from other settings showing elevated risk continuing for 1 month [9, 10].

In an effort to reduce diarrheal diseases among the household members of diarrhea patients, our research group developed the Preventative Intervention for Cholera for 7 Days (PICH7) WASHmobile program in eastern DRC through 18 months of community-centered formative research [11]. “Picha” means picture in Swahili for the pictorial WASH module delivered as part of the program, and “7” indicates the 7-day high-risk period for the household members of diarrhea patients after the patient with diarrhea is admitted to a healthcare facility for treatment. The PICH7 program is healthcare facility initiated through an initial healthcare facility visit delivered by a health worker to diarrhea patients and their household members. This program is then reinforced through the PICH7 mobile health (mHealth) program, delivered through weekly voice and text messages and quarterly home visits during a 12-month period. These activities are part of our WASHmobile program, which is a WASH mHealth messaging program for populations at high risk for diarrhea including diarrhea patient households and those individuals residing in diarrhea outbreak areas. We developed a similar Cholera Hospital Based Intervention for 7 Days (CHoBI7) WASHmobile program in Bangladesh [12].

We investigated whether delivery of the PICH7 WASHmobile program through weekly voice and text messages and quarterly in-person visits to diarrhea patient households could lower diarrhea prevalence and cholera serological responses, improve child growth, and increase handwashing with soap, water quality, and water treatment behaviors during the 12-month program period.

MATERIALS AND METHODS

Study Design

The PICH7 WASHmobile study was a 2-arm cluster randomized controlled trial (RCT) conducted in urban Bukavu in South Kivu

Province of eastern DRC from 22 December 2021 to 20 December 2023. An individual diarrhea patient household was defined as a cluster. Diarrhea patients were recruited from 115 public and private healthcare facilities in Bukavu. This study compared a single in-person healthcare facility visit to deliver the DRC government’s standard message to patients with diarrhea on the use of oral rehydration solution for dehydration and a basic 5-minute WASH message (standard arm) to this standard message plus the PICH7 WASHmobile program. The PICH7 intervention includes a single in-person healthcare facility visit to deliver a WASH module, an mHealth program with weekly voice, interactive voice response, and text messages sent to patient households using the engageSPARK platform (<https://www.engagespark.com>), and quarterly home visits to reinforce WASH behaviors for 12 months. The Catholic University of Bukavu (7107) and the Johns Hopkins Bloomberg School of Public Health Institutional Review Board (9848) approved the study protocol.

Participants

To be eligible, people with diarrhea had to (1) be admitted to a healthcare facility with ≥ 3 loose stools over a 24-hour period; (2) have no running water inside of their home (mostly informal settlements areas); (3) provide a blood and a stool sample within 24 hours of enrollment (for etiology of diarrhea); (4) plan to reside in Bukavu for the next 12 months (assessed during screening prior to study enrollment); (5) have a child <5 years of age in the household; and (6) have at least 1 working mobile phone in the household. There was no age restriction for index diarrhea patients; all age groups were included if found to be eligible. Household members of the diarrhea patient were eligible for the trial 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) they planned to reside with the diarrhea patient for the next 12 months (assessed during screening prior to study enrollment). Recruitment of diarrhea patients occurred daily from December 2021 to December 2022. All study participants or their guardians provided written informed consent.

Randomization

Randomization of diarrhea patients to study arms (1:1) was performed using a random number generator. The study biostatistician (J. P.) assigned study randomization using R (version 3.3.0). J. P. was not involved in trial data collection. 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 by the study manager (P. S.). Blinding was not possible because of visible intervention components. To minimize bias, we used separate teams for intervention and evaluation activities.

Intervention Procedures

We developed the PICH7 WASHmobile program through 18 months of community-centered formative research using a

theory-informed approach guided by the Integrated Behavioral Model for Water, Sanitation, and Hygiene (IBM-WASH) [11, 13, 14]. Formative research included semi-structured interviews and a pilot study of 518 participants. A detailed description of the intervention protocol is published elsewhere [11]. The PICHA7 WASHmobile program targets 5 key behaviors: (1) preparing soapy water using water and detergent powder or water and small leftover bar soap pieces; (2) handwashing with soap or ash at food- and stool-related events; (3) safe drinking water storage in a water vessel with a lid and tap; (4) treating household drinking water using chlorine tablets; and (5) heating of household drinking water until it reaches a rolling boil after the 7-day high-risk period. The PICHA7 WASHmobile program was initially designed to focus on cholera patients and their household members. However, based on the recommendation of the DRC Ministry of Health, this WASH program was broadened to include diarrhea patients of all etiologies to allow the program to benefit millions more beneficiaries in the DRC. The PICHA7 WASHmobile program is described in detail in [Supplementary File 1](#).

Outcomes

The primary outcome was self- or caregiver-reported diarrhea prevalence captured at monthly clinical surveillance visits during the 12-month study period (at a total of 12 timepoints). Diarrhea prevalence was defined as ≥ 3 loose stools in a 24-hour period in the past 2 weeks and was investigated among all age groups, including children < 5 years and < 2 years of age. Severe diarrhea (secondary outcomes assessed monthly, which included all participants) was defined as participants visiting a healthcare facility for diarrhea treatment and participants with diarrhea with rice water stool in the past 2 weeks (key symptom of cholera [15]) at least once during the study period. A *V. cholerae* serological response (secondary outcome) was defined by a rise in immunoglobulin A (IgA) or immunoglobulin G (IgG) antibodies to *V. cholerae* O1 Ogawa or Inaba O-specific polysaccharide (OSP) from baseline to the 1-month follow-up for individuals ≥ 2 years of age. Child growth (secondary outcome) included the following measures of child growth for children < 5 years of age: (1) stunting (height-for-age z-scores [HAZ] < -2); (2) underweight (weight-for-age z-scores [WAZ] < -2); and (3) wasting (weight-for-height [WHZ] z-scores < -2). WASH-related secondary outcomes were (1) observed handwashing with soap at stool- and food-related events; (2) *Escherichia coli* in stored drinking water; and (3) free chlorine in stored drinking water < 0.2 and < 0.5 mg/L.

Research officers conducting evaluation activities received a 3-month formal training during the pilot study period prior to the RCT start. Diarrhea prevalence was assessed during monthly clinical surveillance visits. In a nested substudy of a randomly selected subset of participants, blood samples were collected at baseline and 1 month for *V. cholerae* serological analyses for

individuals ≥ 2 years of age. Blood was collected by venipuncture by nurses during healthcare facility and household visits. Serum was separated from blood and frozen at -80°C . Serum samples were shipped to the United States and analyzed for IgG and IgA antibodies to *V. cholerae* O1 Ogawa and Inaba OSP using an enzyme-linked immunosorbent assay (ELISA) adapted from previously published methods [16].

In brief, using the Tecan Freedom EVO 96-well liquid handling system, Nunc Maxisorp 384-well plates (Invitrogen) were coated with $1.0\text{ }\mu\text{g/mL}$ OSP:bovine serum albumin (BSA) (from Dr Edward Ryan, Massachusetts General Hospital, Boston, Massachusetts, USA) in carbonate buffer and incubated overnight at 4°C . All plates were then blocked, and serum (diluted 1:10 in BioStab antibody stabilizer [Sigma-Aldrich], further diluted 1:10 in 0.1% BSA-phosphate-buffered saline-Tween [0.05%]) was added to the plate to incubate for 2 hours at room temperature. Plates were incubated with 1:1000 dilution of anti-human IgG or IgA (Invitrogen) horseradish peroxidase conjugate for 2 hours at room temperature. Plates were developed by using the substrate 3,3',5,5'-tetramethylbenzidine (Sigma) and were read kinetically at 405 nm for 20 minutes at 2-minute intervals using a BioTek Synergy plate reader (Agilent). ELISA units were normalized to a monoclonal antibody standard (from Dr Richelle Charles, Massachusetts General Hospital, Boston, Massachusetts, USA).

For children < 5 years of age, research officers trained in standardized anthropometry measured each child's weight and length (< 2 years)/height (≥ 2 years) 3 times at baseline and at a 12-month follow-up [17]. Seca infant length boards model 417 were used for children aged < 2 years and Seca model 213 height boards for children aged 2–5 years. The average of these 3 measurements was taken at each timepoint. The window for anthropometric measurements at baseline was < 48 hours after enrollment, and for the 12-month follow-up the anthropometric measurement was collected at ≥ 365 days after enrollment. Due to the coronavirus disease 2019 pandemic and ongoing conflict at our study site, only a subset of children had baseline anthropometric measurements collected within the required window of 48 hours after enrollment. HAZ, WAZ, and WHZ were calculated according to the World Health Organization (WHO) child growth standards [18].

Unannounced spot checks to prevent households preparing for the study team's arrival were performed in a random subset of 100 households per study arm at day 7 and at 1, 3, 6, 9, and 12 months after enrollment to collect a household stored water sample to measure free chlorine and *E. coli*. The WHO guideline for drinking water quality of < 1 colony-forming unit (CFU)/100 mL of *E. coli* in drinking water was used as the cut-off to define safe drinking water quality relative to microbial contamination [19]. The WHO free chlorine guidelines of > 0.2 mg/L and > 0.5 mg/L for drinking water were used as cut-offs for a safe minimum drinking water level of free chlorine

[20]. Five-hour structured observations were conducted in a random subset of 50 households per study arm at day 7 and at 1, 3, 6, 9, and 12 months after enrollment. Handwashing with soap was recorded at the following key events promoted in PICHA7: (1) after using the toilet; (2) after cleaning a child's anus; (3) after removing a child's feces; (4) before eating; (5) before feeding a child; (6) before preparing food; and (7) before serving food.

Statistical Analysis

The sample size calculation for diarrhea prevalence was based on a diarrhea prevalence of 10% for all ages using Global Burden of Disease Study [21] estimates and 22% for children aged <5 years from the DRC Demographic Health Survey [22]. The calculation assumed a 25% minimum detectable difference between study arms, a type I error α of .05, a power $(1-\beta)$ of .80, and 6 individuals per household (based on PICHA7 pilot surveillance data) [23]. The sample size calculation indicated 250 diarrhea patient households per study arm (500 households total, 3000 participants), assuming a 23% loss to follow-up (based on the PICHA7 WASHmobile pilot), to detect a 2.5% change in diarrhea prevalence for all ages (10% standard arm vs 7.5% in the intervention arm) and to detect a 5.5% change in diarrhea prevalence for children aged 0–4 years (22% vs 16.5%).

We analyzed participant data according to their randomized assignment (intention-to-treat), irrespective of their adherence to the assigned intervention. The statistical analysis plan implemented was the same as that for the CHoBI7 WASHmobile RCT (NCT04008134), our RCT conducted in Bangladesh with the identical study design for evaluation activities [24]. This statistical analysis plan was finalized prior to data analysis. Log binomial regression was performed to estimate the prevalence ratio (PR) for diarrheal disease using generalized estimating equations (GEEs) to account for clustering at the individual (repeated surveillance visits) and household level and to approximate 95% confidence intervals (CIs). Diarrhea prevalence was calculated using all monthly visits during the 12-month surveillance period and was defined as a 12-month diarrhea prevalence (multiple observations are included for each individual).

Logistic regression was performed to estimate odds ratios (ORs) for binary growth measures and linear regression was performed for changes in *V. cholerae* serological antibodies using GEEs to account for household clustering. Models for diarrheal disease were adjusted for follow-up timepoint (timepoint for each observation was included in the model to adjust for seasonality), and models for child growth were adjusted for baseline growth measurements. For the growth analysis, we excluded observations with z-scores outside the biologically plausible ranges according to WHO recommendations [18]. Models for serum *V. cholerae* serological antibodies were adjusted for baseline IgA or IgG to *V. cholerae* O1 Ogawa or Inaba OSP,

and the higher value for the change in either Inaba or Ogawa was used to define the change in *V. cholerae* O1 antibodies. Logistic regression models were performed to compare WASH intervention fidelity indicators by study arm using GEEs to account for household clustering and approximate 95% CIs. Analyses were performed in SAS software (version 9.4). The trial is registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT05166850). Loss to follow-up was defined as individuals with no diarrhea prevalence data after baseline (individuals who did not contribute to the analysis for the primary study outcome).

RESULTS

Research officers identified 853 diarrhea patients with a child aged <5 years in their household during screening; 40% (337) were found to be ineligible. The most common reason for ineligibility was having a tap with running water in one's home at 30% (101/337). Sixty-nine percent (359/516) of diarrhea patients eligible for the study agreed to participate from 87 health facilities. Between December 2021 and December 2022, we randomly allocated 359 diarrhea patient households (2334 participants) to the standard and PICHA7 program arms (Figure 1). A map of the study area is shown in [Supplementary File 2](#). Fourteen percent of participants (342/2334) were lost to follow-up after baseline enrollment. When a sensitivity analysis was performed comparing participants lost to follow-up after baseline versus those participants available during the study follow-up period, there were no significant differences observed in baseline diarrhea prevalence or baseline household and individual-level characteristics ([Supplementary Table 1](#)). Eighteen participants died during the study period (3 adults and 15 children). Enrolled household baseline characteristics were similar across study arms ([Table 1](#)). Most study households had at least 1 person who could read and write (98%). Thirty-three percent of children aged <5 years (259/794) were index diarrhea patients in their households (35% in the standard arm and 30% in the PICHA7 arm).

Among all participants (all ages), 12-month diarrhea prevalence was significantly lower (diarrhea prevalence over the 12-month study period assessed through monthly visits) in the PICHA7 arm (PR: 0.39 [95% CI: .32–.48]) compared to the standard arm (Figure 2). Similarly, significantly lower 12-month diarrhea prevalence in the PICHA7 arm was observed for children aged <5 years (PR: 0.38 [95% CI: .31–.46]) and children aged <2 years (PR: 0.43 [95% CI: .35–.53]). [Supplementary Table 2](#) includes analyses by age group and sex.

There was a 56% lower odds of participants visiting a health-care facility for diarrhea during the 12-month surveillance period in the PICHA7 arm compared to the standard arm (all age groups) (OR: 0.44 [95% CI: .25–.77]) (5% vs 2% [$n = 1981$]). Participants in the PICHA7 arm had a 52% lower odds of

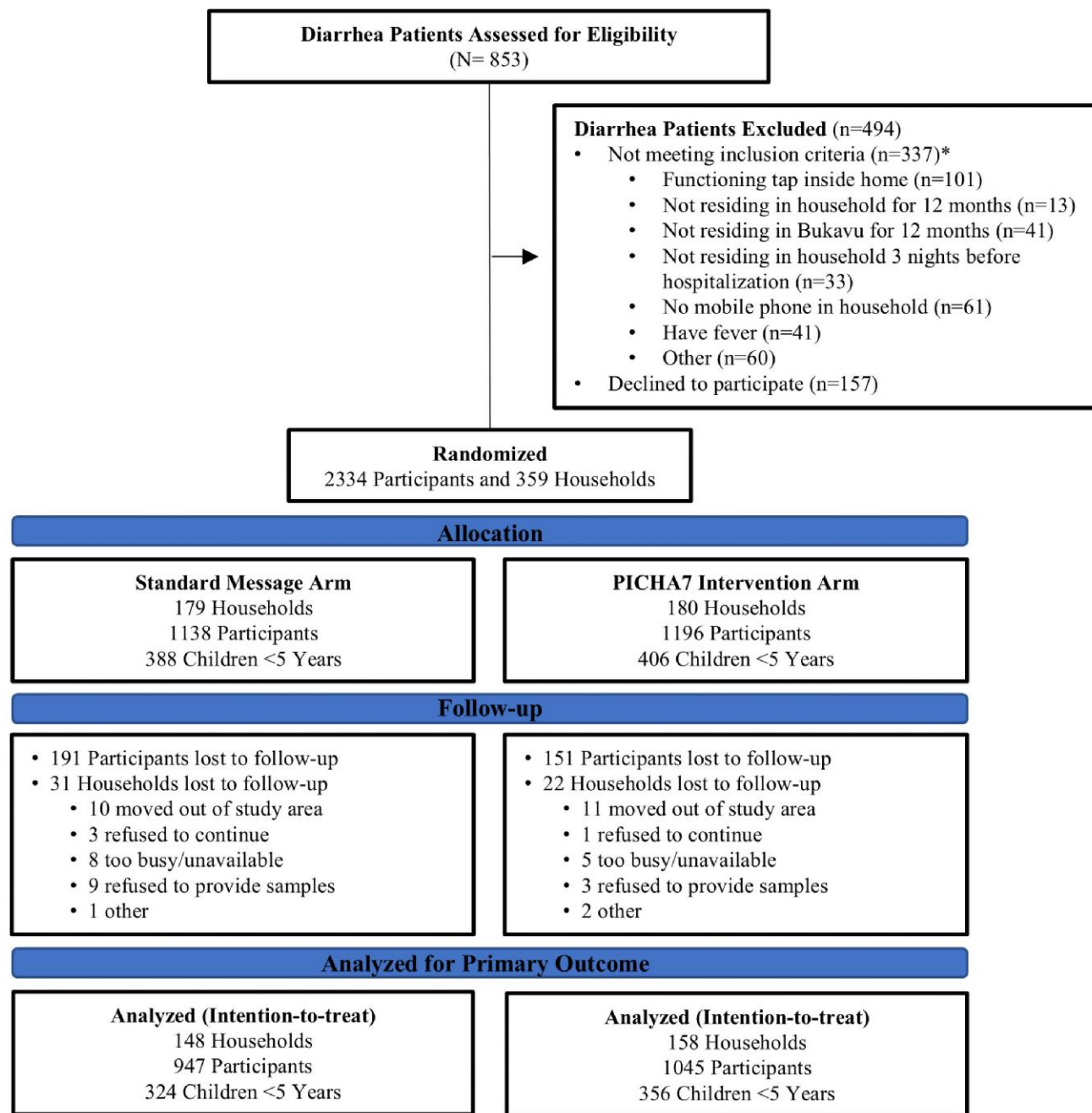


Figure 1. Trial profile and analysis populations for primary outcomes. *Inclusive; participants may be listed under multiple exclusion criteria. Abbreviation: PICHA7, Preventative Intervention for Cholera for 7 Days.

diarrhea with rice water stool during the 12-month surveillance period compared to the standard arm (all age groups) (OR: 0.48 [95% CI: .27–.86]) (4% vs 2% [n = 1992]). Significantly lower *V. cholerae* IgA serological responses were observed in the PICHA7 arm compared to the standard arm, defined by a change in IgA to *V. cholerae* O1 OSP from baseline to the 1-month

follow-up (coefficient, -0.85 [95% CI, -1.60 to $-.09$]) for individuals ≥ 2 years of age (n = 573) (Figure 3 and Supplementary Figure 1). No other significant associations were found. Baseline demographic characteristics of those who provided serological data for *V. cholerae* are shown in Supplementary Table 3.

Table 1. Baseline Population Characteristics by Study Arm

Characteristic	Standard Message Arm			PICHA7 Arm		
	%	no.	No.	%	no.	No.
Index diarrhea patient households			179			180
All study participants			1138			1196
Household members of index diarrhea patients	84%	957	1138	85%	1016	1196
Children aged <5 y	34%	388	1138	34%	406	1196
Baseline participant age						
Mean $\pm$ SD (Min–Max), y		13.2 $\pm$ 13.3 (0–70.7)			13.6 $\pm$ 13.8 (0–78.5)	
0–1 y	19%	212	1138	18%	213	1196
2–4 y	15%	176	1138	16%	193	1196
5–17 y	38%	435	1138	38%	454	1196
≥ 18 y	28%	315	1138	28%	336	1196
Sex						
Female	58%	663	1138	59%	709	1196
Household size						
Mean $\pm$ SD (Min–Max)		7.2 $\pm$ 2.6 (3–16)			7.3 $\pm$ 2.7 (1–15)	
Household roof type						
Concrete	6%	10	169	5%	8	171
Other	94%	159	169	95%	163	171
Household income						
Yes	93%	156	168	96%	163	170
No	7%	12	168	4%	7	170
Refrigerator ownership	4%	6	169	4%	6	171
Baseline water source						
<1 CFU/100 mL of <i>E. coli</i>	65%	64	99	61%	57	93
1–10 CFUs/100 mL of <i>E. coli</i>	11%	11	99	15%	14	93
>10–100 CFUs/100 mL of <i>E. coli</i>	11%	11	99	11%	10	93
>100 CFUs/100 mL of <i>E. coli</i>	13%	13	99	13%	12	93
At least 1 household member can read and write	98%	165	168	98%	168	171

Abbreviations: CFU, colony-forming unit; *E. coli*, *Escherichia coli*; PICHA7, Preventative Intervention for Cholera for 7 Days; SD, standard deviation.

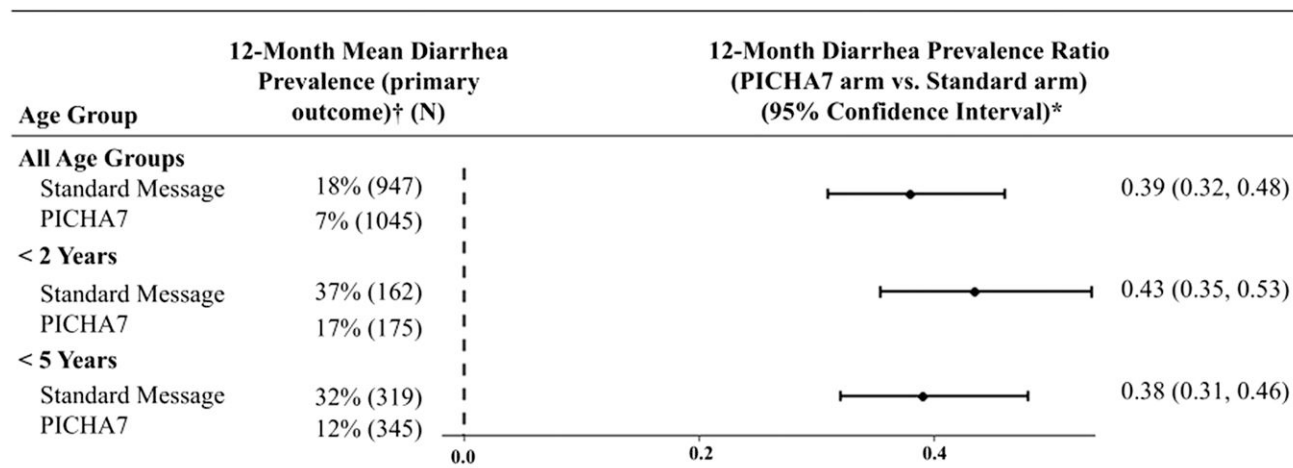


Figure 2. Effects of the PICHA7 program on 12-month diarrhea prevalence (primary outcome). †Diarrhea is ≥ 3 loose stools in a 24-hour period in the past 2 weeks from monthly surveillance visits after baseline. *Adjusted for follow-up timepoint. N indicates total sample size. Abbreviation: PICHA7, Preventative Intervention for Cholera for 7 Days.

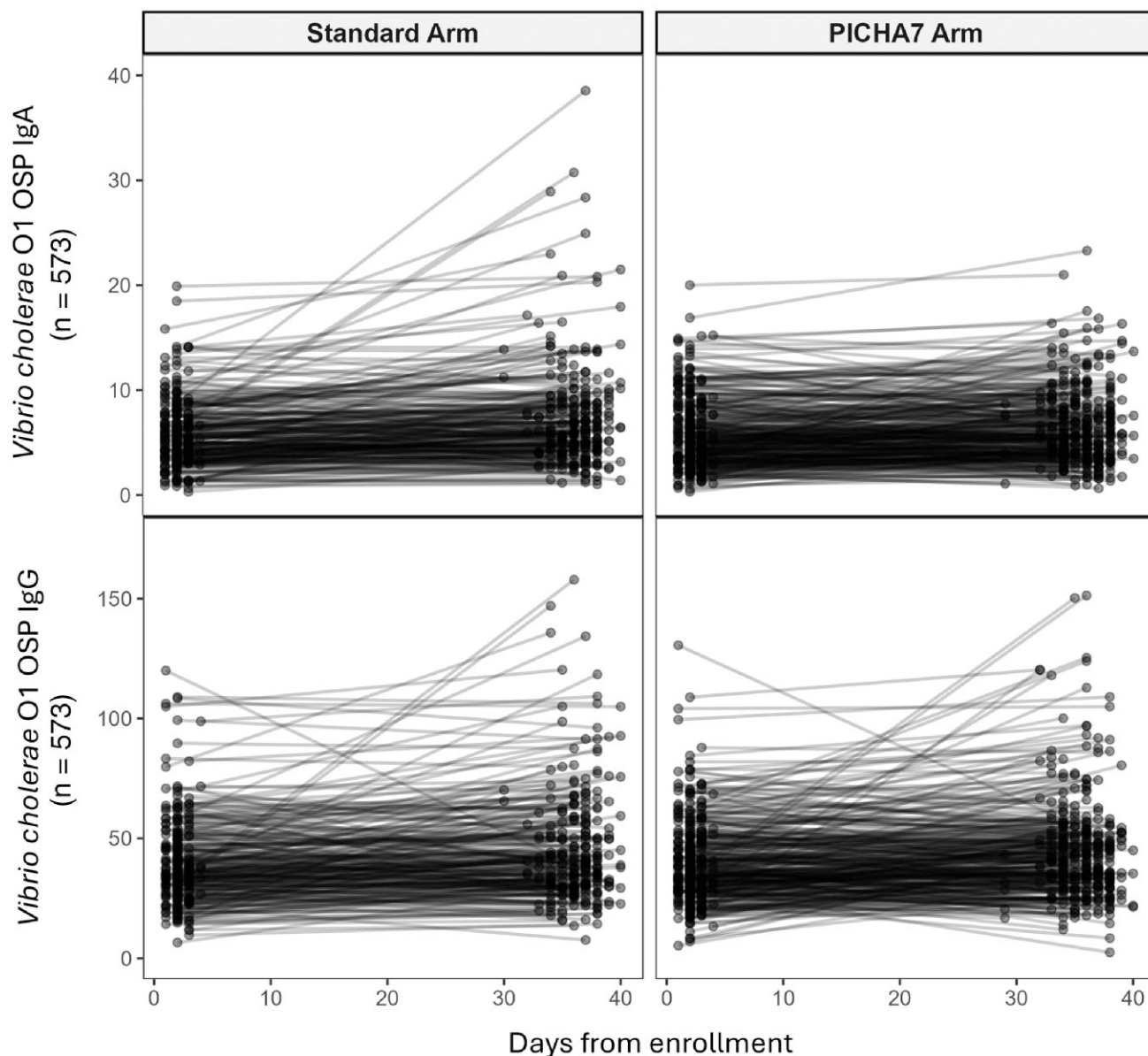


Figure 3. Line graph by study arm of serum IgA and IgG *Vibrio cholerae* O1 O-specific polysaccharide serological antibody responses from baseline to the 1-month follow-up for individuals ≥ 2 years of age ($n = 573$). Abbreviations: IgA, immunoglobulin A; IgG, immunoglobulin G; OSP, *Vibrio cholerae* O1 O-specific polysaccharide; PICHA7, Preventative Intervention for Cholera for 7 Days.

Children < 5 years of age were significantly less likely to be stunted at the 12-month follow-up in the PICHA7 arm compared with the standard arm (52% vs 63%) in the unadjusted model (OR: 0.65 [95% CI: .43–.99]) and after adjustment for baseline growth measures (OR: 0.45 [95% CI: .21–.98]) (Table 2). Stunting worsened in both study arms during the study period; however, this decline was less in the PICHA7 arm (48% stunting at baseline to 52% at the 12-month follow-up in the PICHA7 arm and compared to 52% to 63% in the standard arm). There were no other significant differences in stunting, wasting, or underweight identified between study arms.

Compared to the standard arm, handwashing with soap at stool- or food-related events was significantly higher in the PICHA7 arm at all timepoints (week 1: OR: 11.4 [95% CI: 5.51–26.6] to month 12: OR: 11.8 [95% CI: 6.41–21.7]) (Table 3). This impact was similar for both stool- and food-related events individually. Relative to the WHO water quality guideline of < 1 CFU/100 mL of *E. coli*, the PICHA7 arm had significantly higher water quality compared to the standard arm at all timepoints (week 1: OR: 6.48 [95% CI: 2.61–16.1] to month 12: OR: 4.28 [95% CI: 1.83–10.0]). Relative to the WHO free chlorine guidelines for household

Table 2. Effects of PICHA7 Program on Child Growth at the 12-Month Timepoint

12-Month Timepoint	Standard Message Arm				PICHA7 Arm				Effect Size or OR (95% CI) (PICHA7 vs Standard arm)	
	Mean	SD	%	No.	Mean	SD	%	No.	Unadjusted	Adjusted Model ^a
Children aged <5 y										
Stunting (HAZ)	0.63	0.48	63%	240	0.52	0.50	52%	246	0.65 (.43–.99)	0.45 (.21–.98)
Underweight (WAZ)	0.25	0.44	25%	238	0.21	0.41	22%	247	0.82 (.51–1.34)	1.11 (.49–2.54)
Wasting (WHZ)	0.03	0.17	3%	237	0.04	0.20	4%	247	1.39 (.52–3.70)	1.79 (.37–8.65)
Children aged <2 y										
Stunting (HAZ)	0.57	0.49	59%	116	0.52	0.50	52%	121	0.76 (.45–1.30)	0.70 (.26–1.87)
Underweight (WAZ)	0.20	0.40	20%	114	0.23	0.42	23%	121	1.19 (.62–2.29)	1.20 (.43–3.35)
Wasting (WHZ)	0.04	0.18	4%	114	0.05	0.22	5%	121	1.53 (.43–5.51)	^b

Abbreviations: CI, confidence interval; HAZ, height-for-age z-score; OR, odds ratio; PICHA7, Preventative Intervention for Cholera for 7 Days; SD, standard deviation; WAZ, weight-for-age z-score; WHZ, weight-for-height z-score.

^aModel adjusted for baseline HAZ, WAZ, and WHZ.

^bNot estimable due to the low prevalence of wasting using a Fisher exact test $P = .75$. Length used for children <2 years of age.

water treatment, PICHA7 arm households had significantly higher free chlorine >0.2 mg/L and >0.5 mg/L compared to the standard arm households at all timepoints (>0.2 mg/L free chlorine: week 1: OR: 13.7 [95% CI: 7.03–26.8] to month 12: OR: 17.5 [95% CI: 8.71–35.1]; >0.5 mg/L free chlorine: week 1: OR: 84.0 [95% CI: 28.2–250.1] to month 6: OR: 40.3 [95% CI: 13.5–120.5]).

DISCUSSION

Delivery of the PICHA7 WASHmobile program to diarrhea patient households resulted in significantly lower diarrhea prevalence, cholera serological responses, and stunting compared to those receiving the standard of care given by the DRC government of ORS and a basic WASH message. Severe diarrhea, including healthcare facility visits for diarrhea and diarrhea with rice water stool (key cholera symptom) were also halved. Furthermore, PICHA7 led to improvements in handwashing with soap and water treatment behaviors and stored drinking water quality, which program households sustained for 12 months. These findings suggest that the targeted PICHA7 WASHmobile program, which combines mHealth messaging with quarterly in-person visits, can be delivered to reduce diarrhea, decrease cholera serological responses, and improve child growth in the DRC among diarrhea patient households.

The findings from the PICHA7 RCT in the DRC are consistent with our previous RCT of the similar CHoBI7 WASHmobile program in Bangladesh, which found that CHoBI7 significantly lowered diarrhea and stunting among diarrhea patient households [24]. This promising result suggests that this targeted WASH program for diarrhea patient households delivered through mHealth messaging and quarterly in-person visits has the potential to reduce diarrhea and improve child growth in two distinct contexts. Our study site in urban DRC differs from our site in urban Bangladesh because of a

lower proportion of safely managed water services (24% DRC vs 54% Bangladesh) [25], lower improved sanitation (53% vs 90%) [25], lower population density (13 449 [Bukavu] vs 41 000 [Dhaka] individuals per sq km) [26], higher prevalence of moderate/severe food insecurity (77% vs 31%) [27], and higher household size (6.5 individuals per household [from our PICHA7 RCT] vs 3.4 [24]). Our formative research was critical to tailor the CHoBI7 WASHmobile program from Bangladesh to this different context [11].

An important finding from our PICHA7 and CHoBI7 WASHmobile RCTs is that WASH behavior change is possible without needing frequent promoter home visits. In CHoBI7, only a single in-person visit in a healthcare facility was delivered with or without 2 home visits (there was no added benefit found for the two home visits) [24], and in PICHA7 an in-person visit in the healthcare facility followed by quarterly in-person home visits were delivered for 12 months. Our findings are in contrast to previous WASH intervention studies which found that frequent in-person visits (fortnightly or more) were needed for a positive effect on diarrhea [28]. Public community health workers currently conduct household visits for WASH promotion in South Kivu province in the DRC; therefore, PICHA7 delivery through in-person visits quarterly has the potential to be integrated into this existing community health worker programming at scale. Furthermore, mHealth messaging appears to be a promising approach to reinforce WASH recommendations delivered during in-person visits to facilitate WASH behavior change. The process evaluation of the PICHA7 mHealth program found that 84% of text messages were received and 90% of voice calls were answered during the 12-month program (Sanvura et al, unpublished data). Our recent pilot in the DRC of the PICHA7 WASHmobile mHealth program combined with e-vouchers for chlorine tablets delivered to areas with ongoing diarrhea outbreaks found this program resulted in the majority of households redeeming e-vouchers for

Table 3. Effects of the PICH7 Program on Individuals Handwashing With Soap at Stool- and Food-Related Events During 5-Hour Structured Observation (Individuals >2 Years) and Household Stored Drinking Water Quality and Chlorination Assessed During Unannounced Spot Checks

Timepoint	1 Week		1 Month		3 Months		6 Months		9 Months		12 Months	
	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)	%	OR (95% CI)
Individuals handwashing with soap at a stool- or food-related event												
Standard message arm (n = 617)	10%		12%		8%		5%		4%		7%	
PICH7 arm (n = 693)	57%	11.4 (5.51–26.6)	49%	7.09 (3.41–14.7)	46%	8.34 (3.15–22.1)	51%	17.3 (7.37–40.6)	49%	18.5 (7.12–48.3)	48%	11.8 (6.41–21.7)
Individuals handwashing with soap at a food-related event												
Standard message arm (n = 564)	8%		10%		8%		4%		4%		7%	
PICH7 arm (n = 651)	52%	11.6 (4.92–27.2)	47%	7.27 (3.28–16.1)	42%	7.95 (2.81–22.5)	46%	17.5 (6.62–46.2)	44%	15.6 (4.98–49.1)	44%	9.09 (4.62–17.9)
Individuals handwashing with soap at a stool-related event												
Standard message arm (n = 411)	6%		6%		7%		2%		3%		4%	
PICH7 arm (n = 455)	54%	13.1 (5.04–33.7)	36%	8.18 (3.35–19.9)	48%	11.4 (3.02–43.2)	51%	38.4 (8.80–167.4)	45%	22.9 (6.43–81.9)	44%	20.2 (8.14–49.9)
Households with stored drinking water with <1 CFU/100mL <i>E. coli</i>												
Standard message arm (n = 134)	61%		67%		57%		56%		61%		48%	
PICH7 arm (n = 151)	90%	6.48 (2.61–16.1)	92%	5.76 (2.08–16.0)	91%	7.13 (2.20–23.1)	95%	15.7 (4.12–59.1)	82%	2.86 (1.04–7.91)	85%	4.28 (1.83–10.0)
Households with stored drinking water with free chlorine >0.2 mg/L												
Standard message arm (n = 154)	30%		27%		34%		40%		24%		25%	
PICH7 arm (n = 161)	86%	13.7 (7.03–26.8)	75%	8.00 (4.17–15.4)	82%	8.59 (3.96–18.7)	77%	5.02 (2.60–9.69)	84%	16.5 (7.17–38.1)	85%	17.5 (8.71–35.1)
Households with stored drinking water with free chlorine >0.5 mg/L												
Standard message arm (n = 154)	4%		2%		5%		5%		2%		1%	
PICH7 arm (n = 161)	78%	84.0 (28.2–250.1)	64%	76.4 (17.8–329.1)	74%	58.0 (16.3–205.5)	67%	40.3 (13.5–120.5)	78%	^a	76%	^a

Water quality analyses adjusted for water source *Escherichia coli* concentration.

Abbreviations: CFU, colony-forming units; CI, confidence interval; OR, odds ratio; PICH7, Preventative Intervention for Cholera for 7 Days.

^aNot estimable due to the low prevalence of the outcome.

chlorine tablets at their local pharmacies and having free chlorine >0.2 mg/L in stored drinking water (George et al, unpublished data). However, PICHA7 and CHoBI7 are the only RCTs of WASH mHealth programs. Additional trials are needed in rural settings and other settings globally to evaluate the impact of WASH mHealth programs on diarrheal diseases and child growth.

The effect of the PICHA7 WASHmobile program on diarrhea prevalence was stronger than the effect we observed in the CHoBI7 WASHmobile RCT over the same 12-month program period (diarrhea reduction for all ages: 61% PICHA7 vs 33% CHoBI7). This may be because of the higher diarrhea prevalence for children aged <5 years in the PICHA7 RCT (32% PICHA7 vs 21% CHoBI7), allowing for more room for WASH delivery improvement in diarrhea. Additionally, this may be because of the higher intensity of the PICHA7 WASHmobile program, which had quarterly in-person intervention visits over a 12-month period compared to only 2 in-person visits during the 7-day high-risk period after diarrhea patient admission in the CHoBI7 program.

The PICHA7 WASHmobile program significantly lowered a serological response to cholera during the 1-month high-risk period for cholera infections for the household members of cholera patients after the healthcare facility admission. Consistent with this finding, the PICHA7 program was found to be effective in reducing severe diarrhea by half, including diarrhea healthcare facility visits and diarrhea with rice water stool (cholera symptom). Our findings are consistent with a study conducted in the DRC, which found that hygiene kit delivery to suspected cholera patient households resulted in a 56% lower incidence of suspected cholera (defined by diarrhea, vomiting, or a diarrhea healthcare facility visit) [29]. These findings are also consistent with our CHoBI7 RCT in Bangladesh, which found that delivery of the CHoBI7 program to cholera patient households (bacterial culture confirmed) resulted in a 47% reduction in cholera infections confirmed by bacterial culture among household members [30].

In our recent cohort study conducted at the same study site in the DRC, we found that 67% of cholera patients' households had at least 1 cholera-infected household contact during the 1-month period after the cholera patient was admitted at the healthcare facility (George et al, 2025, in press). This finding demonstrated the high-risk of cholera for the household members of cholera patients and the need for targeted WASH for this population. The promising results from the RCTs of the PICHA7 and CHoBI7 WASHmobile programs suggest that this type of targeted WASH program for high risk populations for diarrhea may be effective in reducing healthcare facility visits for diarrhea including severe forms of diarrhea such as cholera.

There have only been 3 published WASH studies to date that have used serological markers to detect recent enteric infections. In Rwanda, an RCT of a point-of-use water filters found

significant reductions in IgG responses to *Cryptosporidium* 12 months after intervention delivery [31]. In Guatemala, an RCT of a chlorination, flocculation, and safe drinking water storage program found no significant differences by study arm in serologic antibody responses to *Cryptosporidium*, *Giardia*, enterotoxigenic *E. coli* (ETEC), or norovirus at the 12-month follow-up [32]. In Mali, a matched-control trial found that a latent variable combining IgG antibody responses for ETEC and *V. cholerae* was positively associated with delivery of a school-based WASH intervention [33]. Interestingly, in the RCT of the PICHA7 WASHmobile program we saw a significant effect on IgA *Vibrio cholerae* serological markers, with a similar coefficient but nonsignificant effect on IgG. This is likely due to the higher initial fold-change rise in anti-OSP IgA compared to IgG responses (seen especially in children) upon exposure to *V. cholerae*, which would be more likely to be captured in the 1-month time window for follow-up [16, 34]. Future studies are needed that investigate the impact of PICHA7 on cholera exposure over a longer duration and that analyze serum samples for multiple enteropathogen exposures.

The PICHA7 WASHmobile program significantly reduced stunting among children aged <5 years. This finding is consistent with an RCT in Mali, which found that a WASH program focused on community-led total sanitation (CLTS) reduced stunting [35]. The RCTs of PICHA7 in DRC, CHoBI7 in Bangladesh, and CLTS in Mali are the only 3 RCTs to date, to our knowledge, that have found a significant association between WASH delivery and improvements in children's linear growth. In the CLTS RCT in Mali, stunting was reduced, but not diarrhea [35], whereas the PICHA7 and CHoBI7 WASHmobile RCTs are the only WASH RCTs that significantly reduced both stunting and diarrhea among young children [24]. For the interpretation of PICHA7 RCT stunting findings, it should be noted that stunting worsened in both study arms during the 12-month study period but less for those in the PICHA7 arm (48% to 52% in the PICHA7 arm and 52% to 63% in the standard arm). We attribute the impact of the PICHA7 program on stunting to the large reduction in diarrhea prevalence (>60% reduction for children aged <5 years), the high adherence observed for handwashing with soap and water treatment, and high baseline stunting prevalence (50%), which likely allowed more room for improvement in child growth with WASH intervention delivery.

No significant impact of PICHA7 was observed for any other growth parameter other than stunting. One potential explanation for this finding is the need for PICHA7 to be combined with nutritional supplements for young children. Our previous work at this study site found that only 26% of children consumed 5 or more minimum dietary diversity food groups [36], and moderate/severe food insecurity in the DRC is estimated to be 77% [27]. However, previous trials investigating the impact of combined WASH and nutrition programming

did not observe an impact on child growth [37, 38]. Future RCTs are needed to evaluate if combining the PICHA7 and CHoBI7 WASHmobile programs targeted at high-risk populations for diarrheal diseases with nutritional supplements can facilitate improvements in wasting and other growth parameters in children.

This study has limitations. First, we relied on self- or caregiver-reported diarrhea. We did assess *V. cholerae* serological responses using OSP IgA and IgG responses by ELISA. However, exposure is often defined by vibriocidal responses, future studies can examine this marker. Second, we only assessed the impact of PICHA7 among diarrhea patient households. This group was selected since they represent a high-risk population for diarrheal diseases; however, studies have shown that other households residing within 500 m of diarrhea patients' households are also at higher risk of diarrheal diseases [9, 10, 39]. Future studies should evaluate the impact of delivery of PICHA7 in a ring around diarrhea patient households on reducing diarrhea in these diarrheal disease hotspots. Additionally, because all PICHA7 intervention components were combined and not evaluated separately, it is not possible to determine which PICHA7 intervention component was most influential in the success of this program. Future studies should investigate the efficacy of the individual components of PICHA7 on diarrheal disease and child growth.

The PICHA7 WASHmobile RCT has several strengths: First is the monthly clinical surveillance data for both children and adults, building on previous WASH studies that focused mostly on diarrhea among children <5 years of age. Second is the inclusion of severe diarrhea measures including healthcare facility visits for diarrhea and diarrhea with rice water stool (symptom of cholera). Most WASH studies focus on mild to moderate diarrhea. Third is the inclusion of 115 healthcare facilities in the PICHA7 RCT patient recruitment, which allowed for the intervention to be tested in a wide range of public and private health facilities. Fourth is the inclusion of serology to assess cholera immune responses.

CONCLUSIONS

The PICHA7 WASH program significantly lowered diarrhea and stunting and led to sustained WASH behavior during the 12-month program period. Furthermore, PICHA7 resulted in lower cholera serological responses and severe diarrhea, including healthcare facility visits for diarrhea and diarrhea with rice water stool. These findings suggest that the PICHA7 WASH program can be used as a targeted approach to reduce cholera exposure among this high-risk population. We are currently partnering with the DRC Ministry of Health to develop strategies to scale the PICHA7 WASHmobile program as part of the DRC National Cholera Control Plan. Our findings suggest that the PICHA7 WASHmobile program, which combines mHealth

and quarterly in-person visits, presents a promising approach to reduce diarrhea, cholera, and improve child growth for diarrhea patient households in the DRC. This is consistent with our earlier findings from our CHoBI7 WASHmobile program in Bangladesh. Future trials are needed in diverse settings globally to investigate the health impacts of WASH programs combining mHealth and in-person visits for intervention delivery.

Supplementary Data

Supplementary materials are available at [Clinical Infectious Diseases](https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaf417/8251358) online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

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