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# Refining hand washing interventions by identifying active ingredients: A cluster-randomized controlled trial in rural Zimbabwe

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## Introduction

Diarrhea is one of the leading infectious causes of infant death and caused 700,000 deaths in 2011 (Walker et al., 2013). Consistent hand washing with soap can reduce diarrhea (Borghi et al., 2002, Curtis et al., 2003, Freeman et al., 2014, Prüss-Ustün et al., 2014). However, frequencies of consistent hand washing with soap remain low, even though knowledge of the benefits of hand washing is widespread (Biran et al., 2014). Several intervention approaches, such as health education, seek to promote hand washing with soap, but recent reviews indicate heterogeneous effects (De Buck et al., 2017; Watson et al., 2017). De Buck et al.'s (2017) review suggests that including theory-based elements in interventions increases the interventions' effectiveness (De Buck et al., 2017). In addition to increased effectiveness, theory-based interventions also provide systematic frameworks for investigating the mechanisms of change (i.e., an intervention's active ingredients), and hence the opportunity to further refine behavior change interventions (Michie and Abraham, 2004; Mosler, 2012). In this study, we aim to demonstrate the effectiveness of theory-based interventions for hand-washing promotion. More generally, we show the benefits of using a systematic, theory-based approach to identify the active ingredients of health behavior change interventions.



## Promoting Hand Washing with Soap

Hand washing with soap has been suggested to be one of the most cost-effective ways to prevent infectious diseases in low- and middle-income countries (Curtis et al., 2009). A recent systematic review of 34 intervention studies suggests that using theory to inform interventions is an effective way to improve the promotion of hand washing with

soap (De Buck et al., 2017). For example, an intervention based on an extended theory of planned behavior (Ajzen, 1991) found self-reported hand washing with soap between 9.3% (after visiting toilet) and 60% (before cooking) greater than a control group at follow-up (Langford and Panter-Brick, 2013). In India, an intervention based on a model of emotional drivers of behavior found 31% more hand washing with soap at 6-month follow-up than controls (Biran et al., 2014). More recently, studies in Bangladesh found 6.8% (Ram et al., 2017) and 32% more observed hand washing with soap at key times than controls (George et al., 2016a). Finally, an intervention study based on the RANAS (risk, attitude, norms, ability, self-regulation) model of behavior change (Mosler, 2012) found 23% more observed hand washing with soap at key times in intervention participants compared to controls (Friedrich et al., 2018).

**Identifying the Active Ingredients of Interventions Using Theory**

An important but often untapped resource of theory-based approaches is their potential to identify the active ingredients of health behavior change interventions. Knowing which ingredients are active in turn provides valuable suggestions for intervention refinement. A theory-based approach that enables clear identification of the active ingredients of an intervention is the RANAS model (Mosler, 2012). It includes a framework of various behavior change theories (e.g. the theory of planned behavior, Ajzen, 1991, and the health action process approach, Schwarzer, 2008) that summarizes the psychosocial mechanisms by which an intervention may change behavior. These factors are grouped into five factor blocks: risk (e.g. perceived vulnerability to a health threat), attitude (e.g. affective and instrumental attitudes), norms (e.g. injunctive norms),

ability (e.g. self-efficacy), and self-regulation (e.g. action planning). The RANAS model links these psychosocial factors with specific behavior change techniques based on the literature (Abraham, 2012). To develop a behavior change intervention using the RANAS model, the key psychosocial drivers of a target behavior are first identified using a baseline assessment and regression analysis (Mosler, 2012). Behavior change techniques targeting the identified key factors are subsequently selected, combined in an intervention, and tested in a randomized trial.

To refine an intervention, its psychosocial mechanisms can be tested using mediation analysis (Baron and Kenny, 1986). First, the effect of the intervention on the potential mediator is tested (a path, see Figure 1). Then, the association of the potential mediator on the outcome is tested (b path; adjusting for the intervention effect). Finally, the significance of the mediation is tested (by multiplication of a and b), which reveals whether the mediator can wholly or partially explain the intervention effect on the outcome.

<<< ADD FIGURE 1 HERE >>>

If the intervention did not affect the potential mediator (i.e., insignificant a path), it can be concluded that the intervention was too weak to impact the respective psychosocial factor. If this psychosocial factor was found to be relevant for the outcome (i.e., significant association with behavior), the intervention may be further strengthened to target this factor. In turn, if a factor was successfully altered through the intervention but was not associated with behavior change, future interventions will not need to focus on this factor.

Several studies have investigated effects on psychosocial factors of hand-washing interventions. They mostly focused on knowledge (Galiani et al., 2016; Mascie-Taylor et al., 2003) and skills (e.g. washing both hands, Biran et al., 2014; Bowen et al., 2013). However, because these studies did not test the full mediation model, it remains unknown whether the psychosocial factors affected were in fact responsible for the behavior change effect of the intervention.

To the best of our knowledge, only two studies in the hand-washing intervention literature have fully investigated the mediating role of psychosocial factors to identify which factors can explain the intervention effect on hand washing with soap. Contzen and Inauen (2015) found that the descriptive norm, forgetting, and commitment strength explained the intervention effects of infrastructural and commitment-based interventions in Ethiopia. More recently, George et al. (2017) found that greater cholera awareness, disgust, and lower perceived inconvenience mediated the effects of a hospital-based intervention on hand washing with soap at 6–12-month follow-up. However, neither of these studies used their findings to systematically derive hypotheses for intervention refinement. The present study adds to the previous hand-washing intervention literature by illustrating how the active ingredients of hand-washing interventions can be identified using theory and how these results can be used to systematically derive hypotheses about intervention refinement. We illustrate this point with a complex intervention that uses the RANAS model to promote hand washing with soap in rural Zimbabwe.



## Materials and Methods

This study employed a two-armed cluster-randomized controlled trial in Bikita and Zaka districts of Masvingo province in rural Zimbabwe. After the baseline survey in

May 2016, 16 wards, which constitute the next lower level subdivision of districts, were randomly allocated to the intervention or the wait-list control group using a random number generator. The interventions were implemented from October to December 2016, and their effects were assessed in February 2017.

**Participants and Procedures**

The Research Council of Zimbabwe, the Medical Research Council of Zimbabwe, and the Ethics Committee of the Faculty of Arts and Social Sciences of the University of Zurich approved this study. ActionAid Zimbabwe employed and trained interviewers during a 5-day training course. In each ward, the interviewers selected 28 households based on a random route procedure (Hoffmeyer-Zlotnik, 2003). The primary caregiver of a household was chosen as the participant, because this person is key in children's and household hygiene. Inclusion criteria were that the primary caregiver was (a) at least 18 years old, and (b) available for the interview. Further criteria were that (c) at least one child of the household should be attending the project school within the same community (as interventions were implemented in schools as well as communities) and (d) no other child of the household should be attending any of the other schools included in the study (to avoid cross-contamination). Written informed consent was obtained from all participants prior to the baseline survey.

In total, 448 randomly selected households participated in the trial. A subsample of 224 households were randomly selected for 3-hour standardized observations of hand washing with soap and are therefore analyzed in this study. This sample size was estimated based on the expectation of finding a large difference in hand washing with soap between the intervention and control groups at follow-up ($f = 0.4$; Cohen, 1988),

based on an earlier study using a similar intervention (Friedrich et al., 2018), given a power of 0.8, an alpha error probability of 0.05, and allowing for dropout (Faul et al., 2009). There were no statistical differences between observed and unobserved households in self-reported hand washing with soap, gender, age, education, or household income and expenditures. Households that were observed were on average larger than those unobserved ($M$ = 6.3 vs. $M$ = 5.9 household members; $p$ = .041). See Figure 2 for the participant flow.

<<< ADD FIGURE 2 HERE >>>

**Measures**

**Observed hand washing with soap.** Data on the dependent variable, hand washing of both hands with soap and water at key times, was collected during standardized 3-hour observations in each selected household at baseline and follow-up. Direct observation is considered the most valid measure of actual hand washing behavior (Contzen et al., 2015b). Interviewers collected information on all potential hand-washing situations from all household members. A hand-washing situation was defined as a situation that required hand washing with soap either before or afterwards. We distinguished food-related situations, which were defined as any contact with food (e.g. preparing food; cooking, feeding a child), and stool-related situations after any potential contact with feces (e.g. after using the toilet, after assisting a child on the toilet, cleaning up after a child). For each situation, interviewers noted the kind of situation that occurred, who was involved, and whether household members washed their hands with soap and water using both hands.

**Psychosocial factors.** Psychological constructs were operationalized according to the RANAS approach (Mosler, 2012). Each psychosocial factor was assessed using several items where possible or single items otherwise. The items were based on the original measurement of the respective constructs (see Mosler, 2012) and were then carefully contextualized to be accessible to the rural population through multiple piloting steps (Contzen and Inauen, 2015; Contzen and Mosler, 2015). Items that assessed the same factor were averaged to form constructs for analysis (see Table 1). The interviewers collected participants' answers electronically using handheld tablet devices and Open Data Kit software. Interviewers were closely supervised throughout, and regular quality checks were performed.

**Socio-economic status.** We assessed monthly income and expenditure, years of formal education, and household assets, including availability of a latrine. A validated procedure (Vyas and Kumaranayake, 2006) was used to combine items as an index using principal components analysis.

<<< ADD TABLE 1 HERE >>>

## Interventions

Interventions were designed and implemented by ActionAid Zimbabwe. They trained governmental health promoters to deliver the interventions to the participants and in the schools of the intervention communities. To avoid bias, one team delivered the intervention (promoters) and another collected the data (interviewers). The wait-list control communities only received the interventions after the finalization of the follow-up.

Following the RANAS approach (Mosler, 2012), intervention content was developed according to the key psychosocial factors relevant for hand washing with soap

identified in the baseline survey. Because the psychosocial factors identified were similar to those of a previous RANAS-based intervention study in peri-urban Zimbabwe (Friedrich et al., 2018), the subsequent intervention was both based on and contrasted against the previous one. The interventions are briefly explained below. See Table S1 in the online supplemental material for a more detailed overview of behavior change techniques (BCTs), communication channels, activities, and targeted psychosocial factors.

The intervention consisted of four blocks. In the first block, a handwashing exercise was implemented during a community meeting to visualize dirt on hands and evoke the feeling of disgust. Then, a discussion was initiated to elicit the need to become a positive role model for one's own children. In the second block, a community meeting discussed the advantages of having a designated hand-washing place, together with providing instruction on how to build a hand-washing station. The participants were encouraged to work in groups or in pairs and to visit each other to share experiences on tippy tap construction (a simple wooden structure to hold water and soap) and advice on how to maintain and use the new device. In the third block, the promoters visited households to help participants and other household members plan when, where, and how to wash hands before contact with food and after contact with stool. These plans were hung on the wall in the kitchen area and on the toilet. Additionally, a self-monitoring calendar was distributed for household members to record when hands were washed before contact with food and after contact with stool. Group discussions between household members were initiated about how to support and remind each other to wash hands with soap. In the fourth block, a final community meeting was arranged at which volunteer participants presented small dramas to show their social support strategies to

the other participants. Thereafter, participants were prompted to commit in groups of 10 in front of other community members to always wash their hands with soap at key times. Participants were rewarded with a certificate for participating and filling in the self-monitoring calendar.

**Data Analysis**

The structure of the data for the main effects analysis differed from that for the mediation models. The main effects models used hand-washing situations as the unit of analysis, and these were clustered in households, which were clustered in villages. In contrast, the mediation models were based on participants (i.e., caregivers), because they were the main intervention target, and psychosocial mechanisms were assessed only for them. A significance level of $p = 0.05$ was adopted for all analyses. We describe the two approaches in the following; syntax examples can be found in the online supplemental material.

**Main effects models.** For the effects of the intervention on the outcome, we estimated three generalized estimation equation (GEE) models (Hardin and Hilbe, 2013) in IBM SPSS Statistics 22.0; one for all stool- and food-related hand-washing situations combined, one solely for stool-related situations, and the third solely for food-related situations. GEEs model the unbiased population average fixed effects of clustered data by incorporating the correlated residuals for estimates and inference. To this end, a working correlation matrix is specified. We used an exchangeable covariance structure with constant intracluster dependency, which assumes that hand-washing rates within a household or within a village are more similar than those between different households or

between different villages. We used a binomial model due to the binary nature of the outcomes (hand washing with soap occurred = 1 or did not = 0) and reported odds ratios as a standard measure of effect size in addition to unstandardized regression coefficients (B). Socio-economic status was included as a covariate in all analyses to ensure intervention effects were independent of the availability of resources.

**Mediation models.** To investigate the mediating psychosocial mechanisms of the intervention, we conducted mediation analyses (Baron and Kenny, 1986). The unit of analysis was the participant (i.e., the caregiver), which means that other household members' observations were excluded, and multiple observations of a participant in a single observational period were averaged. Doing so resulted in a continuous outcome that reflected the proportion of a participants' observed hand washing with soap relative to observed hand-washing situations.

We used Mplus 8 to conduct the mediation analyses; this software uses full information maximum likelihood estimation to handle missing data (Muthén and Muthén, 2017). Simple mediations were computed for each RANAS factor. Additionally, a multiple mediation model was computed including all the RANAS factors that were significantly changed by the intervention (a prerequisite of mediation analysis, see Baron & Kenny, 1984) to account for tany interdependencies in psychosocial factors on the b path. The indirect effect was estimated as the multiplication product of the a and b paths. Its significance was tested using 95% confidence intervals estimated using bias-corrected bootstrapping with 10,000 resamples, which is recommended due to the non-normal distribution of the indirect effect (Shrout and Bolger, 2002). We estimated the proportion of variance explained by the mediators relative to the total intervention effect as a

measure of effect size (Hayes, 2013). Socio-economic status was included as a covariate in all analyses to ensure intervention effects were independent of the availability of resources.

## Results

The sample for this analysis consisted of 196 households who were observed at baseline and follow-up. The mean household size was 6.4 persons (*SD* = 2.3), with an average of about one child below the age of five years (see Table 2). The average weekly expenditure of all households was 10 USD (*SD* = 10.0) and the average monthly income was 57 USD (*SD* = 68.3). The interview partners in most cases were female (96.4 %), 43 years old on average (*SD* = 12.8), and had gone to school for approximately 8.2 years (*SD* = 3.3).

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### Preliminary Analyses

**Dropout analysis.** Of the 224 households in the observation sample, 201 were observed pre–post and completed psychosocial surveys. Dropout was mostly due to relocation of the caregiver or the whole household (21 cases or 9.4%). A further two caregivers refused to participate in the follow-up survey (<1%). In addition, five households did not show any hand-washing-related events during the observation periods and were therefore not analyzed. Dropouts were almost evenly distributed between intervention group (13) and control group (10).

Compared to analyzed participants, those who dropped out of the study were younger (*M* = 30.6 vs. *M* = 43.5 years; *F* = 20.057, *p* <.001) and more educated (*M* =

10.0 vs. $M = 8.1$ years; $F = 6.585$, $p = .011$). Dropouts also showed higher observed food-related hand-washing frequency at baseline ($M$ =1.4% vs. M=1.1%; $F = 7.829$, $p = .006$) and had higher values for coping planning at baseline ($M = 2.16$ vs. $M = 1.72$; $F = 4.195$; $p = .042$). No other differences were found.

**Randomization check.** As indicated in Table 2, there were no statistical differences between participants allocated to the control group or the intervention group in any of the socio-economic variables or in observed hand washing with soap. Regarding psychosocial factors (see Table 3), intervention and control group participants differed in merely two of these. Intervention group participants had a higher perception of the severity of diarrheal disease and more action knowledge at baseline.

<<< ADD TABLE 3 HERE >>>

**Intervention fidelity and acceptance.** Participant attendance over all blocks was 82%. Absenteeism was mostly due to competing activities or external factors (e.g. funerals, field work, etc.). Almost all households in the intervention group had received the intervention materials (94–99%, depending on the material), and a majority of these were able to present it during follow-up visits (86–99%, see also Figure 2). Recall of the interventions and their contents was very good, indicating that more than 80% of participants remembered the individual elements from the intervention. All elements were rated positively; almost all participants liked the elements much or very much (>95%) and found them very or extremely convincing (>95%). At follow-up, 75.8% of intervention households had built a hand-washing station, with soap and water available, compared to 7.9% in the control group ($p < .010$, see Table 2).

**Intervention Effects on Hand Washing with Soap**

At baseline, participants washed hands with soap in 1.2% of food-related and 5.6% of stool-related situations. At follow-up, intervention group participants washed hands with soap in 27.0% of food-related (*SD* = 44.4%) and 38.9% of stool-related situations (*SD* = 48.9%). In comparison, control group participants washed hands with soap in 7.2% (*SD* = 25.9%) of food-related and 13.2% (*SD* = 34.0%) of stool-related situations. The GEE model, which adjusts for interdependencies within households and clusters, confirmed these group differences (see Table 4) over and above differences in socio-economic status. The odds of washing hands at key times were 6.6 times higher in the intervention group than in the control group (95% CI: 3.5, 12.4).

<<< ADD TABLE 4 HERE >>>

**Active Ingredients of the Intervention: Mediation Analysis**

As indicated in Figure 3 and Table 5, the intervention significantly increased the perceived return of hand washing with soap, the descriptive norm, the injunctive norm, action knowledge, action self-efficacy, maintenance self-efficacy, action planning, and remembering. Changes in disgust and remembering were significantly associated with greater hand washing with soap at follow-up. Simple mediation analysis and multiple mediation analysis of all RANAS factors that were significantly changed by the intervention indicated that remembering was the only significant mediator of the intervention. Overall, 10% of variance in the intervention effect was explained by increased remembering.

Because we encountered low internal consistencies for some of the measures, we conducted a mediation model with single items as a sensitivity analysis (see Table S2 in the online supplemental material). Congruent with the main analysis, this sensitivity

analysis showed a significant indirect effect for remembering, although the association between remembering and hand washing was not significant in this model ($B = 0.01$, $SE = 0.01$, $p = .096$).

<<< ADD FIGURE 3 HERE >>>

<<< ADD TABLE 5 HERE >>>

## Discussion

This study investigated the effectiveness and active ingredients of a theory- and evidence-based intervention to promote hand washing with soap using the RANAS model (Mosler, 2012). With this example, we aimed to demonstrate how the analysis of mechanisms of health behavior change interventions can be used to systematically derive hypotheses for intervention refinement. The main results confirmed the effectiveness of the RANAS approach in promoting hand washing with soap. Intervention group participants washed hands with soap in up to 38.9% of key hand-washing situations. This figure represents an increase of 27% pre–post, compared to a 6.3% increase in the wait-list control group. This effect of 21% increased hand washing with soap compared to controls is comparable with that of a similar intervention study in urban Zimbabwe (Friedrich et al., 2018). Thus, our results indicate the generalizability of this intervention to both urban and rural contexts. Some theory-based hand-washing interventions have reported smaller effect sizes (Contzen et al., 2015a; Ram et al., 2017). Others have found somewhat stronger effects (Biran et al., 2014; George et al., 2016b), and one study even found much larger effects (Langford and Panter-Brick, 2013), although this last study used a self-reported outcome, which can be biased (Contzen et al., 2015b). Overall, the intervention reported here was successful in promoting hand washing with soap,

especially considering the intervention's low cost of 12 USD per household excluding research costs, or 22 USD per household including these (Guenat et al., 2017). Whether this change leads to better health is a question for future research.

Our study is one of the first to investigate the psychosocial mechanisms by which an intervention promoted hand washing with soap. An increase in remembering emerged as the key psychosocial mechanism, explaining 10% of the intervention's effect on hand washing with soap. This effect confirms earlier studies that found that remembering plays an important role in hand washing with soap (Contzen and Inauen, 2015) and research that has effectively increased hand washing using reminders and cues (also called nudges, e.g. Dreibelbis et al., 2016; Jannat et al., 2016; Tidwell et al., 2019). Furthermore, disgust was related to hand washing with soap at follow-up. This corroborates findings in the hand-washing literature that emotional responses are important in changing hand-washing behavior (Biran et al., 2014).

Further mediators found in other studies (George et al., 2017), including the descriptive norm and commitment strength, did not mediate intervention effects. However, this effect is not surprising; we expect that different interventions will operate through different psychosocial mechanisms. To build a cumulative science of behavior change, it is therefore crucial that intervention studies use standardized protocols to describe intervention content (Michie et al., 2013), and analyze change mechanisms.

**Implications for Practice: Refining Hand Washing Interventions**

While intervention effects on hand washing with soap compared to controls can be considered medium sized and were comparable to previous intervention studies, there

is room for improvement. Using the insights generated by the mediation analyses (see Figure 3), we are able to derive hypotheses about the active ingredients of the intervention and suggest refinements to it. The effectiveness of the refined intervention can subsequently be tested in a randomized controlled trial.

First, the results indicate that increased remembering was the active ingredient of the intervention effect on hand washing with soap. We therefore recommend that the BCTs targeting remembering (i.e., BCT 16: Provide infrastructure, and BCT 34: Use memory aids and environmental prompts) should be included in future hand washing interventions. Over and above facilitating remembering, providing infrastructure should be a key intervention component because the availability of a designated hand-washing station with soap and water is an important prerequisite of hand washing with soap.

Some psychosocial factors were changed by the intervention but did not affect hand washing: Return (BCT 8), Descriptive norm (BCT 10), Injunctive norm (BCT 21), Action self-efficacy (BCT 16), Maintenance self-efficacy (BCTs 21, 30), and Action planning (BCT 26). Potentially, these BCTs might be omitted from future hand-washing interventions in this target population. Further experimental investigations can test such omissions.

Disgust was not changed by the intervention, but changes in this factor were associated with increased hand washing. Future interventions might be improved by demonstrating the disgust of touching food without washing hands in a more powerful way, such as by using theater (Biran et al., 2014).

**Strengths and Limitations**

The main strength of this study is its theory-based approach, which enables health behavior change interventions to be analyzed in a systematic way. First, it provides a valid set of behavioral factors derived from theory and not from intuition or guesswork. Second, it defines which factors have to be measured and how. This allows intervention mechanisms to be traced; these have rarely been studied in hand washing interventions. Additionally, the intervention content was described in a standardized way, enabling the accumulation of evidence on health behavior change interventions.

An additional strength of this study is that we were able to ensure very good intervention fidelity, as the preliminary analyses show. This was because the implementing organization had conducted a similar campaign in peri-urban Harare previously (Friedrich et al., 2018) and was therefore well prepared for the implementation.

Another strength is that we investigated the mediating mechanisms of the intervention effect on observed, and not self-reported, hand washing with soap in a cluster-randomized controlled trial. To the best of our knowledge, only one previous study has done so for hand washing with soap (George et al., 2017). We went further than that study, by demonstrating how linking the results of a theory-based mediation analysis to behavior change techniques can be used to systematically derive hypotheses for refining behavior change interventions.

Structured observations are considered the gold standard for assessing hand washing with soap (Contzen et al., 2015b). Self-reports as an alternative measure are highly inflated (Contzen et al., 2015b), and proxies for hand washing perform poorly (Biran et al., 2008). Nevertheless, observed hand washing can be prone to observational bias (Gittelsohn et al., 1997), which can occur when observations are overt, as was the

case in our study. We would expect people to wash hands more frequently while under observation because this action is the socially desirable. While we cannot definitively rule out observational bias, it seems likely that it was small in our study, because hand-washing rates were very low at baseline and remained low in the control group at follow-up.

Remembering was the only significant psychosocial mechanism of the intervention, which confirms the importance of remembering for hand washing with soap that has been found in earlier studies (e.g. Contzen and Inauen, 2015). However, remembering only explained 10% of the intervention effect. Even though other psychosocial factors were successfully promoted by the intervention, changes in these factors were unrelated to changes in hand washing with soap. This pattern confirms the results of the one previous study on mechanisms of intervention effects on observed hand washing (George et al., 2017). In fact, both our and George et al.'s studies identified very few psychosocial predictors of observed hand washing, indicating a need for more research in this area.

One further limitation, the absence of further mediating effects, may also be due to measurement error. The internal consistencies of several factors were rather low, even though the items were based on the literature and careful piloting. One reason for this finding may be that each construct was assessed by few items. Using more items is generally related to greater internal consistency (Iacobucci and Duhachek, 2003), but a decision to include more items always has to be weighed against increased participant burden. A future validation study is recommended to select a low number of valid key items that assess the RANAS model reliably. The low number of mediators identified

may also have been due to lack of power. While this study was sufficiently powered to detect the large main effects of the intervention, the sample size might have been insufficient to detect small mediating effects. Future studies should therefore aim for larger sample sizes to detect more subtle effects on social-cognitive mechanisms of behavior change interventions.

A further limitation of our study is that we only analyzed short-term effects. Hence, we do not know how the behavior change and changes in psychosocial factors will persist over time. Psychosocial mechanisms for uptake and maintenance of hand washing can differ (George et al., 2017). Therefore, more long-term studies are needed to analyze the processes that sustain changes in hand washing with soap, as has been done in other water and sanitation domains (Inauen and Mosler, 2016; Lilje and Mosler, 2016).

A further shortcoming of our study is that we do not know exactly which BCT changed which psychosocial factors because we applied a multitude of BCTs in this intervention. This problem is typical for complex interventions, and theory proved useful in this process because it linked specific BCTs to particular psychosocial factors (based on Abraham, 2012). Further theoretical advancements (Michie et al., 2016), and experimental tests of the mechanisms of specific BCTs in isolation will further facilitate the investigation of intervention mechanisms and their accuracy.

## Conclusions

This study adds to the growing body of evidence that shows that theory-based interventions can cost-effectively promote hand washing with soap. Moreover, we demonstrated how mediation analysis can be used to identify the mechanisms of complex

interventions and how these results can in turn be used to derive hypotheses for the systematic refinement of behavior change interventions. Doing so should help advance the science of behavior change. Methodological research on measurement of behavioral factors, particularly in an intercultural context, is needed to improve the reliable detection of change mechanisms and to ultimately ensure that social science can make a significant contribution to reducing diarrhea-related mortality.

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Table 1

*Example Items for Psychosocial Factors and Cronbach's Alphas*

| Psychosocial factor | Example items | Response scale | Number of items | Cronbach's Alpha | |
|---|---|---|---|---|---|
| | | | | Baseline | Follow-Up |
| Health knowledge | What are typical ways that you can get diarrhea? | Sum of correct ways | 3 | 0.57 | 0.68 |
| Perceived vulnerability | If you never wash your hands with soap and water after contact with stool, how high do you feel is the risk that you contract diarrhea? | Likert (1-5) | 4 | 0.48 | 0.48 |
| Perceived severity | Imagine you contracted diarrhea, how severe would the impact be on your daily life? | Likert (1-5) | 1 | n.a. | n.a. |
| Investment | How effortful do you think is always washing hands with soap and water after contact with stool? | Likert (1-5) | 2 | 0.61 | 0.63 |
| Return | How certain are you that always washing hands with soap and water after contact with stool prevents you from getting diarrhea? | Likert (1-5) | 2 | 0.60 | 0.62 |
| Attractiveness | How attractive do you feel to your partner when you always wash your hands with soap and water? | Likert (1-5) | 1 | | |
| Liking | How much do you like washing hands with soap and water after contact with stool? | Likert (1-5) | 3 | 0.62 | 0.63 |
| Disgust | How disgusting do you think it is not to always wash hands with soap and water after contact with stool? | Likert (1-5) | 2 | 0.58 | 0.49 |
| Pride | How proud do you feel if you always wash your hands with soap and water? | Likert (1-5) | 1 | n.a. | n.a. |

| | | | | | |
|---|---|---|---|---|---|
| Descriptive norm | How many people of your community always wash hands with soap and water after contact with stool? (make respondent choose the most likely option if he/she cannot say for sure) | Likert (1-5) | 4 | 0.69 | 0.75 |
| Injunctive norm | People who are important to you, how much do they think you should always wash your hands with soap and water after contact with stool? | Likert (1-5) | 2 | 0.77 | 0.75 |
| Action knowledge | In which situations is it critical to wash hands with soap? | Sum of critical situations | 1 | n.a. | n.a. |
| Action self-efficacy | How confident are you that you can get enough water to always wash your hands with soap and water? | Likert (1-5) | 2 | 0.60 | 0.66 |
| Maintenance self-efficacy | How confident are you that you can always wash hands with soap and water after contact with stool, even if circumstances are difficult? (for example, there's no soap, there's no water, you're in a hurry or the baby is sick) | Likert (1-5) | 6 | 0.86 | 0.86 |
| Recovery self-efficacy | Imagine you have stopped always washing hands with soap and water for several days, for example because there was no water or soap for handwashing. How confident are you to start washing hands again? | Likert (1-5) | 1 | n.a. | n.a. |
| Action planning | Do you have a plan where you keep the soap for hand washing before handling food? | Sum of plans | 6 | n.a. | n.a. |
| Coping planning | Do you have a plan how to avoid forgetting to always wash hands with soap and water before handling food or after contact with stool? | Sum of plans | 3 | n.a. | n.a. |
| Action control | How aware are you of your goal to wash hands with soap and water before handling food? | Likert (1-5) | 2 | 0.66 | 0.68 |

| | | | | | |
|---|---|---|---|---|---|
| Remembering | When you think about the last 24 hours: How often did it happen that you intended to wash hands with soap and water before handling food and then forgot to do so? | 0-10 times | 2 | 0.59 | 0.61 |
| Commitment | How strongly do you feel obliged by yourself to always wash hands with soap and water? | Likert (1-5) | 8 | 0.82 | 0.80 |

*Note*. n.a. = not applicable.

Table 2

*Socio-Demographic Characteristics, Handwashing Infrastructure, and Observed Handwashing with Soap*

| | Intervention group | | | | | Control group | | | | | Differences | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Baseline | | | | | | | | | | | | | |
| Socio-demographic characteristics | *f* | *M* | *SD* | *Min* | *Max* | *f* | *M* | *SD* | *Min* | *Max* | *t* | *df* | *p* | *r* |
| Age | 95 | 43.14 | 12.55 | 18 | 71 | 101 | 43.41 | 13.18 | 18 | 78 | -0.15 | 194 | .884 | 0.01 |
| Education | 95 | 8.48 | 3.14 | 0 | 14 | 101 | 7.84 | 3.44 | 0 | 13 | 1.36 | 194 | .174 | 0.10 |
| Household size | 95 | 6.39 | 2.42 | 2 | 17 | 101 | 6.40 | 2.15 | 3 | 12 | -0.02 | 194 | .984 | <0.01 |
| Monthly income | 95 | 62.18 | 80.25 | 0 | 500 | 101 | 51.79 | 54.79 | 0 | 400 | 1.06 | 194 | .289 | 0.08 |
| Monthly expenditure | 95 | 9.77 | 9.56 | 0 | 60 | 101 | 10.73 | 10.35 | 0 | 50 | -0.68 | 194 | .500 | 0.05 |
| Socio-economic status | 95 | 95 | 0.08 | 0.453 | -1.07 | 101 | 0 | 0.446 | -1.25 | 1.37 | 1.19 | 194 | .234 | 0.09 |
| | *f* | *f%* | | | | *f* | *f%* | | | | $X^2$ | *df* | *p* | |
| Female participants | 92 | 97 | | | | 97 | 96 | | | | 0.119 | 1 | .730 | |
| Hand-washing infrastructure | *f* | *f%* | | | | *f* | *f%* | | | | $X^2$ | *df* | *p* | |
| Proportion of households with a hand washing station | 95 | 39 | | | | 101 | 43.6 | | | | 5.898 | 1 | .015 | |
| with water and soap available | 95 | 8.4 | | | | 101 | 14.9 | | | | 111.80 | 1 | <.001 | |
| | Events | | HWWS | | | Events | | HWWS | | | Differences | | | |
| Observed hand washing with soap | *f* | *f%* | *M* | *SD* | | *f* | *f%* | *M* | *SD* | | *t* | *df* | *p* | *r* |
| Food-related | 6 | 33.3 | 1.1% | 10.2% | | 7 | 50.0 | 1.3% | 11.1% | | -0.31 | 1126 | .756 | 0.01 |
| Stool-related | 12 | 66.7 | 6.3% | 24.8% | | 7 | 50.0 | 4.1% | 19.8% | | 1.05 | 346 | .296 | 0.06 |
| Food- and stool-related | 18 | 100.0 | 2.4% | 15.3% | | 14 | 100.0 | 1.9% | 13.7% | | 0.63 | 1483 | .526 | 0.02 |

| | | | Follow-up | | | | | |
|---|---|---|---|---|---|---|---|---|
| Hand-washing infrastructure | *f* | *f%* | *f* | *f%* | $X^2$ | *df* | *p* | |
| Proportion of households with a hand washing station | 95 | 84.2 | 101 | 28.7 | 2.469 | 1 | 0.116 | |
| with water and soap available | 95 | 75.8 | 101 | 7.9 | 6.612 | 1 | 0.01 | |

| | Events | | HWWS | | Events | | HWWS | | Differences | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Observed hand washing with soap | *f* | *f%* | *M* | *SD* | *f* | *f%* | *M* | *SD* | *t* | *df* | *p* | *r* |
| Food-related | 134 | 73.2 | 27.0% | 44.4% | 41 | 74.5 | 7.2% | 25.9% | 8.71 | 774 | <.001 | 0.30 |
| Stool-related | 49 | 26.8 | 38.9% | 48.9% | 14 | 25.5 | 13.2% | 34.0% | 4.47 | 222 | <.001 | 0.29 |
| Food- and stool-related | 183 | 100.0 | 29.4% | 45.6% | 55 | 100.0 | 8.2% | 27.4% | 10.07 | 1003 | <.001 | 0.30 |

*Note*. *f* = absolute frequency, *f%* = relative frequency, *M* = mean, *SD* = standard deviation, *Min* = minimum, *Max* = maximum, *t* = test distribution, *df* = degrees of freedom, *p* = level of significance, *r* = effect size *r* (Rosenthal and Rubin, 1982). HWWS = hand washing with soap.

Table 3

*Psychosocial Factors at Baseline and Follow-Up for the Intervention and Control Groups.*

| | Intervention group | | | | Control group | | | | Differences | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Baseline | *M* | *SD* | *Min* | *Max* | *M* | *SD* | *Min* | *Max* | *t* | *df* | *p* | *r* |
| Health knowledge | 2.39 | 0.68 | 1.00 | 4.00 | 2.25 | 0.59 | 1.00 | 4.00 | -1.58 | 194 | .116 | 0.11 |
| Perceived vulnerability | 4.47 | 0.52 | 2.75 | 5.00 | 4.36 | 0.55 | 2.50 | 5.00 | -1.53 | 194 | .128 | 0.11 |
| Perceived severity | 4.09 | 0.99 | 1.00 | 5.00 | 3.66 | 1.20 | 1.00 | 5.00 | -2.75 | 191 | .007 | 0.20 |
| Investment | 4.46 | 0.92 | 1.00 | 5.00 | 4.55 | 0.68 | 2.00 | 5.00 | 0.75 | 194 | .454 | 0.05 |
| Return | 4.33 | 0.57 | 2.50 | 5.00 | 4.33 | 0.65 | 1.50 | 5.00 | -0.06 | 194 | .956 | 0.00 |
| Attractiveness | 4.35 | 1.24 | 1.00 | 5.00 | 4.17 | 1.11 | 1.00 | 5.00 | -0.95 | 194 | .343 | 0.07 |
| Liking | 4.28 | 0.72 | 2.00 | 5.00 | 4.24 | 0.78 | 1.25 | 5.00 | -0.46 | 194 | .648 | 0.03 |
| Disgust | 4.33 | 0.88 | 1.00 | 5.00 | 4.35 | 0.80 | 1.00 | 5.00 | 0.21 | 194 | .834 | 0.02 |
| Pride | 4.02 | 1.01 | 1.00 | 5.00 | 4.07 | 1.10 | 1.00 | 5.00 | 0.32 | 194 | .750 | 0.02 |
| Descriptive norm | 2.83 | 0.94 | 1.00 | 5.00 | 2.85 | 0.84 | 1.25 | 5.00 | 0.16 | 194 | .874 | 0.01 |
| Injunctive Norm | 3.65 | 1.19 | 1.00 | 5.00 | 3.78 | 0.14 | 1.00 | 5.00 | 0.81 | 194 | .420 | 0.06 |
| Action knowlegde | 1.90 | 0.40 | 1.00 | 3.15 | 1.71 | 0.33 | 1.00 | 2.70 | -3.53 | 194 | .001 | 0.25 |
| Action self-efficacy | 4.08 | 0.82 | 2.00 | 5.00 | 4.00 | 0.84 | 2.00 | 5.00 | -0.75 | 194 | .454 | 0.05 |
| Maintenance self-efficacy | 3.49 | 0.95 | 1.00 | 5.00 | 3.45 | 0.90 | 1.33 | 5.00 | -0.27 | 194 | .788 | 0.02 |
| Recovery self-efficacy | 4.17 | 0.96 | 1.00 | 5.00 | 4.12 | 1.00 | 1.00 | 5.00 | -0.35 | 194 | .725 | 0.03 |
| Action planning | 3.62 | 1.28 | 1.00 | 5.00 | 3.52 | 1.32 | 1.00 | 5.00 | -0.55 | 194 | .580 | 0.04 |
| Coping planning | 1.80 | 0.96 | 1.00 | 5.00 | 1.65 | 0.97 | 1.00 | 5.00 | -1.11 | 194 | .269 | 0.08 |
| Action control | 4.03 | 0.86 | 1.50 | 5.00 | 3.96 | 0.79 | 2.00 | 5.00 | -0.60 | 194 | .549 | 0.04 |
| Remembering | 4.29 | 0.85 | 2.00 | 5.00 | 4.27 | 0.87 | 1.00 | 5.00 | -0.16 | 194 | .877 | 0.01 |
| Commitment | 3.60 | 0.61 | 1.19 | 4.38 | 3.59 | 0.60 | 1.25 | 4.38 | -0.16 | 194 | .872 | 0.01 |

| Follow-up | *M* | *SD* | *Min* | *Max* | *M* | *SD* | *Min* | *Max* | *t* | *df* | *p* | *r* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Health knowledge | 2.57 | 0.68 | 1.50 | 4.00 | 2.50 | 0.73 | 1.00 | 4.00 | -0.78 | 194 | .437 | 0.06 |
| Perceived vulnerability | 4.75 | 0.33 | 3.25 | 5.00 | 4.46 | 0.54 | 2.00 | 5.00 | -4.63 | 169 | <.001 | 0.34 |
| Perceived severity | 4.42 | 0.91 | 2.00 | 5.00 | 4.04 | 1.08 | 1.00 | 5.00 | -2.68 | 194 | .008 | 0.19 |
| Investment | 4.57 | 0.78 | 1.50 | 5.00 | 4.41 | 0.94 | 1.00 | 5.00 | -1.28 | 191 | .204 | 0.09 |
| Return | 4.57 | 0.52 | 2.50 | 5.00 | 4.32 | 0.64 | 2.50 | 5.00 | -3.05 | 190 | .003 | 0.22 |
| Attractiveness | 4.61 | 0.82 | 1.00 | 5.00 | 4.43 | 0.92 | 1.00 | 5.00 | -1.34 | 166 | .182 | 0.10 |
| Liking | 4.68 | 0.41 | 3.50 | 5.00 | 4.46 | 0.64 | 2.00 | 5.00 | -3.01 | 171 | .003 | 0.22 |
| Disgust | 4.65 | 0.46 | 3.00 | 5.00 | 4.47 | 0.70 | 2.00 | 5.00 | -2.10 | 172 | .037 | 0.16 |
| Pride | 4.60 | 0.61 | 2.00 | 5.00 | 4.40 | 0.81 | 1.00 | 5.00 | -1.68 | 185 | .094 | 0.12 |
| Descriptive norm | 3.86 | 0.61 | 2.00 | 5.00 | 3.16 | 0.87 | 1.25 | 4.75 | -6.52 | 180 | <.001 | 0.44 |
| Injunctive Norm | 4.15 | 0.84 | 1.50 | 5.00 | 3.83 | 0.95 | 1.00 | 5.00 | -2.54 | 194 | .012 | 0.18 |
| Action knowlegde | 3.11 | 0.63 | 1.65 | 4.25 | 2.19 | 0.52 | 1.20 | 3.40 | -10.36 | 167 | <.001 | 0.63 |
| Action self-efficacy | 4.51 | 0.51 | 3.00 | 5.00 | 4.17 | 0.70 | 2.00 | 5.00 | -3.88 | 183 | <.001 | 0.28 |
| Maintenance self-efficacy | 4.08 | 0.70 | 2.33 | 5.00 | 3.67 | 0.83 | 1.50 | 5.00 | -3.46 | 167 | .001 | 0.26 |
| Recovery self-efficacy | 4.56 | 0.60 | 3.00 | 5.00 | 4.40 | 0.75 | 1.00 | 5.00 | -1.67 | 194 | .097 | 0.12 |
| Action planning | 4.92 | 0.24 | 3.67 | 5.00 | 3.91 | 1.22 | 1.00 | 5.00 | -7.47 | 92 | <.001 | 0.61 |
| Coping planning | 1.72 | 1.01 | 1.00 | 5.00 | 1.67 | 0.95 | 1.00 | 5.00 | -0.37 | 167 | .710 | 0.03 |
| Action control | 4.55 | 0.53 | 2.50 | 5.00 | 4.26 | 0.75 | 2.00 | 5.00 | -3.15 | 181 | .002 | 0.23 |
| Remembering | 4.87 | 0.30 | 3.20 | 5.00 | 4.49 | 0.78 | 1.00 | 5.00 | -4.18 | 111 | <.001 | 0.37 |
| Commitment | 3.95 | 0.40 | 2.88 | 4.38 | 3.77 | 0.50 | 1.63 | 4.38 | -2.71 | 194 | .007 | 0.19 |

*Note*. *M* = mean, *SD* = standard deviation, *Min* = minimum, *Max* = maximum, *t* = test distribution, *df* = degrees of freedom, *p* = level of significance, *r* = effect size (Rosenthal and Rubin, 1982).

Table 4

*Generalized Linear Estimating Equation Model of Hand Washing with Soap at Follow-Up*

| | | | | | $CI_{95}$ | |
|---|---|---|---|---|---|---|
| Parameters | *B* | *SE* | *p* | *OR* | *LL* | *UL* |
| All key situations (stool- and food-related) | | | | | | |
| Intercept | 0.63 | 0.20 | .001 | 1.88 | 1.28 | 2.80 |
| Intervention[1] | 1.88 | 0.32 | <.001 | 6.55 | 3.47 | 12.37 |
| Baseline HWWS | 0.33 | 3.05 | .914 | 1.39 | <.01 | 545.04 |
| Socio-economic status | -0.07 | 0.34 | .834 | 0.93 | 0.48 | 1.81 |
| Food-related situations | | | | | | |
| Intercept | 0.77 | 0.20 | <.001 | 2.16 | 1.46 | 3.19 |
| Intervention[1] | 1.94 | 0.36 | <.001 | 6.95 | 3.46 | 13.96 |
| Baseline HWWS | -2.05 | 1.90 | .280 | 1.29 | <.01 | 5.33 |
| Socio-economic status | 0.19 | 0.34 | .578 | 1.21 | 0.62 | 2.35 |
| Stool-related situations | | | | | | |
| Intercept | -0.18 | 0.34 | .603 | 0.84 | 0.43 | 1.64 |
| Intervention[1] | 1.80 | 0.60 | .003 | 6.02 | 1.86 | 19.48 |
| Baseline HWWS | 9.73 | 4.18 | .020 | 1.68E + 04 | 4.67 | 6.00E + 07 |
| Socio-economic status | -7.75 | 0.68 | .011 | 0.18 | 0.05 | 0.67 |

*Note*. $N = 196$; HWWS = hand washing with soap; *B* = regression coefficient; *SE* = standard error; *p* = level of significance, *OR* = odds ratio; $CI_{95}$ = 95% confidence interval; *LL* = lower level; *UL* = upper level; [1] Intervention = 1, wait-list control group = 0.

Table 5

*Mediation Models: Intervention Effects on Observed Hand Washing with Soap Through Changes in Psychosocial Factors*.

| | Intervention effects | | | Hand washing with soap at key times[1] | | | Indirect effects (95% CI) | | |
|---|---|---|---|---|---|---|---|---|---|
| Mediator | *B* | *SE* | *p* | *B* | *SE* | *p* | *B* | *LL* | *UL* |
| Health knowledge | -0.06 | 0.14 | .676 | -0.04 | 0.02 | .130 | <0.01 | <-0.01 | 0.02 |
| Vulnerability | 0.18 | 0.10 | .070 | 0.02 | 0.04 | .702 | <0.01 | -0.01 | 0.03 |
| Severity | -0.06 | 0.20 | .774 | -0.03 | 0.02 | .118 | <0.01 | -0.01 | 0.02 |
| Investment | 0.23 | 0.16 | .156 | <0.01 | 0.02 | .859 | <0.01 | -0.01 | 0.02 |
| Return | 0.26 | 0.10 | .013 | 0.03 | 0.03 | .255 | 0.01 | < -0.01 | 0.03 |
| Attractiveness | 0.03 | 0.24 | .906 | -0.03 | 0.02 | .200 | < -0.01 | -0.02 | 0.01 |
| Liking | 0.19 | 0.12 | .102 | -0.04 | 0.02 | .122 | < -0.01 | -0.03 | <0.01 |
| Disgust | 0.20 | 0.14 | .139 | 0.05 | 0.02 | .042 | <0.01 | < -0.01 | 0.03 |
| Pride | 0.24 | 0.17 | .166 | 0.02 | 0.02 | .383 | <0.01 | < -0.01 | 0.03 |
| Descriptive norm | 0.74 | 0.15 | < .001 | 0.03 | 0.02 | .192 | 0.02 | -0.01 | 0.06 |
| Injunctive norm | 0.48 | 0.18 | .007 | -0.01 | 0.02 | .631 | < -0.01 | < -0.03 | 0.01 |
| Action knowledge | 0.71 | 0.09 | < .001 | 0.05 | 0.05 | .268 | 0.04 | -0.03 | 0.11 |
| Action self-efficacy | 0.27 | 0.14 | .048 | 0.03 | 0.02 | .179 | <0.01 | < -0.01 | 0.03 |
| Maintenance self-efficacy | 0.36 | 0.14 | .010 | 0.02 | 0.03 | .493 | <0.01 | < -0.01 | 0.03 |
| Recovery self-efficacy | 0.13 | 0.16 | .428 | 0.04 | 0.02 | .057 | <0.01 | < -0.01 | 0.02 |
| Action planning | 0.85 | 0.20 | < .001 | 0.02 | 0.02 | .117 | 0.02 | < -0.01 | 0.03 |
| Coping planning | -0.12 | 0.18 | .514 | <-0.01 | 0.02 | .974 | <0.01 | -0.01 | 0.01 |
| Action control | 0.25 | 0.14 | .072 | 0.04 | 0.03 | .157 | <0.01 | < -0.01 | 0.04 |
| Remembering | 0.36 | 0.15 | .016 | 0.06 | 0.03 | .017 | 0.02 | < 0.01 | 0.06 |
| Commitment | 0.17 | 0.10 | .069 | 0.02 | 0.04 | .643 | <0.01 | < -0.01 | 0.03 |

*Note*. All models adjusted for socio-economic status. Indirect effects were calculated using bias-corrected bootstrapping with 10,000 re-samples. *B* = unstandardized regression coefficients from linear regressions. *SE*= standard error, CI = confidence interval, *LL* = lower limit, *UL* = upper limit. Bold: significant result at $p < .05$. [1] Relationship of changes in psychosocial factor and changes in hand washing with soap at follow-up, adjusting for the intervention effect.

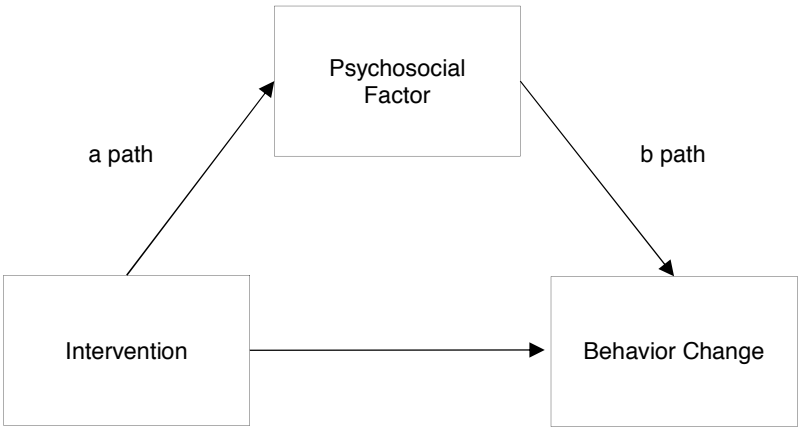


*Figure 1.* Mediation model of an intervention effect on behavior change via a mediating psychosocial factor. a path: effect of the intervention on the mediator; b path: association of the mediator with the outcome (adapted from Baron and Kenny, 1986).

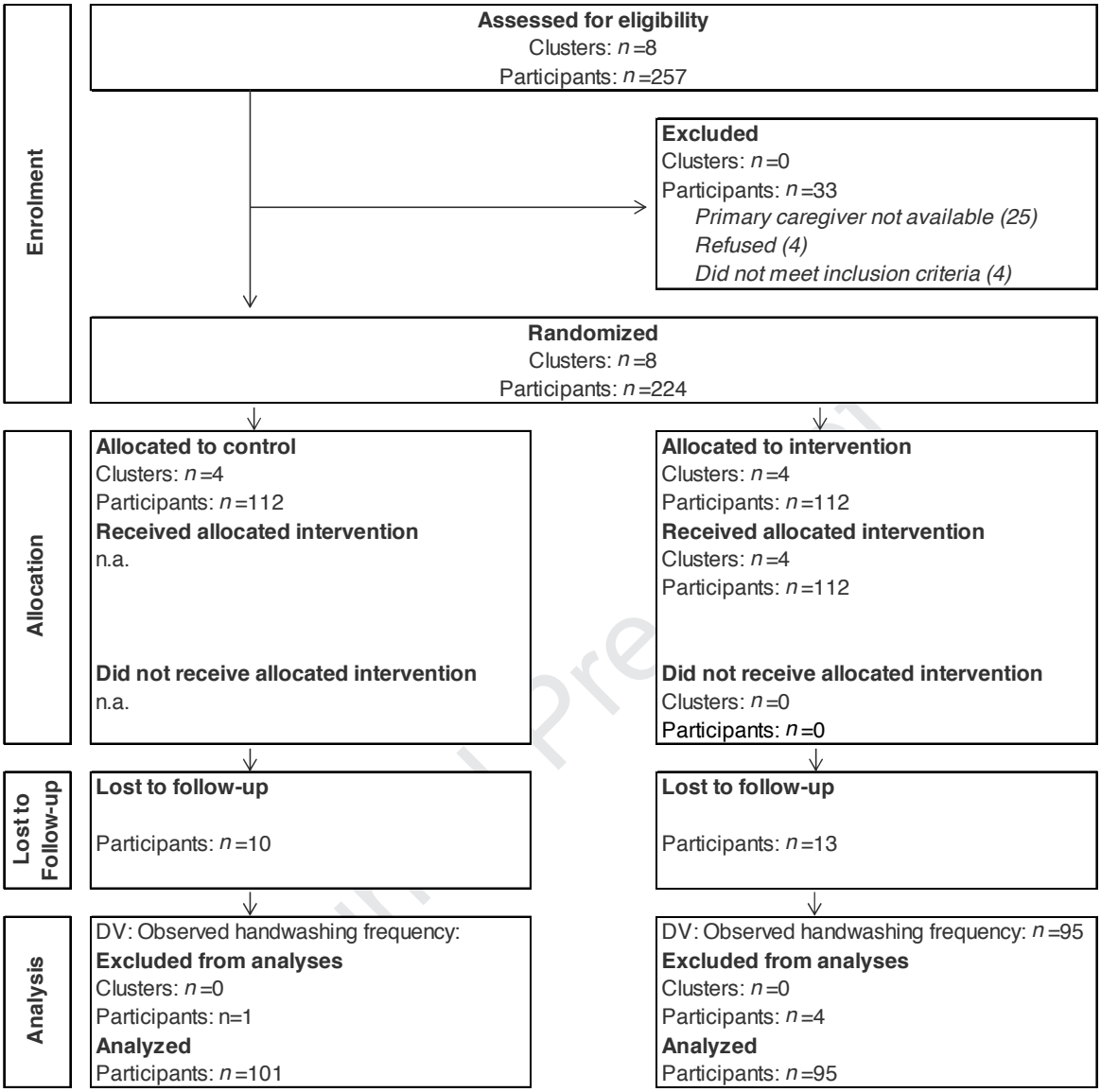


*Figure 2.* Participant flow through the cluster-randomized controlled trial. n.a. = not applicable, DV = dependent variable.

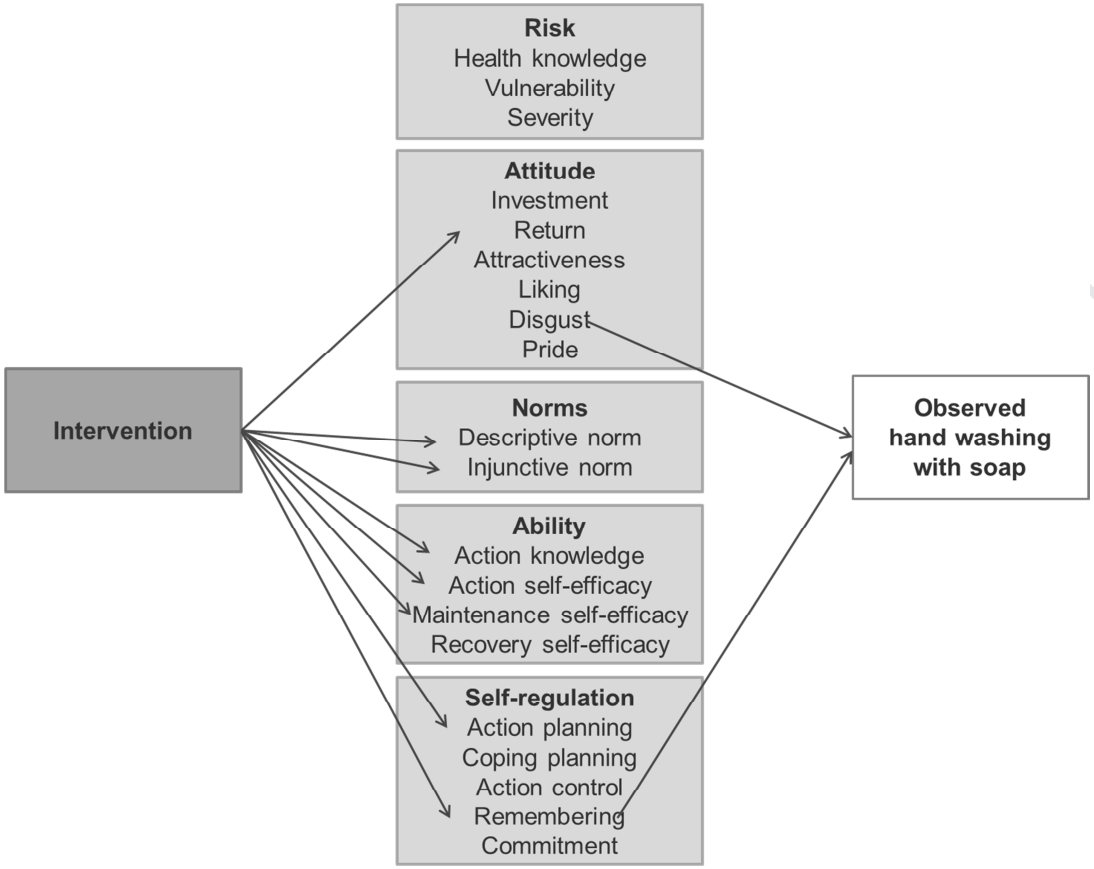


*Figure 3.* Summary of mediation analyses that tested intervention effects on changes in psychosocial factors (a paths), and relationship of changes in psychosocial factors on changes in observed hand washing with soap (b paths). Solid lines represent significant effects at $p < .05$, and missing lines represent effects at $p > .05$.

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## Research Highlights

- A systematic approach increased hand washing with soap by 21% compared to controls.
- Increased remembering was the active ingredient of the intervention.
- Mediation analysis can give indication how to refine behavior change interventions.

**Authorship Contributions**

**Are needed for this article. Please request these from the authors, describing the role of each author in this article and the research it reports.**