

Psychosocial Factors Mediating the Effect of the CHoBI7 Mobile Health Program on Handwashing With Soap and Household Stored Water Quality: A Randomized Controlled Trial

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Abstract

Household members of diarrhea patients are at higher risk of developing diarrheal diseases (>100 times for cholera) than the general population during the 7 days after the diarrhea patient is admitted at a health facility. There is growing evidence demonstrating that theory-driven water, sanitation, and hygiene (WASH) interventions are likely to yield greater behavior change than those based on health education alone. The Cholera Hospital-Based Intervention for 7-Days (CHoBI7) mobile health (mHealth) program is a theory-driven WASH intervention initially delivered to a diarrhea patient by a health promoter during a health facility visit and reinforced through weekly voice and text messages. In the recent randomized controlled trial (RCT) of the CHoBI7-mHealth program in Bangladesh, this intervention significantly reduced diarrheal disease and stunting, and increased handwashing with soap and stored drinking water quality over the 12-month program period. The aim of this study was to assess the underlying mechanism of change of this intervention. Handwashing with soap was measured by 5-hour structured observation. Stored drinking water quality was assessed by the presence of *Escherichia coli* during unannounced spot checks. Psychosocial factors were measured among 1,468 participants in the CHoBI7-mHealth RCT. Perceived susceptibility, response efficacy, self-efficacy, dirt reactivity, and diarrhea knowledge were mediators of the CHoBI7-mHealth program's effect on stored drinking water quality at the 1-week follow-up. Self-efficacy, response efficacy, and diarrhea knowledge were mediators of the intervention's effect on handwashing with soap habit maintenance and stored drinking water quality at the 12-month follow-up. This study demonstrates how theory-driven approaches for intervention design can facilitate WASH behavior change.

Keywords

Bangladesh, formative research, interpersonal communication, mobile health, psychosocial factors, mediation analysis, randomized trials

Diarrheal diseases cause 1.6 million deaths annually (GBD-Collaborators, 2018). Water, sanitation, and hygiene (WASH) programs promoting water treatment and handwashing with soap have the potential to reduce diarrheal disease incidence in young children (Wolf et al., 2018). However, sustaining these WASH behaviors over time remains a major challenge (Luby et al., 2009). There is an urgent need for scalable effective WASH interventions to reduce diarrheal diseases globally among young children in low resource settings.

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Mobile Health to Facilitate Behavior Change

Mobile phone reminders are an emerging low-cost intervention approach to deliver public health information that has been shown to lead to significantly improved case management and disease prevention practices (Cole-Lewis & Kershaw, 2010; Free et al., 2013; Gibson et al., 2017; Higgs et al., 2014; Zurovac et al., 2011). Globally, mobile phone subscriptions have doubled over the past 10 years (ICT, 2017). In Bangladesh alone, more than 165 million phone numbers are registered (Bangladesh Telecommunication Regulatory Commission, 2019; GSMA, 2018). Given the high mobile phone coverage globally, the use of mobile phones to deliver WASH behavioral recommendations presents a potentially scalable approach to deliver diarrheal disease control programs. However, there is very limited evidence on effective approaches for delivering WASH mHealth programs (George et al., 2020; Tidwell et al., 2019).

Theory-Driven Approaches for Water, Sanitation, and Hygiene Program Development

WASH programs often solely focus on increasing WASH knowledge (Curtis et al., 2011). This is despite the growing evidence demonstrating that theory-driven interventions are likely to yield greater behavior change than those based on increasing health knowledge alone (Contzen et al., 2015; Inauen & Mosler, 2013; Michie & Prestwich, 2010; Taylor et al., 2012; Webb et al., 2010). Theory-based interventions are guided by behavior change theories and models that identify factors known to facilitate behavior change and provide a framework for intervention delivery. Examples of these theories and models include the theory of planned behavior, protection motivation theory, the integrated behavioral model for WASH (IBM-WASH), the health belief model, and the risks, attitudes, norms, abilities, and self-regulation (RANAS) model (Ajzen, 1985; Carpenter, 2010; Dreibelbis et al., 2013; Mosler, 2012; Rogers, 1975). Furthermore, beyond assessing the efficacy of WASH interventions, it is important to understand their underlying mechanism of change (Michie & Abraham, 2004). This allows for a better understanding of why an intervention was effective or ineffective, and for future interventions to target identified psychosocial factors associated with WASH behaviors (Lippke & Ziegelmann, 2008; Michie & Abraham, 2004). However, the use of behavior change techniques (a systematic procedure included as a potentially active component of an intervention designed to change behavior; Michie et al., 2016) for the development of WASH programs that are guided by behavior change theories and models is relatively rare (Curtis et al., 2009; Curtis et al., 2011; Devine et al., 2012).

Rationale for Study

Household members of diarrhea patients are at a much higher risk of developing diarrheal diseases (>100 times for

cholera) than the general population during the 7 days after the diarrhea patients presents at a health facility for treatment (George et al., 2015; George et al., 2018). However, despite this risk, there are limited interventions targeting this highly susceptible population (George, Monira, et al., 2016; Khan, 1982). The time diarrhea patients and their household members spend at a health facility for treatment presents an ideal opportunity to deliver WASH communication programs when perceived severity of diarrheal diseases and perceived benefits of WASH behaviors are likely the highest (Figuerola & Kincaid, 2007). This led to the development of the Cholera Hospital-Based Intervention for 7 Days (CHoBI7; George, Monira, et al., 2016). *Chobi* means “picture” in Bangla for the pictorial modules delivered as part of the intervention. This targeted WASH intervention focuses on promoting handwashing with soap and water treatment to diarrhea patients and their household members. This intervention is delivered during the 1-week period after the patient is admitted to the health facility through health facility and home visits by a promoter. In the 2013–2014 randomized controlled trial (RCT) of the CHoBI7 program among cholera patient households in Dhaka, Bangladesh, this intervention was shown to significantly reduce symptomatic cholera and led to significant sustained improvements in household stored drinking water quality and handwashing with soap practices 12 months postintervention (George, Jung, et al., 2016; George, Monira, et al., 2016).

Building on these findings, the current work in partnership with the Bangladesh Ministry of Health and Family Welfare focuses on developing and evaluating approaches to take the CHoBI7 program to scale across Bangladesh. This led to the development of the CHoBI7-mHealth program, which delivers the CHoBI7 program through a health facility visit, and reinforces WASH behavioral recommendations through weekly text and voice mobile phone reminders (George et al., 2019). This intervention approach removes the need for home visits for intervention delivery. The recent 2016–2019 RCT of the CHoBI7-mHealth program among diarrhea patient households in Dhaka, Bangladesh, demonstrated that this intervention was effective in significantly reducing diarrhea prevalence and stunting among young children and led to sustained increases in handwashing with soap and improved stored drinking water quality at the 12-month follow-up (George et al., 2020).

In this study, we investigate why the CHoBI7-mHealth program was effective in increasing handwashing with soap and stored drinking water quality. The first objective was to determine the impact of this intervention on targeted psychosocial factors at 1 week (habit formation) and 12 months after enrollment (habit maintenance). The second objective was to conduct a mediation analysis to investigate the psychosocial factors mediating habit formation and habit maintenance for handwashing with soap and stored drinking water quality.

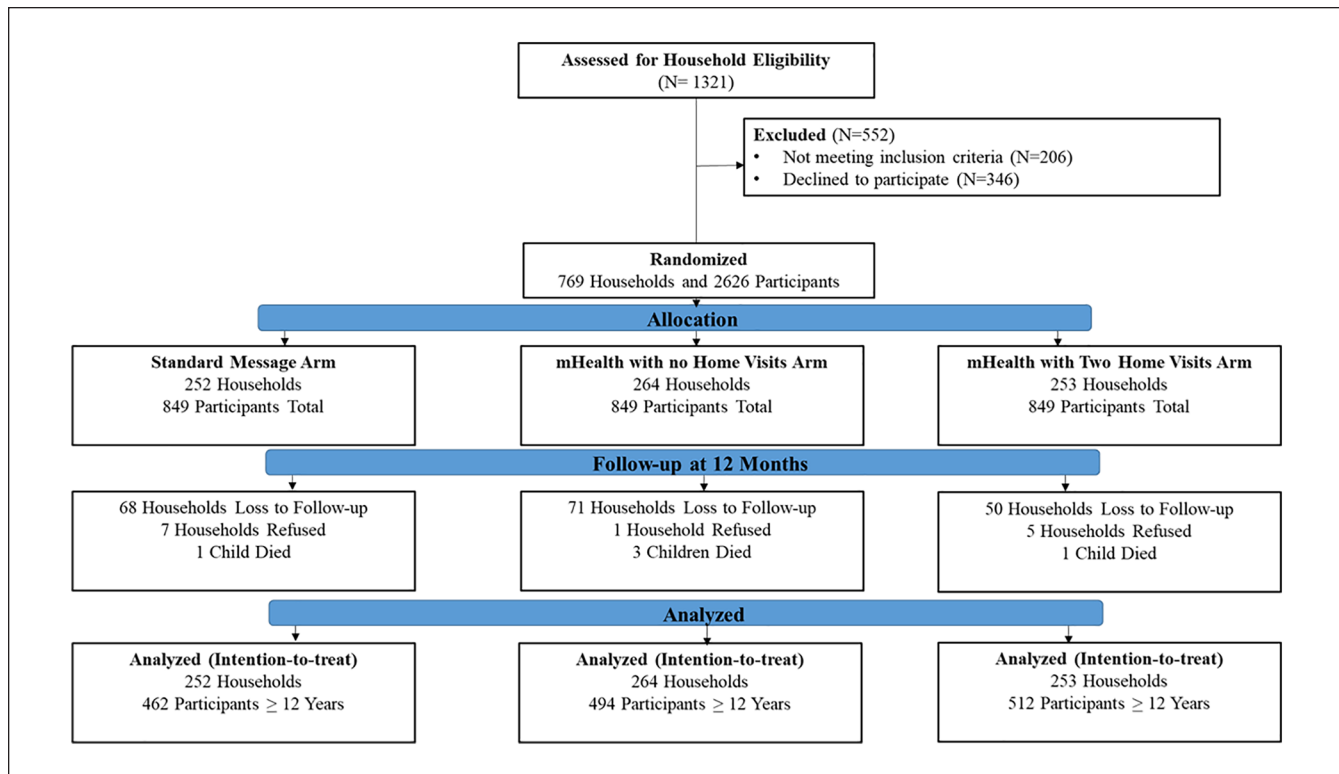


Figure 1. Trial profile and analysis populations for outcomes.

Method

Study Design

A three-arm cluster RCT of the CHoBI7-mHealth program was conducted in urban Dhaka, Bangladesh, from December 2016 to April 2019, where a diarrhea patient's household was a cluster including the patient and their corresponding household members. Diarrhea patients were recruited from two tertiary-level health facilities. The RCT compared the standard recommendations given in Bangladesh to diarrhea patients at discharge from the health facility on oral rehydration solution use for dehydration (standard message arm) to 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; Figure 1). The two home visits were delivered by health promoters twice during the 1-week high-risk period after the diarrhea patient was discharged from the health facility. All study participants provided informed consent; consent included adult participants (≥ 18 years of age) signing an informed consent and/or parental consent form and children 12 to 17 years of age signing an assent form.

Interventions

The CHoBI7-mHealth program was developed through a theory-driven approach informed by the IBM-WASH model, the

RANAS model, and protection motivation theory (Dreibelbis et al., 2013; Mosler, 2012; Rogers, 1975). This intervention was developed to target psychosocial, technological, and contextual factors at the habitual, individual, household, community, and structural levels that were found to be important drivers of our target WASH behaviors during our formative research. For example, to increase descriptive norms around target WASH behaviors, voice and text messages were sent describing the proportion of others in the community performing the same behavior. To target self-efficacy, instructions were provided on how to prepare soapy water from water and detergent powder (a low-cost alternative to bar soap). A detailed description of our formative research for intervention development is published elsewhere (George et al., 2019; Thomas et al., 2020). The CHoBI7-mHealth program is initially delivered by a health promoter during a health facility visit using a pictorial module bedside to a diarrhea patient and their accompanying household members during the time of illness. This module covers diarrhea transmission and handwashing with soap at stool (any contact with feces) and food-related (before eating, feeding a child, and food preparation) events and water treatment. A diarrhea prevention package with a 1-month supply of chlorine tablets for water treatment, a soapy water bottle containing water and detergent powder, a handwashing station, and a water vessel with a lid and tap to ensure safe water storage is provided. Households are encouraged to boil their drinking water once their supply of chlorine tablets is completed. After health facility delivery of the

program, diarrhea patient households receive weekly voice and text WASH-mobile-messages from the CHoBI7-mHealth program over a 12-month period.

Outcome Measures

To assess household stored drinking water quality, unannounced spot checks were performed in a randomly selected subset of 150 households per study arm at 1 week and at 12 months after enrollment to collect a water sample from the household's stored drinking water and water source to test for *Escherichia coli* by bacterial culture using previously published methods (Islam et al., 2001). The World Health Organization (WHO) guidelines of <1 colony-forming units (CFU)/100 ml of *E. coli* (safe drinking water quality cutoff) and <100 CFU/100 ml (high-risk drinking water cutoff) in stored drinking water were used as the cutoffs for this analysis based on the water quality outcomes specified for the RCT (George et al., 2020; WHO, 2011). Reported water treatment was not used as an outcome because 99% of participants reported boiling or treating their water with chlorine at the 1-week follow-up across all study arms. Key times for handwashing with soap promoted as part of the CHoBI7-mHealth program were (1) after using the toilet, (2) after cleaning a child's anus and feces, (3) before eating and feeding a child, and (4) before preparing food. To observe handwashing behaviors at these key times, 5-hour structured observation was conducted in a randomly selected subset of 50 households per study arm at 1 week and at 12 months after enrollment.

Psychosocial Factors

Participants 12 years of age or older were administered a structured psychosocial factor questionnaire at baseline, 1 week, and at 12 months after enrollment. Psychosocial items were derived from protection motivation theory, IBM-WASH, and the RANAS model, and from items previously published in the earlier RCT of the first CHoBI7 program (Dreibelbis et al., 2013; George et al., 2017; Mosler, 2012; Rogers, 1975). Due to time limitations during household visits, most factors were limited to a single item. Given that most factors were measured by one or two items for handwashing with soap and water quality outcomes, all items were analyzed individually. Items were ordinal and measured using Likert-type scale answering options ranging from 1 to 5, except for diarrhea knowledge, which had a score range of 0 to 10. Definitions of factors, item statements, and behavior change technique used to target each psychosocial factor are included in Table 1. The statements for all items are included in Table 2. The following psychosocial factors were measured: remembering (two items), diarrhea knowledge (one item), dirt reactivity (three items), response efficacy (three items), instrumental attitudes (two items), self-efficacy (six items), impediments (six items), perceived susceptibility (four items), and disgust (two items). Answering options

were as follows for remembering, dirt reactivity, response efficacy, instrumental attitudes, impediments, and disgust: 1 = *strongly disagree*, 2 = *slightly disagree*, 3 = *neither agree nor disagree*, 4 = *slightly agree*, and 5 = *strongly agree*. For perceived susceptibility the answering options were 1 = *very low*, 2 = *low*, 3 = *neither low nor high*, 4 = *high*, and 5 = *very high*. For self-efficacy, the answering options were 1 = *not sure at all*, 2 = *not sure*, 3 = *neither sure nor not sure*, 4 = *a little sure*, and 5 = *very sure*. For diarrhea knowledge, a quiz score from 0 to 10 points was calculated based on the number of points from the following three questions: (1) Can you name three important ways diarrhea can be prevented? (maximum score 3 points), (2) Can you name three important ways diarrhea is spread? (maximum score 3 points), and (3) Can you please name the four key times for handwashing with soap? (maximum score 4 points). The hypothesized change in factors with the behavior change techniques delivered is as follows:

- Hypothesis 1:** Higher Remembering
- Hypothesis 2:** Higher Diarrhea Knowledge
- Hypothesis 3:** Lower Dirt Reactivity
- Hypothesis 4:** Higher Response Efficacy
- Hypothesis 5:** Higher Convenience
- Hypothesis 6:** Higher Self-Efficacy
- Hypothesis 7:** Less Impediments
- Hypothesis 8:** Higher Perceived Susceptibility
- Hypothesis 9:** Higher Disgust.

Power Calculation

The sample size calculation for this study was based on the primary outcome of diarrhea prevalence in the past 2 weeks using the rate of 8% for children younger than 5 years from an urban cohort in Dhaka, Bangladesh (Dr. A. S. G. Faruque, personal communication, 2015) and a minimum detectable difference between study arms of 25% based on the 2015 Cochrane review (Ejemot-Nwadiaro et al., 2015). The calculation assumed a two-sided type I error α of .05, a power $(1 - \beta)$ of .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

Pearson correlations were calculated for psychosocial factors at baseline in the standard message arm. Linear regression models were performed for psychosocial factor outcomes and logistic regression models for behavioral outcomes using generalized estimating equations to account for clustering within households, with study arm as the predictor. Because initial enrollment of diarrhea patients was conducted in the health

Table 1. Psychosocial Factors Measured in the Randomized Controlled Trial of the CHoB17-mHealth Program.

Factor category ^a	Definition	Behavior change technique delivered ^d	Hypothesized change with intervention	Example statement
Remembering	To perform a behavior, it has to be remembered at the right time/situation (Tobias, 2009)	Voice and text mobile messages reminding households to wash hands with soap at food and stool related events and to treat household drinking water.	H1: Higher Remembering	It is hard to remember to wash your hands with soap after using the toilet.
Diarrhea Knowledge	An awareness of diarrhea transmission and prevention	Pictorial module delivered by a promotor and text and voice mobile messages on diarrhea transmission and prevention.	H2: Higher Diarrhea Knowledge	Quiz Score (0–10): (1) Can you name three important ways diarrhea can be prevented? (2) Can you please name the four key times for handwashing with soap? (3) Can you name three important ways diarrhea is spread?
Dirt Reactivity	Only washing hands with soap or treating water in response to dirt, feces, or smell	Pictorial module delivered by a promotor and text and voice mobile messages stating "Diarrhea germs have no taste or smell; they're invisible, therefore visibly clean hands and water will still have these diarrhea germs."	H3: Lower Dirt Reactivity	If your water looks clear, you do not need to boil your water.
Response Efficacy ^b	Judgments about the efficacy of a preventive response that will avert the perceived threat (Prentice-Dunn & Rogers, 1986)	Pictorial module delivered by a promotor and voice and text mobile messages stating "To prevent getting diarrhea and spreading diarrhea to the ones you love, you should wash your hands with soap at the key moments specified."	H4: Higher Response Efficacy	How high or low are the chances you will develop diarrhea if you always boil your household water?
Convenience (Instrumental Attitudes)	Beliefs about the benefits and costs of a behavior (Fishbein & Ajzen, 2010)	Enabling technology: Distribution of handwashing station, soapy water bottle, water vessel with lid and tap, and chlorine tablets by a promotor to facilitate hand washing with soap and water treatment behaviors.	H5: Higher Convenience	Boiling your household drinking water is too costly.
Self-Efficacy ^c	The belief in one's capabilities to organize and execute the courses of action required to manage prospective situations (Bandura, 1997)	Enabling technology: Distribution of handwashing station, soapy water bottle, water vessel with lid and tap, and chlorine tablets by a promotor to facilitate hand washing with soap and water treatment behaviors.	H6: Higher Self-Efficacy	How sure are you that you can make hand washing soap available for your family every day?
Impediments	Anticipated barriers and distractions to a behavior (Contzen et al., 2015)	Enabling technology: Distribution of handwashing station, soapy water bottle, water vessel with lid and tap, and chlorine tablets by a promotor to facilitate hand washing with soap and water treatment behaviors.	H7: Less Impediments	You have no place to wash your hands with soap.
Perceived Susceptibility ^b	A person's subjective perception of their risk of contracting diarrhea (Orbell et al., 2009)	Pictorial module delivered by a promotor and voice and text mobile messages stating "Because someone in your family got diarrhea, you are at a very high risk of developing diarrhea for next 7 days."	H8: Higher Perceived Susceptibility	If a family member gets diarrhea, how high or low are the chances that you would contract diarrhea?
Disgust	Revulsion that is occasioned by the sight of excreta, rotten food, slime, and bugs (Curtis & Biran, 2001)	Pictorial module delivered by a promotor and voice and text mobile messages stating as follows: (1) The most upsetting fact about diarrhea germs is that it comes from human feces. (2) Diarrhea may spread from water and hands contaminated with feces; therefore, when we prepare food or eat food without washing our hands with soap or drink untreated water, we could be consuming feces.	H9: Higher Disgust	You wash your hands with soap after toileting because your hands could have feces on them.

Note. H = hypothesis; CHoB17 = Cholera Hospital-Based Intervention for 7 Days; mHealth = mobile health.

^aFactors are ordinal and range between 1 and 5, except for Diarrhea Knowledge that has a score range of 0 to 10 based on responses to open-ended questions. Answering options were as follows unless otherwise noted: 1 = strongly disagree, 2 = slightly disagree, 3 = neither agree nor disagree, 4 = slightly agree, and 5 = strongly agree. ^bThe answering options were 1 = very low, 2 = low, 3 = neither low nor high, 4 = high, and 5 = very high. ^cThe answering options were 1 = not sure at all, 2 = not sure, 3 = neither sure nor not sure, 4 = A little sure, and 5 = very sure. ^dA behavior change technique as defined by Michie et al. (2016) is a systematic procedure included as a potentially active component of an intervention designed to change behavior.

Table 2. Analysis of Psychosocial Factors by Study Arm at 1 Week and 12 Months for All Participants.

Factor category	Statement	1-Week follow-up (N = 842) ^a						12-Month follow-up (N = 882) ^a									
		Standard message arm			mHealth no home visits arm			Standard message arm			mHealth no home visits arm						
		M	SD	p	M	SD	p	M	SD	p	M	SD	p				
Remembering	It is hard to remember to wash your hands with soap before preparing a meal.	3.32	1.54	2.30	1.48	<.0001	2.28	1.56	<.0001	3.01	1.66	2.44	1.65	<.0001	2.33	1.64	<.0001
	Washing your hands with soap after using the toilet is hard to remember.	2.36	1.59	1.66	1.26	<.0001	1.67	1.28	<.0001	2.06	1.58	1.77	1.42	.04	1.63	1.33	.001
	You only wash your hands with soap when they have a bad smell.	2.74	1.70	2.11	1.54	<.0001	2.27	1.60	<.002	2.40	1.76	2.22	1.65	.27	2.30	1.75	.54
Dirt Reactivity	If your water looks clear, you do not need to boil your water.	1.79	1.48	1.44	1.14	.004	1.50	1.22	.02	1.906	1.61	1.64	1.4	.06	1.64	1.43	.07
	You only boil your drinking water when it has a bad smell.	1.79	1.47	1.57	1.27	.08	1.64	1.36	.24	1.811	1.54	1.68	1.44	.41	1.67	1.44	.33
	Soap is too costly to use for handwashing.	1.80	1.38	1.47	1.14	.003	1.49	1.15	.01	1.73	1.43	1.52	1.21	.11	1.52	1.25	.11
Instrumental Attitudes	You only boil your household drinking water is too costly.	1.44	1.11	1.47	1.19	.73	1.28	0.90	.07	1.583	1.36	1.56	1.34	.87	1.54	1.29	.70
	How high or low are the chances you will develop diarrhea if you always wash your hands?	1.76	0.66	1.60	0.59	.004	1.61	0.68	.01	1.83	0.61	1.74	0.55	.11	1.78	0.61	.42
	How high or low are the chances you will develop diarrhea if you always boil your household water?	1.71	0.56	1.52	0.54	.0001	1.52	0.54	.0001	1.83	0.77	1.6	0.8	.003	1.60	0.79	.001
Response Efficacy	You believe that boiling your drinking water would make your family free from diarrhea.	4.90	0.45	4.90	0.54	.99	4.91	0.53	.84	4.91	0.51	4.85	0.71	.21	4.96	0.32	.19
	How sure are you that you can make handwashing soap available for your family every day?	4.68	0.59	4.88	0.37	<.0001	4.82	0.46	.004	4.87	0.42	4.89	0.36	.57	4.88	0.53	.76
	How sure are you that you always wash your hands with soap after using the toilet?	4.47	0.89	4.80	0.49	<.0001	4.78	0.53	<.0001	4.76	0.62	4.82	0.53	.26	4.82	0.54	.23
Self-Efficacy	How sure are you that you always wash your hands with soap before eating?	3.75	1.31	4.35	0.99	<.0001	4.52	0.83	<.0001	4.23	1.19	4.43	1.03	.01	4.52	0.99	<.0001
	If someone in your home gets diarrhea, how sure are you that you can prevent the spread of diarrhea?	3.44	1.37	4.08	1.08	<.0001	4.16	1.03	<.0001	3.77	1.19	4.19	0.99	<.0001	4.14	0.97	.0002
	How sure are you that after you boil your water, you can protect it from becoming dirty?	4.43	0.88	4.67	0.61	.0007	4.62	0.80	.02	4.642	0.76	4.64	0.9	.97	4.76	0.61	.09
Impediments	How sure are you that you can explain to your other family members how to boil drinking water?	4.42	0.89	4.78	0.49	<.0001	4.74	0.56	<.0001	4.65	0.56	4.8	0.5	.001	4.87	0.48	<.0001
	Presently, soap for handwashing is not available in your home.	1.33	1.03	1.12	0.65	.01	1.15	0.71	.03	1.25	0.96	1.28	0.99	.72	1.32	1.08	.48
	If you put soap near the toilet, people will steal it.	3.14	1.73	3.22	1.74	.61	3.12	1.78	.88	2.72	1.84	2.62	1.87	.58	2.72	1.87	.99
Perceived Susceptibility	You have no place to wash your hands with soap.	1.80	1.44	1.31	0.95	<.0001	1.29	0.96	<.0001	1.45	1.21	1.30	1.03	.14	1.28	0.97	.11
	If a family member gets diarrhea when they do not wash their hands with soap before eating.	4.87	0.59	4.91	0.49	.31	4.88	0.64	.81	4.72	0.95	4.83	0.74	.14	4.79	0.87	.36
	People can get sick with diarrhea when they do not wash their hands with soap before eating.	3.63	1.01	3.69	1.00	.51	3.66	0.97	.75	3.755	0.95	3.79	0.93	.66	3.79	0.86	.68
Disgust	How high or low are the chances that you would get diarrhea this year?	3.00	1.04	2.76	1.06	.01	2.62	1.05	<.0001	2.309	0.93	2.22	0.88	.28	2.18	0.89	.14
	Many people in your neighborhood can get sick with diarrhea from unboiled water here.	4.88	0.53	4.84	0.65	.44	4.86	0.67	.66	4.874	0.55	4.9	0.5	.59	4.86	0.65	.77
	You feel your hands are disgusting after cleaning up a child's feces.	4.02	1.55	3.89	1.60	.37	4.09	1.47	.63	4.08	1.44	4.07	1.50	.94	3.91	1.56	.23
Diarrhea Knowledge	You wash your hands with soap after toileting because your hands could have feces on them.	4.84	0.60	4.87	0.56	.54	4.87	0.56	.50	4.85	0.65	4.79	0.70	.37	4.88	0.51	.47
	Quiz Score (0–10) based on the following questions: (1) Can you name three important ways diarrhea can be prevented? (2) Can you name the four key times for handwashing with soap? (3) Can you name three important ways diarrhea is spread?	4.45	1.44	4.95	1.94	.0008	5.15	1.80	<.0001	4.43	1.61	4.8	1.7	.02	0.01	1.89	<.0001

Note. mHealth = mobile health.

^ap Value compares standard message arm to the respective mHealth arm (boldface indicates significant effects, $p < .05$).

facility followed by enrollment of household members of the patient within 24 hours, some household members of diarrhea patients in the intervention arms may have been exposed to the intervention before enrollment and being administered the psychosocial item questionnaire at baseline. Therefore, we do not have a representative baseline assessment of psychosocial factors from all intervention arm study participants.

To investigate potential mediators of the CHoBI7-mHealth program effect, simple mediation models were performed using the "INDIRECT" macro (Preacher & Hayes, 2008). Because directional hypotheses were tested for the mediation analysis, 90% confidence intervals were estimated. Bootstrapping with 10,000 resamples was performed. Psychosocial items were included in the mediation analysis if they were found to be significantly different between the mHealth arms and the standard message arm. Mediation models for stored drinking water quality included source water *E. coli* in the model to adjust for variation in source water quality between households. All analyses were performed in SAS software (Version 9.4).

Results

A total of 1,468 participants from 769 households enrolled in the RCT of the CHoBI7-mHealth program were 12 years of age or older and were administered the psychosocial factor questionnaire at baseline (462 standard message arm participants, 494 mHealth with no home visit arm participants, and 512 mHealth with two home visits arm participants). Twenty-one percent (313/1,468) of participants were lost to follow-up (no follow-up surveillance data available), and 1,155 participants had 1-week or 12-month follow-up data available. The mean baseline age for participants was 29 years ($SD = 10$, range 12–80). Sixty-three percent (918/1,468) of participants were female. Seventy percent (540/769) of households had a concrete roof. Ninety-three percent (715/769) of households had electricity. Seventy percent (536/769) of households owned a television and 43% (330/769) owned a refrigerator. Ninety-three percent (717/769) of households had at least one person that could read and write. At baseline, 26% (197/762) of households had source water with *E. coli* < 1 CFU/100 ml, and 34% (261/762) had stored drinking water with *E. coli* < 1 CFU/100 ml. Ninety-six percent (371/385) of participants at baseline reported treating their drinking water by boiling in the past 48 hours, and 99% (365/370) at the 1-week follow-up. The median number of individuals in a household was 4 and the mean was 4.7 individuals (range 2–12).

CHoBI7-mHealth Program Effect on Handwashing With Soap and Stored Drinking Water Quality

At the 1-week follow-up, 89% (65/73) of participants in the mHealth with two home visits arms ($p \leq .0001$) and 82%

(51/62) in the mHealth with no home visits arm ($p = .017$) washed their hands with soap at a key time during 5-hour structured observation compared with 53% (24/45) in the standard message arm. For food-related events at the 1-week follow-up, 73% (52/71) of participants washed their hands with soap in the mHealth with two home visits arm ($p < .0001$) and 56% (34/61) in the mHealth with no home visits arm ($p = .02$), compared with 33% (14/43) in the standard message arm. For stool-related events at the 1-week follow-up, 77% (46/60) of participants washed their hands with soap in the mHealth with two home visits arm ($p = .003$) and 81% (44/54) in the mHealth with no home visits arm ($p = .0006$), compared with 46% (17/37) in the standard message arm. At the 12-month follow-up, 43% (36/84) of participants in the mHealth with two home visits arm washed their hands with soap at a key time during structured observation ($p = .92$) and 51% (42/82) in the mHealth with no home visits arm ($p = .25$), compared with 42% (32/76) in the standard message arm. For food-related events at the 12-month follow-up, 34% (27/80) of participants washed their hands with soap in the mHealth with two home visits arm ($p = .003$) and 42% (31/73) in the mHealth with no home visits arm ($p = .0064$), compared with 14% (9/66) in the standard message arm. For stool-related events at the 12-month follow-up, 40% (23/58) of participants washed their hands with soap in the mHealth with two home visits arm ($p = .43$) and 38% (21/55) in the mHealth with no home visits arm ($p = .35$), compared with 47% (25/53) in the standard message arm.

At the 1-week follow-up, 68% of participants (130/190) had stored drinking water in their households with <1 CFU/100 ml of *E. coli* during unannounced spot checks in the mHealth with two home visits arm ($< .0001$) and 50% (90/179) of participants in the mHealth with no home visits arm ($< .0001$) compared with 8% (17/205) in the standard message arm. At the 1-week follow-up, 81% (158/194) of participants had stored drinking water quality in their households with <100 CFU/100 ml of *E. coli* during unannounced spot checks in the mHealth with two home visits arm ($< .0001$) and 73% (133/183) of participants in the mHealth with no home visits arm ($< .0001$) compared with 51% (107/208) in the standard message arm. At the 12-month follow-up, 16% (44/279) of participants in the mHealth with two home visits arm had <1 CFU/100 ml *E. coli* in stored drinking water ($p = .79$) and 16% (38/236) in the mHealth with no home visits arm ($p = .70$), compared with 15% (33/223) in the standard message arm. Sixty percent (170/282) of participants in the mHealth with two home visits arm had <100 CFU/100 ml *E. coli* in stored drinking water ($p = .02$) and 59% (139/237) in the mHealth with no home visits arm ($p = .05$), compared with 50% (111/224) in the standard message arm at the 12-month follow-up.

Analyses of Psychosocial Factors

The largest Pearson correlation coefficients for psychosocial items measured at baseline in the standard message arm were

for two self-efficacy items (Supplemental Tables 1 and 2). Psychosocial factors at baseline by study arm are presented in Supplemental Tables 3 and 4.

One-Week Follow-Up. At the 1-week follow-up, there was significantly less difficulty remembering to wash hands with soap before preparing a meal and after using the toilet in both mHealth arms compared with the standard message arm, consistent with Hypothesis 1 (H1) in Table 1 (Table 2). Diarrhea knowledge (H2) was significantly higher in both mHealth arms. There was significantly less dirt reactivity around washing hands with soap and boiling water (H3) in both mHealth arms. Response efficacy of handwashing with soap and boiling water to reduce diarrhea (H4) was also significantly higher in both mHealth arms. In addition, soap for handwashing was considered significantly less costly (instrumental attitudes; H5) in both mHealth arms, and these arms had higher reports of soap being available for handwashing and a designated place for handwashing in the home (less impediments; H7). Self-efficacy for handwashing with soap, teaching family members to boil water, and the ability to stop the spread of diarrhea in the home (H6) were also significantly higher in both mHealth arms. Perceived susceptibility of developing diarrhea over the next year was significantly lower (H8) in both mHealth arms.

Twelve-Month Follow-Up. At the 12-month follow-up, there was significantly higher remembering of handwashing with soap before preparing a meal and after using the toilet in both mHealth arms (H1). There was also significantly higher diarrhea knowledge (H2) and higher response efficacy for boiling water to reduce diarrhea (H4) in both mHealth arms. Self-efficacy was significantly higher for handwashing with soap before eating, reducing the spread of diarrhea in the home, and teaching family members to boil water (H6) in both mHealth arms.

Mediation Analyses. In the handwashing with soap mediation models, self-efficacy for handwashing with soap was found to significantly mediate the CHoBI7-mHealth program effect at the 12-month follow-up (Table 3 and Supplemental Figures 1 and 2). This same association was also found when this analysis was restricted to food-related handwashing with soap (Supplemental Tables 5 and 6). In the stored water quality mediation models for *E. coli* <1 CFU/100 ml, perceived susceptibility, diarrhea knowledge, response efficacy, and self-efficacy were found to significantly mediate the CHoBI7 intervention effect at the 1-week follow-up (Table 4 and Supplemental Table 3). In the stored water quality mediation models for *E. coli* <100 CFU/100 ml, perceived susceptibility, diarrhea knowledge, dirt reactivity, response efficacy, and self-efficacy were found to significantly mediate the CHoBI7 intervention effect at the 1-week follow-up (Supplemental Table 7 and Supplemental Figure 3). At the 12-month follow-up for stored drinking water with *E. coli* <1 CFU/100 ml, response efficacy and self-efficacy were

significant mediators of the CHoBI7-mHealth program effect (Supplemental Figure 4). In the stored water quality mediation models for *E. coli* <100 CFU/100 ml, diarrhea knowledge was a significant mediator of the CHoBI7 intervention effect at the 12-month follow-up.

Discussion

This is the first RCT to investigate the underlying mechanism of change of a WASH mHealth program. The CHoBI7-mHealth program significantly increased remembering, response efficacy, self-efficacy, and diarrhea knowledge, and lowered dirt reactivity compared with the standard message given in Bangladesh on ORS. These results were consistent with H1 to H7. Response efficacy, self-efficacy, perceived susceptibility, and diarrhea knowledge were mediators of the CHoBI7-mHealth program's effect on stored drinking water quality meeting the WHO guideline at the 1-week follow-up. Furthermore, self-efficacy, response efficacy, and diarrhea knowledge were mediators of the CHoBI7-mHealth program's effect on handwashing with soap habit maintenance and stored drinking water quality at the 12-month follow-up. These findings were consistent across the mHealth arms. The findings from this RCT allowed us to identify the psychosocial factors that were mediators of the high efficacy of the CHoBI7-mHealth program in increasing handwashing with soap and household stored drinking water quality at the 1 week follow-up and sustained behavior at the 12 month follow-up. These psychosocial factors will be targeted during the scaling of the CHoBI7-mHealth program across Bangladesh.

Psychosocial Factors Mediating High Handwashing With Soap and Stored Drinking Water Quality in CHoBI7-mHealth Program

Response efficacy, self-efficacy, perceived susceptibility, and dirt reactivity were significant mediators of high household stored drinking water quality at the 1-week follow-up. Response efficacy, self-efficacy, and diarrhea knowledge were significant mediators of high household stored drinking water quality at the 12-month follow-up. These results highlight the effectiveness of targeting response efficacy and self-efficacy to promote sustained improvements in household stored drinking water quality. These findings are consistent with a recent review that found that self-efficacy and action knowledge were influential factors driving safe drinking water use (Lilje & Mosler, 2017). There are only three other studies that have conducted a mediation analysis to investigate the psychosocial factors associated with the successful implementation of a drinking water quality intervention (Inauen et al., 2014; Inauen & Mosler, 2016; Lilje & Mosler, 2018). Two of these studies were conducted in Bangladesh and focused on interventions promoting the use of arsenic safe drinking water. These studies found self-efficacy, instrumental attitudes, commitment, behavioral

Table 3. Simple Mediation Results for Psychosocial Factors at 1 Week and 12 Months for Observed Handwashing With Soap by Study Arm.^a

Factor category	Statement	1-Week follow-up (N = 180)						12-Month follow-up (N = 242)											
		mHealth no home visits arm			mHealth and two home visits arm			mHealth no home visits arm			mHealth and two home visits arm								
		Indirect effects (c' = a path × b path; 90% CI)			Indirect effects (c' = a path × b path; 90% CI)			Indirect effects (c' = a path × b path; 90% CI)			Indirect effects (c' = a path × b path; 90% CI)								
		b Path ^a	a Path ^b	c'	LL	UL	a Path ^b	c'	LL	UL	b Path ^a	a Path ^b	c'	LL	UL				
Remembering	It is hard to remember to wash your hands with soap before preparing a meal.	-0.13	-0.93	0.12	-0.06	0.41	-1.12	0.15	-0.09	0.47	-0.11	-0.29	0.03	-0.01	0.14	-0.19	0.02	-0.01	0.13
	Washing your hands with soap after using the toilet is hard to remember.	-0.28	-0.25	0.07	-0.02	0.28	-0.33	0.09	-0.004	0.32	-0.01	-0.44	0.005	-0.07	0.09	-0.61	0.01	-0.10	0.11
Diarrhea Knowledge	Quiz Score (0–10) based on the following questions: (1) Can you name three important ways diarrhea can be prevented? (2) Can you please name the four key times for handwashing with soap? (3) Can you name three important ways diarrhea is spread?	0.16	0.46	0.07	-0.01	0.29	1.07	0.17	-0.0007	0.44	0.12	0.18	0.02	-0.02	0.12	0.46	0.05	-0.0007	0.19
Dirt Reactivity	You only wash your hands with soap when they have a bad smell.	0.11	-0.66	-0.07	-0.30	0.04	-0.65	-0.07	-0.32	0.03	—	—	—	—	—	—	—	—	—
Response Efficacy	How high or low are the chances you will develop diarrhea if you always wash your hands?	0.22	-0.07	-0.02	-0.17	0.02	-0.13	-0.03	-0.24	0.03	—	—	—	—	—	—	—	—	—
Instrumental Attitudes	Soap is too costly to use for handwashing.	0.02	-0.22	-0.01	-0.15	0.07	-0.27	-0.01	-0.18	0.07	—	—	—	—	—	—	—	—	—
Self-Efficacy	If someone in your home gets diarrhea, how sure are you that you can prevent the spread of diarrhea.	0.08	0.66	0.05	-0.09	0.29	0.97	0.08	-0.18	0.34	0.15	0.31	0.05	-0.01	0.18	0.37	0.06	-0.01	0.19
	How sure are you that you can make handwashing soap available for your family every day?	-0.06	0.10	-0.01	-0.16	0.07	-0.06	0.004	-0.08	0.14	—	—	—	—	—	—	—	—	—
	How sure are you that you always wash your hands with soap after using the toilet?	0.25	0.23	0.06	-0.02	0.26	0.24	0.06	-0.02	0.29	—	—	—	—	—	—	—	—	—
	How sure are you that you always wash your hands with soap before eating?	0.19	0.34	0.06	-0.02	0.29	0.87	0.16	-0.08	0.46	0.24	0.47	0.14	0.02	0.33	0.57	0.11	0.02	0.28
Impediments	Presently, soap for handwashing is not available in your home.	-0.06	-0.15	0.01	-0.04	0.20	-0.24	0.02	-0.09	0.17	—	—	—	—	—	—	—	—	—
	You have no place to wash your hands with soap	-0.14	-0.65	0.09	-0.07	0.33	-0.72	0.10	-0.09	0.34	—	—	—	—	—	—	—	—	—
Perceived Susceptibility	How high or low are the chances that you will get diarrhea this year?	0.18	-0.03	-0.01	-0.13	0.05	-0.19	-0.03	-0.22	0.02	—	—	—	—	—	—	—	—	—

Note. Psychosocial items were included in the mediation analysis if they were found to be significantly different between the mHealth arms and the standard message arm in the linear regression analysis in Table 2. mHealth = mobile health.

^aHandwashing with soap defined as handwashing with soap event at a key time during the 5-hour structured observation period. Key times are defined as after using the toilet or cleaning a child's anus and before eating, feeding, or preparing food. The 90% confidence intervals for indirect effects were calculated using bootstrapping. ^bPath a = effects of both intervention arms on the mediators (psychosocial factors). ^cPath b = effects of the mediators (psychosocial factors) on handwashing with soap with study arm in the model (boldface indicates significant effects, $p \leq .05$, one-tailed).

Table 4. Simple Mediation Results for Psychosocial Factors at 1 Week and 12 Months for *E. coli* <1 Colony Forming Units/100 ml in Stored Drinking Water by Study Arm.^a

Factor category	Statement	1-Week follow-up (N = 573)						12-Month follow-up (N = 738)					
		mHealth no home visits arm			mHealth and two home visits arm			mHealth no home visits arm			mHealth and two home visits arm		
		b Path ^c	a Path ^b	c'	Indirect effects (c' = a path × b path; 90% CI)	UL	LL	b Path ^c	a Path ^b	c'	Indirect effects (c' = a path × b path; 90% CI)	UL	LL
Diarrhea Knowledge	Quiz Score (0–10) based on the following questions: (1) Can you name three important ways diarrhea can be prevented? (2) Can you name the four key times for handwashing with soap? (3) Can you name three important ways diarrhea is spread?	0.12	0.67	0.08	0.02	0.18	0.03	0.19	0.03	0.09	0.03	0.19	0.03
Dirt Reactivity	If your water looks clear, you do not need to boil your water.	–0.05	–0.26	0.01	–0.02	0.07	–0.31	0.01	–0.02	0.07	—	—	—
	How high or low are the chances you will develop diarrhea if you always boil your household water?	–0.36	–0.18	0.06	0.01	0.15	–0.14	0.05	0.01	0.13	–0.21	–0.17	0.04
Self-Efficacy	How sure are you that after you boil your water, you can protect it from becoming dirty?	0.36	0.20	0.07	0.02	0.19	0.17	0.06	0.005	0.18	—	—	—
	How sure are you that you can explain to your other family members how to boil drinking water?	0.40	0.33	0.13	0.04	0.29	0.28	0.11	0.03	0.28	0.62	0.12	0.08
Perceived Susceptibility	If someone in your home gets diarrhea, how sure are you that you can prevent the spread of diarrhea.	0.26	0.75	0.20	0.08	0.36	0.76	0.20	0.08	0.36	0.15	0.38	0.06
	How high or low are the chances that you will get diarrhea this year?	–0.15	–0.25	0.04	0.002	0.11	–0.40	0.06	0.003	0.15	—	—	—

Note. Psychosocial items were included in the mediation analysis if they were found to be significantly different between the mHealth arms and the standard message arm in the linear regression analysis in Table 2.

mHealth = mobile health.

^a90% Confidence Intervals for indirect effects were calculated using bootstrapping. All models are adjusted for source water *E. coli* concentration. ^bPath a = effects of both intervention arms on the mediators (psychosocial factors).

^cPath b = effects of the mediators (psychosocial factors) on stored household drinking water quality with study arms in the model (boldface indicates significant effects, $p \leq .05$, one-tailed).

intentions, and injunctive and descriptive norms to be significant mediators of using arsenic safe drinking water sources (Inauen et al., 2014; Inauen & Mosler, 2016). The third study was conducted in Chad and focused on household drinking water chlorination, and found self-efficacy, health knowledge, personal norms, and social support to be significant mediators of water treatment behavior (Lilje & Mosler, 2018). We had anticipated that weekly mHealth messages would serve as important reminders that facilitated behavior change. However, while remembering increased among study households, this was not a significant mediator of stored drinking water quality. This suggests that self-efficacy and response efficacy were more important drivers of household water quality than remembering. Future studies are needed that investigate a larger number of psychosocial factors to determine mediators of safe drinking water programs in other settings globally.

Self-efficacy was a significant mediator of handwashing with soap habit maintenance at the 12-month follow-up. This result was likely attributed to the weekly mobile phone reminders on how and when to perform handwashing with soap behaviors and the provision of a handwashing station delivered as part of the CHoBI7-mHealth program. This finding is consistent with Contzen et al. conducted in Ethiopia (Contzen & Inauen, 2015). Previous studies have found that handwashing stations can facilitate handwashing with soap behavior, increase self-efficacy, and serve as reminders to perform this behavior (Biran, 2011; Curtis et al., 2009; Devine et al., 2012; Devine & Koita, 2010). Self-efficacy for food-related events rather than stool-related events emerged as the significant mediator for handwashing with soap behavior at the 12-month follow-up. This finding is consistent with the behavioral outcomes that showed significantly higher handwashing with soap at food-related events and not stool-related events at the 12-month follow-up. This result is likely reflective of the emphasis placed on food-related handwashing with soap in the CHoBI7-mHealth behavioral recommendations. No significant mediators were identified for handwashing with soap habit formation in the present study. This is despite observing increases in remembering, response efficacy, self-efficacy, and lower impediments and dirt reactivity. A future study including more psychosocial items to measure factors is likely needed to identify significant mediators for handwashing with soap habit formation for this intervention program.

CHoBI7-mHealth program participants had significantly lowered perceived susceptibility for contracting diarrhea and lower dirt reactivity for both handwashing with soap and water treatment compared with standard message arm participants at the 1-week follow-up. Both of these factors were also significant mediators of high stored drinking water quality at the 1-week follow-up. The perceived susceptibility finding is consistent with Inauen et al. (2013) and was likely because those adhering to the intervention thought their risk of diarrheal diseases was lower. For dirt reactivity those individuals that disagreed with the statement "If your water looks clear,

you do not need to boil your water," were more likely to have higher stored drinking water quality. This finding suggests that our intervention was effective in reducing the misconception that water that is clear does not need to be boiled, and that the change in this factor facilitated improved stored drinking water quality. The impact of interventions on dirt reactivity should be investigated in future studies.

The findings from the present study differ from the previous CHoBI7 program that included frequent home visits during the 1-week high-risk period and focused on cholera patient households, where we found that response efficacy mediated the intervention's effect on handwashing with soap habit formation at the 1-week follow-up, and that disgust, convenience, and cholera awareness were mediators of habit formation at the 6- to 12-month follow-up (George et al., 2017). This difference is likely because of three reasons. First, mobile messages rather than home visits were used to reinforce program behavioral recommendations. This different mode of intervention delivery may have operated through different psychosocial mechanisms. Second, because of the weekly reminders using mobile messages instead of home visits only during the 1-week high-risk period. These more frequent reminders likely increased self-efficacy to perform the promoted behaviors. Third, because psychosocial factors were measured among diarrhea patients of all etiologies, not just those with cholera. Intervention delivery may have operated through different psychosocial mechanisms for cholera compared with other enteric diseases.

Strengths and Limitations

This study has several strengths. First is the use of 5-hour structured observation to measure handwashing with soap behavior, instead of participant-reported behavior which is prone to reporting bias. Second is the use of household stored drinking water quality from unannounced spot checks as a proxy measure for water treatment practices. This allowed us to assess a direct measure of drinking water quality that was not prone to reporting bias. This could serve as a valuable measure in future studies. Third is that psychosocial factors were measured at 1 week and 12 months after enrollment to allow us to identify mediators of both habit formation and maintenance for the recommended WASH behaviors. Fourth is the RCT study design, which allowed us to rigorously evaluate the impact of the CHoBI7-mHealth program on the measured psychosocial factors. Fifth is the theory-driven approach for intervention development and evaluation. Sixth was the mediation analysis, which allowed us to determine the underlying mechanism of change for the impact of the CHoBI7-mHealth program on household stored drinking water quality and handwashing with soap.

This study also has some limitations. First is that we used a single item to measure most factors to limit the time spent in study households. Future studies should include multiple items to measure factors with high content validity. Second, the structured observation performed could be subject to the

Hawthorne effect (Adair, 1984). We attempted to limit this impact by stating that structured observation was performed to observe household practices; handwashing practices were not mentioned. Third, the CHoBI7-mHealth program combined multiple behavior change techniques to target both handwashing with soap and water treatment behaviors. Therefore, we do not know the impact of each intervention component alone on facilitating WASH behavior change. Future studies could investigate the impact of each intervention component separately. Fourth, psychosocial items focused mostly on the individual and habitual levels of the IBM-WASH model. Future studies should include items that measure factors at the interpersonal and structural levels.

Conclusions

The CHoBI7-mHealth program conducted a theory-driven approach for intervention development and evaluation that allowed for psychosocial factors to be identified that mediated the high efficacy of this intervention on handwashing with soap and improved stored drinking water quality. We are currently partnering with the Bangladesh Ministry of Health and Family Welfare to target these identified psychosocial factors during the scale-up of the CHoBI7-mHealth program across Bangladesh. This study demonstrates how theory-driven approaches for intervention design can be used to facilitate WASH behavior change.

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Supplemental Material

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