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A cluster-randomised controlled equivalence trial of the Surprise Soap handwashing intervention among older children living in a refugee settlement in Sudan

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ABSTRACT

Introduction Increasing handwashing with soap (HWWS) among older children in emergency settings can have a large public health impact, however, evidence on what works is limited. One promising approach is the 'Surprise Soap' intervention in which a novel soap with an embedded toy is delivered to children in a short, participatory household session that includes a glitter game and HWWS practice. Here, we evaluate this intervention against a standard intervention in a complex emergency setting.

Methods A cluster-randomised controlled equivalence trial was conducted in Naivasha refugee settlement, Sudan. Blinding was not possible. 203 randomly selected households, with at least one child aged 5–12, were randomised to receive the Surprise Soap intervention (n=101) or a standard intervention comprising a short household session with health messaging and plain soap distribution (n=102). The primary outcome was the proportion of prespecified potential HWWS events observed for children aged 5–12, accompanied by HWWS, at baseline, 4, 12 and 16 weeks post intervention delivery.

Results 200 households were included in the analyses: 101 intervention and 99 control. No difference in intervention effectiveness was observed at any follow-up (4 weeks: adjusted rate ratio (RR) 1.2, 95% CI 0.8 to 1.7; 12 weeks: RR 0.8, 95% CI 0.5 to 1.1; 16 weeks: RR 1.1, 95% CI 0.8 to 1.5). However, we observed increased HWWS in both arms at 4 weeks (27 and 23 percentage point increase in the intervention and control arm, respectively) that was sustained at 16 weeks.

Conclusions We find that the Surprise Soap intervention is no more effective at increasing older children's HWWS than a standard, household-level, health-based intervention in this complex humanitarian emergency. There appears to be no marginal benefit in terms of HWWS that would justify the additional cost of implementing the Surprise Soap intervention. Further trials that include a passive control arm are needed to determine the independent effects of each intervention and guide future intervention design.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The Surprise Soap intervention—a handwashing intervention in which a novel soap with an embedded toy is delivered to older children in a participatory household session including a glitter game—has had promising results in a refugee camp in Iraq but it is unclear if it is effective in different complex humanitarian settings.

WHAT THIS STUDY ADDS

⇒ This study adds to the limited evidence base on what works in handwashing promotion for children in humanitarian contexts and specifically to existing evidence on the effectiveness of the Surprise Soap intervention in different humanitarian settings. Results show that the Surprise Soap intervention is no more effective at increasing children's handwashing than a standard, household-level intervention involving health-based messaging and provision of plain soap, in a refugee settlement in Sudan.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Implementing agencies should note that there appears to be no marginal benefit, in terms of handwashing, of implementing the Surprise Soap intervention over a standard intervention that would justify the additional cost. Further research is needed to determine the independent effects of each intervention and guide future intervention design.

INTRODUCTION

Handwashing with soap (HWWS) is an important public health behaviour that reduces transmission of infectious disease. HWWS alone can reduce diarrhoeal disease by 30%[1] and acute respiratory infections (ARIs) by 21%–23%.[2 3] HWWS has also been shown to reduce some neglected tropical diseases, such

as trachoma[4] and certain soil-transmitted helminth infections.[5 6]

To date, the majority of HWWS interventions have targeted caregivers as they are typically responsible for the hygiene of children under the age of 5—the age group at greatest risk of diarrhoeal disease and ARIs.[7] However, older children (classified as children between the ages of 5 and 14 by the Global Burden of Disease studies[7]), also bear a high burden of these diseases.[7] Older children are becoming more independent. They are likely leaving the house more often, they may be starting or are already in school and are taking responsibility for their own handwashing. Interventions directly targeting older children and encouraging them to practise HWWS are therefore also of great public health importance.

HWWS interventions that reduce the transmission of diarrhoeal disease and ARIs among older children not only leads to lower rates of morbidity and mortality but also to non-health benefits such as reductions in rates of school absence,[8–12] and consequently to higher academic attainment,[13 14] and associated economic and health benefits later in life.[15] After receiving HWWS interventions, older children may also act as agents of change, spreading these messages to their family members and the broader community.[16–20]

Interventions that increase older children's HWWS in humanitarian settings are especially important. Children may constitute over half of the humanitarian population[21] and factors in the environment, such as overcrowding, unclean water and sanitation facilities, environmental contamination and limited access to healthcare heighten their risk of disease.[21–24] Faecal-oral diseases such as diarrhoea, for example, are responsible for up to 40% of all deaths in the acute phase of an emergency.[23]

Evidence on what works in HWWS interventions targeted at older children is limited, particularly in humanitarian settings. Few HWWS interventions have been rigorously evaluated and those that have, have had mixed success.[25 26] One recent intervention which may be effective among older children in humanitarian settings is the 'Surprise Soap' intervention.[27] This intervention purports to encourage children's HWWS by appealing to their innate motives of play and curiosity. Children receiving the intervention are given bars of Surprise Soap—transparent soaps with a toy embedded inside—within a short household session that communicates the importance of HWWS through fun, participatory activities including a glitter game and HWWS practice, rather than via traditional health-based messaging, which past research suggests may be a poor motivator of behaviour change.[28–31] The toy inside the soap incentivises children to wash their hands.

An initial proof-of-concept trial of the Surprise Soap intervention among children living in an internally displaced persons (IDP) camp in Iraq found that after receiving this intervention children were four times more likely to practice HWWS at key times compared with the counterfactual—a standard health-based household-level handwashing intervention.[27] This trial was, however, limited to just one camp where the population was stable and homogenous (100% Yezidi), there was good access to soap and water, and children were already frequently exposed to hygiene promotion. Additionally, HWWS was only measured at one follow-up, 4 weeks after intervention delivery. After this study, there were still unanswered questions: can the intervention be effective in different, more complex humanitarian settings where populations may be mixed and unstable, access to soap and water are lower, and there is little pre-existing exposure to hygiene promotion and can the effect of the intervention be sustained beyond 4 weeks?

To address these questions, two separate cluster-randomised controlled equivalence trials were conducted, each with a follow-up period of 16 weeks—one across IDP camps in Somalia and one in a large refugee settlement in Sudan. Both of these are complex humanitarian sites, which face specific challenges. Both sites suffer from limited infrastructure, political and population instability, poor access to healthcare, poor access to handwashing facilities with both soap and water, and limited exposure to health promotion, including HWWS promotion. The site in Somalia, however, hosts an ethnically heterogeneous, internally displaced population whereas the site in Sudan hosts an ethnically homogeneous refugee population. In each trial, the effect of the Surprise Soap intervention on older children's HWWS was compared with an active control—'standard' household-level intervention comprising health-based messages and plain soap. The results of the Somalia trial have been reported elsewhere.[32] Here, we report the results of the trial in Sudan. Our findings contribute both to the limited evidence base for HWWS interventions targeting older children and serve as a guide for any organisation seeking to deliver effective HWWS interventions in humanitarian settings.

METHODS

As described above, this is the second of two trials to assess the same intervention delivered in two different humanitarian settings by two different agencies. The study design and methods were standardised across both sites to permit comparison between studies and have been described previously.[32]

Study design and participants/eligibility

This study is reported according to the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.[33] This study was a cluster-randomised controlled equivalence trial with an intervention arm receiving the Surprise Soap intervention and an active control arm receiving a standard handwashing intervention. The study took place between October 2021 and March 2022. Households were eligible to participate in the study if they included at least one child aged between 5 and 12 years and had no plans to travel away for more than 1 week over the ensuing 6 months. Individual

households were then randomly assigned (1:1) to the intervention arm or the active control arm.

Study setting

The study took place among households in the Naivasha refugee settlement in Khartoum state, Sudan. Naivasha is one of the largest of the nine informal refugee settlements, termed 'open areas', within Khartoum state. The settlement was established in 2017 and is managed by the Humanitarian Aid Commission. It houses over 10 000 registered refugees, mostly from South Sudan[34] and specifically from the Dinka ethnic group. Due to restrictions on shelter distribution, most of the population in Naivasha reside in makeshift shelters created from plastic sheets, burlap, branches and bamboo. The settlement suffers from a lack of integration within the networked infrastructure system found within Khartoum, leading to frequent power cuts, (assuming the household has electricity), as well as limited access to drinking water, sanitation and solid waste management services. Beyond water and sanitation, access to other basic services such as healthcare and education is limited, with health services dependent on humanitarian funding and 24% of children out-of-school. Protection risks are also high, particularly gender-based violence.[34] At the time of this study, Care International was the provider of Water, Sanitation, and Hygiene (WASH) services to Naivasha. Water was accessed from communal pipes and soap distribution was irregular, leaving residents often without soap as purchasing it is considered unaffordable by many. Forty-five hygiene promoters were active in Naivasha at the time of the study; however, hygiene promotion was rarely targeted at children.

Intervention content and delivery

Households assigned to the intervention arm received the Surprise Soap intervention, and households assigned to the active control arm received a standard handwashing promotion intervention. Each intervention was delivered to children at their house the day after baseline observation was carried out. Hygiene promoters, already active under Care International were trained to deliver both interventions. The main features of the two interventions are presented in table 1 with further details given below.

Surprise Soap intervention

The Surprise Soap intervention consisted of distribution of Surprise Soap bars within a short (approximately 10–15 min) participatory household session in which children played a 'glitter game' and practised HWWS (table 1). Surprise Soaps are transparent glycerine soaps (145 g soap/bar) with toy animals embedded inside (figure 1). All soap bars were manufactured by the company, KIMA, in Jordan. Brief formative work which involved showing photos of potential toy options and soliciting feedback from site leaders, hygiene promoters and adult residents of the camps, was undertaken by Care International to ensure the toys were culturally appropriate. In the end, we had a range of 35 different toy animals and therefore 35 different bars of Surprise Soap. On arriving at their designated household, hygiene promoters gathered the children of the household together and initiated the 'glitter game' to demonstrate how germs spread: petroleum jelly and glitter were applied to one child's hands who then 'high fived' the other children, transferring the 'glitter germs' between hands. The hygiene promoter then revealed the Surprise

Table 1 Overview of intervention activities in each study arm

	Intervention arm	Active control arm
Intervention	Surprise Soap Intervention	Standard Intervention
Setting	Household	Household
Intensity	One-off promotion session with delivery agents, followed by three subsequent visits from agents to replenish soap only	One-off promotion session with delivery agents, followed by three subsequent visits from agents to replenish soap only
Session length	10–15 min	10–15 min
Approach	Targeting motives of play and curiosity and providing knowledge of how and when to wash hands	Delivering health-based messaging and providing knowledge of how and when to wash hands
Products	Surprise Soap ×5 bars, plus later replenishments	Plain soap identical to Surprise Soap but minus the toy ×5 bars, plus later replenishments
Activities	Glitter game to demonstrate germs spreading Demonstration of handwashing technique Information on key times to wash hands Children practicing handwashing with Surprise Soap	Handwashing-related health-messaging using F-diagram Demonstration of handwashing technique Information on key times to wash hands
Delivery agent	Care international hygiene promoters specifically trained to deliver the Surprise Soap intervention (no overlap with the hygiene promoters delivering the standard intervention)	Care international hygiene promoters specifically trained to deliver the standard intervention (no overlap with the hygiene promoters delivering the Surprise Soap intervention)

Figure 1 Surprise Soap image.

Soap bars to the children, explaining that the more often they wash their hands with the soap, the faster they will reach the toy inside, and listing five key handwashing times (before eating, before preparing food, before serving food to another person, after using the toilet and before cleaning another person's faeces). The hygiene promoter then demonstrates the ideal handwashing technique, inviting the children to practice washing the glitter from their hands using the Surprise Soap, and then finally leaving a parcel of five Surprise Soaps with the children in the household (parcel directly handed to a child). At least one adult, usually a caregiver, was present during intervention delivery but they were not personally instructed on the use of these toy soaps. On the same day, directly after the 4 weeks, 12 weeks and 16 weeks follow-up household observations, the hygiene promoters visited the households again to distribute further packages of Surprise Soap but did not repeat the household session. Soap packages all contained soaps with different toy animals so that the children did not receive the same toy twice over the intervention period. No handwashing messages were delivered during these follow-up visits.

Standard intervention received by control group

The standard intervention consisted of the distribution of plain soap (145 g soap/bar), identical to the Surprise Soap in colour, size, shape, volume and quality but without a toy inside, delivered within a short household session (approximately 10–15 min—comparable to the length of the Surprise Soap household session) to control for the effects of soap provision and household-level delivery (table 1). The household session focused on standard health-based messages using some of Care international's existing handwashing promotion material. Hygiene promoters gathered the children and showed them the F-diagram, explaining how the spread of germs from faeces to mouths via hands can lead to diseases such as diarrhoea. They explained that HWWS can prevent these diseases, listed five key times to practice HWWS (as above) and demonstrated ideal handwashing technique. A parcel of five plain soaps were left with the children. Plain soap was also replenished directly after the 4 weeks, 12 weeks and 16 weeks follow-up household observations, in the same quantities as Surprise Soap, without repeating the household session.

Outcomes

The primary outcome of the trial was the proportion of five key potential handwashing events that were accompanied by HWWS (both hands) for children aged 5–12 years. The prespecified five key potential handwashing events were: (1) after defecation or using the toilet, (2) before eating, (3) before preparing food, (4) before serving food to another person and (5) after cleaning another child's faeces. This outcome was measured at four time points: baseline (the day prior to intervention delivery), 4 weeks, 12 weeks and 16 weeks after intervention delivery.

The two secondary outcomes of the trial were: the proportion of all observed handwashing events (handwashing with water) where soap was used, and the total number of observed HWWS events across all time points. Secondary outcomes were assessed through structured observation at all four time points, as for the primary outcome. In addition, the presence of a handwashing station with soap available was also measured at all the four time points.

A series of indicators of intervention compliance were also assessed in the arm receiving the Surprise Soap intervention at 16 weeks after intervention delivery. These included the number of bars of Surprise Soap remaining, whether a bar of Surprise Soap was wet on inspection at endline, the caregiver-reported time in days required to reach the toy in the Surprise Soap, caregiver-reported incidents of 'toy cheats' (ie, where the Surprise Soap bar was broken to access the toy prematurely), and caregiver-reported use of the Surprise Soap by other household members (children <5 years of age and adults) and for other purposes than hand hygiene (bathing, laundry, washing dishes or any other uses).

Data collection

All data collection activities were undertaken by a team of trained enumerators who had no role in the delivery of the intervention. The research team provided a 3-day training to field supervisors, involving both classroom and practical sessions, and supervisors subsequently trained enumerators in the local language. Recruitment was undertaken by enumerators and basic background social and demographic data were collected at the time of recruitment using a verbally administered questionnaire. During the 4 weeks before intervention delivery,

one enumerator returned to each enrolled household to conduct direct structured observations of child handwashing practices and to record data on household handwashing facilities using spot-check observations. Structured observations started at approximately 9:30 hours and continued for 3 hours—a period when most children in this setting would be home. Data were collected for all children aged 5–12 years present in the household during the observation period. Enumerators positioned themselves in an unobtrusive location in or near the household where they had the best view of the children and the handwashing facility (where available). Every instance of the five key handwashing events (as defined above) and the associated handwashing practice (hands not washed, washed with water only, washed with soap and water) was recorded. Any instances of HWWS that were not associated with these five key events were also recorded. Structured observations were repeated 4 weeks, 12 weeks and 16 weeks post intervention delivery. In intervention households only, directly after the 16-week structured observation, field workers also recorded information on intervention compliance. All data were collected using Open Data Kit on android tablets and uploaded onto a dedicated encrypted server at the end of each data collection day for the research team at the London School of Hygiene and Tropical Medicine (LSHTM) to cross check the data daily.

Patient and public involvement

Patients, that is, our research participants, and members of the public were not involved in the design, conduct, reporting or dissemination plans of this research. As described above, we consulted members of the public (site leaders, hygiene promoters and adult residents of the camps) to ensure our design of Surprise Soap bars was culturally appropriate. Results of our research have been communicated with research participants via camp leaders. The authors of this research will disseminate findings via conferences and other presentations.

Sample size and randomisation procedure

We calculated that a sample size of 200 households—corresponding to clusters—was needed to detect an absolute difference in HWWS after key events of 10% between control and intervention arms (15% HWWS after key events in the control arm, 25% in the intervention arm), with 80% power (α=0·05). We assumed an average of seven observed HWWS events (ie, when hands could have been washed or not) per household per 3-hour observation period, a within-household intracluster correlation coefficient of 0.21,[35] and a loss to follow-up of 20%.

Individual random sampling was employed by JW and MA-T to select households in Naivasha using a complete list of all households in the site, randomised within Stata. If a household on the randomised list was non-eligible the next household on the list was approached, and so on until a total of 200 households were enrolled. Enrolled households were then randomly assigned to intervention or control arm with a 1:1 ratio using a random number generator in Stata, V.16.1.[36]

Blinding

The precise nature of the data being collected was not disclosed to participants, instead they were informed that the enumerators would be observing children's routines to build an understanding of how children's health and well-being can be improved in the area. Enumerators were informed that all participating households would receive a hand hygiene intervention, but they were not informed of the nature of the intervention received by intervention and control arms, and they had no role in the intervention delivery. Due to the nature of the intervention, no further blinding of study participants or enumerators was possible.

Statistical analysis

All statistical analyses were undertaken using Stata, V.16.1.[36] We analysed the effect of the intervention, compared with the standard intervention, on the proportion of key handwashing events accompanied by HWWS using a Poisson Generalized Estimating Equations (GEE) model for rates, in which the number of actual HWWS events was offset by the total number of potential handwashing events per child. The proportion of all handwashes that used soap, was similarly assessed using a Poisson model for rates in which the total observed children's handwashes that used soap was offset by the number of observed handwashes per child. Finally, the total number of observed handwashes with soap was analysed using a Poisson GEE model for counts. In all models, clustering was accounted for at the highest level, the household (because children were nested within the household). To increase precision, adjusted rate (or count) ratios were computed, adjusting for factors determined a priori to be associated with the outcome (age, sex, number of children aged 5–12 in the household and number of people earning in the household). A p value threshold of 0.05 was considered statistically significant. The statistical models described above differ from the models we prespecified in our trial registration (osf.io/b6qc7)—multilevel mixed effects Poisson regression models. After further consultation with a statistician and prior to running any analyses, we determined the most appropriate model to be a GEE Poisson model given that we were interested in estimating population-averaged effects. All covariates remained as prespecified. For transparency, we also ran the prespecified analyses and found no difference in overall outcomes (online supplemental file 3: prespecified analyses)

A detailed author reflexivity statement has been provided as online supplemental file 4 accompanying this manuscript.

The trial protocol is registered on the Open Science Framework (OSF), osf.io/va9yn

RESULTS

Participants and baseline data

A total of 203 households were enrolled in the study. A total of 102 were randomly assigned to the active control

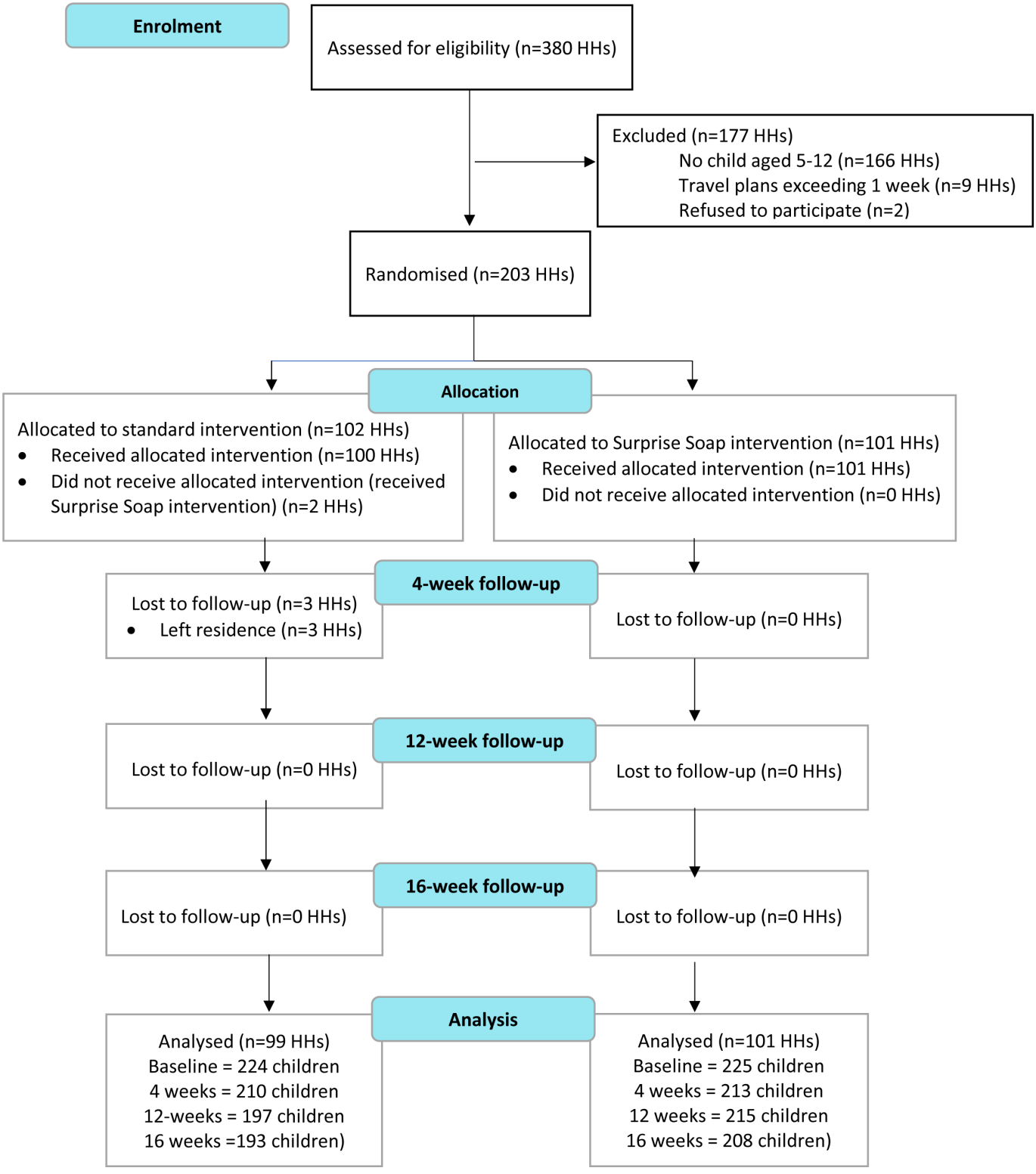

Figure 2 Trial profile. HH, household.

arm and 101 were randomly assigned to the intervention arm. Three households, all from the active control arm, were lost to follow-up. In error, two households from the active control arm received the Surprise Soap intervention instead of the prescribed standard intervention (figure 2). The results we present below are from our intention-to-treat analysis, however, we also ran a per-protocol analysis which aligns with these results (online supplemental file 1). The full data set is published alongside the paper (online supplemental file 2).

Baseline prevalence of HWWS after key handwashing events was 12.4% in the intervention arm and 10.4% in the active control arm. Child-level and household characteristics appeared well balanced between intervention

Table 2 Baseline characteristics

	Overall	Intervention	Control
Handwashing			
n (no of potential handwashing events observed)	1018	541	477
No of potential handwashing events where HWWS observed (n, %)	117 (11.5)	67 (12.4)	50 (10.4)
Child			
n (no of children observed)	449	225	224
Age, years (mean, SD)	8.40±2.49	8.32±2.41	8.48±2.56
Sex, female (n, %)	228 (51)	111 (49)	117 (52)
Household			
n (no of households)	203	101	102
Household head education score (mean, SD)	0.72±0.74	0.78±0.76	0.66±0.71
No earning income (mean, SD)	0.47±0.67	0.56±0.74	0.37±0.58
No household members (mean, SD)	8.11±3.01	8.10±3.11	8.12±2.92
No of children <5 years of age (mean, SD)	1.30±1.14	1.22±0.94	1.37±1.31
No of children 5–12 years of age (mean, SD)	2.81±1.38	2.86±1.44	2.75±1.32
Period of residence, months (mean, SD)	70.79, 10.80	72.20, 8.78	69.39, 12.37
Handwashing station available (n, %)	135 (67)	65 (64)	70 (69)
Soap available in household (n, %)	63 (31)	32 (32)	31 (30)
Water available (n, %)	145 (71)	72 (71)	73 (72)
Station reachable by children (n, %)	128 (95)	63 (97)	65 (93)

HWWS, handwashing with soap.

and active control arm. Baseline characteristics are presented in table 2.

Prevalence of HWWS after intervention

The prevalence of HWWS after key events increased after baseline observations in both the intervention (+27 percentage points) and control arm (+23 percentage points) and remained high throughout the 16-week follow-up. At the final 16-week follow-up, HWWS prevalence was up by 36 percentage points from baseline levels in both the intervention arm and control arm (figure 3).

Availability of a handwashing station and soap after intervention

The proportion of households with a handwashing station available increased in both arms, from 64% at baseline to 86% at endline in the intervention arm, and from 69% to 89% in the control arm. Availability of soap (any type of handwashing soap) in the household also increased in both arms. At endline, 59% of intervention households and 63% of control households were observed to have soap available, compared with baseline levels of 32% and 30%, respectively. Availability of water also increased in both arms. At endline 85% of intervention households and 89% of control households were observed to have water available in the household for handwashing, compared with baseline levels of 71% and 72%, respectively.

Primary outcome

There was no evidence of a difference in the proportion of key handwashing events that were accompanied by HWWS for children aged 5–12 years between the intervention and control arm at the 4-week follow-up, the 12-week follow-up or the 16-week follow-up (16-week follow-up: rate ratio (RR) 1.1, 95% CI 0.8 to 1.5, p=0.71) (table 3).

Secondary outcomes

There was no evidence of a difference in the proportion of all handwashes that used soap between the intervention and control arm at the 4-week follow-up, the 12-week follow-up or the 16-week follow-up (16-week follow-up: RR 1.0, 95% CI 0.8 to 1.3, p=0.90) (table 4).

There was no evidence of a difference in the total number of handwashes with soap between the intervention and control arm at the 4-week, 12-week or 16-week follow-up (Count ratio (CR): 1.0, 95% CI 0.7 to 1.4, p=0.90) (table 5).

To assess the robustness of our findings, we conducted a robustness check by including enumerator identity as a covariate in each of our GEE Poisson regression models, since there may have been inherent differences in the way each enumerator performed observations. The results of this robustness check (online supplemental file 3: robustness check) indicate that enumerator identity did not have a significant impact on the overall outcomes.

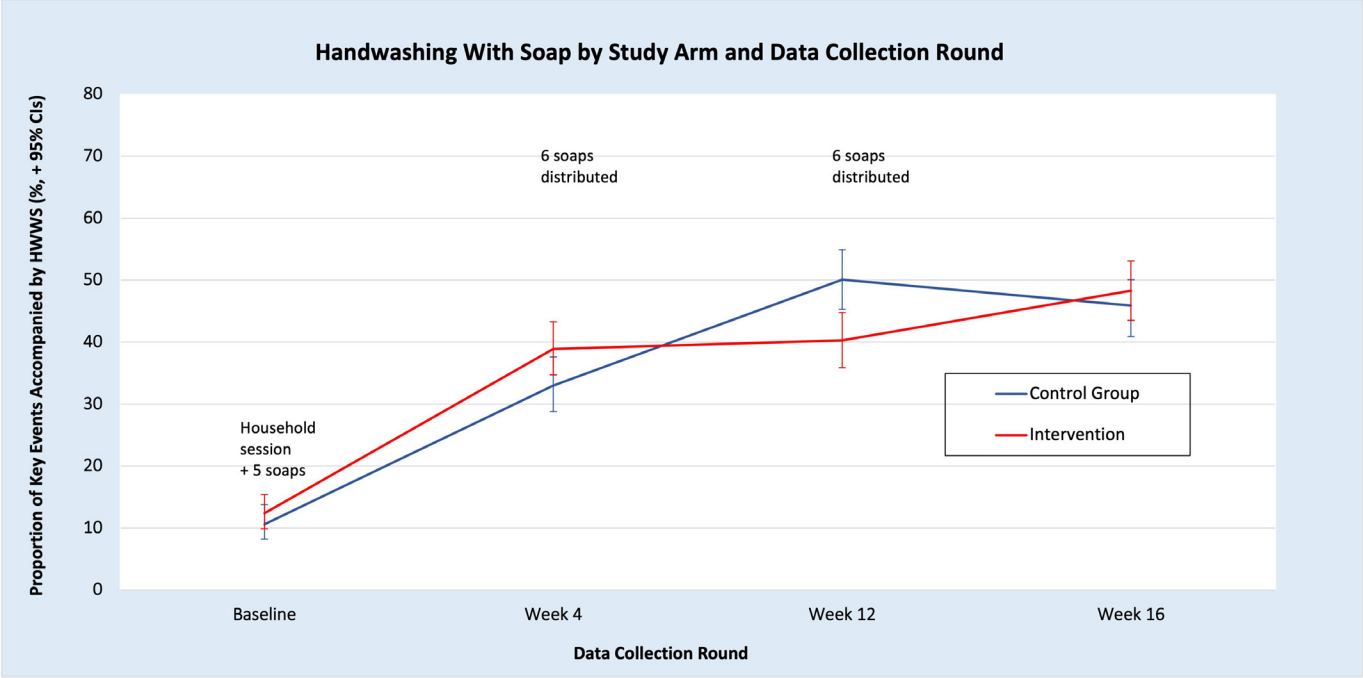

Figure 3 Prevalence of handwashing with soap among the intervention and active control arm at baseline and 4, 12 and 16 weeks postintervention delivery.

We also conducted an exploratory subgroup analysis to assess the impact of a child's age group on our primary results as children of different ages may experience the intervention differently. Two age groups were defined: ages 5–8 and ages 9–12. Results of the analysis revealed no notable difference in the effect of the intervention across the two age groups (online supplemental file 3: subgroup analyses 1).

An exploratory subgroup analysis was also undertaken to assess the impact of the number of children between the age of 5 and 12 living in the household as this appeared to be a source of heterogeneity at baseline. Two subgroups were defined: households with three or fewer children aged 5–12 living in the household and households with four or more children living in the household. Results of the analysis revealed no notable difference in the effect of the intervention across the two groups (online supplemental file 3: subgroup analyses 2).

Compliance in the intervention arm

At the 16-week follow-up, all households in the intervention arm (n=101) reported that they had finished at least one bar of Surprise Soap, indicating they had all engaged with the intervention. Forty-one per cent (n=41) of households still had at least one bar of Surprise Soap remaining and among these households, an average of two (95% CI 1.3 to 1.9) bars of Surprise Soap remained per household. Of the 41 households with some Surprise Soap remaining, 46% (n=19) had a bar of Surprise Soap that was wet on inspection indicating that just under half of these households were still engaging with the intervention 16 weeks later. In 40% of the households, adults also used the Surprise Soaps, and 55% of households with children under 5 reported that these young children also used the Surprise Soaps. Seventy-five percent of households reported that the Surprise Soap bars were used for purposes other than handwashing, with bathing being the most common alternative use reported. It took, on

Table 3 Effect of intervention on the proportion of key handwashing events accompanied by HWWS

	Intervention	Control	Rate ratio*	95% CI	P value
Baseline (n, %)	67 (12.4%)	50 (10.6%)	1.1	0.6 to 1.9	0.81
Week 4 (n, %)	189 (38.9%)	1.46 (33.0%)	1.2	0.8 to 1.7	0.44
Week 12 (n, %)	189 (40.3%)	208 (50.1%)	0.8	0.5 to 1.1	0.11
Week 16 (n, %)	198 (48.3%)	174 (45.9%)	1.1	0.8 to 1.5	0.71

Poisson for rates generalised estimating equations analyses accounting for clustering at the household level.
*Adjusted for age, sex, number of children aged 5–12 in the household, and number of household members earning an income.
HWWS, handwashing with soap.

Table 4 Effect of intervention on the proportion of all handwashes that used soap

	Intervention	Control	Risk ratio*	95% CI	P value
Baseline (n, %)	81 (20.2)	63 (17.4)	1.1	0.7 to 1.9	0.60
Week 4 (n, %)	205 (49.4)	157 (46.2)	1.0	0.8 to 1.4	0.79
Week 12 (n, %)	196 (51.3)	228 (63.5)	0.8	0.6 to 1.1	0.11
Week 16 (n, %)	215 (58.7)	194 (59.0)	1.0	0.8 to 1.3	0.90

Poisson for rates generalised estimating equations analyses accounting for clustering at the household level.
*Adjusted for age, sex, number of children aged 5–12 in the household, and number of household members earning an income.

average, 5 days (95% CI 4.4 to 5.0) for children to reach the toy by washing their hands. Fourteen percent of households reported 'toy cheats'—children who deliberately broke the soap to get the toy inside. On average, these households reported that three bars (95% CI 2.0 to 3.8) of Surprise Soap, out of the 17 bars received over the intervention period, were purposefully broken.

DISCUSSION

We find the Surprise Soap intervention, in which novel soap with embedded toys are delivered to older children in a participatory household session that includes a glitter game and HWWS practice, to be no more effective than a standard household-level handwashing intervention based on health-messaging and the provision of plain soap, in a large refugee settlement in Sudan. These results align with the results of a recent cluster randomised controlled equivalence trial of the Surprise Soap intervention across IDP camps in Somalia.[32] Like the Somalia trial, these results differ from an earlier proof-of-concept study undertaken in Northern Iraq that found the Surprise Soap intervention to be four times more effective than the same standard handwashing intervention employed there.[26] In Sudan and Somalia, there appears to be no marginal benefit of the Surprise Soap intervention over the standard intervention in terms of older children's HWWS behaviour that would justify the additional costs incurred (in our study, a Surprise Soap bar costed US$2 compared with US$1.5 for the plain soap bar).

Although there was no difference in effect between the intervention arm and our active control arm, in both trial arms, we observed an equally large and sustained increase in children's HWWS from baseline to all follow-ups. Our study is not designed to assess the independent effects of each intervention and there are several possible explanations for the increased rates of HWWS over time, for example, seasonal differences, disease outbreaks, exposure to other handwashing awareness campaigns and the introduction of various biases related to lack of blinding in the study. However, one possible explanation for the upwards trends in both trial arms is that both the Surprise Soap intervention and the standard intervention were effective at increasing children's HWWS. Similar upwards trends in the intervention arm and the active control arm were also observed in the Somalia trial meaning all three studies of the Surprise Soap intervention (Iraq, Somalia and Sudan) observed an increase in older children's HWWS.[27 32] Further trials with a passive control arm are needed to determine the individual effects of both interventions. The discussion which follows assumes that the upwards trends observed in both arms of this study are directly attributable to the Surprise Soap and standard intervention. This is only an assumption, and we later discuss other possible explanations for these upwards trends within our limitations section.

The upwards trends in children's HWWS in both trial arms may point to the importance of what some researchers have termed the 'form of delivery'.[37] Both the Surprise Soap intervention and the standard intervention were delivered by hygiene promoters directly to children within their own house. This delivery format is itself rather unusual. Hygiene promotion interventions are typically delivered to children within schools or in child-friendly spaces (in humanitarian settings) as part of a larger programme.[26] Interacting with children in their household one-on-one or in a small group is likely to be more engaging and may instil a greater

Table 5 Effect of intervention on the total number of handwashes with soap

	Intervention	Control	Count ratio*	95% CI	P value
Baseline (n)	81	63	1.1	0.7 to 1.9	0.69
Week 4 (n)	205	157	1.2	0.8 to 1.7	0.47
Week 12 (n)	196	228	0.7	0.5 to 1.0	0.08
Week 16 (n)	215	194	1.0	0.7 to 1.4	0.90

Poisson for counts generalised estimating equations analyses accounting for clustering at the household level.
*Adjusted for age, sex, number of children aged 5–12 in the household, and number of household members earning an income.

sense of ownership over their own handwashing and may encourage caregivers to reinforce messages. Additionally, both interventions were relatively low-resource and quick to implement sessions making them feasible to deliver in emergency settings. When practitioners are designing interventions, it is important that they think not only about intervention content but also about the form of delivery. We cannot say if either intervention would be effective if delivered in schools. However, given that school-based handwashing interventions have faced multiple challenges in the past, we hypothesise that this form of delivery may be less effective.[38–42]

The combination of behaviour change techniques (BCTs) used in both the Surprise Soap intervention and the standard intervention may have also contributed to their apparent effectiveness. Both interventions provided soap, information on key times to wash hands, and a demonstration of correct handwashing technique. All three BCTs have been found to contribute positively to intervention effectiveness and using them in combination in HWWS interventions targeting older children has been recommended previously.[26] Ultimately, what this trial and the trial in Somalia might indicate, if both interventions were shown to be independently effective in future trials, is that well-designed handwashing interventions that directly target children at a household level, ensure an enabling physical environment, and teach children how and when to practise HWWS are important public health interventions in emergency settings.

Our results indicate that implementing the Surprise Soap intervention over a standard household-level HWWS intervention in complex humanitarian settings such as the Naivasha refugee settlement in Sudan is not a cost-effective choice. In the absence of a passive control arm, we cannot make recommendations around the implementation of the standard intervention. If the upwards trends in HWWS observed in both of our trial arms were proven to be directly attributable to the intervention this could encourage prioritisation, and aid in the design of future HWWS interventions for older children in emergencies. We therefore believe similar trials with the addition of a passive control arm to be of public health interest.

Our study has several limitations. First, our results may be subject to observer bias as it was not possible to blind enumerators to intervention status. Sampling both intervention and control households within one site also prevented us from blinding participants to intervention status. Being aware that you received Surprise Soap and others received only plain soap may lead to courtesy bias in the intervention arm. Second, sampling within one site may also have led to contamination of intervention messages across trial arms and biased the estimate of intervention effect towards the null. It is unlikely that intervention households shared their bars of Surprise Soap with active control households given we ensured different toy animals were received in each soap (ie, there was no need for children to trade toys) and no sharing was reported by caregivers or children in follow-up qualitative discussions held with the study participants. Third, as mentioned above, without a passive control arm, our trial design does not permit causal inference regarding the independent effects of each intervention; we are only able to report correlations we observed and make assumptions. Fourth, although we used the 'gold standard'[43] for measuring HWWS, structured observations are still prone to social desirability bias,[44] observer bias and the 'Hawthorne effect' or reactivity bias,[45] where children modify their behaviour in response to their awareness of being observed.[44 46] We tried to minimise the effects of these biases by using prolonged observation periods (3 hours) and by having multiple follow-ups, which likely reduces the risk of reactivity bias.[47] Nonetheless, these biases may have led to inflated rates of HWWS and contributed to the upwards trends in HWWS observed in both trial arms. Fifth, 'Teaching to the test'—where participants alter their behaviour to align with the objectives of the study may have also contributed to upwards trends being observed in both arms, as well as other unknown changes in the camp that were independent of our intervention. The large increase in the availability of soap at handwashing stations from baseline to endline in both trial arms—a proxy indicator of HWWS[48]—however, suggests that the upward trends in HWWS may, at least in part, be attributable to the interventions but without a passive control group, this is still only a hypothesis. Sixth, it should be noted that the plain soap, delivered as part of the standard intervention was identical to the Surprise Soap minus the toy. This is different to the plain soap typically used in Naivasha—it was scented and colourful and participants perceived it to be of higher quality and more attractive. The relative attractiveness of this soap may have provided an additional motivation for children to use it; a study among internally displaced children in Iraq found quality of handwashing materials to be a determinant of children's handwashing behaviour.[49] It is unclear if distributing 'regular' plain soap within a standard household session would have led to the same results. A future multi-arm trial would be necessary to confirm this. Finally, we did not collect data on what toys the children already had access to prior to this study, so we cannot assess how novel the toys we distributed were to them. However, from qualitative discussions we had with the children following the study they all reported finding the toys they received appealing and said that they would like to see Surprise Soap distributed in the future.

CONCLUSIONS

Our findings suggest that, in complex humanitarian emergencies, the Surprise Soap intervention, involving the distribution of bars of soap with embedded toys in a participatory household session that includes a glitter game and handwashing practice, is no more effective at increasing older children's HWWS than a standard, household-level intervention involving health-based

messaging and the provision of plain soap. There is no marginal benefit in terms of HWWS to justify the additional cost of the Surprise Soap intervention, associated with including toys inside of soap. Future trials with a passive control arm are needed to determine the independent effects of each intervention and guide future intervention design.

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