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**Research Paper**

# Impact of hygiene promotion intervention on acute childhood diarrhea: evidence from a cluster-randomized trial in refugee communities in Gambella Region, Ethiopia

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## ABSTRACT

Background: Diarrheal illnesses are mainly linked with poverty, and hygiene promotion programs can significantly reduce childhood diarrhea when interventions are tested in stable communities. However, there is no sufficient evidence in emergency context. Methods: A cluster-randomized controlled trial was conducted in Teirkidi and Pugnido refugee camps. Intention to treat was applied in analyses of the results of this trial. Logistic, poison regression and generalized estimating equation (GEE) models were used to evaluate changes in cluster-level hygiene behaviors and period prevalence and incidence of diarrhea with its confidence intervals (95% CI) and $p < 0.05$ significant cutoff point. Results: The reported diarrhea episodes were 1,307 (15.6 episodes per 100 person-weeks observation) among the intervention households and 1,619 (18.9 episodes per 100 person-weeks observation) in the control households. Under-five children living in households that received hygiene promotion had a 15% [$p < 0.001$; adjusted IRR: 0.85, 95% CI: 0.79 0.92] and a lower incidence of diarrhea compared with children living in control households. Conclusion: The study confirms that hygiene promotion intervention significantly reduces the incidence rate of childhood diarrhea in refugee camps. Hence, gains in the reduction of childhood diarrhea can be achieved in refugee camps through an enhanced hygiene promotion program.

**Key words:** children, diarrhea, hygiene promotion, randomized, refugees

## HIGHLIGHTS

- My research could evaluate the burden of childhood diarrheal diseases and try to address the problem in the refugee context.
- Reducing childhood diarrhea burden.

## ABBREVIATIONS

| | |
|---|---|
| AAU | Addis Ababa University |
| ARRA | Administration for Refugees and Returnees Affairs |
| EIWR | Ethiopian Institute of Water Resources |
| HH | Household |
| UNHCR | United Nations High Commissioner for Refugees |
| WASH | Water, Sanitation and Hygiene |
| WHO | World Health Organization |

## BACKGROUND

Refugees are migrated people outside their country of origin and usually live in crowded conditions without sufficient WASH, health care and other humanitarian services (Lori & Boyle 2016). Poor sanitation and hygiene practices, especially those related to water scarcity and quality, excreta disposal and hand-washing, were overwhelmingly associated with 1.8 million

deaths globally and caused approximately 4 billion cases of illness annually (WHO 2007). Diarrhea accounts for 19% of total child deaths globally and affects about 1.87 million children under the age of 5 years (Cynthia & Lana 2008). However, risk of illness and death from diarrhea varies geographically and even within the same families (Stephen *et al.* 2004). The prevalence of diarrheal diseases linked to inadequate water, sanitation and hygiene is manyfold times higher in Africa than in high-income nations (Annette *et al.* 2002). Various studies in Ethiopia found that the prevalence of childhood diarrhea varies between 15 and 36% (Mekasha & Tesfahun 2003; Nega & Alemayehu 2015; Animut *et al.* 2018; Girma *et al.* 2018). Child aged under-fives is the group most vulnerable to acute diarrhea, especially in refugee camps in developing countries (WHO 2013). In the period from 2005 to 2007, 1,400 deaths were estimated to be directly attributable to incomplete water and sanitation alone in refugee camps in Ethiopia, Kenya and Tanzania (Aidan *et al.* 2009). More than 25% of all deaths in Somalian refugee camps in Kenya were reported to have been associated with diarrhea (Jonathan *et al.* 2013). Increased new patient visits were associated with an increase in patient visits for diarrhea in UNHCR refugee camps (IRR = 1.90, 95% CI: 1.38–2.62) (Hershey *et al.* 2011).

A systematic review estimates that 94% of diarrhea morbidities are preventable through modification of the environment and human behavior (Prüss-Üstün & Corvalán 2016). However, sanitation and hygiene for children have been a neglected area of research; hence, current evidence on the magnitude of the problem is quite limited (Luby *et al.* 2006). Caregiver's knowledge of hygiene, sanitary food preparation and safe drinking water handling practices may help reduce diarrhea in children (Mock *et al.* 1993; Prüss-Ustün *et al.* 2006). Nonetheless, parents in marginalized communities or refugee camps have been found to have poor knowledge about childhood diarrhea (Mukhtar *et al.* 2011; Mekonnen *et al.* 2018). A study conducted in refugee camps in Gambella Region indicated that factors that negatively affect hygiene, such as inadequate water consumption, improper water handling and lack of comprehensive hand-washing facilities, were found to be independent predictors of childhood diarrhea (Mekonnen *et al.* 2019). Evidence from stable contexts indicates that hygiene promotion includes hand-washing with soap can meaningfully reduce diarrhea transmission (Stephen *et al.* 2004; Freeman *et al.* 2014; Null *et al.* 2018). Hygiene promotion is increasingly favored because of its potential to deliver reductions in diarrheal diseases at low cost (Borghi *et al.* 2002; Jamison *et al.* 2006). Apparently, no formative research has been conducted in Ethiopia to assess the effectiveness of sanitation and hygiene interventions in reducing the incidence of childhood diarrhea among refugee communities. Thus, the objective of this study was to carry out a study of the impact of an intervention in hygiene behaviors on childhood diarrhea in Pugnido and Teirkidi refugee camps.

## MATERIALS AND METHODS

### Setting and study population

In 2017, Ethiopia sheltered 889,071 registered refugees who originated mainly from the neighboring countries of South Sudan, Somalia, Eritrea and Yemen (UNHCR 2017a). South Sudanese refugees account for 46% of the total refugee population in Ethiopia, which is scattered widely across the western part of the country (UNHCR 2015). Gambella Region hosted 62,751 refugees in Pugnido camp, followed by Teirkidi, Kule, Jewi, Nguenyyiel and Okugo camps, which hosted 52,222, 47,444, 46,139, >30, 000 and 9,777 individuals, respectively. Gambella is located 753 km west of Addis Ababa, the capital of Ethiopia. Pugnido and Teirkidi refugee camps were randomly selected for this study. The number of households with under-5-year children was 9,085 in Pugnido and 9,863 in Teirkidi refugee camps in 2017 (UNHCR 2015, 2017b).

### Study design

A community cluster-randomized controlled trial was conducted from 15 July to 30 October 2017 in Pugnido and Teirkidi refugee camps to examine the impact of hygiene promotion intervention on the incidence of childhood diarrhea. Households with at least one under-five child were eligible to participate in the study. We hypothesized that the hygiene promotion intervention would reduce the incidence rate of diarrhea in under-five children, and the trial was designed to measure the cluster-level differences in this primary outcome.

### Household selection and randomization

We obtained registries of households in the two camps and sorted all the households with at least one under-five child. On average, 14 neighbor households in refugee camps in Gambella Region were organized as a community. The two communities combined to form a block that has 28 households on average. Each block has a minimum of 25 households with at least one under-five children. As a result, we produced 756 clusters by organizing the 25 neighborhood-eligible households

in a cluster. We identified 34 clusters of 25 households each which are organized by blocks and separated by streets. Following a baseline survey, the 17 clusters (425 HHs) were randomly allocated to the intervention or control arm in 1:1 matching using a lottery method (Figure 1). Study participants with the hygiene promotion trail were informed of their assignment after the baseline data collection. The cluster and household (HH) identification numbers of the intervention groups were communicated directly to the field team of hygiene promoters.

## Intervention

### Hygiene promotion intervention

The study employed the behavior-centered design (BCD) conceptual framework to design, deliver and evaluate the behavioral change intervention. The BCD approach was developed by a team at the Environmental Health Group of the London School of Hygiene and Tropical Medicine and involves five steps: ABCDE.

**A – Assess:** the first step in which the knowledge and programmatic gaps on childhood diarrhea were assessed through reviewing literatures of existing studies. It was important to check out what is known/unknown about diarrhea and hygiene behavior, to identify target audience, when and where hygiene behaviors are practiced, what may change behaviors and how can the target audiences be influenced?

**B – Build:** Build the strongest possible model of change for the identified target behavior through formative research or to generate a hypothesis. It indicates that conducting formative research to assess diarrhea burden, build knowledge of existing hygiene behaviors, identify determinants including motives and environment (physical, social and biological), prioritize key hygiene behaviors and ascertain the design of the intervention package. Hence, a cross-sectional study was conducted for collection and analysis of data about diarrhea burden and community knowledge and practices. The study found that

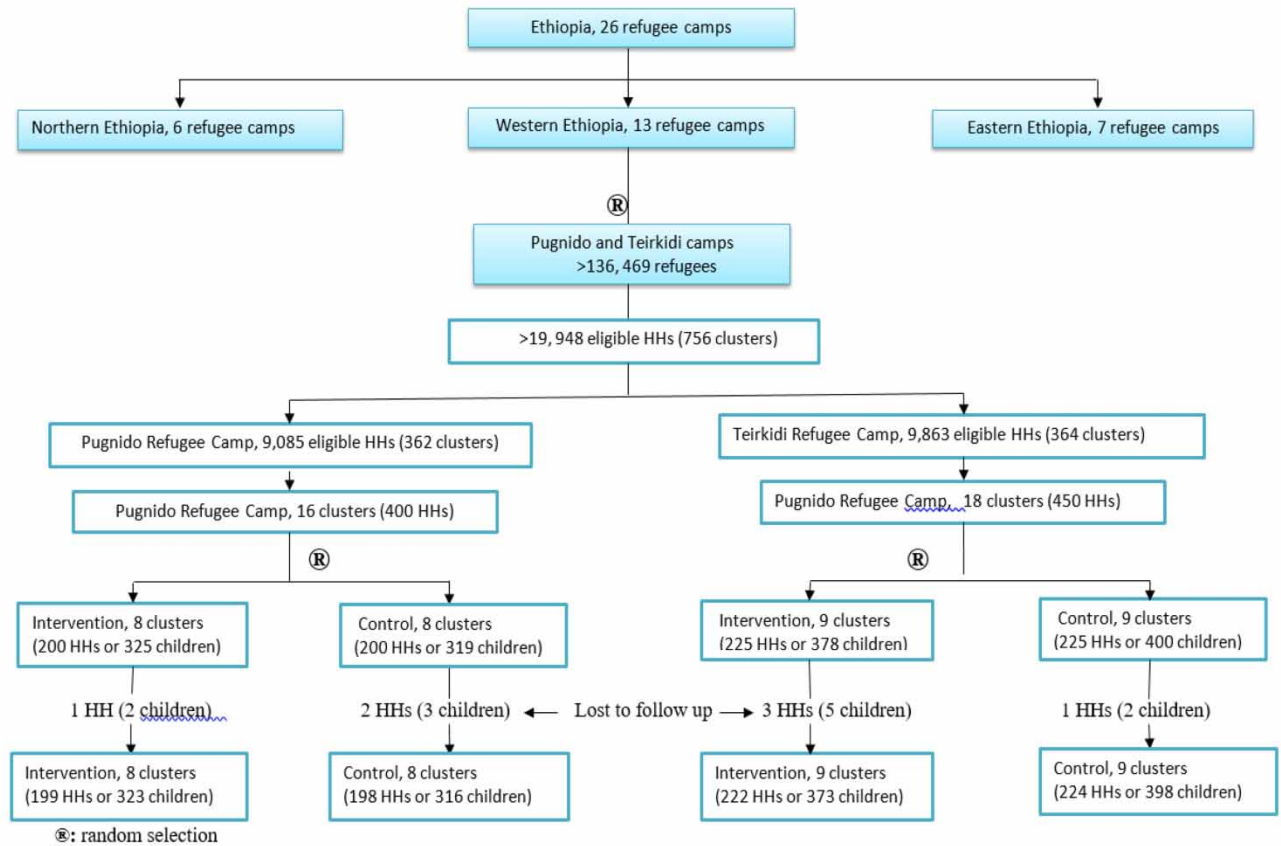


**Figure 1** | Flowchart of enrolled study households by the intervention and control arms in Pugnido and Teirkidi refugee camps in Gambella Region.

poor domestic hygiene behaviors: unsafe fecal disposal, lack of proper hand-washing with soap at five critical times and safe drinking water management at the point of use, were found to be the main influencing behaviors of childhood diarrhea in the refugee camps in Gambella Region (Mekonnen *et al.* 2019).

**C – Create or design** an intervention strategy and materials: A community-based cluster-randomized trial manual was developed to evaluate the impacts of selected hygiene behaviors in acute diarrhea in under-five children.

**D – Deliver:** The hygiene promotion package was delivered through door-to-door HH visits by trained local environmental health extension workers over a period of 12 weeks. The primary target audiences were mothers having a child aged less than 5 years. The hygiene promotion program was focused on educating caregivers about the transmission of germs, diarrheal disease and health benefits of good domestic hygiene behaviors D – Deliver; the intervention is implemented through the appropriate channels: A biweekly house-to-house hygiene education using the hygiene promotion guideline. Posters and leaflets were posted in the intervention clusters. A hand-washing station (a tippy tap) with clean water and 500-gram bar of soap was installed in the intervention households. Caregivers were oriented to cleaning their drinking water containers weekly using a teaspoon of crown detergent powder to remove pathogenic microorganisms, algae and silt. Biweekly scheduled and three unscheduled visits were carried out by the hygiene promoters and supervisors to ensure the HH's adherence to the hygiene promotion intervention program. Adherence of the intervention households to improved hygiene behaviors was established by assessing hygiene indicators using a checklist. We strengthened the implementation efforts in households with inadequate intervention uptake.

This matched pair cluster-randomized controlled trial included the intervention group with improved hygiene promotion and the control group did not receive any intervention. Though data are not collected for analyses, the refugees who newly settled in houses in the intervention clusters were treated similarly. The hygiene promoters who delivered the interventions were not involved in data collection. The enumerators or data collectors remained blinded to the intervention assignments, but they could have inferred the trial status if they saw the intervention materials.

**E – Evaluation or interventions' outcome ascertainment:** Evaluate the intervention mean gathering evidence of outcomes and measuring impact (Aunger & Valerie 2016). Data were collected on the primary outcome (incidence of childhood diarrhea) every 2 weeks, and the targeted key hygiene behaviors at baseline, end of 6th and 12th week of intervention through interview and direct observation. It is not possible to determine the extent to which participants implement the intervention. For this hygiene promotion trial to be effective the beneficiaries need to have access to a functioning intervention, knowledge of how to use it and their practice be monitored. Therefore, indirect assessments of compliance were made by checking for functionality, knowledge transfer, behavioral change and product consumption using a checklist. Baseline data on the diarrheic status, sociodemographic characteristics and other factors were collected through the interview using a structured questionnaire. Data on the targeted key hygiene behaviors were collected through interviews and direct observation. Enumerators visited each HH every 2 weeks for three consecutive months to assess the occurrence of acute diarrhea in under-five children by interviewing their caregivers. Enumerators also conducted interviews with child caregivers about the changes in hygiene behavior and directly observed HH hygiene and WASH facilities.

This matched pair cluster-randomized trial included the intervention group with improved hygiene promotion, and the control group did not receive any intervention (Valdmanis & Cairncross 2006). Study participants with the hygiene promotion trail were informed of their assignment after the baseline data collection. Field workers visited participating intervention households weekly from 15 July 2017 to 30 October 2017 to promote good hygiene practices. A monthly visit manual was developed to provide behavioral recommendations for mothers and other caregivers using basic thematic concepts of hygiene improvement. The hygiene promotion intervention components were safe fecal disposal, proper hand-washing with soap at five critical times and safe drinking water management at the point of use. The hygiene promoters who delivered the interventions were not involved in data collection. The enumerators or data collectors remained blinded to the intervention assignments, but they could have inferred trial status if they saw the intervention materials.

## Data collection

A baseline survey was conducted at the time of enrollment to collect the basic information, including HH composition, sociodemographic characteristics, hygiene behavior and the incidence of diarrhea. The primary outcome of interest was the incidence of diarrhea among those in under-five children, measured through interviews carried out by study enumerators. Enumerators visited each HH every 2 weeks for three consecutive months to assess the occurrence of acute diarrhea in under-five children by interviewing their caregivers. Acute diarrhea is defined as the passage of loose or watery stools at

least three times in 24 h for less than 14 days (WHO 2012). Blood in the stool could also indicate acute diarrheal illnesses or dysentery, irrespective of frequency (King *et al.* 2003; Thielman & Guerrant 2004). Enumerators also conducted interviews using a structured questionnaire with child caregivers about the changes in hygiene behavior and directly observed HH hygiene and WASH facilities. We gathered data for the intermediate outcomes, including improved drinking water point-use management, safe fecal disposal and proper hand-washing at critical times at baseline, midterm and completion of the intervention.

### Operational definitions

Clean water container: when drinking water containers have no visible algae, silt or detergent residual in a real-time view.

Comprehensive hand-washing setup: a hand-washing setup including at least a water container (tippy tap), water and soap.

Hand-washing at critical times: hand-washing with soap and water before eating or feeding a child, before handling food, after using the toilet and after cleaning a child's bottom after it has defecated.

Health education: The active process that inform, motivates and guides people to adopt and maintain healthy practices and live styles, advocates environmental changes, professional training and research about these goals.

Improved latrine: Use of improved facilities which are not shared with other households and where excreta are safely disposed *in situ* or transported and treated off-site.

Improved drinking water: Improved drinking water sources are those which, by nature of their design and construction, have the potential to deliver safe water, which is accessible, available when needed and free from contamination.

Incidence rate of diarrhea: The number of new diarrhea cases reported during each of the biweekly visits to children of the studied households.

JMP guideline: Guidance note to facilitate countries' consultation on estimates for drinking water, sanitation and hygiene (UNHCR 2015).

Kebele: The smallest administrative unit in Ethiopia with an average population of 5,000.

Open defecation: This refers to households that report using *no facilities* as the usual defecation practice. Human feces are disposed of in fields, forests, bushes, open bodies of water, beaches and other open spaces or with solid waste.

Period prevalence rate: The number of diarrhea cases at the time of the interview divided by the total number of under-five children included in the study.

Proper hand-washing: washing hands and wrists with water and plain soap using a rubbing motion on all surfaces of both hands including under the nails for at least 30 s, following the 11 WHO recommended steps (UNHCR 2017b).

Refugees: People who leave their country of origin out of a fear of persecution and unable or unwilling to return there owing to serious and indiscriminate threats to life, physical integrity or freedom resulting from generalized violence or events seriously disturbing public order (UNHCR 2005).

Safe fecal disposal: This includes households that dispose of child feces in a latrine and follow JMP guidelines to make feces-free compound.

Unimproved latrine: Use of pit latrines without a slab or platform, hanging latrines or bucket latrines.

### Sample size

The sample size was estimated using the formula developed for cluster-randomized community trials published by Hayes & Bennett (1999). The number of study subjects was determined by considering the 38% acute diarrhea prevalence detected in the study area (Mekonnen *et al.* 2016) and a 42% reduction in diarrhea rates in target children compared to the control groups (Curtis & Cairncross 2003), with 95% precision ($\alpha = 0.05$), 80% power, allowing for a 10% dropout and loss in statistical efficacy because of repeated measures. We found 17 clusters per intervention or control arm with a sample size of 25 households per cluster or 850 total households in 34 clusters.

$Y = (Z\alpha + Z\beta)^2(\lambda 0 + \lambda 1)/(\lambda 0 - \lambda 1)^2$ is the required number of samples for each group for an individually randomized trial.

$N = Y*\text{design effect} = (Z\alpha + Z\beta)^2(\lambda 0 + \lambda 1)/(\lambda 0 - \lambda 1)^2*[1 + (m-1)\rho] = 366$ per arm in the randomized-cluster trial. The final sample became 425 after we considered a 10% loss to follow up.

where

- $\lambda 0 = 38\%$ prevalence of diarrhea or 0.38 person – week incidence;
- $\lambda 1 = 0.58 \times \lambda 0 = 0.22$ (the intervention intended to reduce diarrhea morbidity by 42%);

- $\rho = 0.03$, the intra-cluster correlation coefficient is the average rho values for 2-week prevalence of diarrhea estimated from the 1984–1993 demographic and health surveys (UN 2005);
- $Z\alpha = 1.96$, $Z\beta = 0.84$;
- $m = 25$, the optimum cluster size was determined to be 25, which considered data collection cost, structure and degree of homogeneity within the primary sampling units or households.

### Statistical methods

Data were entered, cleaned and analyzed using STATA version 14 Statistical Software. The baseline data were analyzed, and the incidence rate of diarrhea (per 100 person-weeks) in children under 5 years of age was determined for the intervention and control communities. Descriptive statistics was used to describe the sample, examine distributions, period prevalence and incidence of diarrhea and compare changes in cluster-level indicators in the study communities using Pearson's chi-square analysis at baseline, midterm and the end of the study. Intention to treat was applied in analyses of the results of this trial. Logistic and generalized estimating equation (GEE) models were used to evaluate the RRs or prevalence ratio (risk ratio). Confidence intervals (95% CIs) were constructed using robust standard errors to account for clustering at the community (cluster) level. Intra-class correlation coefficients were calculated to assess within-HH repeatability. All associations were evaluated for significance at $p < 0.05$.

### Quality measures

The reliability of the intervention was assessed at baseline and follow-up. Outcome parameters and impact indicators or evaluation criteria were developed prior to the start of the study using hygiene promotion guidelines (Cairncross & Valdmanis 2006) and by reviewing the literature (WHO 2006, 2007). The reliability of the randomized-cluster hygiene promotion intervention was assessed at baseline, midterm and follow-up. Longitudinal surveillance of intervention impacts and outcomes began a week following the completed initiation of the intervention in order to avoid potential temporal variations and give sufficient time for clinical signs of a new infection. Supervisors checked the functionality and proper implementation of the intervention and data collection. Households which had no under-five child or newly settled refugees in the intervention clusters were treated similarly, although no data were collected for analysis.

HH visits were carried out morning 8:00Am to 10:00Am, when wastes of poor hygiene behaviors are likely to be seen. Data collectors recorded only the behavior of mothers or caregivers with a child aged 0–59 months in the respective households to avoid interviewer bias and influences on behaviors. The same data collectors were used during baseline and follow-up data collections to avoid inter-observer variation. Hygiene motivators and data collectors were not the same individuals. Behavior observers were not informed about the purposes and activities of the program, but they may spot some residual campaign materials in intervention villages. The study employed separate workforces for data collection and hygiene promotion so as to reduce bias. Recall bias was minimized by limiting the recall period, and socially desirable responses were minimized by inspecting hygiene practices.

## RESULTS

### Baseline characteristics of households and adherence

A total of 843 households (1,410 under-five children) within the 34 clusters were included in the study. Twelve children of seven HHs who began the intervention phase were lost or excluded from the final analysis since they missed two or more visits during the follow-up periods. The response rate was 99.2%, but there was no HH that refused to participate in the study giving rise to 100% compliance. A total of 8,352 and 8,568 person – weeks follow-up were measured for the intervention and control arms, respectively. The mean age of each child was 28.4 (range, 0.5–9) months, and 710 (50.4%) of them were females. Eight hundred twenty-eight (98.6%) of the interviews were with female caregivers with a mean age of 28.3 (range = 15–6) years. Four hundred-five (45%) of the caregivers were not attended formal education (Table 1).

We measured changes in caregivers' behavior at the midterm and end point of the intervention and found substantial differences between intervention and control groups (Table 2). The baseline assessment showed that tap water was the usual source of drinking water for the entire refugee households, and 230 (27.3%) of the households had no improved latrines. Less than half, 343 (40.5%) of the HH water containers were clean and only 181 (21.5%) of them were kept covered. The study also showed that 468 (55.5%) of the latrines were not clean and feces were seen in 250 (30%) of the HH compounds. Three-

**Table 1** | Characteristics of intervention and control households in Pugnido and Teirkidi refugee camps in Gambella Region, 2017

| Characteristic | | Intervention arm (%) | Control arm (%) | Total (%) |
|---|---|---|---|---|
| Child sex | Female | 352 (50.6) | 348 (48.7) | 700 (49.7) |
| | Male | 344 (49.4) | 366 (51.3) | 432 (50.3) |
| Child age group (month) | 0–11 | 78 (11.2) | 91 (12.8) | 169 (12.0) |
| | 12–35 | 307 (44.1) | 331 (46.4) | 638 (45.2) |
| | ≥36 | 311 (44.7) | 292 (40.9) | 603 (42.8) |
| Family size | <5 | 158 (37.5) | 141 (33.6) | 299 (35.6) |
| | ≥5 | 263 (62.5) | 279 (66.4) | 542 (64.4) |
| Number of under-five children in HH | One | 187 (44.3) | 170 (40.4) | 357 (42.3) |
| | Two | 195 (46.2) | 207 (49.2) | 402 (47.7) |
| | Three or four | 40 (9.5) | 44 (11.4) | 84 (10.0) |
| Caregiver's sex | Female | 425 (98.3) | 416 (98.8) | 831 (98.6) |
| | Male | 7 (1.7) | 5 (1.2) | 12 (1.4) |
| Caregiver's age group (year) | <20 | 16 (3.8) | 24 (5.7) | 40 (4.7) |
| | 20–35 | 234 (55.4) | 239 (56.8) | 473 (56.1) |
| | >35 | 172 (40.7) | 158 (37.5) | 330 (39.1) |
| Marital status | Married | 386 (91.5) | 397 (94.2) | 783 (92.9) |
| | Single | 3 (0.7) | 2 (0.6) | 5 (0.6) |
| | Divorced | 12 (2.8) | 6 (1.4) | 18 (2.1) |
| | Widowed | 21 (5.0) | 18 (4.3) | 39 (4.6) |
| Ethnicity | Nuer | 311 (73.7) | 309 (73.4) | 620 (73.5) |
| | Agnuak | 111 (26.3) | 112 (26.6) | 243 (26.5) |
| Educational level | No formal education | 204 (48.3) | 201 (47.8) | 405 (48.0) |
| | Formal education | 218 (51.7) | 220 (52.2) | 438 (52.0) |
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quarters (651, 77.2%) of the caregivers did not safely dispose of their children's feces. At baseline, we observed that 136 (16.1%) of the households had a hand-washing station. However, 31 (22.8%) and 22 (16.2%) of them had no water and soap for hand-washing on the day of data collection, respectively. The great majority of caregivers practiced hand-washing

**Table 2** | Hygiene behaviors of the intervention and control arms at the baseline, midterm and end point in refugee camps in Gambella Region, Ethiopia in 2017

| Behavioral outcome indicators | | Baseline ($n$ = HHs) | | | Midterm ($n$ = HHs) | | | Endpoint ($n$ = HHs) | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Intervene No (%) | Control No (%) | P Value | Intervene No (%) | Control No (%) | P Value | Intervene No (%) | Control No (%) | P value |
| Point-use of drinking water management | | | | | | | | | | |
| Source of drinking water | Tap water | 422 (100) | 421 (100) | NA | 422 (100) | 421 (100) | NA | 422 (100) | 421 (100) | NA |
| Type of water containers | Narrow mouth (≤3 cm diameter) | 262 (62.1) | 257 (61.0) | 0.39 | 313 (74.2) | 271 (64.4) | 0.02 | 357 (84.6) | 265 (63.0) | 0.000 |
| | Wide mouth (>3 cm diameter) | 31 (7.4) | 42 (10.0) | | 19 (4.5) | 39 (9.3) | | 4 (1.0) | 40 (9.5) | |
| | Both types | 129 (30.6) | 122 (29.0) | | 90 (21.3) | 111 (26.4) | | 61 (14.4) | 116 (27.5) | |
| Are all water containers covered? | Yes | 92 (21.8) | 89 (21.1) | 0.14 | 146 (34.6) | 97 (23.0) | 0.000 | 388 (91.9) | 114 (27.1) | 0.000 |
| | Some only | 232 (55.0) | 256 (60.8) | | 199 (47.2) | 251 (59.6) | | 24 (5.7) | 244 (58) | |
| | No | 98 (23.2) | 76 (18.1) | | 77 (18.2) | 73 (17.3) | | 10 (2.4) | 63 (14.9) | |
| Does the household use a separate container for drinking water? | Yes | 204 (48.3) | 209 (49.6) | 0.7 | 276 (65.4) | 234 (55.6) | 0.04 | 352 (83.4) | 249 (59.1) | 0.000 |
| | No | 218 (51.7) | 212 (50.4) | | 146 (34.6) | 187 (44.4) | | 70 (16.6) | 172 (40.9) | |
| Where is the drinking water container placed? | On floor inside home | 189 (44.8) | 180 (42.8) | 0.8 | 214 (50.7) | 205 (48.7) | 0.001 | 245 (58.1) | 208 (49.4) | 0.000 |
| | Elevated place inside | 42 (10.0) | 46 (10.9) | | 88 (20.9) | 49 (11.6) | | 139 (32.9) | 48 (11.4) | |
| | Somewhere outside | 191 (45.2) | 195 (46.3) | | 120 (28.4) | 167 (39.7) | | 38 (9.0) | 139 (39.2) | |
| Method of water takeout | Pouring | 265 (62.8) | 268 (63.7) | 0.89 | 336 (79.6) | 299 (71.0) | | 384 (91.0) | 296 (70.3) | 0.000 |
| | Dipping | 42 (10.0) | 44 (10.4) | | 14 (3.3) | 37 (8.8) | | 11 (2.6) | 35 (8.3) | |
| | Both methods | 115 (27.2) | 109 (25.9) | | 72 (17.1) | 85 (20.2) | | 27 (6.4) | 90 (21.4) | |
| Water containers cleaned last | Less than a week ago | 115 (27.3) | 108 (25.7) | 0.79 | 210 (49.8) | 141 (33.5) | 0.000 | 269 (63.7) | 148 (35.1) | 0.000 |
| | More than a week | 207 (49.0) | 216 (51.3) | | 165 (39.1) | 203 (48.2) | | 136 (32.3) | 189 (44.9) | |
| | Do not remember | 100 (23.7) | 97 (23.0) | | 47 (11.1) | 77 (18.3) | | 17 (4.0) | 84 (20.0) | |
| Cleanness of water containers | Yes | 189 (43.4) | 158 (37.5) | 0.084 | 262 (62.1) | 139 (33.0) | 0.000 | 352 (83.4) | 187 (44.4) | 0.000 |
| | No | 239 (56.6) | 263 (62.5) | | 160 (37.9) | 282 (67.0) | | 70 (16.7) | 234 (55.6) | |
| Point-use water treatment | Yes | 9 (2.1) | 4 (0.9) | 0.16 | 6 (1.4) | 5 (1.2) | 0.76 | 7 (1.7) | 7 (1.7) | 0.99 |
| | No | 413 (97.9) | 417 (99.1) | | 416 (98.6) | 416 (98.8) | | 415 (98.3) | 414 (98.3) | |
| Safe feces disposal | | | | | | | | | | |
| Category of sanitation | Open defecation | 86 (20.4) | 73 (18.0) | | 87 (20.6) | 79 (18.8) | | 87 (20.6) | 83 (19.7) | 0.77 |
| | Unimproved latrine | 32 (7.6) | 36 (8.6) | 0.64 | 27 (6.4) | 31 (7.4) | 0.71 | 25 (5.9) | 21 (5.0) | |
| | Improved latrine | 304 (72.0) | 313 (73.4) | | 308 (73.0) | 311 (73.9) | | 310 (73.5) | 317 (75.3) | |
| How did you dispose of child feces last time? | In the latrine | 95 (22.5) | 97 (23.0) | 0.37 | 157 (37.2) | 96 (22.8) | 0.000 | 304 (72.0) | 149 (35.4) | 0.000 |
| | Somewhere on the ground | 225 (53.3) | 239 (56.8) | | 210 (49.8) | 250 (59.4) | | 100 (23.7) | 230 (54.6) | |
| | Bush | 102 (24.2) | 85 (20.2) | | 55 (13.0) | 75 (17.8) | | 18 (4.2) | 42 (10.0) | |
| Clean latrine | Yes | 150 (35.6) | 157 (37.3) | 0.7 | 211 (50.0) | 159 (37.8) | 0.02 | 294 (69.7) | 192 (45.6) | 0.000 |
| | No | 240 (56.9) | 228 (54.2) | | 186 (44.1) | 231 (54.9) | | 107 (25.3) | 210 (49.9) | |
| | No latrine | 32 (7.6) | 36 (8.6) | | 25 (5.9) | 31 (7.4) | | 21 (5.0) | 19 (4.5) | |
| Presence of flies in the latrine | Yes | 232 (55.0) | 216 (51.3) | 0.56 | 116 (27.5) | 192 (45.7) | 0.000 | 103 (24.4) | 197 (46.9) | 0.000 |
| | No | 158 (37.4) | 169 (40.1) | | 281 (66.6) | 197 (46.9) | | 299 (70.9) | 204 (48.6) | |
| | No latrine | 32 (7.6) | 36 (8.6) | | 25 (5.9) | 31 (7.4) | | 20 (4.7) | 19 (4.5) | 0.000 |
| Feces on the compound | Yes | 126 (29.9) | 124 (29.4) | 0.898 | 72 (17.1) | 137 (32.5) | 0.000 | 54(12.8) | 128 (30.4) | |
| | No | 296 (70.1) | 297 (70.6) | | 350 (82.9) | 284 (67.5) | | 368 (87.2) | 293 (69.6) | |
| Hand-washing practice | | | | | | | | | | |
| Availability of hand-washing device | Yes | 67 (15.9) | 69 (16.4) | 0.84 | 402 (95.5) | 73 (17.3) | 0.000 | 407 (96.7) | 117 (27.8) | |
| | No | 355 (84.1) | 362 (83.6) | | 19 (4.5) | 348 (82.7) | | 14 (3.3) | 304 (72.2) | |

(*Continued.*)

**Table 2** | Continued

| Behavioral outcome indicators | | Baseline ($n$ = HHs) | | | Midterm ($n$ = HHs) | | | Endpoint ($n$ = HHs) | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Intervene No (%) | Control No (%) | P Value | Intervene No (%) | Control No (%) | P Value | Intervene No (%) | Control No (%) | P value |
| Availability of water ($n$ = 421) | Yes | 14 (3.3) | 17 (4.0) | 0.58 | 328 (77.9) | 27 (6.4) | 0.000 | 366 (86.9) | 48 (11.4) | 0.000 |
| | No | 408 (96.7) | 404 (96.0) | | 93 (22.1) | 394 (93.6) | | 55 (13.1) | 387 (88.6) | |
| Availability of soap ($n$ = 421) | Yes | 10 (2.4) | 12 (2.8) | 0.66 | 234 (55.6) | 17 (4.0) | 0.000 | 325 (77.2) | 31 (7.4) | 0.000 |
| | No | 412 (97.6) | 409 (97.2) | | 187 (44.4) | 404 (96.0) | | 96 (22.8) | 390 (92.6) | |
| Hand-washing before eating | Yes | 358 (84.8) | 356 (84.6) | 0.91 | 376 (89.1) | 359 (85.3) | 0.097 | 387 (91.7) | 369 (87.7) | 0.053 |
| | No | 64 (15.2) | 65 (15.4) | | 46 (10.9) | 62 (14.7) | | 35 (8.3) | 52 (12.3) | |
| Hand-washing by caregiver after toilet use | Yes | 230 (54.5) | 239 (56.8) | 0.51 | 311 (73.7) | 259 (61.5) | 0.000 | 325 (77.0) | 267 (63.4) | 0.000 |
| | No | 192 (45.5) | 182 (43.2) | | 111 (26.3) | 162 (38.5) | | 97 (23.0) | 154 (36.6) | |
| Hand-washing after helping child defecate | Yes | 233 (55.2) | 230 (54.6) | 0.87 | 299 (70.9) | 238 (56.5) | 0.000 | 352 (83.4) | 279 (66.3) | 0.000 |
| | No | 189 (44.8) | 191 (45.4) | | 123 (29.1) | 183 (43.5) | | 70 (16.6) | 142 (33.7) | |
| Hand-washing before feeding child | Yes | 202 (47.9) | 204 (48.7) | 0.86 | 297 (70.4) | 239 (56.8) | 0.000 | 316 (74.9) | 243 (57.7) | 0.000 |
| | No | 220 (52.1) | 217 (51.5) | | 125 (29.6) | 182 (43.2) | | 106 (25.1) | 178 (42.3) | |
| Hand-washing before preparing food | Yes | 242 (57.3) | 246 (58.4) | 0.75 | 261 (85.6) | 253 (60.1) | 0.000 | 372 (88.2) | 264 (62.7) | 0.000 |
| | No | 180 (42.7) | 175 (41.6) | | 61 (14.4) | 168 (39.9) | | 50 (11.8) | 157 (37.3) | |
| Proper hand-washing demonstration | Correct | 109 (25.8) | 106 (25.2) | 0.83 | 322 (76.3) | 121 (28.7) | 0.000 | 389 (92.2) | 125 (29.7) | 0.00 |
| | Incorrect | 313 (74.2) | 315 (74.8) | | 100 (23.7) | 300 (71.3) | | 33 (7.8) | 296 (70.3) | |

We found that measuring the prevalence ratio and its difference among the intervention and control group at points in time is important for readers to easily visualize when the statistically significant change is seen in diarrhea prevalence

with soap and water before eating (714, 84.7%), followed by hand-washing before preparing food (488, 57.9%), after toilet use (469, 55.6%), after cleaning a child's bottom (463, 54.9%) and before feeding children (406, 48.2%).

At follow-up, most of the intervention beneficiary households were more likely to meet each of the targets and improved hygiene behaviors compared to the matched control households. At the end of the study, all water containers were covered in 388 (91.9%) of the intervention households and in 114 (27.1%) of the control households. A similarly large proportion (352, 83.4%) of the water containers were kept clean in the intervention households compared with the 187 (44.4%) households in the control groups. According to the data collectors' observations, feces were seen on the compounds of 54 (12.8%) intervention households, and 107 (25.4%) of their latrines were not clean. In the control households, feces were observed in 128 (30.4%) of the compounds and 210 (49.9%) of their latrines were not clean. Hand-washing stations were observed in 407 (96.7%) of the intervention households and 78 (18.5%) of the control households. Water for hand-washing was available in 366 (86.9%) of the intervention households and 34 (8.1%) of the control HH. We observed soap in 325 (77.2%) of the intervention households on the final day of follow-up data collection compared with 31 (7.4%) in control households.

### Longitudinal prevalence and incidences of diarrhea

The 2-week prevalence of diarrhea was 41.1% (95% CI: 37.5 44.7) in the intervention and 39.7% (95% CI: 36.2–43.3) in the control group during the baseline study. There was no significant difference in diarrhea prevalence ($P = 0.62$) between the intervention and the control arms at baseline. At the end of the study, the mean difference in the pooled period of the diarrheal disease in under-five children between the intervention and control groups was 25% (crude PR: 0.84, 95% CI: 0.69 0.81) (Figure 2).

In the intervention households, 1,307 episodes of diarrhea (15.6 episodes per 100 person-weeks observation) were reported and 1,619 episodes (18.9 episodes per 100 person-weeks observation) in the control (Figure 3).

The study indicates that there was a significant difference ($P < 0.001$; Adjusted IRR: 0.85, 95% CI: 0.79 0.92) in the incidence rate of diarrhea between the intervention group and the controls after adjusting for child age, child sex, the number of under-five children, caregiver age and sex, type of water source, point-use water treatment and category of sanitation (Table 3). The intra-cluster correlation for diarrhea was 0.054.

## DISCUSSION

This study is providing evidence of the impact of hygiene promotion intervention in reducing the incidence of acute childhood diarrhea in the two refugee communities. The previous study from these refugee camps indicated that there were

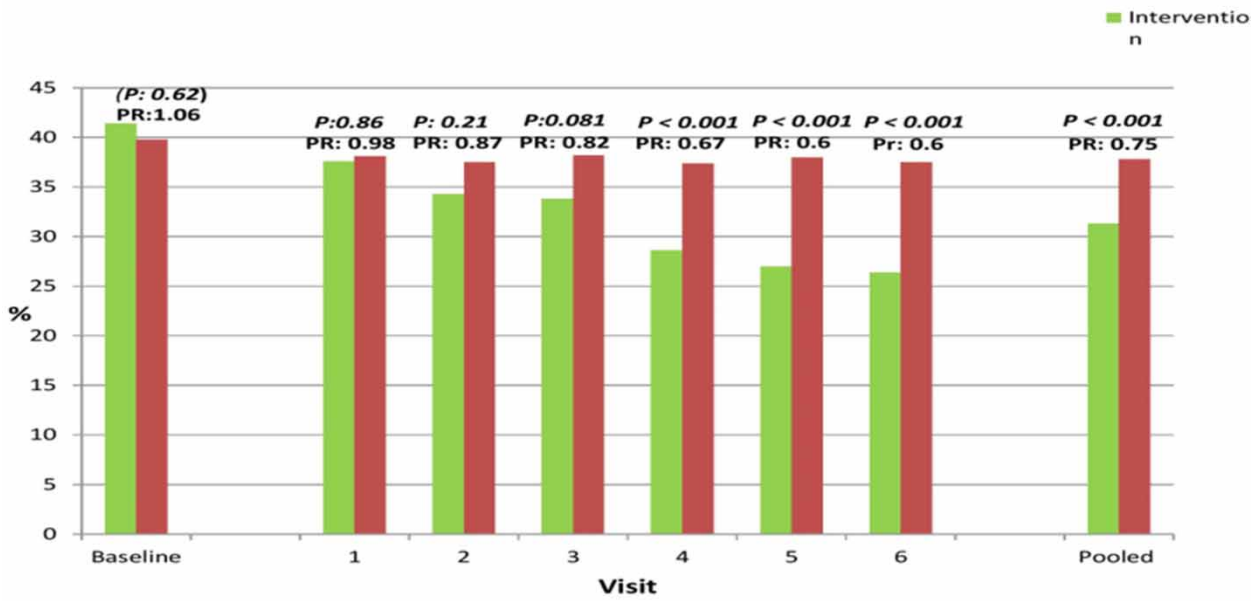


**Figure 2** | Prevalence ratios between the intervention and control groups at each visit in Pugnido and Teirkidi refugee camps, Gambella Region. P, *P* value. PR, prevalence ratio.

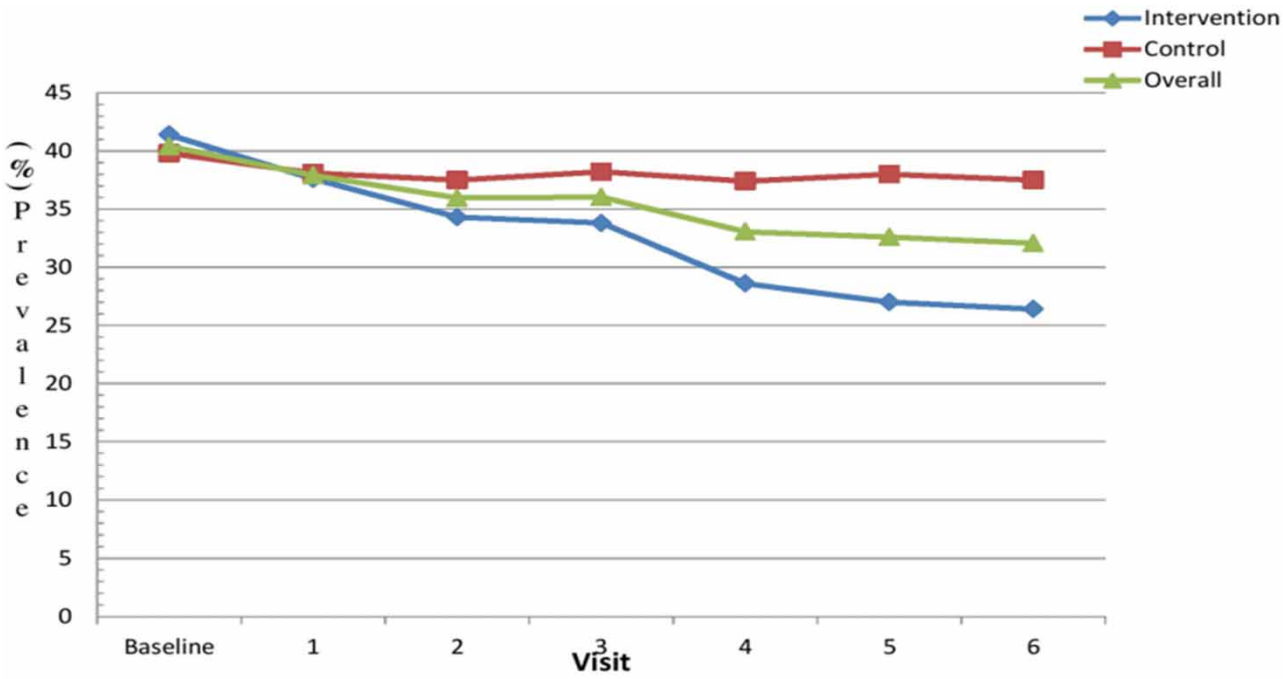


**Figure 3** | Trends of incidences of childhood diarrhea by visit and study group in Pugnido and Teirkidi refugee camps, Gambella Region.

also significant hygiene deficits, which appear to have resulted from low hygiene education and limited familial emphasis on hygiene practices (Mekonnen *et al.* 2016). Children living in households that received information on hygiene promotion had a 15% (95% CI: 8 21) lower incidence of diarrhea than children living in control households. Reduction in the incidence of acute childhood diarrhea in the intervention relative to the control arm was statistically significant (adjusted IRR: 0.85, 95% CI: 0.79 0.92). This corroborates studies done in point-use water management (Gruber *et al.* 2013) and community-based hygiene education (Haggerty *et al.* 1994).

**Table 3** | Impact of the hygiene promotion intervention on diarrhea incidence in under-five children in Pugnido and Teirkidi refugee camps in Gambella Region, Ethiopia in 2017

| Factor | Crude IRR (95% CI) | Adjusted IRR (95% CI) | *P* value |
|---|---|---|---|
| Study group | | | |
| Intervention | 0.83 (0.79 0.89) | 0.85 (0.79 0.92) | 0.000* |
| Control | 1 | 1 | |
| Child sex | | | |
| Female | 0.96 (0.9 1.02) | 0.95 (0.88 1.02) | 0.17 |
| Male | 1 | 1 | |
| Child age | 1.001 (0.99 1.003) | 1.00 (0.99 1.004) | 0.27 |
| Sex of caregiver | | | |
| Female | 1 | 1 | |
| Male | 0.84 (0.62 1.14) | 0.85 (0.63 1.14) | 0.63 |
| Age of caregiver | 1.01 (1.002 1.013) | 1.01 (1.002 1.013) | 0.011* |
| Household water treatment baseline | | | |
| Yes | 1 | 1 | |
| No | 0.91 (0.687 1.22) | 0.89 (0.64 1.23) | 0.48 |
| Category of sanitation baseline | | | |
| Open defecation | 1.02 (0.89 1.17) | 1.02244 (0.89 1.17) | 0.75 |
| Unimproved latrine | 1.09 (0.94 1.28) | 1.11 (0.95 1.29) | 0.19 |
| Improved latrine | 1 | 1 | |

* Statistically significant at P value $\alpha < 0.05$; CI: confidence interval; RR: incidence rate ratio

A study revealed that the integration of improved hygiene could contribute to sustainable control strategies for enteric infections (Pickering *et al.* 2018). Our study finding was lower than in most studies (Darvesh *et al.* 2017; Hashi *et al.* 2017; Lin *et al.* 2018). It could be due to the fact that a continuation of refugee settlement in the study area may dilute the intervention effort and requires the expansion of hygiene promotion program in diarrhea reduction (Darvesh *et al.* 2017; UNHCR 2017c). Moreover, it is a standalone intervention, not integrated with water and sanitation improvement programs that could not provide the highest significant effect on diarrhea reduction (Jamison *et al.* 2006). The study showed that the reduction of the period prevalence rate of diarrhea in the intervention arm became statistically significant ($P < 0.05$) by end of the 8th week and onwards, implying that prolonged interventions may be required to achieve behavioral changes (Fewtrell *et al.* 2005).

Diarrhea incidence was reduced over time in both intervention and control groups as diarrheic children perhaps received antibiotic treatment at the local clinic during the 3-month survey period. Because we were advising the caregivers of diarrheic children both in the intervention and control households to take them to the clinic to get medical care. So, it is possible that some initially infected children who were reported to become diarrhea-negative by the subsequent visits may have been cured by antibiotics and reduced community exposure to infectious diarrhea (Rogawski *et al.* 2015). After 12 weeks of intervention, we assessed the intermediate changes in hygiene practices, and improvements were seen in water container hygiene, sanitation practices and hand hygiene outcomes. The highest level of attainment was observed among the intervention groups in setting a hand-washing station (96.7%), correct hand-washing demonstration (92.2%), hand-washing before eating (91.7%), keeping all water containers covered (91.9%) and take out of container's water by pouring (91.0%). These findings are in agreement with other studies (Davis *et al.* 2011; Rajasingham *et al.* 2018), indicating that hygiene education intervention increases hand hygiene compliance (UNHCR 2017c).

Three months after the end of the program, the improvement was not uniform across hygiene behaviors. Limited improvements were seen at the HH level in placing drinking water containers at elevated points inside the home (32.9%), cleaning water containers within 1 week (63.7%) and cleaning latrines (69.7%). These unanticipated practice outcomes possibly are due to limitations in infrastructure or resources. Moreover, the potential dilution of intervention effects when targeting

multiple hygiene risk factors (Fewtrell *et al.* 2005). Within the intervention group, utilization of clean water containers increased from 43.4 to 83.4% (95% CI: 79.5 86.7), safe child feces disposal from 22.5 to 72% (95% CI: 67.6 76.1) and hand-washing after toilet use from 54.5 to 77.0% (72.7 80.8). The number of households with detected feces in their compound decreased in the intervention groups from 29.9 to 12.8% (95% CI: 9.9 16.3). These findings are in agreement with those of other studies (Ejemot-Nwadiaro *et al.* 2015, 2021; Cronin *et al.* 2016) and demonstrate improvements in hygiene behaviors are promising for reducing diarrhea, given the resource challenges for such practices.

### Strengths and limitations

To our knowledge, this is the first cluster-randomized trial study to assess the impact of hygiene promotion intervention to detect the differences in incidence of acute childhood diarrhea in refugee camps in Ethiopia. The study employed separate workforces for data collection and hygiene promotion so as to reduce bias. Recall bias was minimized by limiting the recall period to 14 days, and socially desirable responses were minimized by inspecting hygiene practices. Despite limitations in infrastructure or resources, the study indicates that improved hygiene is still possible. The brief period of intervention would be a major limitation of this study. Some degree of inaccuracy in self-reported hygiene behaviors was unavoidable due to recall or social desirability bias.

## CONCLUSION AND RECOMMENDATIONS

The study confirms that hygiene promotion intervention can significantly reduce the incidence rate of childhood diarrhea in refugee camps. The observed increase in preventive behavior of refugees and reduction in diarrhea is all the more noteworthy because of the short intervention period of merely 3 months. Hence, gains in the reduction of childhood diarrhea may be achieved in refugee camps through enhanced hygiene promotion programs. This intervention study achieved improvements in several hygiene domains, and results may guide future research for hygiene promotion intervention in Ethiopian refugee camps. We recommend that future studies consider contextual hygiene and time factors and resources required to assess behavior change during the planning and conducting of similar intervention research. A collective effort from governments and nongovernment organizations, the private sector, academia and civil society is urgently needed to implement and evaluate a sustainable applied hygiene promotion program in vulnerable refugee communities. It is important that researchers collaborate with refugee authorities and national health officials to ensure that diarrhea interventions are designed to meet the needs of refugees and facilitate the formulation and implementation of strategies and programs.

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## AVAILABILITY OF DATA AND MATERIALS

The relevant data supporting this publication are summarized in tables in the manuscript. However, the raw data can be accessed from the principal author (GK) whenever required using appropriate procedures and format.

## AUTHORS' CONTRIBUTIONS

The principal investigator, GK, collected and analyzed the data. BM, GS, WM and HK were directing and supervising the research process. All authors contributed to designing the proposal, drafting the manuscript and approving the final version to be submitted for publication. The supporting data for this study are available from the corresponding author upon request.

## ETHICS

The study was reviewed and approved by the Ethiopian Institute of Water Resources, Addis Ababa University. It was ethically approved by the Ethiopian National Research Ethics Review Committee with reference No 310/213/2017. Letters were written by Addis Ababa University to the Ethiopian Administration for Refugees and Returnees Affairs (ARRA), UNHCR, the Ethiopian Public Health Institute and Gambella Regional Health Bureau to obtain support for this research. Official permission was obtained from ARRA to carry out the research in the refugee camps. Informed written consent was obtained from the caregivers of each participating child prior to the research. The purpose and nature of the study were explained to each caregiver in their language using the information sheet that is prepared with nontechnical and understandable terms. The data collectors clear any interviewees' quires, let them sign and dated the informed consent forms. Interviewees were ensured that their participation was voluntary and the information they provided was kept confidential.

## DATA AVAILABILITY STATEMENT

All relevant data are available from an online repository or repositories at https://github.com/GK2006/Getachew#getachew.

## CONFLICT OF INTEREST

The authors declare there is no conflict.

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