PLOS WATER

RESEARCH ARTICLE

# A proof-of-concept randomised controlled trial of an intervention designed to improve food hygiene behaviours among caregivers of young children living in low-income areas of Nairobi, Kenya

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**Citation:** Watson J, Okumu NO, Wasonga JO, Majiwa H, Kiarie A, Masudi SP, et al. (2024) A proof-of-concept randomised controlled trial of an intervention designed to improve food hygiene behaviours among caregivers of young children living in low-income areas of Nairobi, Kenya. PLOS Water 3(7): e0000223. https://doi.org/10.1371/journal.pwat.0000223

**Editor:** Mohan Amarasiri, Tohoku University Graduate School of Engineering School of Engineering: Tohoku Daigaku Daigakuin Kogaku Kenkyuka Kogakubu, JAPAN

**Received:** December 11, 2023

**Accepted:** May 28, 2024

**Published:** July 2, 2024



**Data Availability Statement:** The full data set is openly available under a Creative Commons Attribution (CC-BY) licence via the LSHTM Data Compass repository: https://doi.org/10.17037/DATA.00003671.

**Funding:** This study was financially supported by the Bill & Melinda Gates Foundation and the

## Abstract

Young children are particularly vulnerable to foodborne disease due to their immature immune systems. Safe food hygiene behaviours by caregivers can potentially reduce this disease burden. Here, we evaluate the potential for a locally designed intervention to improve caregivers' food hygiene behaviour in a peri-urban, low-income area of Nairobi, Kenya. In this cluster-randomised proof-of-concept trial, 50 community health volunteers (CHVs) were randomly assigned to intervention or control arm (1:1). 101 households under the CHV's catchment (2-3/CHV), with at least one child aged 6–24 months, participated. Caregivers in intervention households (n = 50) received the CHV-delivered food hygiene intervention. The control arm (n-51) received no intervention. Blinding was not possible due to the nature of the intervention. Our primary outcome was the proportion of caregivers observed to practice all five pre-specified food hygiene behaviours, four weeks post intervention delivery. Secondary outcomes assessed the five observed behaviours individually plus a sixth behaviour—the proportion of caregivers who report always boiling the child's drinking water. We found no between-arm difference in the proportion of caregivers practising all five observed behaviours. However individually, five behaviours were significantly improved. Specifically, caregivers in the intervention arm had higher odds of washing their hands before feeding the child (adjusted odds ratio (aOR) = 7.40, 95%CI 1.85, 29.62) and before preparing the child's food (aOR = 7.05, 95%CI 1.52, 32.71), washing the child's hands before eating (aOR = 21.57, 95%CI 1.15, 405.93) and heating the child's food (aOR = 4.03, 95%CI 1.27, 12.85) and drinking water (aOR = 12.82, 95%CI 2.54, 64.77) to boiling. There was no effect on cleaning and storage of feeding utensils. This study offers promising preliminary evidence that a CHV-led intervention targeting caregivers of young children can improve their food hygiene behaviour. Our findings warrant further research to refine the

Foreign, Commonwealth and Development Office (FCDO) of the UK Government via a grant awarded to OC (grant number INV-008449). No additional external funding was received for this study. The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Competing interests:** The authors have declared that no competing interests exist.

intervention and undertake larger scale trials to explore the intervention's potential impact more comprehensively.

**Trial registration:** This trial was registered with Open Science Framework: osf.io/eu5kf.

## Introduction

Foodborne disease resulting from the consumption of food or beverages contaminated with harmful bacteria, viruses, parasites, toxins, or chemicals is a major public health concern [1]. The World Health Organisation (WHO) estimates that more than 600 million episodes of illness, 420,000 deaths, and 33 million disability-adjusted life years (DALYs) can be attributed to the consumption of contaminated food, excluding any foodborne disease related to contaminated beverages [2]. The burden of foodborne disease is highest in low- and middle-income countries, where levels of food contamination are frequently found to be high, and particularly in subregions of Africa [2–6].

Children under five are disproportionately affected by foodborne disease, with an estimated 40% of the burden borne by this age group [2]. These young children are particularly susceptible to foodborne disease as their immune systems are still developing. They are therefore less able than their older counterparts to fight off infection by foodborne pathogens [7]. Diarrhoea, a common symptom of foodborne disease, is one of the leading causes of morbidity and mortality among children under-five and a contributor to problems of undernutrition [2, 8, 9].

Children transition from exclusive breastfeeding to the consumption of complementary food—referred to as the "complementary feeding period"—generally between 6–24 months of age. In this period, children face a particularly high risk of foodborne disease, as they simultaneously experience elevated exposure to potentially contaminated food and their immune protection from breastmilk wanes [7]. Globally, 72% of all diarrhoeal deaths occur in children under two, with over 50% occurring in children between 6–11 months of age, when complementary food is typically first introduced [10].

Inadequate food hygiene practices in the household increase the risk of food contamination and hence foodborne disease. Past studies have identified factors such as improper handwashing, cross contamination of raw and cooked foods, inadequate food storage conditions, insufficient cooking or reheating of foods, and unclean cooking and feeding utensils to be linked to microbial contamination of complementary foods [4, 11–15].

For children in the complementary feeding period, food safety is influenced by the behaviours of their caregivers, who are responsible for preparation, handling, feeding and storage of the child's food [16, 17]. Mothers typically act as the primary caregiver taking on most of these roles, however, caregiving can be highly dynamic, involving multiple individuals in the day, such as other family members or domestic help [17]. There is a growing recognition of the need for food hygiene interventions targeting caregivers to prevent foodborne disease in young children and the WHO and others have called for rigorous studies and interventions to prevent complementary food contamination [18–20].

Although there has been an increasing number of publications reporting trials of food hygiene interventions targeting caregivers, the evidence is still limited [21–25]. This limited evidence does support the use of caregiver-focused food hygiene interventions to improve food hygiene behaviours. Studies in Nepal, The Gambia, Malawi, and Bangladesh evaluating food hygiene interventions targeting caregivers all report significant improvements in their food hygiene behaviour and another study in Bangladesh found that training caregivers in

critical food hygiene practices led to reductions in levels of weaning food contamination [21–25]. All of these studies however have focused only on caregivers in rural settings yet in low-income urban and peri-urban settings the risk of foodborne disease in children is also high due to poor access to safe water, sanitation, and hygiene (WASH) services, overcrowded living conditions, and to exposure to a highly contaminated environment, including living in close proximity to animals[4, 5]. There is therefore a clear gap in the evidence base on what works to improve caregiver's food-hygiene related behaviour in low-income urban and peri-urban settings.

The aim of this proof-of-concept trial was to evaluate a locally developed, household-level food hygiene intervention for the primary caregivers of children between the ages of 6 and 24 months living in a low-income peri-urban area of Nairobi, Kenya. Prior formative research conducted in the study area revealed six foodborne disease-related risk behaviours commonly practiced by caregivers (unpublished). Our intervention, co-designed by representatives from the community and the local health department, aims to specifically target these risk behaviours and our trial assesses the intervention's impact on these behaviours. Here we report all behavioural outcomes. Laboratory outcomes will be reported separately following analysis of food samples via quantitative polymerase chain reaction with custom TaqMan Array cards.

## Methods

This study is reported according to the CONSORT reporting guidelines [26].

### Study design and participants/eligibility

This study was a cluster-randomised controlled proof-of-concept trial with an intervention arm receiving a food hygiene intervention delivered by community health volunteers (CHVs) and a control arm receiving no intervention. The household recruitment period was from 19$^{th}$ April 2023 to 14$^{th}$ May 2023. Baseline data collection began after the first household was recruited and the one-off intervention was delivered directly after baseline data collection in each household. Endline data collection began four weeks later, continuing until 14$^{th}$ June 2023. Trained enumerators were responsible for both recruitment and data collection. Households were eligible to participate in the study if they included at least one child aged between 6 and 24 months, the primary caregiver of this child consented to participate, and they did not plan to travel away with the child/children for more than one week over the ensuing four months. Randomisation of households to each trial arm (1:1) was at the level of the CHV, with two randomly selected households participating per CHV.

### Study setting

This study took place in Dagoretti South Sub County, a peri-urban, low-income settlement within Nairobi City County, Kenya. The sub-county covers 29.1km$^2$, comprising 9.87% (434,208) of Nairobi County's population [27]. It is characterized by high infectious disease burden, inadequate WASH services and a high population density [28]. Dagoretti South Sub County is divided into five wards. For this study, households (and primary caregivers–one caregiver per household) were recruited from two of these wards—Uthiru/Ruthimitu and Riruta–chosen based on their proximity to health facilities. Dagoretti South Sub County has resident CHVs who act as liaisons between the community and formal healthcare. Each CHV covers approximately 100 households living in their neighbourhood and is responsible for visiting these households on a regular basis to communicate health information and to encourage positive health-seeking behaviours. A map of the study sites can be found in Fig 1.

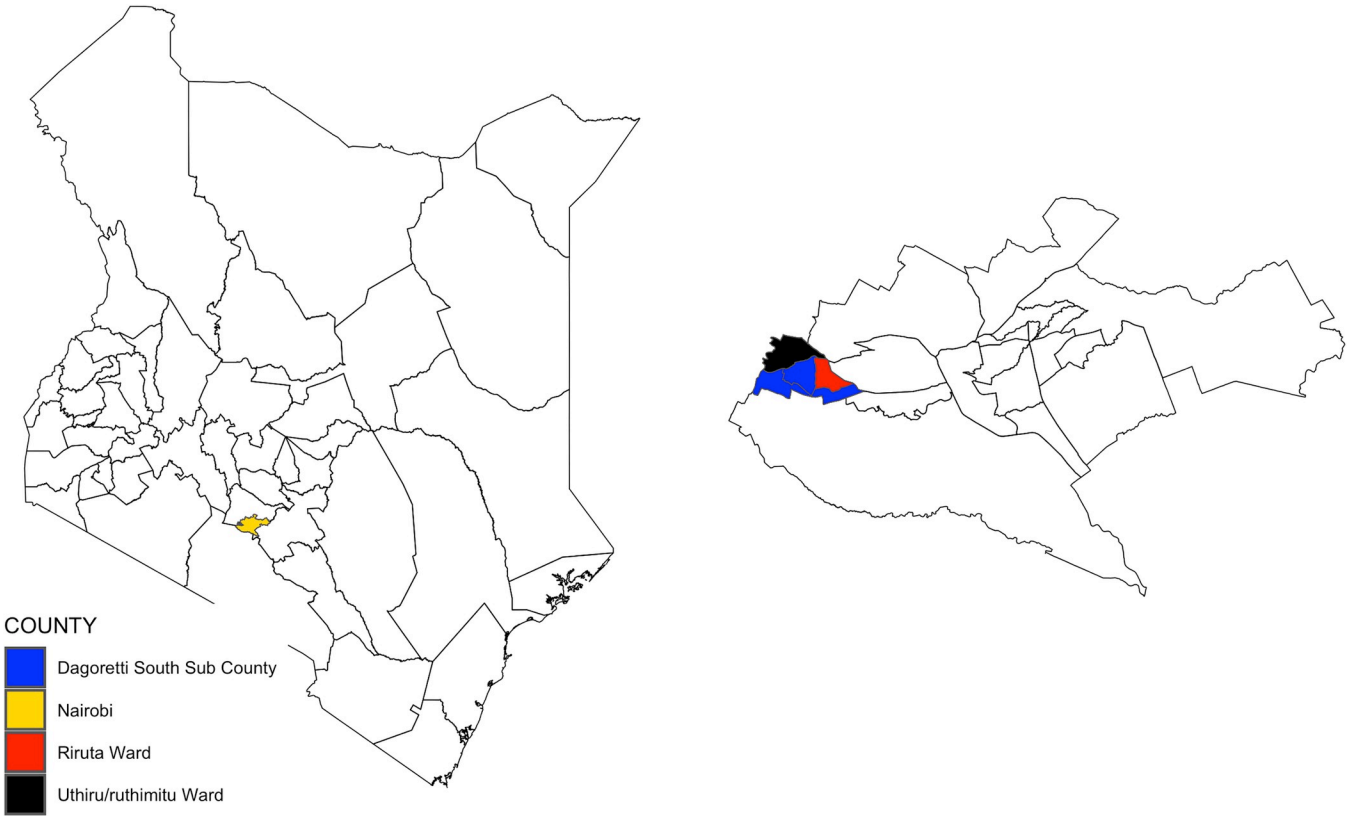


**Fig 1.** Map of Kenya (left) and Nairobi County (right) indicating the location of Riruta Ward (red) and Uthiru/Ruthimitu ward (black) within Dagoretti South Sub County (blue). Map was created in R statistical software using ggplot2 package and base layers were provided by the Humanitarian Data Exchange from the following shapefiles: https://data.humdata.org/dataset/administrative-wards-in-kenya-1450? (CCBY). https://data.humdata.org/dataset/kenya-sub-counties (CCBY). https://data.humdata.org/dataset/47-counties-of-kenya (CCBY).

https://doi.org/10.1371/journal.pwat.0000223.g001

## Intervention content and delivery

Primary caregivers in the intervention arm received a household-level food hygiene intervention delivered by a CHV, already active in the area (Table 1). This intervention consisted of a one-off household visit by a CHV, lasting approximately 20–30 minutes. On arrival to the household, using a preloaded android tablet, the CHV showed the caregiver a two-minute cartoon video, promoting six key food hygiene behaviours: 1. handwashing with soap before preparing the child's food; 2. handwashing with soap before serving food to the child; 3. washing the child's hands with soap before they eat; 4. heating and reheating the child's food to boiling temperature, 5. washing child's feeding utensils with detergent before feeding or storing clean feeding utensils in a sealed container.; 6. boiling child's drinking water. This video, developed with a locally based creative agency, was played in Kiswahili (the local language) and featured a caregiver preparing food and feeding her child while correctly performing the key behaviours with positive outcomes for her child (i.e., the child stays healthy, regularly attends school, graduates, and becomes a successful member of the community). The video, in English for the readers' benefit, is available to view at https://youtu.be/PWU9B-448MM. Following the video, the CHV held an open discussion with the caregiver to answer questions and reinforce the messages from the video. They then showed the video a second time to further reinforce the key messages and ensure that participants had the opportunity to internalise and recall the information presented. The CHV then provided the caregiver with a selection of food hygiene-related hardware. Each household received a handwashing station (handwashing

**Table 1. Intervention content and delivery.**

| Intervention Characteristics | Details |
|---|---|
| Target population | Caregivers of children 6–24 months |
| Implementer | Community Health Volunteer |
| Place of delivery | Household |
| Frequency | One-off household visit |
| Duration | 20–30-minute visit |
| Messages | 1. Handwashing with soap before preparing the child's food.<br>2. Handwashing with soap before serving food to the child.<br>3. Washing the child's hands with soap before they eat.<br>4. Heating and reheating the child's food to boiling temperature.<br>5. Washing child's feeding utensils with detergent before feeding or storing clean feeding utensils in a sealed container.<br>6. Boiling child's drinking water. |
| Techniques | • 2-minute video promoting food hygiene messages<br>• Short discussion with CHV to reinforce video messages.<br>• Provision and placement of hardware around the home:<br>• Handwashing station (handwashing bucket with tap, stool, and a bucket for water run off)<br>• Soap and a soap dish<br>• Child feeding utensil (spoon)<br>• Drying rack to air dry utensils<br>• Four plastic containers ranging from 250ml to 2000ml in size to store child feeding utensils.<br>• Container to store boiled drinking water (20L).<br>• Placement of 5 sticky posters and a calendar around the house depicting food hygiene messages, to serve as environmental cues as well as a poster depicting correct handwashing technique. |

https://doi.org/10.1371/journal.pwat.0000223.t001

bucket with tap, stool, and a bucket for water run off), soap and a soap dish, a child feeding utensil (spoon), a drying rack to air dry utensils, four plastic containers ranging from 250ml to 2000ml in size to store child feeding utensils, and a container to store boiled drinking water (20L). Together, the CHV and caregiver placed each item of hardware around the house in a location where it was convenient to use. The CHV also helped the caregiver to put up five sticky posters and a calendar around the house which showed the key messages from the video and aimed to serve as 'environmental cues' to perform the behaviours, as well as a poster depicting correct handwashing technique, before ending the household visit. The posters and calendar are depicted in Fig 2. Enlisting the caregiver to help the CHV to set up the hardware and stick the environmental cues around the house aimed to reinforce the messages. Examples of hardware and posters placed around the house are shown in Fig 3.

The control group received no intervention. However, after completion of the study, the same intervention was delivered to all control households.

## Outcomes

The primary outcome of the trial was a composite measure of the proportion of primary caregivers observed to practice five key food hygiene behaviours including: 1) handwashing with soap (both hands) before preparing the child's food; 2) handwashing with soap (both hands) before feeding the child; 3) washing the child's hands (both hands) with soap before they eat; 4) heating/reheating food to boiling temperature; and 5) washing utensils with detergent before feeding the child or retrieving clean feeding utensils from a sealed container.

Secondary outcomes of the trial focused on each of the key food hygiene behaviours individually and included:


**Fig 2. Calendar and posters.** From top left: calendar depicting key food hygiene behaviours, poster—'wash hands with soap', poster—'boil drinking water', poster—'heat food to boiling', poster 'clean utensils and store clean in sealed container'.

https://doi.org/10.1371/journal.pwat.0000223.g002

1. The proportion of primary caregivers observed to practice handwashing with soap (both hands) before preparing the child's food.
2. The proportion of primary caregivers observed to practice handwashing with soap (both hands) before feeding the child.
3. The proportion of primary caregivers observed to wash the child's hands (both hands) with soap before the child ate.

**Fig 3. Placement of hardware and posters around the house.** Photo credit: Photo 1: Hannah Wambui Wanjira; Photo 2 & 3: Pauline Mwende.

https://doi.org/10.1371/journal.pwat.0000223.g003

4. The proportion of primary caregivers observed to heat/reheat child's food to boiling temperature before serving.
5. The proportion of caregivers observed to wash utensils with detergents before feeding the child or to retrieve clean feeding utensils from a sealed container.
6. The proportion of caregivers who self-report always boiling the child's drinking water (note that this behaviour was self-reported as it does not necessarily happen every day and is therefore difficult to observe).

The proportion of caregivers who reported boiling the child's drinking water was not included in the primary outcome because, as a self-reported measure, it was at higher risk of bias. This bias may have led to inflated measures compared to the other five behaviours measured by observation [29].

## Data collection

All data collection activities were conducted by a team of trained enumerators who were not involved in delivering the intervention. These enumerators were recently qualified nurses, a requirement as blood and rectal swab samples were also collected as part of the broader study. They were selected through interviews from a larger pool of nurses recommended by the Ministry of Health. The research team provided a two-day training to enumerators in data collection and research ethics. Each enumerator was paired with a CHV who facilitated movement around the study site and introduced them to the household. CHVs were asked to leave the vicinity while the enumerator collected data and returned only after the enumerator had left to deliver the intervention (in households assigned to the intervention arm). Enumerators collected background social and demographic data at the time of recruitment using a verbally administered questionnaire.

To measure the study outcomes described above, the enumerator then returned to the enrolled household to conduct direct structured observations of the caregiver's food hygiene and feeding practices and to record data on household handwashing facilities using spot-check observations. Structured observations commenced around 10:30 AM as caregivers began food preparation for the child and continued until the child had finished eating, lasting approximately 30 minutes. Enumerators positioned themselves in an unobtrusive location in the household where they had the best view of the caregiver's activities and discreetly moved around as needed to capture key events. Enumerators recorded if the five key food hygiene behaviours were performed (as defined above) as well as the presence of a handwashing station with soap and water. At the end of observation period, enumerators also asked the caregivers if they always boil the child's drinking water and recorded this on their tablet. Structured observations were repeated at four-weeks post-intervention delivery (endline). This was deemed an adequate timeframe to assess the immediate impact of the intervention on the targeted behaviours. 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 to cross check the data daily.

## Sample size and randomisation procedure

As a proof-of-concept trial, the purpose of the study was to assess the behavioural impact of the intervention as a first step in considering the potential effectiveness of such an intervention. A sample size of 100 households (one primary caregiver per household) was decided, not through a formal power calculation but by considering the aim of the study, population diversity, budgetary, and time constraints. Working in only two wards within Dagoretti sub-county,

environmental factors were anticipated to be similar between households and the sample size deemed sufficient to reflect the range of socio-economic and household dynamics within the study area. With a sample size of 100 households, we calculated the minimum detectable effect to be between 18–27% if the range of true population proportions of caregivers practicing all key behaviours was between 2–20%, at 80% power and 5% significance level, and assuming a dropout rate of 10% [30].

Our sample frame for this study consisted of a list of 90 CHVs. During earlier formative research, these 90 CHVs were randomly selected for participation from a complete list of active CHVs in the study area (n = 259), obtained from the Sub-County Health Coordinator. Individual random sampling was employed to select 50 CHVs from the list of 90. CHVs were then randomly assigned to the intervention or control arm with a 1:1 ratio using a random number generator in Microsoft Excel. Each selected CHV provided a complete list of eligible households in their catchment areas (households that had at least one child 6–24 months old). From each of these 'eligible household lists', two households were randomly selected to take part in the study, although in error three households were recruited under one CHV and remained in the study, giving a total of 101 participating households. The author Elizabeth Cook performed all randomisation procedures. If a household declined participation or was deemed ineligible, another household was randomly selection from the CHV's list of eligible households.

## Blinding

The precise nature of the data being collected was not disclosed to participants. Enumerators informed participants that they would be observing types of foods eaten by the child, how food is prepared and how the child is fed but avoided disclosing that they were specifically interested in hygiene practices. All households were informed that they would receive an intervention related to child-health (since control households received the intervention directly after study completion). Enumerators were not informed of group assignment, and they had no role in the intervention delivery, however as the intervention involved placing new hardware in the household, enumerators were likely to decipher which households received the intervention. No further blinding of study participants or enumerators was possible due to the nature of the intervention which inherently exposes both to group assignment.

## Statistical analysis

To analyse the effect of the intervention on both primary and secondary outcomes we used binomial logistic regression with robust standard errors to adjust for clustering at the level of the CHV. Although not pre-specified, to enhance precision, we included education level of caregiver and household income (dichotomised as above or below 15,000 shillings per month, reflecting the official minimum wage in Nairobi) as covariates in our model. This decision was prompted by the observed imbalance between the two arms at baseline and by the established association of these factors with food hygiene behaviours in prior research [31]. Where we encountered issues of complete separation (i.e., where one group had zero events) Firth's logistic regression was applied, also adjusting for education level of caregiver and household income. We report results of both the unadjusted and adjusted models. A p-value threshold of 0.05 was considered statistically significant. The statistical model described above deviates from the model pre-specified in our trial registration (osf.io/eu5kf)–a Poisson generalised estimating equations (GEE) model. After further consultation with a statistician and prior to running any analyses, it was agreed that the small number of observations per cluster (i.e., two households per CHV) would cause too much instability in the GEE model. Sample size calculations and all analyses were conducted using STATA 14 (StataCorp).

The full trial protocol is attached as a S1 Protocol.

## Ethics statement

Ethical approval was granted by the London School of Hygiene and Tropical Medicine Research Ethics Committee (Ref: 28140) and the Institutional Research Ethics Committee at the International Livestock Research Institute (ILRI-IREC) (ref: ILRI-IREC2022-70). ILRI-IREC is accredited by the National Commission for Science, Technology, and Innovation in Kenya (NACOSTI). In addition, project approval was obtained from NACOSTI (License No: NACOSTI/P/23/23784). Written informed consent was sought from all participating households before enrolment.

The trial protocol is registered on the Open Science Framework (OSF), osf.io/eu5kf.

# Results

## Participants and baseline data

There were 101 households enrolled in the study, with 51 randomly assigned to the control arm and 50 randomly assigned to the intervention arm. Two households, one from each arm were lost to follow-up after baseline data collection. All participating households remained in their assigned groups (Fig 4).

Most caregiver-level, child-level, household-level, and WASH characteristics appeared well balanced across the trial arms at baseline, however, there were some apparent imbalances.

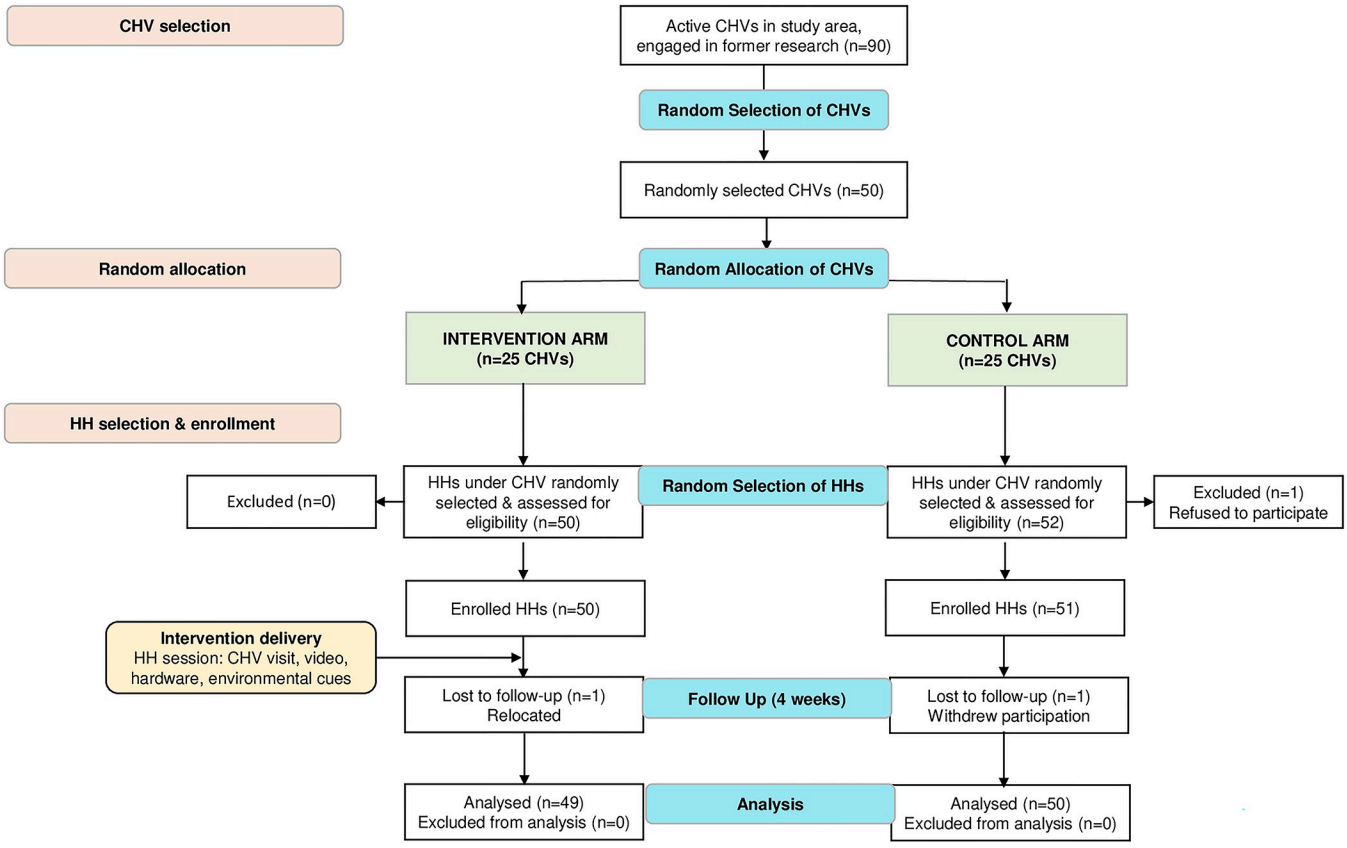


**Fig 4. Consort flow diagram.**

https://doi.org/10.1371/journal.pwat.0000223.g004

Caregivers in the intervention arm had a higher level of education than caregivers in the control arm (72% of caregivers in the intervention arm had completed at least secondary school compared to 55% in the control arm), but the monthly household income in the intervention arm was lower than in the control arm (20% of intervention households had a monthly income of above 15,000 Kenyan shillings compared to 35% of control households). Notably also 14% and 20% of participants in the intervention and control arm, respectively, declined to respond to the question on monthly household income. Although the proportion of households with a handwashing station in the household was similar across arms, more households in the control arm (20%) had a handwashing station with both soap and water available than in the intervention arm (8%). Baseline characteristics are presented in Table 2.

## Primary outcome

At baseline, the proportion of households practising all five key food hygiene behaviours was 0% in both trial arms. This rose to 4.1% in intervention arm and remained 0% in the control arm at endline, with no statistically significant difference between the two arms (aOR 1.1, 95% CI 0.8–1.5, p value = 0.71).

## Secondary outcomes

All outcomes relating to handwashing were rare in both trial arms at baseline with the proportion of caregivers observed to perform each of the three specified handwashing behaviours ranging from 0–4% in the intervention arm and 0–10% in the control arm. At endline, caregivers who received the food hygiene intervention had significantly better handwashing-related behaviours than caregivers in the control arm. Confidence intervals however were notably large, likely due to our small sample size, reflecting uncertainty around the effect estimates. Caregivers in the intervention arm had over seven times the odds of washing their hands before feeding the child (aOR 7.40, 95%CI 1.85, 29.62, p = 0.01) and washing their hands before preparing the child's food (aOR 7.05, 95%CI 1.52, 32.71, p = 0.01), and over 21 times the odds of washing the child's hands before the child ate (aOR 21.57, 95%CI 1.15, 405.93, p = 0.04).

At baseline, boiling the child's food and drinking water was more commonly practiced. 83% and 64% of caregivers were observed to heat or reheat food to boiling temperature in the intervention and control group, respectively. 80% of caregivers in the intervention group and 73% of caregivers in the control group self-reported that they always boil the child's drinking water. At endline, in the intervention group, these proportions rose to 86% and 96% of caregivers heating/reheating food to boiling and reporting that they always boil the child's drinking water, respectively, meaning that caregivers who received the intervention had four times the odds of heating the child's food to boiling temperature (aOR 4.03, 95%CI 1.27, 12.85, p = 0.02) and almost thirteen times the odds of boiling the child's drinking water, compared to caregivers in the control arm (aOR 12.82, 95%CI 2.54, 64.770, <p = 0.01). Confidence intervals around these effect estimates were also large. Caregivers cleaning feeding utensils before use or retrieving clean feeding utensils from a sealed container was uncommon at baseline (18% in the intervention group and 8% in the control group) and there was no significant difference in this outcome between trial arms at endline. Secondary outcomes are presented in Table 3.

As part of a sensitivity analysis, we added baseline access to a handwashing station with soap and water available in the household as a covariate in our adjusted model given this baseline characteristic appeared imbalanced and could be indicative of a difference in existing hygiene habits across trial arms. Results of the sensitivity analysis revealed no differences in any outcomes at baseline or endline (Table 4).

**Table 2. Baseline characteristics.**

| Variable | Intervention (n = 50) | Control (n = 51) |
|---|---|---|
| **Caregiver and child-level characteristics** | | |
| Sex of primary caregiver (female) | 49 (98%) | 49 (96%) |
| Age of primary caregiver (mean, sd) | 29.2 (SD 7.8) | 29.9 (SD 7.5) |
| Primary caregiver's relationship to child: | | |
| Mother | 46 (92%) | 46 (90%) |
| Father | 1 (2%) | 1 (2%) |
| Other | 3 (6%) | 4 (8%) |
| Age of child in months (mean, sd) | 13.2 (SD 4.5) | 15.1 (SD 5.4) |
| Level of education completed by primary caregiver: | | |
| Higher | 12 (24%) | 6 (12%) |
| Secondary | 24 (48%) | 22 (43%) |
| Primary | 13 (26%) | 22 (43%) |
| None | 1 (2%) | 1 (2%) |
| **Household-level characteristics** | | |
| Number of household members (mean, sd) | 4.2 (SD 1.1) | 4.5 (SD 1.6) |
| Number of household members aged <5 (mean, sd) | 1.3 (SD 0.5) | 1.4 (SD 0.5) |
| Main source of household income: | | |
| Permanent job | 9 (18%) | 6 (12%) |
| Casual labour | 22 (44%) | 28 (55%) |
| Petty trading | 18 (36%) | 11 (21%) |
| Other | 1 (2%) | 6 (12%) |
| Monthly household income*: | | |
| ≥15,000 ksh | 10 (20%) | 18 (35%) |
| < 15,000 ksh | 33 (66%) | 23 (45%) |
| Declined to answer | 7 (14%) | 10 (20%) |
| House ownership (owned) | 15 (30%) | 18 (35%) |
| Material of walls in house: | | |
| Cement | 12 (24%) | 14 (27%) |
| Metal | 34 (68%) | 32 (63%) |
| Tin/cardboard/paper/sacks | 2 (4%) | 2 (4%) |
| Wood | 2 (4%) | 3 (6%) |
| Grated windows | 42 (84%) | 42 (82%) |
| Flooring in house | | |
| Cement | 47 (94%) | 46 (90%) |
| Tile | 3 (6%) | 5 (10%) |
| Grated doors | 25 (50%) | 25 (49%) |
| Toilet private to household | 10 (20%) | 13 (26%) |
| Car ownership | 1 (10%) | 0 (0%) |
| Electricity in household | 49 (98%) | 51 (100%) |
| Working refrigerator | 6 (12%) | 8 (16%) |
| Working TV | 44 (88%) | 44 (86%) |
| Working Radio | 29 (58%) | 30 (59%) |
| Working Bluetooth device | 11 (22%) | 12 (24%) |
| Working Stereo | 2 (4%) | 2 (4%) |
| Working DVD player | 8 (16.0%) | 8 (16%) |
| Working Cassette player | 1 (2%) | 2 (4%) |
| **Water, sanitation, and hygiene characteristics** | | |

(*Continued*)

**Table 2.** (Continued)

| Variable | Intervention (n = 50) | Control (n = 51) |
|---|---|---|
| Drinking water source (JMP categories): | | |
| Safe | 6 (12%) | 6 (12%) |
| Basic | 42 (84%) | 41 (80%) |
| Limited | 2 (4%) | 4 (8%) |
| Drinking water storage: | | |
| Sealed container | 50 (100%) | 48 (94%) |
| Open container | 0 (0%) | 3 (6%) |
| Drinking water treatment: | | |
| Boil | 21 (42%) | 22 (43%) |
| Treat with chemicals | 6 (12%) | 2 (4%) |
| Water filter | 1 (2%) | 1 (2%) |
| No treatment | 22 (44%) | 26 (51%) |
| Cooking water source (JMP categories) | | |
| Safe | 7 (14%) | 7 (14%) |
| Basic | 43 (86%) | 44 (86%) |
| Volume of water use per day >50 litres/day | 43 (86.0%) | 46 (90%) |
| Type of sanitation facility (JMP categories) | | |
| Safe | 4 (8%) | 6 (12%) |
| Basic | 6 (12%) | 5 (10%) |
| Limited | 34 (68%) | 37 (72%) |
| Unimproved | 6 (12%) | 3 (6%) |
| Handwashing station available in the household | 14 (28%) | 14 (28%) |
| Handwashing station with both soap and water available in the household | 4 (8%) | 10 (20%) |
| Live animals in the food preparation area | 7 (14%) | 8 (16%) |
| Flies visible in the food preparation area | 16 (32%) | 17 (33%) |

* The income categories reflect the minimum wage set for Nairobi in 'The regulation of wages (general) (amendment) order, 2022'.

https://doi.org/10.1371/journal.pwat.0000223.t002

## Discussion

This proof-of-concept trial provides evidence that a CHV-led food hygiene intervention targeting caregivers of children aged 6–24 months and involving video messages, provision of hardware and environmental cues, can change food hygiene practices around young children in this setting. The statistically significant increase in five of our six targeted behaviours, observed among caregivers who received the intervention, underscores its initial success in promoting crucial food hygiene practices. These results provide a basis for future research to assess whether these changes in behaviour would be sufficient to reduce foodborne disease and whether an intervention of this type could be sustained at a larger scale whilst achieving similar effects on food hygiene practices.

Our results indicate that this intervention can improve caregiver's food hygiene-related handwashing behaviours as well as other behaviours related to treating food and water (i.e., heating to boiling) to kill microorganisms. We did not however see an improvement in our primary outcome—a composite measure of the proportion of caregivers practicing all five observed food hygiene behaviours—because there was no change in one of these behaviours. This is in line with recent findings that simultaneous practice of multiple food hygiene behaviours is rare [24].

**Table 3. Secondary outcomes.**

| | Intervention Group N (%) | Control Group N (%) | Unadjusted OR (95% CI) P value | Adjusted OR (95% CI) P value* |
|---|---|---|---|---|
| **BASELINE** | **N = 50** | **N = 51** | | |
| Handwashing before feeding child | 0 (0%) | 1 (2%) | 0.33[a] (0.01, 8.38) p = 0.50 | 1.15[a] (0.02, 53.27) p = 0.94 |
| Handwashing before preparing child's food | 2 (4%) | 5 (10%) | 0.38 (0.07, 2.09) p = 0.27 | 0.27 (0.05, 1.56) p = 0.14 |
| Washing child's hands before they eat | 0 (0%) | 0 (0%) | No difference | No difference |
| Child's food heated to boiling | 40 (N = 48)** (83%) | 32 (N = 50)** (64%) | 2.81 (1.08, 7.34) p = 0.04 | 2.64 (0.78, 8.91) p = 0.12 |
| Boiling water | 40 (80%) | 37 (73%) | 1.51 (0.60, 3.84) p = 0.38 | 2.47 (0.75, 8.16) p = 0.14 |
| Utensils cleaned with detergents before feeding OR clean utensils retrieved from sealed container | 9 (18%) | 4 (8%) | 2.58 (0.73, 9.10) p = 0.14 | 3.50 (0.80, 15.36) p = 0.10 |
| **ENDLINE** | **N = 49** | **N = 50** | | |
| Handwashing before feeding child | 18 (37%) | 3 (6%) | 9.10 (2.45, 33.72) **p = <0.01** | 7.40, (1.85, 29.62) **p = 0.01** |
| Handwashing before preparing child's food | 10 (20%) | 3 (6%) | 4.02 (1.03, 15.73) **p = 0.05** | 7.05 (1.52, 32.71) **p = 0.01** |
| Washing child's hands before they eat | 10 (20%) | 0 (0%) | 26.85 [a] (1.53, 472.30) **p = 0.03** | 21.57 [a] (1.15, 405.93) **p = 0.04** |
| Child's food heated to boiling | 42 (86%) | 33 ((66%) | 3.09 (1.14, 8.37) **p = 0.03** | 4.03 (1.27, 12.85) **p = 0.02** |
| Boiling water | 47 (96%) | 37 (74%) | 8.26 (1.74, 39.20) **p = 0.01** | 12.82 (2.54, 64.77) **p = <0.01)** |
| Utensils cleaned with detergents before feeding OR clean utensils retrieved from sealed container | 11 (23%) | 5 (10%) | 2.61 (0.83, 8.21) p = 0.10 | 2.97 (0.70, 12.64) p = 0.14 |

a Firth's logistic regression

* Adjusted for education level and income

** N here is lower than total N as it omits households serving food types that could not be heated to boiling (3 households serving only bread, banana, and orange were omitted)

https://doi.org/10.1371/journal.pwat.0000223.t003

In our study, we did not find a statistically significant increase in the proportion of caregivers observed cleaning utensils with detergent before feeding the child or retrieving clean utensils from a sealed container. Similarly, a study testing a food hygiene intervention in Bangladesh, also found that cleaning utensils was practiced less than some other food hygiene behaviours [31]. This may be because, unlike handwashing behaviour, cleaning utensils and storing them in a sealed container is not a message commonly featured in hygiene promotion and research suggests people have a preference for performing familiar behaviours [32, 33]. This behaviour is however important; using unclean feeding utensils provides one of the last opportunities for contamination to be introduced to a child's food before ingestion, even if the caregiver has clean hands and has heated the food to boiling temperature. As part of our intervention, caregivers were provided with the hardware necessary to store clean utensils in a sealed container—feeding utensils and plastic boxes—yet they failed to adopt the behaviour. Future work to refine our messaging around this behaviour, including understanding the barriers to adoption among caregivers, beyond access to hardware, is needed before trialling the intervention again.

While we did observe statistically significant differences between the intervention and control arm in five out of the six promoted food hygiene behaviours, it is important to highlight the substantial 95% confidence intervals surrounding the estimated effects, likely due to our

**Table 4. Sensitivity analyses.**

| | Intervention Group N (%) | Control Group N (%) | Adjusted OR (95% CI) P value* |
|---|---|---|---|
| **BASELINE** | **N = 50** | **N = 51** | |
| Handwashing before feeding child | 0 (0%) | 1 (2%) | 1.21[a] (0.03, 50.24) p = 0.92 |
| Handwashing before preparing child's food | 2 (4%) | 5 (10%) | 0.25 (0.04, 1.76) p = 0.17 |
| Washing child's hands before they eat | 0 (0%) | 0 (0%) | No difference |
| Child's food heated to boiling | 40 (N = 48)** (83%) | 32 (N = 50)** (64%) | 2.97 (0.86, 10.22) p = 0.09 |
| Boiling water | 40 (80%) | 37 (73%) | 2.69 (0.76, 9.52) p = 0.13 |
| Utensils cleaned with detergents before feeding OR clean utensils retrieved from sealed container | 9 (18%) | 4 (8%) | 4.93 (0.94, 25.96) p = 0.06 |
| **ENDLINE** | **N = 49** | **N = 50** | |
| Handwashing before feeding child | 18 (37%) | 3 (6%) | (1.67, 28.41) **p = 0.01** |
| Handwashing before preparing child's food | 10 (20%) | 3 (6%) | 8.29 (1.38, 49.81) **p = 0.02** |
| Washing child's hands before they eat | 10 (20%) | 0 (0%) | 21.95[a] (1.17, 410.66) **p = 0.04** |
| Child's food heated to boiling | 42 (86%) | 33 (66%) | 3.71 (1.15, 11.98) **p = 0.03** |
| Boiling water | 47 (96%) | 37 (74%) | 14.59 (2.75, 77.50) **p = <0.01** |
| Utensils cleaned with detergents before feeding OR clean utensils retrieved from sealed container | 11 (23%) | 5 (10%) | 3.59 (0.79, 16.38) p = 0.21 |

a Firth's logistic regression

* Adjusted for education level, income, and availability of a handwashing station with both soap and water

** N here is lower than total N as it omits households serving food types that could not be heated to boiling (3 households serving only bread, banana, and orange were omitted)

https://doi.org/10.1371/journal.pwat.0000223.t004

small sample size. For example, the confidence intervals were notably wide when considering the effect estimate for caregivers washing the child's hands before they ate, spanning from 1.2 to 410.7. The wide confidence intervals reflect the high level of uncertainty associated with our estimates of the intervention's effect and suggest the true effect size could potentially fall within a broad range. While the point estimates indicate strong positive effects, the large confidence intervals emphasise the need for caution in interpreting these results. Evaluating this intervention using a larger sample size is necessary to obtain more precise estimates of its impact on food hygiene behaviours.

There are three key aspects of the intervention to which the positive changes in food hygiene behaviour that we measured can likely be attributed, although we are unable to disentangle the individual effects associated with each aspect. Firstly, our intervention involved providing hardware to create a physical environment that enabled the practice of good food hygiene behaviours. This is clearly an important aspect of our intervention given less than 20% of households had a handwashing station with both soap and water available at baseline. Without the right hardware to enable handwashing with soap, safe feeding, and safe food and water storage practices, even caregivers with the best intentions are unable to practice good food hygiene. However, it is likely not the only 'active ingredient' of the intervention. Although

studies have shown a positive association between handwashing hardware and handwashing practice, and a recent review indicates that providing a convenient and a desirable handwashing station may be the most effective means to influence handwashing behaviour [34–38], other studies have shown that even with good access to a soap and water at a handwashing station, handwashing rates can still be low [39, 40]. Recent systematic reviews of the literature have concluded that a combination of hardware and software is likely necessary [36, 41].

Secondly, the cartoon video depicted a child who, by avoiding foodborne disease due to her diligent mother adopting good food hygiene behaviour, stays healthy, regularly attends school, and goes on to graduate from university, with her mother proudly attending her graduation ceremony. As well as to inform caregivers of key food hygiene behaviours, this video was designed to act as an emotional driver, appealing to the caregiver's innate motivation to nurture and achieve status, two of fifteen latent motives that some behavioural theorists believe evolved to drive behaviour in all human experiences and support evolutionary important goals [42]. Other interventions using emotional drivers, including nurture and status, have been shown to change hygiene behaviours, including food hygiene behaviours, so we deem this likely to be another active ingredient of our intervention [21, 43, 44]. Thirdly, we placed environmental cues around the house to nudge caregivers to perform the food hygiene behaviours. The stickers and calendar portraying the food hygiene behaviours served as environmental cues, as did the placement of the hardware in convenient places around the house. Environmental cues have been shown to successfully change hygiene behaviours in several studies and our study adds to the growing evidence base [21, 45–47]. Future large-scale trials could consider incorporating multiple arms, allowing for the assessment of hardware provision which enables handwashing with soap, safe feeding, and food and water storage practices, use of emotional drivers via the video, and installation of environmental cues, individually. Beyond the intervention content, how we delivered the intervention may also have contributed to improving caregiver's food hygiene behaviours. CHVs, already known to the community delivered the intervention to caregivers in their homes. Numerous studies support the use of trusted members of the community, such as hygiene promoters or CHVs to encourage and catalyse improved hygiene practices [48–53].

As this was a proof-of-concept trial, CHVs visited households only once and we had only a short follow-up period of four weeks. Research suggests intervention repetition leads to more consistent and sustained changes in behaviour [31, 54–57]. In particular an intervention that successfully improved caregiver's food hygiene behaviour in Nepal involved six household visits [21]. Having CHVs revisit the household multiple times, play the video again and reinforce the messages could potentially lead to larger improvements in food hygiene behaviours and is how we envision future implementation of the intervention. The financial burden of adding multiple CHV visits to the intervention should not be too great as once the hardware is in place after the first CHV visit, repeat visits would involve only the cost of the CHV's time.

Formative work identified six specific behaviours within our study population that our intervention aimed to address. It's worth noting that there are additional behaviours related to food contamination, such as cleaning preparation surfaces and proper storage of food. However, we made a deliberate decision not to include every potential risky behaviour in our intervention and focused only on those particularly prevalent in our population as research has shown that if hygiene messages are too complex they are harder to recall and practice [58]. In different populations the key risky behaviours may vary and, if this were the case, the intervention would require refinement to target these specific behaviours.

Our study has several limitations. First, as discussed above, the small sample size led to substantial variability and uncertainty in our effect estimates. Second, our results may be subject to observer bias as it was not possible to blind enumerators to intervention status. It was also

not possible to blind participants to intervention status which could introduce courtesy bias in the intervention arm as well as contamination between arms, however, we attempted to minimise this risk by randomising at the CHV level so that intervention and control houses were not in close proximity. Third, we measured most behaviours via observation. Although this is considered the gold standard, at least for measuring handwashing [59], this method is still prone to social desirability bias [60], observer bias, and the 'Hawthorne Effect' or reactivity bias [61], where caregiver's modify their behaviour in response to their awareness of being observed [60, 62]. Boiling of drinking water was measured by self-report since it could not be captured during the observation period and this method is associated with even higher risk of bias [29]. Fourth, we visited all households at approximately the same time and observed the preparation, serving and consumption of only one meal. It may be that caregiver's food hygiene behaviours vary at different times of the day when different meals are prepared. We can't say if the intervention improved food hygiene behaviour during every meal preparation and future trials with a larger sample size should aim to capture meal preparation at different times in the day. Finally, this study was conducted in one low-income area of Nairobi. Risk behaviours may vary across different settings and hence the intervention may not be generalisable across settings.

## Conclusions

This proof-of-concept trial provides encouraging initial support for the effectiveness of a CHV-led food hygiene intervention for caregivers which includes video messages, hardware provision, and environmental cues. While the wide 95% confidence intervals demonstrate the inherent uncertainty in our estimate, the magnitude of the observed effects suggest that the intervention could play a meaningful role in improving food hygiene behaviours among caregivers. Given the significant public health implications associated with foodborne disease among young children, this proof-of-concept trial provides a compelling rationale for refining the intervention and expanding our investigation into its efficacy. Future research, with larger and more diverse samples, longer follow-up periods and health outcomes can tell us if this intervention can achieve and sustain similar effects on food hygiene practices at a larger scale and if these improved practices are sufficient to reduce foodborne disease.

## Supporting information

**S1 Checklist. CONSORT checklist.**
(DOC)

**S1 Protocol. Study protocol.**
(DOCX)

## Acknowledgments

We would like to extend our deep gratitude to all the participating households and caregivers who allowed us into their homes and made this study possible. Thank you also to the Community Health Volunteers who supported this study and diligently delivered the intervention and to the enumerators for their hard work collecting the data.

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