Full Title

Effects of an urban sanitation intervention on childhood enteric infection and diarrhoea in Mozambique

Short title

Urban sanitation and childhood enteric infection

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Abstract

Background

Onsite sanitation serves more than 740 million people in urban areas, primarily in low-income countries. Although this critical infrastructure may play an important role in controlling enteric infections in high-burden settings, its health impacts have never been evaluated in a controlled trial.

Methods

We conducted a controlled before and after trial to evaluate the impact an onsite urban sanitation intervention on the prevalence of bacterial and protozoan infection (primary outcome), soil-transmitted helminth (STH) re-infection, and seven-day period prevalence of diarrhoea among children living in informal neighborhoods of Maputo, Mozambique. A non-governmental organization replaced existing shared latrines in poor condition with engineered pour-flush toilets with septic tanks serving household clusters. We enrolled children aged 1-48 months at baseline and measured outcomes before the intervention and at 12 and 24 months following intervention. We measured outcomes concurrently among children served by the sanitation improvements and those in a comparable control arm served by existing poor sanitation. The trial was registered at ClinicalTrials.gov, number NCT02362932.

Findings

At baseline, we enrolled 454 children from 208 intervention clusters and 533 children from 287 control clusters. We enrolled or re-visited 462 intervention and 477 control children 12 months after intervention and 502 intervention and 499 control children 24 months after intervention.
Despite nearly exclusive use of the intervention, we found no evidence that engineered onsite sanitation affected the overall prevalence of any measured bacterial or protozoan infection (12-month adjusted prevalence ratio 1·05, 95% CI [0·95-1·16]; 24-month adjusted prevalence ratio 0·99, 95% CI [0·91-1·09]), any STH re-infection (1·11 [0·89-1·38]; 0·95 [0·77-1·17]), or diarrhoea (1·69 [0·89-3·21]; 0·84 [0·47-1·51]) after 12 or 24 months of exposure. Among children born into study sites after the intervention and measured at the 24-month visit, we observed a reduced prevalence of any STH re-infection of 49% (adjusted prevalence ratio 0·51 [95% confidence interval 0·27 - 0·95]), *Trichuris* of 76% (0·24 [0·10 - 0·60]), and *Shigella* infection by 51% (0·49 [0·28-0·85]) relative to the same age group at baseline.

**Interpretation**

The intervention did not reduce the overall prevalence of enteric infection and diarrhoea among all enrolled children but may have substantially reduced the prevalence of STHs and *Shigella* among children born into clusters with sanitary improvements.

**Funding**

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Introduction

Rapid urbanization has led to the expansion of informal settlements in many low- and middle-income countries (LMICs). Such settlements often have very limited sanitation infrastructure. (UN-Habitat, 2016) Separation of human waste from human contact can prevent exposure to enteric pathogens that cause infection, diarrhoea, (Liu et al., 2016) and potentially long-term health effects such as environmental enteric dysfunction (EED), (Kosek et al., 2017) linear growth deficits, (Rogawski et al., 2018) impaired cognitive development, (Investigators, 2018) and reduced oral vaccine immunogenicity. (Parker et al., 2018) Children living in densely populated slum areas where faecal contamination is pervasive and sanitation infrastructure is limited may be at an increased risk of adverse health effects due to frequent exposure to enteric pathogens. (Fink et al., 2014)

Household-level sewerage has demonstrated health benefits (Barreto et al., 2007, 2010; Norman et al., 2010) and remains an important long-term goal for many urban settings, despite limited evidence from controlled trials. (Norman et al., 2010; Wolf et al., 2018) Such systems may not be a feasible short-term solution due to cost, space, and logistical constraints, challenges that have also impeded their evaluation via randomised trials. (Norman et al., 2010) Further, in densely populated areas, there may not be space for household-level sanitation of any type. Shared sanitation is a subject of considerable debate but may represent the only near-term sanitation option in some settings. Yet, while shared, onsite systems may fill the growing need for safe sanitation in rapidly expanding urban areas in LMICs, to date, there has been little evidence of their health impacts in these settings. Recent large-scale, rigorous evaluations of onsite sanitation interventions and combined water, sanitation, and hygiene interventions have demonstrated mixed effects on
health,(Clasen et al., 2014; Humphrey et al., 2019; Luby et al., 2018; Null et al., 2018; Pickering et al., 2015) but all were conducted in rural areas with household-level interventions and their findings may have limited generalizability to urban areas. A recent meta-analysis estimated that non-sewered interventions reduced the risk of self-reported diarrhoea by 16% but did not estimate effects on objective health outcomes, such as enteric infection, and could not stratify estimates by rural versus urban setting given the lack of evidence in urban areas.(Brown & Cumming, 2019; Wolf et al., 2018) To-date, no controlled trials of urban onsite sanitation have been conducted despite over 740 million urban residents relying on such technologies. (Berendes et al., 2017)

The Maputo Sanitation (MapSan) trial was the first controlled trial to evaluate an onsite, shared sanitation intervention in an urban setting and the first to use the prevalence of enteric infection, as detected by molecular methods, as the primary study outcome.(Brown et al., 2015) The study was located in densely populated, low-income neighborhoods of Maputo, Mozambique where the sanitary conditions are poor and disease burden high.(Knee et al., 2018) As of 2017, half of urban residents in Mozambique had access to at least basic sanitation infrastructure, 3% had access to sewerage, and 9% shared sanitation with multiple households,(UNICEF/WHO, 2019) often in poor neighborhoods where space and resources are limited. We investigated whether an engineered, onsite, shared sanitation intervention could reduce enteric infection and diarrhoea in young children living in these low-income, densely populated neighborhoods in Maputo, Mozambique.
Methods

Study design and intervention

MapSan was a controlled before and after trial, and details of the study design and analysis plan have been published previously. (Brown et al., 2015) We conducted the study in 17 densely populated, low-income, informal neighborhoods in Maputo, Mozambique. The intervention was delivered to compounds - groups of households typically delineated by a wall or barrier, that shared sanitation and outdoor living space. Shared compound sanitation facilities are not considered public facilities. We collected data in an open cohort of children in intervention and control compounds at three time-points: baseline (pre-intervention), 12 months post-intervention, and 24 months post-intervention. We enrolled intervention and control compounds concurrently to limit any differential effects of seasonality or other secular trends on the outcomes (supplemental information p 2-3).

The non-governmental organization (NGO) Water and Sanitation for the Urban Poor selected intervention compounds and designed and built 300 intervention facilities - pour-flush toilets discharging to septic tanks, the liquid effluent of which flows to the soil through soak-away pits (supplemental information p 4-5). Intervention compounds were located in 11 neighborhoods of the Nhlamankulu and KaMaxakeni districts of Maputo. The NGO selected intervention compounds using the following criteria: (1) residents shared sanitation in poor condition as determined by an engineer; (2) the compound was located in the pre-defined implementation neighborhoods; (3) there were no fewer than 12 residents; (4) residents were willing to contribute financially to construction costs; (5) sufficient space was available for construction of the new facility; (6) the compound was accessible for transportation of construction materials and tank-
emptying activities; (7) the compound had access to a legal piped water supply; and (8) the groundwater level was deep enough for construction of a septic tank. Presence of a child was not a selection criterion and therefore not all intervention sites were included in the study. Opening of newly constructed intervention latrines occurred between February 2015 and February 2016. The study team used criteria 1, 3, 4, and 7 to select control sites within the 11 intervention neighborhoods and six adjacent but similar neighborhoods (supplemental information p 6). Additionally, control compounds were required to have at least one child younger than 48 months old in residence.

There were two intervention designs with the same basic sanitation technology: communal sanitation blocks (CSBs) and shared latrines (SLs) (supplemental information p 7-8). The primary difference between CSBs and SLs was size. CSBs (n=50) included multiple stalls with toilets and served compounds of 21 or more people with one stall allocated per 20 residents. CSBs also included rainwater harvesting systems, elevated water storage tanks, a handwashing basin, a laundry facility, a shared water connection, and a well-drained area for bathing. Shared latrines (n=250) were single-stall facilities serving fewer than 21 people. All septic tanks were sized to require emptying after approximately two years. It was not possible to blind participants or enumerators to intervention status.

The study protocol was approved by the Comité Nacional de Bioética para a Saúde (CNBS), Ministério da Saúde (333/CNBS/14), the Research Ethics Committee of the London School of Hygiene & Tropical Medicine (reference # 8345), and the Institutional Review Board of the Georgia Institute of Technology (protocol # H15160).
Participants

We enrolled eligible children at three time points: baseline (0 months), 12 months post-intervention, and 24 months post-intervention. Children aged 1-48 months old were eligible for baseline enrolment if we received written informed consent from a parent or guardian and if the head of the compound provided verbal assent for the compound to be included in the study. Children were eligible for enrolment at 12- and 24-month visits if they were aged 1-48 months or if they were eligible for enrolment at baseline but absent during that study visit. Children who moved into the compound fewer than six months before the 12-month or 24-month visit were not eligible for enrolment during that phase given their limited exposure to their new compound.

Procedures

Trained field enumerators completed consent procedures and surveys in the participant’s preferred language (Portuguese or Changana) and collected biological specimens from enrolled children (supplemental information p 9). At baseline, we aimed to visit intervention compounds two weeks prior to the opening of the new latrines. We scheduled follow-up visits to be 12 months (±2 weeks) and 24 months (±2 weeks) from the date compound members began using their new latrines, with visits to control compounds made concurrently (±2 weeks).

We collected stool specimens independently of reported symptomology. If we were unable to collect a stool sample after multiple attempts, a registered nurse collected a rectal swab after obtaining written consent for the procedure from a parent or guardian. Stool samples were kept cold and delivered to the Laboratory of Molecular Parasitology at the Instituto Nacional de Saúde (INS) within six hours of collection for analysis and storage at -80°C.
Samples were shipped frozen with temperatures monitors to the Georgia Institute of Technology (Atlanta, USA) where we used the xTAG Gastrointestinal Pathogen Panel (Luminex Corp, Austin, USA), a qualitative multiplex molecular assay, to detect 15 enteric pathogens in stool samples: *Campylobacter jejuni/coli/lari; Clostridium difficile*, toxin A/B; enterotoxigenic *Escherichia coli* (ETEC) LT/ST; Shiga-like toxin producing *E. coli* (STEC) stx1/stx2; *E. coli* O157; *Salmonella*; *Shigella boydii/sonnei/flexneri/dysenteriae; Vibrio cholerae; Yersinia enterocolitica; Giardia lamblia; Cryptosporidium parvum/hominis; Entamoeba histolytica; adenovirus 40/41; norovirus GI/GII; and rotavirus A. The Gastrointestinal Pathogen Panel (GPP) has been rigorously and extensively tested for stool-based enteric pathogen detection. (Duong et al., 2016; Kellner et al., 2019; Khare et al., 2014) We analyzed samples according to manufacturer instructions with the addition of elution steps for the pretreatment of rectal swabs and diaper material saturated with liquid stool (supplemental information p 9). Technicians at INS assessed stool specimens for the presence of soil-transmitted helminths (STH) using the single-slide Kato-Katz microscope method (Vestergaard Frandsen, Lausanne, Switzerland).

Representatives of the National Deworming Campaign (NDC) at the Mozambican Ministério da Saúde (MISAU) offered single-dose albendazole (400 mg, 200 mg for children aged six to 12 months) to all eligible members of intervention and control compounds following sample collection activities of each phase. Eligibility was defined by the NDC and included compound members older than six months who were not pregnant.

**Outcomes**

For the 12-month analysis, we pre-specified the primary outcome as infection with one or more of the 12 bacterial or protozoan enteric pathogens detected by the GPP and secondary outcomes as
re-infection with one or more STH as detected by Kato-Katz (following albendazole treatment at baseline), and seven-day period prevalence of caregiver-reported diarrhoea. All three outcomes were considered secondary outcomes in the 24-month analysis. We defined diarrhoea as the passage of three or more loose or liquid stools in a 24-hour period or any stool with blood. (Arnold et al., 2013) We excluded viral enteric pathogens from the primary outcome definition. The intervention may not have interrupted virus transmission due to their low infectious doses, high concentration shed in faeces and extended period of shedding, environmental persistence, and capability for direct person-to-person transmission. (Julian, 2016) Following reported specificity issues with the *Salmonella* target of the GPP, we removed it from our GPP-based outcome definitions. (Duong et al., 2016; Kellner et al., 2019) In addition to the pre-specified outcomes, we evaluated the effect of the intervention on specific pathogen types (bacterial, protozoan, viral) and on individual pathogens.

**Statistical analysis**

Our sample size calculation has been described previously. (Brown et al., 2015) We used an intention-to-treat approach for our analysis. We included all enrolled children at each visit and analysed data as repeated cross-sectional observations. We examined the effect of the intervention at the 12-month and 24-month phases separately. We conducted two sets of exploratory sub-group analyses. The first assessed the effect of the intervention on children with repeat observations at baseline and 12-months and at baseline and 24-months visits. This longitudinal analysis also served as a sensitivity analysis of the impact of participant migration on effect estimates. The second sub-group analysis compared children who were born into study sites after the intervention (or after baseline in controls) but before the 12-month or 24-month visit with children of a similar
We used a difference-in-difference (DID) approach to assess the impact of the intervention on all outcomes at the 12- and 24-month visits. We used generalized estimating equations (GEE) to fit Poisson regression models with robust standard errors. Our GEE models accounted for clustering at the compound level because it was the highest level of nested data and the level of the intervention allocation. We estimated the effect of the intervention as the interaction of variables representing treatment status (intervention versus control) and phase (pre- or post-intervention). Therefore, effect estimates from our DID analysis are presented as ratio measures (ratio of prevalence ratios) instead of absolute differences. Multivariable models were adjusted for covariates determined a priori as potentially predictive of our outcomes, including child age and sex, caregiver’s education, and household wealth. Additional covariates (supplemental information p 10-11) were considered for inclusion in multivariable models if they were imbalanced between arms at baseline (>0.1 standardized difference in prevalence or mean) and resulted in a meaningful change in the DID effect estimate (±10% change in 12-month DID prevalence ratio). We used the same statistical approach for sub-group analyses. All analyses were performed on complete case data, and missing data tables are presented in the supplemental information (p 12-13). We performed all statistical analyses with Stata version 16 (StataCorp, College Station, USA).

The trial was pre-registered at ClinicalTrials.gov (NCT02362932).
Role of the Funding Source

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. The corresponding author had full access to all study data and had final responsibility for the decision to submit for publication.

Results

We enrolled 987 children in 495 compounds during the baseline phase (February 2015 – February 2016), 939 children in 438 compounds during 12-month phase (March 2016 – April 2017) and 1001 children in 408 compounds during the 24-month phase (April 2017 – August 2018) (Figure 1). Fifteen control compounds received an intervention latrine after baseline and children in those compounds were censored at the time of intervention receipt (Figure 1). Children in intervention and control compounds were enrolled at approximately the same rate during each phase (supplemental information p 2-3). Due to migration out of the compound, we collected longitudinal data from 62% of children (59% controls, 67% interventions) between baseline and 12-month and 51% of children (46% controls, 58% interventions) between baseline and 24-month.
Baseline

454 children enrolled & 365 stools collected in INTERVENTION sites
- 366 households
- 208 compounds

152 unavailable at 12-month
- 1 died
- 151 traveling or moved

160 newly eligible
- 92 born-in
- 52 moved in
- 16 traveling at baseline†

533 children enrolled & 400 stools collected in CONTROL sites
- 443 households
- 287 compounds

220 unavailable at 12-month
- 2 died
- 7 refused
- 211 traveling or moved

164 newly eligible
- 85 born-in
- 50 moved in
- 1 refused baseline enrollment
- 28 traveling at baseline†

12-month Follow-Up

462 visited & 408 stools collected
- 351 households
- 198 compounds

132 unavailable at 24-month
- 2 died
- 130 traveling or moved

143 newly eligible
- 75 born in
- 29 moved in
- 39 traveling during prior visits†
- 29 enrolled at baseline but absent at 12-month

477 visited & 397 stools collected
- 369 households
- 240 compounds

163 unavailable at 24-month
- 1 refused
- 136 traveling or moved
- 26 censored from dataset‡

155 newly eligible
- 84 born in
- 27 moved in
- 44 traveling during prior visits†
- 30 enrolled at baseline but absent at 12-month

24-month Follow-up

502 visited & 462 stools collected
- 372 households
- 197 compounds

499 visited & 460 stools collected
- 352 households
- 211 compounds

143 newly eligible
- 50 moved in
- 1 refused baseline enrollment
- 28 traveling at baseline†

163 unavailable at 24-month
- 1 refused
- 136 traveling or moved
- 26 censored from dataset‡

155 newly eligible
- 84 born in
- 27 moved in
- 44 traveling during prior visits†
- 30 enrolled at baseline but absent at 12-month

502 visited & 462 stools collected
- 372 households
- 197 compounds

499 visited & 460 stools collected
- 352 households
- 211 compounds
Figure 1: Trial profile. †Eligible for enrollment at baseline and/or 12-month but traveling at time of visit. ‡Children removed from 24-month analysis because their compound received an intervention after completion of the baseline phase.

At baseline enrolment, intervention compounds had more residents, households, and on-premise water taps than controls, though the number of shared latrines was similar (Table 1). Animals were observed in over half of compounds. Intervention and control households had similar wealth scores, though intervention households had more members and were more crowded while control households more often had walls made of sturdy materials. All households used a municipal water tap as their primary drinking water source with 78% reporting use of a tap on the compound grounds. At baseline, latrines used by intervention households more often had pedestals or slabs, drop-hole covers, and sturdy walls compared with controls. Baseline characteristics of intervention and control children were similar: the average age at enrolment was 23 months (SD = 13), 51% were female, and 32% were still breastfeeding (Table 1).
Table 1: Baseline characteristics of enrolled children, households, and compounds

|                                | Control       | N | n (%) or mean (SD) | Intervention | N | n (%) or mean (SD) |
|--------------------------------|--------------|---|-------------------|--------------|---|-------------------|
| **Child level variables**      |              |   |                   |              |   |                   |
| Age at survey, days\(^{†}\)    | 520          | 700 (405) | 441              | 694 (403)    |   |                   |
| Sex, female                    | 520          | 266 (51%) | 444              | 227 (51%)    |   |                   |
| Child is breastfed with or without complementary feeding | 526 | 169 (32%) | 448 | 143 (32%) |   |                   |
| Child is exclusively breastfed | 526          | 49 (9·3%) | 448              | 37 (8·3%)    |   |                   |
| Child faeces reported to be disposed of in a latrine | 526 | 148 (28%) | 448 | 141 (31%) |   |                   |
| Child wears diapers            | 526          | 342 (65%) | 447              | 294 (66%)    |   |                   |
| Caregiver completed primary school | 528  | 287 (54%) | 451              | 239 (53%)    |   |                   |
| Child's mother is alive        | 513          | 503 (98%) | 435              | 426 (98%)    |   |                   |
| Respondent is child's mother   | 519          | 368 (71%) | 443              | 284 (64%)    |   |                   |
| **Household level variables**  |              |   |                   |              |   |                   |
| Household population           | 441          | 5·4 (2·4) | 365              | 6·1 (3)      |   |                   |
| Household wealth score, 0 (poorer) - 1 (wealthier)\(^{‡}\) | 440 | 0·45 (0·1) | 365 | 0·44 (0·1) |   |                   |
| Household crowding, >3 persons/room | 440  | 54 (12%) | 365              | 60 (17%)     |   |                   |
| Household floor is covered\(^†\) | 440  | 426 (97%) | 365              | 333 (91%)    |   |                   |
| Household wall made of bricks, concrete, or similar\(^‡\)  | 440 | 304 (69%) | 365              | 215 (59%)    |   |                   |
| Household drinking water source inside compound | 435 | 324 (74%) | 360              | 294 (82%)    |   |                   |
| Latrine used by household has a ceramic or masonry pedestal\(^†\) | 432 | 153 (35%) | 359              | 142 (40%)    |   |                   |
| Latrine used by household has a drop-hole cover\(^‡\)  | 434 | 232 (53%) | 359              | 224 (62%)    |   |                   |
| **Compound level variables**   |              |   |                   |              |   |                   |
| Compound population            | 287          | 14 (6·2)  | 208              | 19 (12)      |   |                   |
| Number of households           | 287          | 3·8 (2·1) | 208              | 4·4 (3·7)    |   |                   |
| Number of water taps in compound | 283  | 0·98 (0·95)  | 207              | 1·4 (1·6)    |   |                   |
| Number of latrines in compound  | 287          | 1 (0·2)   | 207              | 1·1 (0·57)   |   |                   |
Latrine walls made of brick, concrete or similar | 282 | 72 (26%) | 204 | 67 (33%)  
Compound population density, persons/square meter* | 281 | 0.071 (0.04) | 205 | 0.087 (0.05)  
Compound has electricity that normally functions | 287 | 251 (87%) | 208 | 189 (91%)  
Compound prone to flooding | 287 | 184 (64%) | 208 | 120 (58%)  
Any animals observed in compound‡ | 287 | 170 (59%) | 208 | 132 (63%)  
Dog(s) observed‡ | 287 | 14 (4.9%) | 208 | 14 (6.7%)  
Chicken(s) or duck(s) observed‡ | 287 | 40 (14%) | 208 | 30 (14%)  
Cat(s) observed‡ | 287 | 149 (52%) | 208 | 116 (56%)  

Data are n (%) or mean (standard deviation) and collected by questionnaire unless otherwise noted. † Age range 32-1819 days, IQR 339-1021 days. ‡ Assessed using Simple Poverty Scorecard for Mozambique (http://www.simplepovertyscorecard.com/MOZ_2008_ENG.pdf).  
*Calculated as # of people living in the compound divided by the area of the compound in square meters.
We detected ≥1 bacterial or protozoan enteric pathogen in 78% (591/753) of stools and ≥1 STH in 45% (308/698) of stools at baseline. The prevalence of predefined outcomes, individual pathogens, and pathogen types were similar between arms at baseline (Table 2). The prevalence of most bacterial, protozoan, and STH infections increased with age while the prevalence of enteric viruses decreased with age (supplemental information p 14-16).

The characteristics of children with repeated observations (including baseline) were similar to characteristics of children measured at baseline only and similar to characteristics of children measured at 12-month and/or 24-month only with the exception of age-related characteristics (supplemental information p 17-26). Over half of the children enrolled after baseline were born into study sites (336/622 [54%], Figure 1).

Our main analyses included observations from all eligible children enrolled at baseline (mean sampling age 664 days, SD=393) and the 12-month (940 days, SD=498) and 24-month (1137 days, SD=603) follow-up visits. We found no evidence that the intervention had an effect on the prevalence of any bacterial or protozoan infection (primary outcome, adjusted PR 1·05, 95% CI [0·95 – 1·16]), or any STH re-infection (secondary outcome, 1·11 [0·89 – 1·38]) 12 months after implementation (Table 2). The prevalence of diarrhoea remained fairly constant in both arms in all three phases with the exception of the 12-month measure in the control arm which was lower, resulting in a larger effect estimate with low precision (1·69 [0·89-3·21]).
Table 2: Effect of the intervention on bacterial, protozoan, and STH infection and diarrhoea at 12 and 24 months post-intervention.

|                        | Prevalence | BL-12M Prevalence ratio* | BL-24M Prevalence ratio‡ |
|------------------------|------------|---------------------------|--------------------------|
|                        | Baseline   | 12-month | 24-month | unadjusted | adjusted† | unadjusted | adjusted† |
| **Any bacterial or protozoan infection‡** |            |          |          |           |           |           |           |
| Control                | 313/392 (80%) | 329/395 (83%) | 403/459 (88%) | -- | -- | -- | -- |
| Intervention           | 278/361 (77%) | 344/407 (85%) | 392/462 (85%) | 1·05 (0·95 - 1·16) | 1·05 (0·95 - 1·16) | 1·00 (0·91 - 1·10) | 0·99 (0·91 - 1·09) |
| **Any STH infection‡** |            |          |          |           |           |           |           |
| Control                | 170/360 (47%) | 143/283 (51%) | 142/253 (56%) | -- | -- | -- | -- |
| Intervention           | 138/329 (42%) | 150/305 (49%) | 136/292 (47%) | 1·12 (0·89 - 1·40) | 1·11 (0·89 - 1·38) | 0·94 (0·75 - 1·17) | 0·99 (0·77 - 1·17) |
| **Diarrhoea‡**         |            |          |          |           |           |           |           |
| Control                | 67/526 (13%) | 40/430 (9·3%) | 53/390 (14%) | -- | -- | -- | -- |
| Intervention           | 59/448 (13%) | 59/305 (14%) | 53/410 (13%) | 1·41 (0·80 - 2·48) | 1·69 (0·89 - 3·21) | 0·92 (0·55 - 1·54) | 0·84 (0·47 - 1·51) |
| **Any Bacteria**       |            |          |          |           |           |           |           |
| Control                | 271/392 (69%) | 281/395 (71%) | 345/459 (75%) | -- | -- | -- | -- |
| Intervention           | 227/361 (63%) | 285/407 (70%) | 324/462 (70%) | 1·08 (0·94 - 1·24) | 1·08 (0·95 - 1·24) | 1·03 (0·90 - 1·18) | 1·00 (0·87 - 1·15) |
| **Shigella**           |            |          |          |           |           |           |           |
| Control                | 179/392 (46%) | 201/395 (51%) | 269/459 (59%) | -- | -- | -- | -- |
| Intervention           | 152/361 (42%) | 213/407 (52%) | 245/462 (53%) | 1·12 (0·91 - 1·39) | 1·12 (0·92 - 1·36) | 0·98 (0·80 - 1·20) | 0·95 (0·79 - 1·16) |
| **ETEC**               |            |          |          |           |           |           |           |
| Control                | 116/392 (30%) | 136/395 (34%) | 127/459 (28%) | -- | -- | -- | -- |
| Intervention           | 110/361 (30%) | 144/407 (35%) | 126/462 (27%) | 0·99 (0·72 - 1·37) | 1·01 (0·73 - 1·41) | 0·95 (0·67 - 1·35) | 0·83 (0·57 - 1·19) |
| **Campylobacter**      |            |          |          |           |           |           |           |
| Control                | 39/392 (9·9%) | 31/395 (7·8%) | 48/459 (10%) | -- | -- | -- | -- |
| Intervention           | 21/361 (5·8%) | 33/407 (8·1%) | 34/462 (7·4%) | 1·74 (0·86 - 3·52) | 1·57 (0·76 - 3·25) | 1·20 (0·60 - 2·39) | 1·28 (0·62 - 2·62) |
| **C. difficile**       |            |          |          |           |           |           |           |
| Control                | 22/392 (5·6%) | 12/395 (3·0%) | 13/459 (2·8%) | -- | -- | -- | -- |
| Intervention           | 13/361 (3·6%) | 17/407 (4·2%) | 11/462 (2·4%) | 2·12 (0·77 - 5·83) | 2·27 (0·85 - 6·07) | 1·32 (0·47 - 3·73) | 1·41 (0·46 - 4·30) |
| **E. coli O157**       |            |          |          |           |           |           |           |
| Control                | 13/392 (3·3%) | 15/395 (3·8%) | 25/459 (5·5%) | -- | -- | -- | -- |
| Intervention           | 18/361 (5·0%) | 14/407 (3·4%) | 16/462 (3·5%) | 0·61 (0·23 - 1·63) | 0·59 (0·22 - 1·55) | 0·43 (0·15 - 1·29) | 0·52 (0·17 - 1·59) |
| **STEC**               |            |          |          |           |           |           |           |
| Control                | 3/392 (0·77%) | 8/395 (2·0%) | 17/459 (3·7%) | -- | -- | -- | -- |
| Pathogen                  | Control                      | Intervention                  | Odds Ratio | 95% CI       |
|---------------------------|------------------------------|------------------------------|------------|--------------|
| **Any Protozoa**          |                              |                              |            |              |
|                           | 205/392 (52%)                | 195/361 (54%)                | 0.86       | (0.22 - 3.33) |
|                           | 228/395 (58%)                | 253/407 (62%)                | 0.87       | (0.23 - 3.25) |
|                           | 303/459 (66%)                | 296/462 (64%)                | 0.46       | (0.11 - 1.93) |
| **Giardia**               |                              |                              |            |              |
|                           | 201/392 (51%)                | 186/361 (52%)                | 0.74       | (0.34 - 1.76) |
|                           | 222/395 (56%)                | 244/407 (60%)                | 0.71       | (0.42 - 1.21) |
|                           | 294/459 (64%)                | 289/462 (63%)                | 0.96       | (0.55 - 1.68) |
| **Cryptosporidium**       |                              |                              |            |              |
|                           | 8/392 (2%)                   | 16/361 (4.4%)                | 0.64       | (0.34 - 1.20) |
|                           | 8/395 (2.0%)                 | 15/407 (3.7%)                | 0.61       | (0.32 - 1.14) |
|                           | 14/459 (3.0%)                | 15/462 (3.3%)                | 1.00       | (0.52 - 1.93) |
| **Any virus**             |                              |                              |            |              |
|                           | 53/392 (14%)                 | 52/361 (14%)                 | 0.74       | (0.34 - 1.20) |
|                           | 52/395 (13%)                 | 43/407 (11%)                 | 0.71       | (0.42 - 1.21) |
|                           | 59/459 (13%)                 | 62/462 (13%)                 | 0.96       | (0.55 - 1.68) |
| **Norovirus GI/GII**      |                              |                              |            |              |
|                           | 38/392 (9.7%)                | 39/361 (11%)                 | 0.76       | (0.41 - 1.75) |
|                           | 46/395 (12%)                 | 35/407 (8.6%)                | 1.08       | (0.91 - 1.29) |
|                           | 47/459 (10%)                 | 55/462 (12%)                 | 1.08       | (0.91 - 1.29) |
| **Adenovirus 40/41**      |                              |                              |            |              |
|                           | 13/392 (3.3%)                | 9/361 (2.5%)                 | 0.76       | (0.41 - 1.75) |
|                           | 7/395 (1.8%)                 | 9/407 (2.2%)                 | 1.67       | (0.39 - 7.10) |
|                           | 7/459 (1.5%)                 | 6/462 (1.3%)                 | 1.18       | (0.23 - 5.98) |
| **Coinfection, ≥2 GPP pathogens** |                              |                              |            |              |
|                           | 206/392 (53%)                | 139/360 (39%)                | 0.95       | (0.80 - 1.12) |
|                           | 229/395 (58%)                | 124/253 (49%)                | 1.16       | (0.93 - 1.43) |
|                           | 302/459 (66%)                | 120/305 (39%)                | 0.89       | (0.69 - 1.16) |
| **Trichuris**             |                              |                              |            |              |
|                           | 185/361 (51%)                | 117/329 (36%)                | 0.80       | (0.67 - 1.10) |
|                           | 248/407 (61%)                | 120/305 (39%)                | 0.86       | (0.67 - 1.10) |
|                           | 282/462 (61%)                | 117/292 (40%)                |            |              |
| **Ascaris**               |                              |                              |            |              |
|                           | 95/360 (26%)                 | 117/329 (36%)                | 0.89       | (0.69 - 1.16) |
|                           | 82/283 (29%)                 | 120/305 (39%)                | 0.86       | (0.67 - 1.10) |
|                           | 78/253 (31%)                 | 117/292 (40%)                |            |              |
| **Coinfection, ≥2 STH**   |                              |                              |            |              |
|                           | 68/329 (21%)                 | 68/329 (21%)                 | 1.33       | (0.92 - 1.93) |
|                           | 87/305 (29%)                 | 56/292 (19%)                 | 0.80       | (0.52 - 1.21) |
|                           | 56/292 (19%)                 | 87/305 (29%)                 | 0.83       | (0.54 - 1.27) |
| **Any virus**             |                              |                              |            |              |
|                           | 120/354 (32%)                | 120/354 (32%)                | 0.80       | (0.63 - 1.03) |
|                           | 120/354 (32%)                | 120/354 (32%)                | 0.80       | (0.63 - 1.03) |
*Analysis includes all children measured at baseline and 12-month visits. ‡Analysis includes all children measured at baseline and 24-month visits. ‡Outcome was pre-specified in trial registration. All other outcomes are exploratory. †Pathogen outcomes adjusted for child age and sex, caregiver’s education, and household wealth index. Reported diarrhoea was also adjusted for baseline presence of a drop-hole cover and reported use of a tap on compound grounds as primary drinking water source. Sample sizes for adjusted analyses are slightly smaller than numbers presented in prevalence estimates due to missing covariate data. *Y. enterocolitica, V. cholerae, E. histolytica, and rotavirus A detected in <2% of samples in each arm at each phase. Descriptive data for these pathogens are available in the supplemental information.
The intervention had no relevant effect at 12 months on the prevalence of infection with any of the three pathogen types measured by the GPP (bacterial, protozoan, viral), pathogen coinfection, or on any individual pathogen (Table 2). There was poor precision in the effect estimates for infrequently detected pathogens, evident from their wide confidence intervals. Therefore, some estimates suggestive of a large protective or detrimental effect (Campylobacter, C. difficile, E. coli O157, STEC, Norovirus GI/GII, Adenovirus 40/41) may have arisen by chance. While the NDC provided albendazole to all compound members following baseline, during 12-month visitation only 58% of caregivers (56% control, 60% intervention) confirmed that their child was dewormed during these visits. A sensitivity analysis restricted to children confirmed to have been dewormed produced similar results to the main analysis (supplemental information p 27).

There was no evidence that the intervention had an effect on the prevalence of any bacterial or protozoan infection, any STH reinfection, or diarrhoea after 24-months (Table 2). We also found limited evidence of effect on the prevalence of any pathogen type or coinfection with ≥2 GPP pathogens 24-months after intervention. Results for several individual outcomes were suggestive of a protective (STEC, E. coli O157, Cryptosporidium, STH coinfection) or adverse (Campylobacter, C. difficile) effect but evidence was weak as estimates were accompanied by wide confidence intervals. At 24-months, caregivers confirmed baseline and/or 12-month deworming more frequently for intervention children (339/502 [68%]) than control children (286/499 [57%]). Adjustment for deworming status or time since deworming had no impact on effect estimates (supplemental information p 27).

Multivariable models for GPP outcomes and STH outcomes were adjusted for covariates selected a priori (child age, sex, caregiver education, and household wealth index) as no other variables
met our inclusion criteria. Point estimates of effect and associated confidence intervals were largely similar in unadjusted and adjusted models with few exceptions (e.g. ETEC at 24-month) (Table 2). For diarrhoea, two additional variables met our inclusion criteria and were included in adjusted models: presence of a latrine drop-hole cover at baseline and reported use of a water tap located within the compound grounds at baseline. The effect estimates were larger and confidence intervals wider for diarrhoea in adjusted versus unadjusted models in the 12-month and 24-month analyses (Table 2).

In sub-group analyses comparing children born into study compounds before the 24-month visit with children of similar ages at baseline (<2 years old), there was suggestive evidence that the intervention reduced the prevalence of infection with any STH by half (n= 522; adjusted prevalence ratio 0·51, [95% CI 0·27 - 0·95]), *Trichuris* by 76% (n=522; 0·24, [0·10 - 0·60]), and *Shigella* by 51% (n=630; 0·49, [0·28 - 0·85]) (Table 3). We did not observe similar results among children born into the study by the 12-month visit (supplemental information p 28-29), but the sample size was small, resulting in high uncertainty in effect estimates.

Longitudinal sub-group analyses explored the effect of the intervention on children with repeated measures at baseline and 12-month (for unadjusted analyses: n=572 for Kato-Katz outcomes, n=868 for GPP outcomes, and n=1112 for diarrhoea) and at baseline and 24-month (n=402, n=716, n=834). Effect estimates were consistent with results from the main analyses (supplemental information p 30-35) but less precise due to the reduced sample numbers.
Table 3: Effect of intervention on bacterial, protozoan, and STH infection and reported diarrhoea in children born into study sites post implementation (post-baseline) but by 24-month visit compared with children of a similar age at baseline (<2 years old).

|                          | Prevalence | Prevalence ratio |
|--------------------------|------------|------------------|
|                          | Baseline  | 24-month, Born-in | unadjusted | adjusted† |
| **Any bacterial or protozoan infection‡** |           |                  |            |          |
| Control                  | 158/228 (69%) | 79/106 (75%) |            |          |
| Intervention             | 129/201 (64%) | 71/107 (66%) | 0·96 (0·77 - 1·21) | 0·99 (0·80 - 1·22) |
| **Any STH infection‡**   |           |                  |            |          |
| Control                  | 67/205 (33%) | 25/68 (37%) |            |          |
| Intervention             | 52/183 (28%) | 13/75 (17%) | 0·52 (0·26 - 1·05) | 0·51 (0·27 - 0·95) |
| **Diarrhoea‡**           |           |                  |            |          |
| Control                  | 46/283 (16%) | 18/105 (17%) |            |          |
| Intervention             | 43/238 (18%) | 22/100 (22%) | 1·20 (0·57 - 2·5) | 1·37 (0·47 - 4·03) |
| **Any Bacteria**         |           |                  |            |          |
| Control                  | 142/228 (62%) | 70/106 (66%) |            |          |
| Intervention             | 102/201 (51%) | 51/107 (48%) | 0·89 (0·66 - 1·20) | 0·90 (0·67 - 1·19) |
| **Shigella**             |           |                  |            |          |
| Control                  | 67/228 (29%) | 36/106 (34%) |            |          |
| Intervention             | 49/201 (24%) | 15/107 (14%) | 0·48 (0·28 - 0·83) | 0·49 (0·28 - 0·85) |
| **ETEC**                 |           |                  |            |          |
| Control                  | 70/228 (31%) | 30/106 (28%) |            |          |
| Intervention             | 58/201 (29%) | 24/107 (22%) | 0·84 (0·46 - 1·52) | 0·85 (0·48 - 1·51) |
| **Campylobacter**        |           |                  |            |          |
| Control                  | 27/228 (12%) | 14/106 (13%) |            |          |
| Intervention             | 14/201 (7%) | 13/107 (12%) | 1·75 (0·63 - 4·87) | 1·75 (0·61 - 4·98) |
| **C. difficile**         |           |                  |            |          |
| Control                  | 20/228 (8·8%) | 7/106 (6·6%) |            |          |
| Intervention             | 13/201 (6·5%) | 7/107 (6·5%) | 1·33 (0·36 - 4·86) | 1·49 (0·41 - 5·44) |
| **E. coli O157**         |           |                  |            |          |
| Control                  | 7/228 (3·1%) | 3/106 (2·8%) |            |          |
| Intervention             | 9/201 (4·5%) | 2/107 (1·9%) | 0·45 (0·06 - 3·66) | 0·53 (0·07 - 4·24) |
| **STEC**                 |           |                  |            |          |
| Control                  | 1/228 (0·44%) | 2/106 (1·9%) |            |          |
| Intervention             | 9/201 (4·5%) | 1/107 (0·93%) | 0·05 (0·00 - 1·13) | 0·05 (0·00 - 1·26) |
| **Any Protozoa**         |           |                  |            |          |
| Control                  | 82/228 (36%) | 47/106 (44%) |            |          |
| Intervention             | 74/201 (37%) | 43/107 (40%) | 0·84 (0·55 - 1·28) | 0·90 (0·62 - 1·30) |
| **Giardia**              |           |                  |            |          |
| Pathogen                  | Control          | Intervention     | Odds Ratio | 95% CI          |
|--------------------------|------------------|------------------|------------|-----------------|
| **Cryptosporidium**      |                  |                  |            |                 |
| Control                  | 7/228 (3.1%)     | 5/106 (4.7%)     | 0.45       | 0.08 - 2.57     |
| Intervention             | 12/201 (6%)      | 5/107 (4.7%)     | 0.45       | 0.08 - 2.57     |
| **Any virus**            |                  |                  |            |                 |
| Control                  | 34/228 (15%)     | 18/106 (17%)     | 1.24       | 0.48 - 3.17     |
| Intervention             | 36/201 (18%)     | 17/107 (16%)     | 1.24       | 0.48 - 3.17     |
| **Norovirus GI/GII**     |                  |                  |            |                 |
| Control                  | 26/228 (11%)     | 12/106 (11%)     | 0.83       | 0.37 - 1.83     |
| Intervention             | 26/201 (13%)     | 17/107 (16%)     | 0.83       | 0.37 - 1.83     |
| **Adenovirus 40/41**     |                  |                  |            |                 |
| Control                  | 7/228 (3.1%)     | 4/106 (3.8%)     | 1.26       | 0.48 - 3.17     |
| Intervention             | 7/201 (3.5%)     | 0/107 (0.0%)     | 1.26       | 0.48 - 3.17     |
| **Coinfection, ≥2 GPP pathogens** |      |                  |            |                 |
| Control                  | 92/228 (40%)     | 52/106 (49%)     | 0.82       | 0.36 - 1.91     |
| Intervention             | 74/201 (37%)     | 39/107 (36%)     | 0.82       | 0.36 - 1.91     |
| **Trichuris**            |                  |                  |            |                 |
| Control                  | 48/205 (23%)     | 18/68 (26%)      | 0.25       | 0.09 - 0.68     |
| Intervention             | 41/183 (22%)     | 5/75 (6.7%)      | 0.25       | 0.09 - 0.68     |
| **Ascaris**              |                  |                  |            |                 |
| Control                  | 45/205 (22%)     | 16/68 (24%)      | 0.70       | 0.30 - 1.64     |
| Intervention             | 29/183 (16%)     | 9/75 (12%)       | 0.70       | 0.30 - 1.64     |
| **Coinfection, ≥2 STH**  |                  |                  |            |                 |
| Control                  | 26/205 (13%)     | 9/68 (13%)       | 0.24       | 0.08 - 0.73     |
| Intervention             | 18/183 (9.8%)    | 1/75 (1.3%)      | 0.24       | 0.08 - 0.73     |

Analysis includes children <2 years old at baseline and children born into the study after baseline and <2 years old at the time of the 24-month visit. ‡Outcome was pre-specified in trial registration. All other outcomes are exploratory. Pathogen outcomes adjusted for child age and sex, caregiver’s education, and household wealth index. Reported diarrhoea was also adjusted for baseline presence of a drop-hole cover and reported use of a tap on compound grounds as primary drinking water source. Sample sizes for adjusted analyses are slightly smaller than numbers presented in prevalence estimates due to missing covariate data. Models would not converge due to sparse data. Y. enterocolitica, V. cholerae, E. histolytica, and rotavirus A were detected in <2% of samples in each arm at each phase and excluded. Descriptive data for these pathogens are available in the supplemental information.
Discussion

We found no evidence that this urban, onsite shared sanitation intervention was protective for our pre-specified child health outcomes of enteric infection, STH reinfection, or diarrhoea. We also found no strong evidence that the intervention affected prevalence of any individual pathogen, pathogen type, or coinfection with ≥2 enteric pathogens or STH. In exploratory sub-group analyses, we found suggestive evidence that the intervention may have reduced the prevalence of any STH, Trichuris, and Shigella infections among children born into the study by the 24-month follow-up visit. Studying children born into intervention sites after implementation allowed us to examine the effect of the intervention from birth through the first two years of life. This result suggests that the intervention delayed pathogen exposure and the accumulation of enteric infections during early childhood, but it needs to be treated with caution as this was an exploratory subgroup analysis and included multiple comparisons.

To our knowledge, MapSan was the first trial to estimate the health impact of an urban, onsite shared sanitation intervention. Most of the urban sanitation literature published to date has demonstrated reductions in diarrhoea and enteric parasite infection,(Barreto et al., 2010; Norman et al., 2010) but has focused on the expansion of sewerage. Our findings are consistent with the results of recent, large-scale, rigorous trials of basic water, sanitation, and hygiene improvements in rural areas, which found mixed effects on health outcomes including linear growth, diarrhoea, and enteric infection.(Clasen et al., 2014; Ercumen et al., 2019; Humphrey et al., 2019; Lin et al., 2018; Luby et al., 2018; Null et al., 2018; Pickering et al., 2015; Rogawski McQuade et al., 2019)

In this setting, where fecal contamination was pervasive and burden of infection high,(Holcomb et al., 2020; Knee et al., 2018) even considerable reductions in contamination and exposure may
have been insufficient to realize measurable health gains. (Julian, 2016) The intervention did not address child faeces disposal practices or handwashing behaviours and it is unlikely that the intervention infrastructure would have changed these. (Majorin et al., 2019) The intervention may not have reduced exposure via consumption of contaminated food – particularly foods contaminated prior to arrival in the compound – an important source of enteric pathogen transmission in some settings. (Julian, 2016) Children’s exposure to animal faeces has been documented in rural, peri-urban, and urban settings and could be an important, unmitigated source of exposure to enteric pathogens in both intervention and control arms where animals were frequently observed. (Penakalapati et al., 2017) Observation of animals in compounds was examined as a potential confounder but did not change effect estimates.

While we hypothesized that the majority of exposures young children experienced in this setting occurred in the compound, (Brown et al., 2015) exposure to external sources of contamination could have influenced health outcomes. The proximity of intervention and non-intervention compounds and movement of adults, school-aged children, free-roaming animals, and flies, may have increased the likelihood of exposure to external sources of faecal contamination within the compound boundaries. The intervention was not designed to achieve a sanitation coverage threshold in the study neighborhoods, which may be necessary to reduce disease burdens. (Wolf et al., 2018) We did not measure neighborhood-level exposures, which may be important even for young children, (Medgyesi et al., 2019) and their impact on our health outcomes is unclear. Further, the transience of the study population meant that trips to provinces outside of Maputo, where exposures were varied and unmeasured, were common.
It is unlikely that our findings are due to poor intervention fidelity or use, an issue encountered in trials of rural sanitation interventions. (Clasen et al., 2014) The use of the intervention required minimal behaviour change as the existing latrine was replaced with a new hygienic latrine. It is possible that development in the study neighborhoods, including changes to sanitation facilities in control compounds, contributed to the limited effect of the intervention. By the 12-month visit, 19 control compounds (19/240 [8.0%]) had independently upgraded their facilities to pour-flush toilets, and by the 24-month visit, 35 control compounds (35/211 [17%]) had upgraded their facilities. Results from sensitivity analyses excluding children living in control compounds with independently upgraded facilities were consistent with the main results (supplemental information p 36).

While the NDC dewormed every study compound annually during the study period, it is possible that not all study participants received, or took, the medication and that the time between deworming and subsequent measurement of re-infection varied among children. Additionally, single-dose albendazole can have limited effectiveness against certain STH, notably *Trichuris.* (Moser et al., 2017) Inadequate or ineffective deworming could have limited our ability to detect an effect on STH outcomes. Sensitivity analyses adjusting for caregiver-confirmed deworming and estimated time between deworming and re-infection measurement produced similar results to the main analysis (supplemental information p 28).

There are several important limitations of this study. As the intervention was pre-planned and not implemented by the study team, we could not randomize its allocation, increasing the risk of confounding. We assessed potential confounding variables at baseline and used a DID analysis, which accounts for baseline outcome measures, to limit the effect of unmeasured, residual
confounding. To assess the validity of the parallel trend assumption, a key assumption of DID analyses, we ran “placebo tests” by replacing outcomes with variables unrelated to the intervention, such as child age, respondent role, and presence of animals. Placebo tests showed no effect of the intervention on these variables.

It was not possible to mask participants to their intervention status, and our measure of caregiver-reported diarrhoea could be subject to respondent and recall biases. To reduce the risk of respondent bias, the MapSan field enumerator team and implementation team were different, and respondents were not informed explicitly that the MapSan team was evaluating the health effect of the intervention. To limit recall bias, we used a 7-day recall period. Our other pre-specified outcomes were objective measures of pathogen infection and not subject to the same biases.

Due to the greater than expected losses to follow-up in both study arms, we were not able to follow all children enrolled at baseline through time as expected, but we still achieved our target enrolment numbers due to migration and births into study compounds. We conducted the originally planned longitudinal analysis as a sub-group analysis. It also served as a sensitivity analysis to estimate the impact of migration on our effect estimates. Results from this sub-group analysis were largely similar to results of the main analysis which treated measures as repeated cross-sections, though the reduction in sample size led to wider confidence intervals (supplemental information p 30-35). Measures of outcomes and covariates in children with and without repeated measures were mostly similar, further limiting the likelihood that changes in the study population biased our results.
While molecular detection of enteric pathogens in stool is evidence of pathogen exposure, it is not necessarily evidence of active infection, making its clinical significance less clear. (Brown & Cumming, 2019) We assumed pathogen detection by the GPP indicated infection because the assay’s limits of detection exceeded the median infectious dose of most pathogens. While the GPP detects many enteric pathogens recognized as important causes of childhood diarrhoea in LMICs, (Liu et al., 2016) it does not detect all enteric pathogens of importance. Further, qualitative, cross-sectional analysis of stools does not provide information on the duration or intensity of infection. Some studies have demonstrated overall good performance of the GPP but observed elevated false positive detection rates for the *Salmonella* targets. (Duong et al., 2016; Kellner et al., 2019) For this reason, we removed *Salmonella* results from our pre-specified outcome definition. Results from analyses including and excluding *Salmonella* were similar.

We had limited ability to evaluate the impact of seasonality or weather-related trends on our effect estimates due to drought conditions during the 2015/2016 rainy season. We assessed cumulative 30-day rainfall as a potential confounder but excluded it because it did not meet our inclusion criteria for adjusted models.

Our results demonstrate that access to hygienic, shared onsite sanitation systems was not sufficient to reduce enteric infection or diarrhoea in children aged 6 years or younger (≤4 at baseline) 12-24 months after implementation. Results from our sub-group analysis of children born into intervention sites showed a substantial reduction in the prevalence of any STH, *Trichuris*, and *Shigella* infection, suggesting that children may require protection from birth to delay infection. Our results do not suggest that shared sanitation is inadvisable in this setting, as we did not compare against household-level sanitation improvements, nor do they account for the many non-health
related benefits associated with this intervention or upgraded sanitation generally.(Shiras et al., 2018)

The need for effective sanitation solutions may be most urgent in densely populated, low-income, informal communities like our study setting where ubiquitous fecal contamination drives high infection burdens. Disease transmission in these settings may be driven by multiple interrelated pathways, complicated by frequent migration and the diversity of circulating pathogens, and therefore difficult to interrupt. While decades of research have demonstrated meaningful health gains following sanitation improvements, the results of this study, and other rigorous trials of sanitation interventions, suggest that the relationship between sanitation and health is complex, difficult to measure, and may not be generalizable across diverse settings and populations.

Contributors

JB as principal investigator and OC as co-principal investigator designed the trial and drafted the study protocol with input from WPS, JK, DH, PK, JS, VZ, and RN. JK was the study manager, co-led laboratory work and data analysis with TS, and drafted the manuscript. TS curated the data, designed data collection tools and activities with JK, and produced figures. ZA led field data collection. CA, FB, DC, VC, EM, JMB, CR, WZ helped with sample organization and laboratory analysis. WPS designed the analytical approach and JK, DH, and AM helped refine it. JB and OC secured funding for the trial. All authors contributed critically to the final version of the manuscript.
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Data sharing

De-identified participant data which underlie the results reported in this manuscript will be made available beginning three months after publication and ending 60 months after publication. A corresponding data dictionary, the study protocol, and analysis plan and code will also be available for the stated period. Data will be available to researchers who provide a methodologically sound proposal. Proposals for data use can be submitted to joe.brown@ce.gatech.edu and authors of approved proposals will need to sign a data access agreement. Once approved, requestors will be able to access data on the MapSan trial Open Science Forum website (https://osf.io/p5shk). The published trial protocol can be accessed at: https://bmjopen.bmj.com/content/5/6/e008215.

Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.
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Supplemental information for Effects of an urban sanitation intervention on childhood enteric infection and diarrhoea in Maputo, Mozambique

Figure 1: Cumulative enrolment and stool sample collection profile for intervention and control children during (a) baseline, (b) 12-month, and (c) 24-month phases.

Figure 2b: Construction of a soakaway pit for discharge of liquid effluent from intervention latrines.

Figure 3: Map illustrating locations of intervention and control sites (compounds).

Figure 4a: Photo of communal sanitation block as constructed

Figure 4b: Photo of shared latrine as constructed

Consent procedures, survey administration, and specimen collection

Table 1: Confounding assessment for primary outcome and both secondary outcomes (any STH, diarrhoea) at 12-month.

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Table 3: Age stratified baseline prevalence of bacterial, protozoan, viral, and STH infections and diarrhoea in children.

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Table 6: Balance of characteristics measured at 12-month visits between children with repeat observations at BL and 12-month and children with only 12-month observations.

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Table 10: Effect of the intervention on children with repeated observations at baseline and 12-month visit.

Table 11: Effect of the intervention on children with repeated observations at baseline and 24-month visit.

Table 12: Sensitivity analysis assessing impact of independent upgrading of control sanitation facilities on effect estimates.

Table 13: Consort 2010 Checklist Extension for Cluster Trials.
Figure 1: Cumulative enrolment and stool sample collection profile for intervention and control children during (a) baseline, (b) 12-month, and (c) 24-month phases.
Figure 2a: Schematic of communal sanitation block design from the NGO (Water and Sanitation for the Urban Poor). Pictured: 2 latrine stalls, 2 pour-flush toilets, septic tank, elevated water storage tank, laundry basin, door. Not pictured: soakaway pit. Source: Water and Sanitation for the Urban Poor.
Figure 2b: Construction of a soakaway pit for discharge of liquid effluent from intervention latrines.
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Consent procedures, survey administration, and specimen collection

Enumerators visited households with enrolled children at least twice at each point of follow-up. On the first visit of each phase enumerators completed consent procedures, administered child-, household-, and compound-level surveys, and delivered stool specimen collection supplies. The child’s mother was the target respondent for child and household surveys, though the father or another guardian was also eligible. For compound-level surveys, the head of the compound or his or her spouse was the preferred respondent. We sought written, informed consent from the parent or guardian of each eligible child prior to initial enrolment. We sought verbal assent from parents or guardians at each follow-up visit. Consent procedures, surveys, and all study-related verbal communication was performed in Portuguese or Changana as requested by the participant. Written materials were provided in Portuguese.

Enumerators provided each caregiver with stool collection supplies, including disposable diapers, a plastic potty if the child was no longer wearing diapers, and a pre-labeled sterile sample bag. Enumerators returned the next day to collect the specimens. If a specimen was unavailable during the scheduled pickup, caregivers called the field team, using phone credit provided by the study, as soon as one was available or if fresh collection supplies were needed. If field enumerators were unable to collect a stool sample after multiple attempts, a registered nurse used an anatomically designed rectal swab (Copan Diagnostics Inc, Murrieta, CA, USA) to collect fecal material.

Parents or guardians were required to complete a separate written consent procedure prior to collection of rectal swabs. Stool specimens and rectal swabs were stored in coolers with cold packs and delivered to the Medical Parasitology Laboratory at the Mozambican Ministry of Health (MISAU/INS) within six hours of collection.

Technicians at INS prepared Kato Katz slides for soil-transmitted helminth (STH) detection the day of receipt and read results within 30 minutes of preparation for hookworm and within 24 hours for other STH. In addition to STH analysis, laboratory technicians at INS also aliquoted stools into several sterile tubes and stored them, and any rectal swabs, at -80°C. If a child produced a liquid stool, lab technicians stored a piece of the saturated diaper material (“diaper samples”) at -80°C. Stool samples were shipped frozen on dry ice with temperature probes to the Georgia Institute of Technology in Atlanta, Georgia, USA where they were stored at -80°C until analysis.

We followed manufacturer instructions for the pretreatment, extraction, and analysis of stool specimens by the Luminex Gastrointestinal Pathogen Panel (GPP) with additional elution steps added to the pretreatment protocol for rectal swabs and diaper samples. We eluted diaper samples in 2.5 mL of lysis buffer (ASL buffer, Qiagen, Hilden, Germany). We used a sterile 10-mL syringe to facilitate elution via agitation by taking in and expelling the buffer 5 times. We used 1 mL of the final eluate in the pretreatment. We agitated rectal swabs in 1 mL of lysis buffer for 1 minute and used the eluate in the pretreatment. Following pretreatment, we extracted DNA and RNA using the QIAcube HT platform and the QIAamp 96 Virus QIAcube HT Kit (Qiagen, Hilden, Germany). We added MS2, a non-pathogenic RNA virus, to each sample prior to nucleic acid extraction as an extraction and RT-PCR inhibition control. We included at least one sample process control (containing only lysis buffer and MS2) and negative extraction control (containing only lysis buffer) with each set of extractions. During the PCR step, we included at least one no-template control, containing molecular grade water and all PCR reagents, with each run. To assess elution and extraction of nucleic acid from diaper and swab samples, we measured the concentration of double-stranded DNA (dsDNA) present in extracts using the Qubit® High Sensitivity dsDNA kit (Invitrogen™, Carlsbad, CA, USA) and Qubit® 4 Fluorimeter (Invitrogen™, Carlsbad, CA, USA). Following extraction, we stored all extracts at 4°C and analyzed them by GPP within 24 hours. For long-term storage, we archived samples at -80°C. We extracted and analyzed approximately 10% of samples in duplicate. If duplicate analyses yielded different results, we combined the results from all analyses. If we could not detect a MS2 signal in a given sample, we either re-extracted or diluted the extract 1:10 in molecular grade water and re-assayed by GPP.
| Variable | Control | Interv. | Primary outcome Unadjusted | Primary outcome Adjusted | Any STH Unadjusted | Any STH Adjusted | Diarrhoea Unadjusted | Diarrhoea Adjusted |
|----------|---------|---------|---------------------------|--------------------------|-------------------|-----------------|---------------------|-------------------|
| Female   | 266/520 (51%) | 227/444 (51%) | 259/454 (51%) | 0.00 | 1.05 (0.95 - 1.16) | 1.05 (0.95 - 1.16) | 1.05 (0.95 - 1.16) | 1.05 (0.95 - 1.16) |
| Any breastfeeding | 169/526 (32%) | 143/448 (32%) | 0.00 | 1.06 (0.96 - 1.16) | 1.05 (0.96 - 1.16) | 1.11 (0.90 - 1.38) | 1.11 (0.90 - 1.38) | 1.39 (0.79 - 2.46) | 1.32 (0.75 - 2.33) |
| Caregiver completed primary school | 207/528 (54%) | 239/451 (53%) | 0.03 | 1.05 (0.95 - 1.16) | 1.05 (0.95 - 1.16) | 1.12 (0.90 - 1.41) | 1.11 (0.89 - 1.38) | 1.40 (0.80 - 2.48) | 1.32 (0.75 - 2.33) |
| Respondent is mother | 368/519 (71%) | 284/443 (64%) | 0.15 | 1.06 (0.96 - 1.17) | 1.05 (0.95 - 1.16) | 1.13 (0.90 - 1.42) | 1.11 (0.89 - 1.38) | 1.37 (0.78 - 2.42) | 1.29 (0.73 - 2.28) |
| HH floors covered | 511/530 (96%) | 413/453 (91%) | 0.22 | 1.05 (0.95 - 1.16) | 1.05 (0.95 - 1.16) | 1.12 (0.89 - 1.40) | 1.12 (0.90 - 1.39) | 1.39 (0.79 - 2.47) | 1.32 (0.74 - 2.34) |
| HH walls sturdy material | 370/530 (70%) | 272/453 (60%) | 0.21 | 1.05 (0.95 - 1.15) | 1.05 (0.95 - 1.15) | 1.12 (0.89 - 1.40) | 1.11 (0.89 - 1.38) | 1.41 (0.80 - 2.48) | 1.32 (0.75 - 2.33) |
| Drinking water source in compound | 386/522 (74%) | 367/448 (82%) | 0.19 | 1.03 (0.93 - 1.14) | 1.02 (0.93 - 1.13) | 1.08 (0.85 - 1.36) | 1.05 (0.83 - 1.33) | 1.65 (0.89 - 3.06) | 1.59 (0.85 - 2.95) |
| Faeces visible around compound grounds | 282/521 (54%) | 171/447 (38%) | 0.32 | 1.03 (0.93 - 1.13) | 1.03 (0.93 - 1.13) | 1.14 (0.91 - 1.43) | 1.12 (0.90 - 1.40) | 1.43 (0.81 - 2.54) | 1.35 (0.76 - 2.40) |
| Compound floods when it rains | 348/533 (65%) | 255/454 (56%) | 0.19 | 1.05 (0.95 - 1.16) | 1.05 (0.95 - 1.16) | 1.12 (0.89 - 1.40) | 1.11 (0.89 - 1.38) | 1.41 (0.80 - 2.49) | 1.32 (0.74 - 2.33) |
| Latrine drop-hole has cover | 278/521 (53%) | 274/447 (61%) | 0.16 | 1.03 (0.93 - 1.14) | 1.03 (0.93 - 1.13) | 1.10 (0.87 - 1.39) | 1.07 (0.85 - 1.35) | 1.71 (0.90 - 3.24) | 1.65 (0.87 - 3.14) |
| Latrine has ceramic/concrete slab or pedestal | 181/518 (35%) | 176/447 (39%) | 0.09 | 1.03 (0.93 - 1.14) | 1.03 (0.93 - 1.14) | 1.10 (0.87 - 1.39) | 1.07 (0.85 - 1.35) | 1.71 (0.90 - 3.24) | 1.65 (0.87 - 3.14) |
| Latrine walls made of sturdy material | 142/521 (27%) | 161/447 (36%) | 0.19 | 1.04 (0.94 - 1.14) | 1.03 (0.94 - 1.14) | 1.14 (0.91 - 1.43) | 1.12 (0.90 - 1.40) | 1.42 (0.80 - 2.51) | 1.33 (0.75 - 2.37) |
| Standing water observed around compound | 14/521 (2.7%) | 56/447 (13%) | 0.38 | 1.03 (0.94 - 1.14) | 1.03 (0.94 - 1.14) | 1.14 (0.91 - 1.42) | 1.12 (0.90 - 1.39) | 1.42 (0.80 - 2.51) | 1.34 (0.75 - 2.38) |
| Leaking or standing wastewater observed around grounds | 363/521 (70%) | 241/447 (54%) | 0.33 | 1.03 (0.94 - 1.14) | 1.03 (0.94 - 1.14) | 1.14 (0.91 - 1.43) | 1.12 (0.90 - 1.40) | 1.42 (0.80 - 2.51) | 1.34 (0.75 - 2.38) |
| Compound has electricity that normally functions | 467/533 (88%) | 420/454 (93%) | 0.16 | 1.05 (0.95 - 1.16) | 1.05 (0.95 - 1.16) | 1.11 (0.89 - 1.39) | 1.11 (0.89 - 1.38) | 1.41 (0.80 - 2.48) | 1.32 (0.75 - 2.34) |
| Any animal observed in compound | 318/533 (60%) | 303/454 (67%) | 0.15 | 1.05 (0.95 - 1.16) | 1.05 (0.95 - 1.16) | 1.13 (0.91 - 1.41) | 1.13 (0.91 - 1.40) | 1.39 (0.79 - 2.44) | 1.29 (0.73 - 2.28) |
| Dog observed | 28/533 (5.3%) | 46/454 (10%) | 0.18 | 1.05 (0.95 - 1.16) | 1.05 (0.95 - 1.16) | 1.13 (0.90 - 1.41) | 1.12 (0.90 - 1.39) | 1.38 (0.79 - 2.40) | 1.30 (0.75 - 2.27) |
| Chicken or duck observed | 70/533 (13%) | 60/454 (13%) | 0.00 | 1.05 (0.96 - 1.16) | 1.05 (0.96 - 1.16) | 1.12 (0.90 - 1.41) | 1.12 (0.90 - 1.40) | 1.37 (0.78 - 2.40) | 1.27 (0.72 - 2.23) |
| Cat observed | 287/533 (54%) | 259/454 (57%) | 0.06 | 1.05 (0.95 - 1.16) | 1.05 (0.95 - 1.16) | 1.14 (0.91 - 1.42) | 1.13 (0.91 - 1.41) | 1.39 (0.79 - 2.45) | 1.30 (0.74 - 2.29) |

Table 1: Confounding assessment for primary outcome and both secondary outcomes (any STH, diarrhoea) at 12-month.
|                          |   |   |   |   |   |   |   |   |
|--------------------------|----|----|----|----|----|----|----|----|
| **Compound density, terciles** |   |   |   |   |   |   |   |   |
| 0 (least dense)          | 199/519 (38%) | 120/447 (27%) |   |   |   |   |   |   |
| 1                       | 195/519 (38%) | 137/447 (31%) |   |   |   |   |   |   |
| 2 (most dense)           | 125/519 (24%) | 190/447 (43%) |   |   |   |   |   |   |
| **Child age at survey, days** |   |   |   |   |   |   |   |   |
|                          | 700 (405) | 694 (403) | 0·02 |   |   |   |   |   |
| **Child age at sample, days** |   |   |   |   |   |   |   |   |
|                          | 659 (396) | 669 (391) | 0·03 |   |   |   |   |   |
| **Cumulative monthly rainfall at survey, mm** |   |   |   |   |   |   |   |   |
|                          | 22 (23) | 23 (24) | 0·07 |   |   |   |   |   |
| **Cumulative monthly rainfall at sample, mm** |   |   |   |   |   |   |   |   |
|                          | 25 (30) | 32 (38) | 0·19 |   |   |   |   |   |
| **Wealth score**          | 0·44 (0·1) | 0·43 (0·1) | 0·16 |   |   |   |   |   |
| **Number HH residents**   | 5·7 (2·7) | 6·6 (3·4) | 0·32 |   |   |   |   |   |
| **Number of Compound residents** | 16 (7·3) | 25 (19) | 0·64 |   |   |   |   |   |
| **Number of compound latrines** | 1 (0·22) | 1·2 (0·9) | 0·33 |   |   |   |   |   |
| **Number of compound waterpoints** | 0·99 (0·98) | 1·9 (2·4) | 0·47 |   |   |   |   |   |

*Standardized difference between arms in baseline covariates. † Compared with 12-month unadjusted prevalence ratio. ‡ Compared with 12-month prevalence ratio adjusted for a priori covariates child age, sex, caregiver education, and poverty. ‡‡ Compared with 12-month prevalence ratio adjusted for covariates child age, sex, caregiver education, and poverty.
Table 2: Outcome and covariate descriptions, coding, and % missing.

|                          | Baseline, n=987 | 12-month, n=939 | 24-month, n=1001 | Variable description                                                                 | Data source                                                                 |
|--------------------------|-----------------|-----------------|------------------|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| **Outcome Data**         |                 |                 |                  |                                                                                      |                                                                            |
| Enteric infection outcome | 24              | 15              | 8.0              | Binary; 0/1                                                                          | Based on collection of stool material and successful analysis by GPP         |
| STH infection outcome    | 30              | 37              | 46               | Binary; 0/1                                                                          | Based on collection of stool material and successful analysis by Kato-Katz   |
| Caregiver-reported       | 1.3             | 7.8             | 20               | Binary; 0/1                                                                          | Child Survey                                                               |
| diarrhoea, 7-day recall  |                 |                 |                  |                                                                                      |                                                                            |
| **Covariate data**       |                 |                 |                  |                                                                                      |                                                                            |
| Child sex, female        | 2.3             | 1.3             | 7.0              | Binary; 0=male, 1=female                                                               | Child Survey                                                               |
| Respondent is child's    | 2.5             | 7.6             | 20               | Binary; 0/1                                                                          | Child Survey                                                               |
| mother                   |                 |                 |                  |                                                                                      |                                                                            |
| Child completed primary   | 0.8             | 1.7             | 6.7              | Binary; 0/1                                                                          | Child Survey                                                               |
| school                   |                 |                 |                  |                                                                                      |                                                                            |
| Child exclusively         | 1.3             | 7.7             | 20               | Binary; 0/1                                                                          | Child Survey                                                               |
| breastfeeds              |                 |                 |                  |                                                                                      |                                                                            |
| Child wears a diaper     | 1.4             | 7.6             | 20               | Binary; 0/1                                                                          | Child Survey                                                               |
| Child faeces disposed    | 1.3             | 7.1             | 20               | Binary; 0/1                                                                          | Created from survey questions in Child Survey                               |
| in a latrine             |                 |                 |                  |                                                                                      |                                                                            |
| Child age at sampling,   | 23              | 16              | 17               | Integer                                                                              | Created from birthdate (Child Survey) and date of sampling                  |
| days                     |                 |                 |                  |                                                                                      |                                                                            |
| Child age at survey,     | 2.6             | 7.5             | 19               | Integer                                                                              | Created from birthdate (Child Survey) and date of Survey                    |
| days                     |                 |                 |                  |                                                                                      |                                                                            |
| 30-day cumulative rainfall| 22              | 14              | 10               | Continuous                                                                           | Created from sample date and data from the National Oceanic and Atmospheric Information (https://www.ncdc.noaa.gov/cdo-web/datatools/findstation) |
| at sampling              |                 |                 |                  |                                                                                      |                                                                            |
| Household crowding, >3   | 0.4             | 0.3             | 2.7              | Binary; 0/1                                                                          | Created from questions in Household Survey                                 |
| persons/room             |                 |                 |                  |                                                                                      |                                                                            |
| Household floor covered  | 0.4             | 0.3             | 2.7              | Binary; 0/1                                                                          | Observation                                                                |
|                          |                 |                 |                  |                                                                                      |                                                                            |
| Household walls made of  | 0.4             | 0.3             | 2.7              | Binary; 0/1                                                                          | Observation                                                                |
| concrete, bricks or      |                 |                 |                  |                                                                                      |                                                                            |
| similar                  |                 |                 |                  |                                                                                      |                                                                            |
| Household population     | 0.3             | 0.3             | 1.6              | Integer                                                                              | Household survey                                                           |
|                          |                 |                 |                  |                                                                                      |                                                                            |
| Number of rooms in       | 0.4             | 0.3             | 2.3              | Integer                                                                              | Created from questions in Household Survey                                 |
| household                |                 |                 |                  |                                                                                      |                                                                            |
| Wealth score, 0 (poorest) | 0.4             | 0.3             | 2.7              | Continuous                                                                           | Created from questions in Household Survey using Simple Poverty Scorecard for Mozambique (http://www.simplepoverty.sourceforge.com/MOZ_2008_ENG.pdf). Questions referencing latrine removed from 12-month and 24-month score. All scores normalized by total number of points available. |
| (wealthiest), unitless   |                 |                 |                  |                                                                                      |                                                                            |
| Household uses tap in    | 1.7             | 1.0             | 2.0              | Binary; 0/1                                                                          | Created from drinking water source question in Household Survey             |
| compound as primary      |                 |                 |                  |                                                                                      |                                                                            |
| drinking water source    |                 |                 |                  |                                                                                      |                                                                            |
| Latrine has drop-hole    | 1.9             | 0.0             | 0.0              | Binary; 0/1                                                                          | Observation                                                                |
| cover                    |                 |                 |                  |                                                                                      |                                                                            |
| Latrine has a ventpipe   | 1.8             | 0.0             | 0.0              | Binary; 0/1                                                                          | Observation                                                                |
| Latrine has a ceramic,   | 2.2             | 0.1             | 0.1              | Binary; 0/1                                                                          | Observation                                                                |
| tile, or concrete        |                 |                 |                  |                                                                                      |                                                                            |
| pedestal or slab         |                 |                 |                  |                                                                                      |                                                                            |
| Latrine has sturdy walls made of concrete, bricks, or similar. | 1.9 | 0.0 | 0.0 | Binary; 0/1 | Observation |
|---------------------------------------|------|-----|-----|-------------|------------|
| Compound population                   | 0.0  | 0.0 | 0.0 | Integer     | Compound Survey, enrolment checklists |
| Number of households in compound      | 0.0  | 0.0 | 0.0 | Integer     | Compound Survey, enrolment checklists |
| Number of latrines present in the compound | 0.1 | 0.0 | 0.0 | Integer | Compound Survey |
| Persons per latrine                   | 1.8  | 0.1 | 0.3 | Continuous  | Created by dividing the compound population by the number of latrines/drop-holes |
| Households per latrine                | 1.8  | 0.1 | 0.3 | Continuous  | Created by dividing the number of households in the compound by the number of latrines in the compound |
| Number of water taps present in the compound | 1.1 | 0.0 | 0.0 | Integer | Compound Survey |
| Standing water visible around compound grounds | 1.9 | 0.3 | 0.0 | Binary; 0/1 | Observation |
| Standing or leaking wastewater visible around compound grounds | 1.9 | 0.3 | 0.0 | Binary; 0/1 | Observation |
| Faeces or used diapers observed around compound grounds or in solid waste | 1.9 | 0.3 | 0.0 | Binary; 0/1 | Observation |
| Compound floods when it rains         | 0.0  | 0.0 | 0.0 | Binary; 0/1 | Compound Survey |
| Compound has electricity that normally functions | 0.0 | 0.0 | 0.0 | Binary; 0/1 | Compound Survey |
| Compound-level population density     | 2.2  | 1.5 | 1.5 | Continuous, persons/m² | Created by dividing the population of the compound by the measured area of the compound |
| Any animal present in the compound    | 0.0  | 0.0 | 0.0 | Binary; 0/1 | Observation |
| Dog(s) present in the compound        | 0.0  | 0.0 | 0.0 | Binary; 0/1 | Observation |
| Chicken(s) and/or duck(s) present in the compound | 0.0 | 0.0 | 0.0 | Binary; 0/1 | Observation |
| Cat(s) present in the compound        | 0.0  | 0.0 | 0.0 | Binary; 0/1 | Observation |
| Any other animal(s) present in the compound | 0.0 | 0.0 | 0.0 | Binary; 0/1 | Observation |
Table 3: Age stratified baseline prevalence of bacterial, protozoan, viral, and STH infections and diarrhoea in children.

|                       | Baseline Prevalence | 1 - 11 months | 12-23 months | 24 - 48 months |
|-----------------------|---------------------|---------------|--------------|---------------|
| **Any bacterial or protozoan infection** |                     |               |              |               |
| All children          | 108/208 (52%)       | 179/221 (81%) | 277/297 (93%)|
| Control               | 57/109 (52%)        | 101/119 (85%) | 143/152 (94%)|
| Intervention          | 51/99 (52%)         | 78/102 (76%)  | 134/145 (92%)|
| **Any STH infection** |                     |               |              |               |
| All children          | 30/185 (16%)        | 89/203 (44%)  | 171/277 (62%)|
| Control               | 17/93 (18%)         | 50/112 (45%)  | 94/144 (65%) |
| Intervention          | 13/92 (14%)         | 39/91 (43%)   | 77/133 (58%) |
| **Diarrhoea**         |                     |               |              |               |
| All children          | 32/217 (15%)        | 47/226 (21%)  | 36/427 (8.4%)|
| Control               | 17/116 (15%)        | 25/123 (20%)  | 20/234 (8.6%)|
| Intervention          | 15/101 (15%)        | 22/103 (21%)  | 16/193 (8.3%)|
| **Any bacterial infection** |                   |               |              |               |
| All children          | 94/208 (45%)        | 150/221 (68%) | 229/297 (77%)|
| Control               | 53/109 (49%)        | 89/119 (75%)  | 117/152 (77%)|
| Intervention          | 41/99 (41%)         | 61/102 (60%)  | 112/145 (77%)|
| **Shigella**          |                     |               |              |               |
| All children          | 19/208 (9.1%)       | 97/221 (44%)  | 192/297 (65%)|
| Control               | 10/109 (9.2%)       | 57/119 (48%)  | 101/152 (66%)|
| Intervention          | 9/99 (9.1%)         | 40/102 (39%)  | 91/145 (63%) |
| **ETEC**              |                     |               |              |               |
| All children          | 47/208 (23%)        | 81/221 (37%)  | 90/297 (30%) |
| Control               | 25/109 (23%)        | 45/119 (38%)  | 43/152 (28%) |
| Intervention          | 22/99 (22%)         | 36/102 (35%)  | 47/145 (32%) |
| **Campylobacter**     |                     |               |              |               |
| All children          | 22/208 (11%)        | 19/221 (8.6%) | 16/297 (5.4%)|
| Control               | 14/109 (13%)        | 13/119 (11%)  | 10/152 (6.6%)|
| Intervention          | 8/99 (8.1%)         | 6/102 (5.9%)  | 6/145 (4.1%) |
| **C. difficile**      |                     |               |              |               |
| All children          | 23/208 (11%)        | 10/221 (4.5%) | 2/297 (0.67%)|
| Control               | 13/109 (12%)        | 7/119 (5.9%)  | 2/152 (1.3%) |
| Intervention          | 10/99 (10%)         | 3/102 (2.9%)  | 0/145 (0.0%) |
| **E. coli O157**      |                     |               |              |               |
| All children          | 6/208 (2.9%)        | 10/221 (4.5%) | 15/297 (5%)  |
| Control               | 4/109 (3.7%)        | 3/119 (2.5%)  | 6/152 (4%)   |
| Intervention          | 2/99 (2%)           | 7/102 (6.9%)  | 9/145 (6.2%) |
| **STEC**              |                     |               |              |               |
| All children          | 3/208 (1.4%)        | 7/221 (3.2%)  | 3/297 (1%)   |
| Control               | 0/109 (0.0%)        | 1/119 (0.84%) | 2/152 (1.3%)|
| Intervention          | 3/99 (3%)           | 6/102 (3.9%)  | 1/145 (0.69%)|
| **Y. enterocolitica** |                     |               |              |               |
| All children          | 0/208 (0.0%)        | 1/221 (0.45%) | 0/297 (0.0%) |
| Control               | 0/109 (0.0%)        | 0/119 (0.0%)  | 0/152 (0.0%)|
| Intervention          | 0/99 (0.0%)         | 1/102 (0.98%) | 0/145 (0.0%)|
| **Y. cholerae**       |                     |               |              |               |
| All children          | 0/208 (0.0%)        | 0/221 (0.0%)  | 0/297 (0.0%) |
| Control               | 0/109 (0.0%)        | 0/119 (0.0%)  | 0/152 (0.0%)|
| Intervention          | 0/99 (0.0%)         | 0/102 (0.0%)  | 0/145 (0.0%)|
| **Any Protozoa**      |                     |               |              |               |
| Pathogen            | All children | Control | Intervention |
|---------------------|--------------|---------|--------------|
| **Giardia**         | 28/208 (13%) | 12/109 (11%) | 16/99 (16%) |
| **Cryptosporidium** | 10/208 (4.8%) | 2/109 (1.8%) | 8/99 (8.1%) |
| **E. histolytica**  | 1/208 (0.48%) | 0/109 (0.0%) | 1/99 (1%) |
| **Any virus**       | 36/208 (17%) | 15/109 (14%) | 21/99 (21%) |
| **Norovirus GI/GII**| 27/208 (13%) | 12/109 (11%) | 15/99 (15%) |
| **Adenovirus 40/41**| 7/208 (3.4%) | 4/109 (3.7%) | 3/99 (3%) |
| **Rotavirus A**     | 3/208 (1.4%) | 0/109 (0.0%) | 3/99 (3%) |
| **Coinfection, ≥2 GPP pathogens** | 48/208 (23%) | 23/109 (21%) | 25/99 (25%) |
| **Trichuris**       | 20/185 (11%) | 10/93 (11%) | 10/92 (11%) |
| **Ascaris**         | 21/185 (11%) | 12/93 (13%) | 9/92 (9.8%) |
| **Coinfection, ≥2 STH** | 11/185 (6%) | 5/93 (5.4%) | 6/92 (6.5%) |
| **Number of GPP infections†** | 0.94 (1.1) | 0.88 (1.1) | 1 (1) |
| **Number of STH infections†** | 0.23 (0.55) | 0.61 (0.75) | 0.86 (0.76) |
|               | Control     | Intervention | Intervention |
|---------------|-------------|--------------|--------------|
|               | 0.24 (0.54) | 0.64 (0.78)  | 0.9 (0.76)   |
|               | 0.23 (0.56) | 0.57 (0.72)  | 0.8 (0.76)   |

Data presented n/N (%) or †mean (standard deviation)
Table 4: Baseline enrolment characteristics of children with and without repeated measures at the 12-month phase. Results are presented for all children combined and stratified by study arm.

| Outcomes                        | All children | Control | Intervention |
|---------------------------------|--------------|---------|--------------|
|                                 | BL & 12M*    | BL only† | BL & 12M     | BL only     | Std. Diff.‡ | BL & 12M     | BL only     | Std. Diff.‡ |
|                                 |              |         |              |             |             |              |             |             |
| Diarrhoea                       | 83/609 (14%) | 43/365 (12%) | 38/310 (12%) | 29/216 (13%) | 0.03        | 45/299 (15%) | 14/149 (9.4%) | 0.17        |
| Any bacterial or protozoan infection | 576/485 (78%) | 215/268 (80%) | 184/234 (79%) | 129/158 (82%) | 0.08        | 192/251 (76%) | 86/110 (78%) | 0.04        |
| Any GPP infection               | 390/485 (80%) | 225/268 (84%) | 188/234 (80%) | 135/158 (85%) | 0.14        | 202/251 (80%) | 90/110 (82%) | 0.03        |
| Any bacterial infection         | 311/485 (64%) | 187/268 (70%) | 157/234 (67%) | 114/158 (72%) | 0.11        | 154/251 (61%) | 73/110 (66%) | 0.10        |
| Shigella                        | 200/485 (41%) | 131/268 (49%) | 101/234 (43%) | 78/158 (49%) | 0.12        | 99/251 (39%) | 53/110 (48%) | 0.18        |
| ETEC                            | 147/485 (30%) | 79/268 (29%) | 68/234 (29%) | 48/158 (30%) | 0.03        | 79/251 (31%) | 31/110 (28%) | 0.07        |
| Campylobacter                   | 37/485 (7.6%) | 23/268 (8.6%) | 22/234 (9.4%) | 17/158 (11%) | 0.05        | 15/251 (6%) | 6/110 (5.5%) | 0.02        |
| C. difficile                    | 23/485 (4.7%) | 12/268 (4.5%) | 15/234 (6.4%) | 7/158 (4.4%) | 0.09        | 8/251 (3.2%) | 5/110 (4.5%) | 0.07        |
| E. coli O157                    | 19/485 (3.9%) | 12/268 (4.5%) | 9/234 (3.9%) | 4/158 (2.5%) | 0.07        | 10/251 (4%) | 8/110 (7.3%) | 0.14        |
| STEC                            | 7/485 (1.4%) | 6/268 (2.2%) | 1/234 (0.43%) | 2/158 (1.3%) | 0.09        | 6/251 (2.4%) | 4/110 (3.6%) | 0.07        |
| Any protozoan infection         | 257/485 (53%) | 143/268 (53%) | 126/234 (54%) | 79/158 (50%) | 0.08        | 131/251 (52%) | 64/110 (58%) | 0.12        |
| Giardia                         | 247/485 (51%) | 140/268 (52%) | 122/234 (52%) | 79/158 (50%) | 0.04        | 125/251 (50%) | 61/110 (55%) | 0.11        |
| Cryptosporidium                 | 20/485 (4.1%) | 4/268 (1.5%) | 7/234 (3%) | 1/158 (0.63%) | 0.18        | 13/251 (5.2%) | 3/110 (2.7%) | 0.13        |
| E. histolytica                  | 2/485 (0.41%) | 2/268 (0.75%) | 0/234 (0.0%) | 0/158 (0.0%) | -‡         | 2/251 (0.80%) | 2/110 (1.8%) | 0.09        |
| Any viral infection             | 66/485 (14%) | 39/268 (15%) | 31/234 (13%) | 22/158 (14%) | 0.02        | 35/251 (14%) | 17/110 (15%) | 0.04        |
| Adenovirus 40/41                 | 14/485 (2.9%) | 8/268 (3%) | 8/234 (3.4%) | 5/158 (3.2%) | 0.01        | 6/251 (2.4%) | 3/110 (2.7%) | 0.02        |
| Norovirus GI/GII                | 50/485 (10%) | 27/268 (10%) | 23/234 (9.8%) | 15/158 (9.5%) | 0.01        | 27/251 (11%) | 12/110 (11%) | 0.00        |
| Rotavirus A                     | 5/485 (1%) | 5/268 (1.9%) | 1/234 (0.43%) | 2/158 (1.3%) | 0.09        | 4/251 (1.6%) | 3/110 (2.7%) | 0.08        |
| Coinfection, ≥2 GPP infections  | 251/485 (52%) | 140/268 (52%) | 126/234 (54%) | 80/158 (51%) | 0.06        | 125/251 (50%) | 60/110 (55%) | 0.10        |
| Any STH infection               | 202/447 (45%) | 106/247 (44%) | 106/238 (49%) | 64/142 (45%) | 0.07        | 96/229 (42%) | 42/100 (42%) | 0.00        |
| STH              | Group Data | 109/447 (24%) | 54/242 (22%) | 0.05 | 65/218 (30%) | 30/142 (21%) | 0.20 | 44/229 (19%) | 24/100 (24%) | 0.12 |
|------------------|------------|---------------|--------------|-------|--------------|--------------|-------|--------------|--------------|------|
| Ascaris          |            |               |              |       |              |              |       |              |              |      |
| Trichuris        |            | 170/447 (38%) | 86/242 (36%) | 0.05  | 85/218 (39%) | 54/142 (38%) | 0.02  | 85/229 (37%) | 32/100 (32%) | 0.11 |
| Coinfection, ≥2 STH infections | 77/447 (17%) | 34/242 (14%) | 0.09 | 44/218 (20%) | 20/142 (14%) | 0.16 | 33/229 (14%) | 14/100 (14%) | 0.01 |
| Number of GPP infections | 1·6 (1·1) | 1·7 (1·1) | 0.07 | 1.6 (1·1) | 1.6 (1·1) | 0.02 | 1.6 (1·1) | 1.7 (1·2) | 0.14 |
| Number of STH infections | 0·64 (0·77) | 0·58 (0·73) | 0.08 | 0.7 (0·79) | 0.59 (0·73) | 0.14 | 0.59 (0·75) | 0.57 (0·73) | 0.03 |
| Child-, household-, compound-level characteristics |            |               |              |       |              |              |       |              |              |      |
| Child sex, female |            | 319/614 (52%) | 174/350 (50%) | 0.04  | 169/312 (54%) | 97/208 (47%) | 0.15  | 150/302 (50%) | 77/142 (54%) | 0.09 |
| Child breastfed   |            | 206/609 (34%) | 106/365 (29%) | 0.10  | 107/310 (35%) | 62/216 (29%) | 0.13  | 99/299 (33%) | 44/149 (30%) | 0.08 |
| Child exclusively breastfed | 51/609 (8·4%) | 35/365 (9·6%) | 0.04  | 27/310 (8.7%) | 22/216 (10%) | 0.05  | 24/299 (8%) | 14/149 (8.7%) | 0.03 |
| Child age at survey, days | 697 (409) | 697 (396) | 0.00 | 698 (409) | 703 (400) | 0.01 | 696 (409) | 689 (391) | 0.02 |
| Child age at sampling, days | 668 (399) | 656 (382) | 0.03 | 661 (397) | 655 (395) | 0.02 | 674 (402) | 657 (364) | 0.04 |
| Child wears diapers |            | 402/609 (66%) | 234/364 (64%) | 0.04  | 209/310 (67%) | 133/216 (62%) | 0.12  | 193/299 (65%) | 101/148 (68%) | 0.08 |
| Child faeces disposed in latrine |            | 173/609 (28%) | 116/365 (32%) | 0.07  | 79/310 (25%) | 69/216 (32%) | 0.14  | 94/299 (31%) | 47/149 (32%) | 0.00 |
| Caregiver completed primary school | 333/614 (54%) | 193/365 (53%) | 0.03  | 163/312 (52%) | 124/216 (57%) | 0.10  | 170/302 (56%) | 69/149 (46%) | 0.20 |
| Mother alive      |            | 576/590 (98%) | 353/358 (99%) | 0.07  | 295/301 (98%) | 208/212 (98%) | 0.01  | 281/289 (97%) | 145/146 (99%) | 0.16 |
| Respondent is child's mother |            | 414/605 (68%) | 238/357 (67%) | 0.04  | 222/307 (72%) | 146/212 (69%) | 0.08  | 192/298 (64%) | 92/145 (63%) | 0.02 |
| Household floors covered |            | 575/615 (94%) | 349/368 (95%) | 0.06  | 300/313 (96%) | 211/217 (97%) | 0.08  | 275/302 (91%) | 138/151 (91%) | 0.01 |
| Household walls made of sturdy material | 399/615 (65%) | 243/368 (66%) | 0.02  | 216/313 (69%) | 154/217 (71%) | 0.04  | 183/302 (61%) | 89/151 (59%) | 0.03 |
| Latrine has drop-hole |            | 359/604 (59%) | 193/364 (53%) | 0.13  | 109/307 (55%) | 109/214 (51%) | 0.08  | 190/297 (64%) | 84/150 (56%) | 0.16 |
| Latrine has vent-pipe |            | 93/605 (15%) | 44/364 (12%) | 0.10  | 21/308 (6.8%) | 12/214 (5.6%) | 0.05  | 72/297 (24%) | 32/150 (21%) | 0.07 |
| Latrine has ceramic or concrete slab or pedestal | 224/602 (37%) | 133/363 (37%) | 0.01  | 101/305 (33%) | 80/213 (38%) | 0.09  | 123/297 (41%) | 53/150 (35%) | 0.13 |
| Latrine has sturdy walls | 193/605 (32%) | 110/363 (30%) | 0.03  | 84/306 (27%) | 58/215 (27%) | 0.01  | 109/299 (36%) | 52/148 (35%) | 0.03 |
| Water tap on compound grounds | 468/606 (77%) | 285/364 (78%) | 0.03  | 224/308 (73%) | 162/214 (76%) | 0.07  | 244/298 (82%) | 123/150 (82%) | 0.00 |
| Household crowding, ≥3 persons/room | 122/615 (20%) | 45/368 (12%) | 0.21  | 55/313 (18%) | 22/217 (10%) | 0.22  | 67/302 (22%) | 23/151 (15%) | 0.18 |
| Compound electricity normally functions | 356/615 (90%) | 331/372 (89%) | 0.05  | 272/313 (87%) | 195/220 (89%) | 0.05  | 284/302 (84%) | 136/152 (89%) | 0.17 |
| Standing water observed in compound | 44/605 (7.3%) | 26/363 (7.2%) | 0.00 | 7/306 (2.3%) | 7/215 (3.3%) | 0.06 | 37/299 (12%) | 19/148 (13%) | 0.01 |
| Leaking or standing wastewater observed in compound | 371/605 (61%) | 233/363 (64%) | 0.06 | 214/306 (70%) | 149/215 (69%) | 0.01 | 157/299 (53%) | 84/148 (57%) | 0.09 |
| Any animal observed | 395/615 (64%) | 226/372 (62%) | 0.08 | 18/313 (5.8%) | 10/220 (4.5%) | 0.05 | 33/302 (11%) | 13/152 (8.6%) | 0.08 |
| Dog observed | 51/615 (8.3%) | 23/372 (6.2%) | 0.17 | 43/313 (14%) | 27/220 (12%) | 0.04 | 51/302 (17%) | 9/152 (5.9%) | 0.35 |
| Chicken or duck observed | 94/615 (15%) | 36/372 (9.7%) | 0.17 | 43/313 (14%) | 27/220 (12%) | 0.04 | 51/302 (17%) | 9/152 (5.9%) | 0.35 |
| Cat observed | 341/615 (55%) | 205/372 (55%) | 0.01 | 167/313 (53%) | 120/220 (55%) | 0.02 | 174/302 (58%) | 85/152 (56%) | 0.03 |
| Faeces or used diapers observed around compound | 276/605 (46%) | 177/363 (49%) | 0.06 | 166/306 (54%) | 118/215 (54%) | 0.01 | 110/299 (37%) | 61/148 (41%) | 0.09 |
| Compound floods during rain | 377/615 (61%) | 226/372 (61%) | 0.01 | 211/313 (67%) | 137/220 (62%) | 0.11 | 166/302 (55%) | 89/152 (59%) | 0.07 |
| Number of household members | 6.4 (3.3) | 5.6 (2.6) | 0.27 | 6 (3) | 5.2 (2.1) | 0.33 | 6.8 (3.5) | 6.3 (3.1) | 0.18 |
| Household wealth score, 0-1 | 0.43 (0.1) | 0.44 (0.099) | 0.10 | 0.44 (0.1) | 0.45 (0.097) | 0.15 | 0.43 (0.1) | 0.43 (0.1) | 0.01 |
| Number of households in compound | 5.2 (4.6) | 4.7 (4.4) | 0.11 | 4.4 (2.9) | 3.8 (1.7) | 0.21 | 6.1 (5.6) | 6 (6.4) | 0.02 |
| Compound population | 21 (15) | 19 (14) | 0.18 | 17 (8.1) | 15 (6.1) | 0.22 | 26 (18) | 24 (20) | 0.11 |
| Number of water taps in compound | 1.5 (2.2) | 1.2 (1) | 0.22 | 1 (1.1) | 0.97 (0.83) | 0.04 | 2.1 (2.8) | 1.4 (1.2) | 0.30 |
| Number of latrines/drop-holes in compound | 1.1 (0.63) | 1.1 (0.65) | 0.00 | 1 (0.24) | 1 (0.2) | 0.04 | 1.2 (0.86) | 1.3 (0.97) | 0.03 |
| Compound population density | 0.084 (0.046) | 0.078 (0.045) | 0.13 | 0.076 (0.04) | 0.07 (0.039) | 0.14 | 0.092 (0.051) | 0.089 (0.05) | 0.06 |

Results are presented as prevalence (n/N (%)) or mean (standard deviation) at baseline. * Prevalence (or mean (SD)) for children with repeated observations at baseline and 12-month visits. † Prevalence (or mean (SD)) for children with observations from the baseline visit and not the 12-month visit. ‡ Standardized mean difference between observations of children with and without repeated measures at baseline and 12-month visits. ⁑ Could not be calculated.
| Outcomes                          | All children | Control | Std· Diff· | Intervention | Std· Diff· |
|----------------------------------|--------------|---------|-----------|--------------|-----------|
|                                  | BL & 24M*    | BL only† |           | BL & 24M     | BL only   |
|                                  |              |          |           |              |           |
| Diarrhoea                       | 75/504 (15%) | 51/470  (11%) | 0.12     | 35/244 (14%) | 32/282 (11%) | 0.09   |
|                                  |              |          |           |              |           |
|                                  | 40/260 (15%) | 19/188  (10%) |          |              |           |
| Any bacterial or protozoan infection | 310/394 (79%) | 281/359 (76%) | 0.01     | 144/183 (79%) | 160/209 (81%) | 0.05   |
|                                  |              |          |           | 166/211 (79%) | 112/150 (75%)  | 0.09   |
| Any GPP infection                | 322/394 (82%) | 293/359 (82%) | 0.00     | 148/183 (81%) | 175/209 (84%) | 0.07   |
|                                  |              |          |           | 174/211 (82%) | 118/150 (79%)  | 0.10   |
| Any bacterial infection          | 251/394 (64%) | 247/359 (69%) | 0.11     | 120/183 (66%) | 151/209 (72%) | 0.14   |
|                                  |              |          |           | 131/211 (62%) | 96/150 (64%)  | 0.04   |
| Shigella                         | 158/394 (40%) | 173/359 (48%) | 0.16     | 74/183 (40%) | 105/209 (50%) | 0.20   |
|                                  |              |          |           | 84/211 (40%) | 68/150 (45%)  | 0.11   |
| ETEC                            | 115/394 (29%) | 111/359 (31%) | 0.04     | 53/183 (29%) | 63/209 (30%) | 0.03   |
|                                  |              |          |           | 62/211 (29%) | 48/150 (32%)  | 0.06   |
| Campylobacter                    | 31/394 (7.9%) | 29/359 (8.1%) | 0.01     | 18/183 (9.8%) | 21/209 (10%) | 0.01   |
|                                  |              |          |           | 13/211 (6.2%) | 8/150 (5.3%)  | 0.04   |
| C. difficile                     | 18/394 (4.6%) | 17/359 (4.7%) | 0.01     | 10/183 (5.5%) | 12/209 (5.7%) | 0.01   |
|                                  |              |          |           | 8/211 (3.8%) | 5/150 (3.3%)  | 0.02   |
| E. coli O157                     | 17/394 (4.3%) | 14/359 (3.9%) | 0.02     | 7/183 (3.8%) | 6/209 (2.9%) | 0.05   |
|                                  |              |          |           | 10/211 (4.7%) | 8/150 (5.3%)  | 0.03   |
| STEC                            | 6/394 (1.5%) | 7/359 (1.9%) | 0.03     | 2/183 (1.1%) | 1/209 (0.48%) | 0.07   |
|                                  |              |          |           | 4/211 (1.9%) | 6/150 (4%)   | 0.12   |
| Any protozoan infection          | 214/394 (54%) | 186/359 (52%) | 0.05     | 96/183 (52%) | 109/209 (52%) | 0.01   |
|                                  |              |          |           | 118/211 (56%) | 77/150 (51%)  | 0.09   |
| Giardia                         | 204/394 (52%) | 183/359 (51%) | 0.02     | 92/183 (50%) | 109/209 (52%) | 0.04   |
|                                  |              |          |           | 112/211 (53%) | 74/150 (49%)  | 0.08   |
| Cryptosporidium                 | 20/394 (5.1%) | 4/359 (1.1%) | 0.23     | 7/183 (3.8%) | 1/209 (0.48%) | 0.23   |
|                                  |              |          |           | 13/211 (6.2%) | 3/150 (2%)   | 0.21   |
| E. histolytica                   | 2/394 (0.51%) | 2/359 (0.56%) | 0.01     | 0/183 (0.0%) | 0/209 (0.0%) | - | 2/211 (0.95%) | 2/150 (1.3%) | 0.04   |
| Any viral infection             | 55/394 (14%) | 50/359 (14%) | 0.00     | 22/183 (12%) | 31/209 (15%) | 0.08   |
|                                  |              |          |           | 33/211 (16%) | 19/150 (13%) | 0.09   |
| Adenovirus 40/41                | 14/394 (3.5%) | 8/359 (2.2%) | 0.08     | 7/183 (3.8%) | 6/209 (2.9%) | 0.05   |
|                                  |              |          |           | 7/211 (3.3%) | 2/150 (1.3%) | 0.13   |
| Norovirus GI/GII                | 42/394 (11%) | 35/359 (9.8%) | 0.03     | 15/183 (8.2%) | 23/209 (11%) | 0.10   |
|                                  |              |          |           | 27/211 (13%) | 12/150 (8%)  | 0.16   |
| Rotavirus A                     | 3/394 (0.76%) | 7/359 (1.9%) | 0.10     | 1/183 (0.55%) | 2/209 (0.96%) | 0.05   |
|                                  |              |          |           | 2/211 (0.95%) | 5/150 (3.3%)  | 0.17   |
| Coinfection, ≥2 GPP infections  | 206/394 (52%) | 185/359 (52%) | 0.02     | 97/183 (53%) | 109/209 (52%) | 0.02   |
|                                  |              |          |           | 109/211 (52%) | 76/150 (51%)  | 0.02   |
| Any STH infection               | 156/394 (43%) | 152/327 (46%) | 0.07     | 80/171 (47%) | 90/189 (48%) | 0.02   |
|                                  |              |          |           | 76/191 (40%) | 62/138 (45%)  | 0.10   |
|                                | 85/362 (23%) | 78/327 (24%) | 0.01 | 50/171 (29%) | 45/189 (24%) | 0.12 | 35/191 (18%) | 33/138 (24%) | 0.14 |
|--------------------------------|--------------|---------------|-------|--------------|--------------|------|--------------|--------------|------|
| **Ascaris**                    | 128/362 (35%)| 128/327 (39%) | 0.08  | 63/171 (37%) | 76/189 (40%) | 0.07 | 65/191 (34%) | 52/138 (38%) | 0.08 |
| Coinfection, ≥2 STH infections | 57/362 (16%) | 54/327 (17%)  | 0.02  | 33/171 (19%) | 31/189 (16%) | 0.08 | 24/191 (13%) | 23/138 (17%) | 0.12 |
| Number of GPP infections       | 1.0 (1.1)    | 1.6 (1.2)     | 0.04  | 1.6 (1.1)    | 1.7 (1.1)    | 0.10 | 1.6 (1.1)    | 1.6 (1.2)    | 0.01 |
| Number of STH infections       | 0.61 (0.75)  | 0.64 (0.76)   | 0.04  | 0.67 (0.78)  | 0.65 (0.75)  | 0.03 | 0.55 (0.72)  | 0.63 (0.77)  | 0.10 |
| Child-, household-, compound-level characteristics |          |               |       |              |              |      |              |              |      |
| **Child sex, female**          | 260/503 (52%)| 233/461 (51%) | 0.02  | 124/241 (51%)| 142/279 (51%)| 0.01 | 136/262 (52%)| 91/182 (50%) | 0.04 |
| **Child breastfed**            | 172/504 (34%)| 140/470 (30%)| 0.09  | 87/244 (78%) | 82/282 (29%) | 0.14 | 85/260 (33%) | 58/188 (31%) | 0.04 |
| **Child exclusively breastfed**| 35/504 (6.9%)| 51/470 (11%)  | 0.14  | 19/244 (78%) | 30/282 (11%) | 0.10 | 16/260 (6.2%)| 21/188 (11%) | 0.18 |
| **Child age at survey, days**  | 698 (403)    | 696 (405)     | 0.01  | 689 (400)    | 709 (410)    | 0.05 | 707 (406)    | 675 (398)    | 0.08 |
| **Child wears diapers**        | 343/504 (68%)| 293/469 (62%) | 0.12  | 171/244 (70%)| 171/282 (61%)| 0.20 | 172/260 (66%)| 122/187 (65%)| 0.02 |
| **Child faeces disposed in latrine** | 138/504 (27%)| 151/470 (32%)| 0.10  | 57/244 (23%) | 91/282 (32%) | 0.20 | 81/260 (31%) | 60/188 (32%) | 0.02 |
| **Caregiver completed primary school** | 274/507 (54%)| 252/472 (53%)| 0.01  | 131/245 (53%)| 156/283 (55%)| 0.03 | 143/262 (55%)| 96/189 (51%) | 0.08 |
| **Mother alive**               | 474/486 (98%)| 455/462 (98%) | 0.07  | 232/236 (98%)| 271/277 (98%)| 0.03 | 242/250 (97%)| 184/185 (99%)| 0.20 |
| **Household floors covered**   | 337/500 (67%)| 315/462 (68%) | 0.02  | 173/241 (72%)| 195/278 (70%)| 0.04 | 164/259 (63%)| 120/184 (65%)| 0.04 |
| **Household walls made of sturdy material** | 337/500 (66%)| 305/476 (64%) | 0.05  | 184/245 (75%)| 186/285 (65%)| 0.22 | 153/262 (58%)| 119/191 (62%)| 0.08 |
| **Latrine has drop-hole**      | 294/497 (59%)| 258/471 (55%) | 0.09  | 133/239 (56%)| 145/282 (51%)| 0.08 | 161/258 (62%)| 113/189 (60%)| 0.05 |
| **Latrine has vent-pipe**      | 80/497 (16%) | 57/472 (12%)  | 0.12  | 18/239 (7.5%) | 15/283 (5.3%) | 0.09 | 62/258 (24%) | 42/189 (22%) | 0.04 |
| **Latrine has ceramic or concrete slab or pedestal** | 184/494 (37%)| 173/471 (37%)| 0.01  | 77/236 (33%) | 104/282 (37%) | 0.09 | 107/258 (41%)| 69/189 (37%) | 0.10 |
| **Latrine has sturdy walls**   | 165/501 (33%)| 138/467 (30%) | 0.07  | 67/240 (28%) | 75/281 (27%) | 0.03 | 98/261 (38%) | 63/186 (34%) | 0.08 |
| **Water tap on compound grounds** | 389/498 (78%)| 364/472 (77%) | 0.02  | 171/239 (72%)| 215/283 (76%)| 0.10 | 218/259 (84%)| 149/189 (79%)| 0.14 |
| **Household crowding, ≥3 persons/room** | 114/507 (22%)| 53/476 (11%)| 0.31  | 45/245 (18%) | 32/285 (11%) | 0.20 | 69/262 (26%) | 21/191 (11%) | 0.40 |
| **Compound electricity normally functions** | 454/507 (90%)| 433/480 (90%) | 0.02  | 214/245 (87%)| 253/288 (88%) | 0.02 | 240/262 (92%)| 180/192 (94%) | 0.08 |
| Parameter                                           | Baseline | Follow-up | p-value | * Baseline | Follow-up | p-value | † Baseline | Follow-up | p-value | ‡ Baseline | Follow-up | p-value |
|-----------------------------------------------------|----------|-----------|---------|------------|-----------|---------|------------|-----------|---------|------------|-----------|---------|
| Standing water observed in compound                 | 39/501   | 31/467    | 0.04    | 7/240 (2.9%) | 7/281 (2.5%) | 0.03    | 32/261 (12%) | 24/186 (13%) | 0.02    |
| Leaking or standing wastewater observed in compound | 308/501  | 296/467   | 0.04    | 164/240 (68%) | 199/281 (71%) | 0.05    | 144/261 (55%) | 97/186 (52%) | 0.06    |
| Any animal observed                                 | 337/507  | 284/480   | 0.15    | 156/245 (64%) | 162/281 (56%) | 0.15    | 181/262 (69%) | 122/192 (64%) | 0.12    |
| Dog observed                                        | 49/507   | 25/480    | 0.17    | 17/245 (6.9%) | 11/288 (3.8%) | 0.14    | 32/262 (12%) | 14/192 (7.3%) | 0.17    |
| Chicken or duck observed                            | 71/507   | 59/480    | 0.05    | 32/245 (13%) | 38/288 (13%) | 0.00    | 39/262 (15%) | 21/192 (11%) | 0.12    |
| Cat observed                                        | 294/507  | 252/480   | 0.11    | 143/245 (58%) | 144/288 (50%) | 0.17    | 151/262 (58%) | 108/192 (56%) | 0.03    |
| Faeces or used diapers observed around compound     | 218/501  | 235/467   | 0.14    | 120/240 (50%) | 162/281 (58%) | 0.15    | 98/261 (38%) | 73/186 (39%) | 0.03    |
| Compound floods during rain                         | 310/507  | 293/480   | 0.00    | 166/245 (68%) | 182/288 (63%) | 0.10    | 144/262 (55%) | 111/192 (58%) | 0.06    |
| Number of household members                         | 6·7 (3·4) | 5·5 (2·6) | 0·39    | 6.3 (3) | 5·2 (2·2) | 0·42 | 7.1 (3·6) | 6.1 (3) | 0.31    |
| Household wealth score, 0-1                         | 0·43 (0·11) | 0·44 (0·097) | 0·12 | 0·44 (0·1) | 0·45 (0·095) | 0·10 | 0·42 (0·11) | 0·43 (0·1) | 0·11    |
| Number of households in compound                    | 5·3 (4·7) | 4·7 (4·3) | 0·13    | 4·4 (3·1) | 3·9 (1·8) | 0·21 | 6·1 (5·7) | 5·9 (6·2) | 0·03    |
| Compound population                                 | 22 (15) | 18 (14) | 0·26 | 17 (8.1) | 15 (6.5) | 0·27 | 27 (18) | 23 (19) | 0.18    |
| Number of water taps in compound                    | 1·6 (2·2) | 1·2 (1·3) | 0·24 | 1 (1) | 0·99 (0·92) | 0·02 | 2·2 (2·8) | 1·4 (1·8) | 0.31    |
| Number of latrines in compound                      | 1·1 (0·62) | 1·1 (0·65) | 0·01 | 1 (0·25) | 1 (0·19) | 0·04 | 1·2 (0·82) | 1·3 (0·99) | 0.08    |
| Compound population density                         | 0·084 (0·049) | 0·079 (0·042) | 0·13 | 0·072 (0·038) | 0·075 (0·04) | 0·05 | 0·096 (0·055) | 0·084 (0·044) | 0.23    |

Results are presented as prevalence (n/N (%)) or mean (standard deviation) at baseline. * Prevalence (or mean (SD)) for children with repeated observations at baseline and 24-month visits. † Prevalence (or mean (SD)) for children with observations from the baseline visit and not the 24-month visit. ‡ Standardized mean difference between observations of children with and without repeated measures at baseline and 24-month visits. ＊ Could not be calculated.
|                                | All Children | Control | Intervention | Std. Diff. Control v. Interv.†|
|--------------------------------|--------------|---------|--------------|-----------------------------|
|                                | BL & 12M*    | 12M only† | BL & 12M     | 12M only                    |
| Child sex, female              | 319/614 (52%)| 156/313 (50%) | 169/312 (54%) | 73/155 (47%) | 1.04 |
| Child breastfed                | 27/562 (4.8%)| 161/305 (53%) | 13/280 (4.6%) | 76/151 (50%) | 1.25 |
| Child exclusively breastfed    | 3/562 (0.5%) | 38/305 (12%)  | 2/280 (0.71%) | 16/151 (11%) | 0.50 |
| Caregiver completed primary    | 305/614 (50%)| 144/309 (47%) | 156/312 (50%) | 62/153 (41%) | 0.14 |
| Child wears diapers            | 193/615 (65%)| 236/305 (77%) | 188/281 (67%) | 121/151 (80%) | 0.06 |
| Respondent is child's mother   | 365/615 (65%)| 275/324 (85%) | 235/309 (76%) | 151/164 (90%) | 0.09 |
| Household floors covered       | 584/615 (95%)| 305/321 (95%) | 299/313 (94%) | 155/163 (95%) | 0.02 |
| Household walls made of sturdy  | 398/615 (65%)| 189/321 (59%) | 212/313 (68%) | 101/163 (62%) | 0.12 |
| Household crowding, ≥3 persons/room | 110/615 (34%) | 111/313 (35%) | 54/163 (33%) | 99/302 (33%) | 0.05 |
| Compound electricity normally | 575/615 (94%)| 304/324 (94%) | 286/313 (91%) | 152/164 (93%) | 0.05 |
| Compound floods during rain     | 220/615 (36%)| 119/324 (37%) | 132/313 (42%) | 64/164 (39%) | 0.06 |
| Child age at survey, days      | 1114 (415)  | 622 (502)  | 1105 (413)  | 684 (535)  | 0.08 |
| Child age at sampling, days    | 1102 (417)  | 605 (484)  | 1080 (414)  | 649 (516)  | 0.02 |
| Number of household members    | 65 (3.2)    | 63 (3.3)   | 62 (3.2)    | 64 (3.5)   | 0.05 |
| Household wealth score, 0-1    | 0.4 (0.11)  | 0.39 (0.11)| 0.4 (0.11)  | 0.39 (0.11)| 0.12 |
| Number of households in compound | 5 (2.4)    | 5 (2.9)    | 4 (2.3)     | 6 (3.9)    | 0.09 |

Table 6: Balance of characteristics measured at 12-month visits between children with repeat observations at BL and 12-month and children with only 12-month observations.
| Compound population | 23 (22) | 24 (26) | 0.04 | 18 (9.7) | 18 (8.7) | 0.05 | 28 (29) | 30 (35) | 0.07 | 0.50 |
|----------------------|---------|---------|-------|----------|----------|-------|---------|---------|-------|------|
| Compound population density | 0.086 (0.049) | 0.084 (0.051) | 0.04 | 0.08 (0.043) | 0.078 (0.044) | 0.05 | 0.091 (0.054) | 0.089 (0.058) | 0.03 | 0.22 |

Results are presented as prevalence (n/N (%)) or mean (standard deviation) at 12-month visit. * Prevalence (or mean (SD)) for children with repeated observations at baseline and 12-month visits. † Prevalence (or mean (SD)) for children with observations from the 12-month visit and not the baseline visit. ‡ Standardized mean difference between observations of children with and without repeated measures at baseline and 12-month visits. § Standardized mean difference between observations from control and intervention children measured at 12-month visit only.
### Table 7: Balance of characteristics measured at 24-month visits between children with repeat observations at BL and 24-month and children with only 24-month observations.

|                             | All Children | Control | Intervention |
|-----------------------------|--------------|---------|--------------|
|                             | BL & 24M*    | 24M only† | BL & 24M    | 24M only† | BL & 24M    | 24M only† |
|                             | Std· Diff·†  | Std. Diff. | Std. Diff. | Std. Diff. | Std. Diff. |
| Child sex, female           | 260/503 (52%) | 190/428 (44%) | 0·15 | 124/241 (51%) | 96/222 (43%) | 0.16 | 136/262 (52%) | 94/206 (46%) | 0.13 | 0.05 |
| Child breastfed             | 0/418 (0% )  | 129/381 (34%) | 1·01 | 0/195 (0% )  | 68/194 (35%) | 1.04 | 0/223 (0% )  | 61/187 (33%) | 0.98 | 0.05 |
| Child exclusively breastfed | 0/418 (0%)   | 36/381 (9·4%) | 0·46 | 0/195 (0%)   | 16/194 (8·3%) | 0.42 | 0/223 (0%)   | 20/187 (11%) | 0.49 | 0.08 |
| Caregiver completed primary school | 199/507 (39%) | 164/427 (38%) | 0·02 | 88/245 (36%) | 82/221 (37%) | 0.02 | 111/262 (42%) | 82/206 (40%) | 0.05 | 0.06 |
| Child wears diapers         | 3/419 (0·72%)| 196/381 (51%) | 1·42 | 1/196 (0·51%)| 101/241 (51%) | 1.44 | 2/223 (0·9%) | 95/187 (51%) | 1.39 | 0.03 |
| Respondent is child's mother | 259/419 (62%) | 298/381 (78%) | 0·36 | 129/196 (66%) | 161/194 (83%) | 0.40 | 130/223 (58%) | 137/187 (73%) | 0.32 | 0.24 |
| Household floors covered    | 484/507 (95%) | 459/467 (98%) | 0·16 | 237/245 (97%) | 234/239 (98%) | 0.07 | 247/262 (94%) | 225/228 (99%) | 0.24 | 0.06 |
| Household walls made of sturdy material | 352/507 (69%) | 296/467 (63%) | 0·13 | 180/245 (73%) | 157/239 (66%) | 0.17 | 172/262 (66%) | 139/228 (61%) | 0.10 | 0.10 |
| Household crowding, ≥3 persons/room | 137/507 (27%) | 108/467 (23%) | 0·09 | 74/245 (30%) | 66/239 (28%) | 0.06 | 63/262 (24%) | 42/228 (18%) | 0.14 | 0.22 |
| Compound electricity normally functions | 485/507 (96%) | 472/494 (96%) | 0·01 | 230/245 (94%) | 237/254 (93%) | 0.02 | 255/262 (97%) | 235/240 (98%) | 0.04 | 0.23 |
| Any animal observed         | 384/507 (76%) | 359/494 (73%) | 0·07 | 162/245 (66%) | 182/254 (72%) | 0.12 | 222/262 (85%) | 177/240 (74%) | 0.27 | 0.05 |
| Dog observed                | 70/507 (14%)  | 78/409 (16%) | 0·06 | 30/245 (12%) | 40/254 (16%) | 0.10 | 40/262 (15%) | 38/240 (16%) | 0.02 | 0.00 |
| Chicken or duck observed    | 63/507 (12%)  | 52/494 (11%) | 0·06 | 22/245 (9%)  | 32/254 (13%) | 0.12 | 41/262 (16%) | 20/240 (8·3%) | 0.23 | 0.14 |
| Cat observed                | 360/507 (71%) | 340/494 (69%) | 0·05 | 154/245 (63%) | 174/254 (69%) | 0.12 | 206/262 (79%) | 166/240 (69%) | 0.22 | 0.01 |
| Compound floods during rain | 182/507 (36%) | 184/494 (37%) | 0·03 | 89/245 (36%) | 107/254 (42%) | 0.12 | 93/262 (36%) | 77/240 (32%) | 0.07 | 0.21 |
| Child age at survey, days   | 1518 (407)   | 740 (518) | 1·67 | 1520 (406) | 749 (541) | 1.61 | 1516 (408) | 731 (494) | 1.73 | 0.04 |
| Child age at sampling, days | 1510 (415)   | 694 (478) | 1·82 | 1505 (408) | 716 (512) | 1.70 | 1516 (422) | 672 (439) | 1.96 | 0.09 |
| Number of household members | 6·6 (3·1)    | 6·3 (3·4) | 0·10 | 6·5 (3)    | 6·6 (3·8) | 0·04 | 6·7 (3·1) | 6 (2·8)  | 0·26 | 0·20 |
| Household wealth score, 0-1 | 0·41 (0·11)  | 0·41 (0·11) | 0·01 | 0·41 (0·12) | 0·4 (0·11) | 0·11 | 0·41 (0·1) | 0·42 (0·097) | 0·15 | 0·19 |
| Number of households in compound | 5·3 (4·9)     | 5·5 (5·5) | 0·04 | 4·3 (2·8) | 4·4 (3·2) | 0·03 | 6·2 (6·1) | 6·6 (6·9) | 0·06 | 0·41 |
| Compound population | 21 (15) | 21 (16) | 0.04 | 18 (9.5) | 17 (8.9) | 0.07 | 25 (19) | 25 (21) | 0.00 | 0.47 |
|---------------------|---------|---------|-------|----------|----------|-------|---------|---------|------|------|
| Compound population density | 0.08 (0.047) | 0.08 (0.047) | 0.01 | 0.074 (0.037) | 0.075 (0.042) | 0.03 | 0.087 (0.053) | 0.085 (0.052) | 0.03 | 0.22 |

Results are presented as prevalence (n/N (%)) or mean (standard deviation) at 24-month visit. * Prevalence (or mean (SD)) for children with repeated observations at baseline and 24-month visits. † Prevalence (or mean (SD)) for children with observations from the 24-month visit and not the baseline visit. ‡ Standardized mean difference between observations of children with and without repeated measures at baseline and 24-month visits. § Standardized mean difference between observations from control and intervention children measured at 24-month visit only.
Table 8: Sensitivity analysis of deworming scenarios on STH effect estimates 12 and 24 months after the intervention.

|                      | 12-month Prevalence ratio | 24-month effect estimates |
|----------------------|---------------------------|---------------------------|
|                      | Main analysis, all children* | Adjusted for reported deworming status† | Restricted to children dewormed at baseline ‡ | Main analysis, all children* | Adjusted for reported deworming † | Adjusted for time since deworming‡ |
|                      | n=1239 | n=1239 | n=1031 | n=1161 | n=1161 | N=1159 |
| Any STH infection    | 1.11 (0.89 - 1.38) | 1.09 (0.87 - 1.35) | 1.06 (0.84 - 1.33) | 0.95 (0.77 - 1.17) | 0.93 (0.77 - 1.16) | 0.94 (0.76 – 1.16) |
| Trichuris            | 1.01 (0.79 - 1.28) | 0.98 (0.77 - 1.24) | 0.96 (0.74 - 1.23) | 0.86 (0.67 - 1.10) | 0.85 (0.66 - 1.08) | 0.85 (0.66 – 1.08) |
| Ascaris              | 1.33 (0.92 - 1.93) | 1.30 (0.90 - 1.88) | 1.30 (0.87 - 1.94) | 0.83 (0.54 - 1.27) | 0.84 (0.55 - 1.29) | 0.84 (0.54 – 1.29) |
| Coinfection, ≥2 STH | 1.16 (0.76 - 1.79) | 1.12 (0.73 - 1.71) | 1.16 (0.73 - 1.85) | 0.63 (0.37 - 1.07) | 0.63 (0.37 - 1.08) | 0.63 (0.37 – 1.08) |

All models adjusted for child age, sex, caregiver education level, and household wealth. *Analysis includes all children regardless of caregiver-reported deworming status. †Analysis is adjusted for reported deworming status. Effect estimates at 12-month are adjusted for baseline deworming confirmation, effect estimates at 24-month are adjusted for baseline and/or 12-month deworming confirmation. ‡Analysis is restricted to children whose caregivers confirmed baseline deworming. ‡‡Adjusted for time between 12-month deworming and 24-month sample collection, with deworming considered as intention-to-treat and time broken into 3 intervals: 0-3 months, 4-6 months, and >6 months. NDC 12-month deworming activities at the end of the 12-month phase instead of concurrent to 12-month sample collection resulting in some variation in the amount of time between 12-month deworming and 24-month sample collection among participants. All samples during 12-month phase were collected >6 months after deworming and no adjustment for time since deworming was made.
Table 9: Effect of intervention on bacterial, protozoan, and STH infection and reported diarrhoea in children born into study sites post implementation (post-baseline) and before 12-month visit compared with children of a similar age at baseline (<1 year old).

|                               | Prevalence | Prevalence ratio |
|-------------------------------|------------|------------------|
|                               | Baseline, <1 year old | 12-month, Born-in <1 year old | unadjusted | adjusted† |
| Any bacterial or protozoan infection |            |                  |           |          |
| Control                       | 57/109 (52%) | 28/48 (58%) | ·· | ·· |
| Intervention                  | 51/99 (52%) | 31/55 (56%) | 0·95 (0·63 - 1·44) | 1·05 (0·69 - 1·59) |
| Any STH infection             |            |                  |           |          |
| Control                       | 17/93 (18%) | 3/25 (12%) | ·· | ·· |
| Intervention                  | 13/92 (14%) | 4/32 (13%) | 1·31 (0·32 - 5·42) | 1·38 (0·35 - 5·45) |
| Diarrhoea                     |            |                  |           |          |
| Control                       | 19/138 (14%) | 6/50 (12%) | ·· | ·· |
| Intervention                  | 18/120 (15%) | 13/69 (19%) | 1·38 (0·47 - 4·0) | 1·80 (0·35 - 9·31) |
| Any Bacteria                  |            |                  |           |          |
| Control                       | 53/109 (49%) | 22/48 (46%) | ·· | ·· |
| Intervention                  | 41/99 (41%) | 28/55 (51%) | 1·28 (0·78 - 2·09) | 1·35 (0·81 - 2·23) |
| Shigella                      |            |                  |           |          |
| Control                       | 10/109 (9·2%) | 5/48 (10%) | ·· | ·· |
| Intervention                  | 9/99 (9·1%) | 7/55 (13%) | 1·23 (0·32 - 4·73) | 1·23 (0·32 - 4·72) |
| ETEC                          |            |                  |           |          |
| Control                       | 25/109 (23%) | 11/48 (23%) | ·· | ·· |
| Intervention                  | 22/99 (22%) | 11/55 (20%) | 0·88 (0·37 - 2·10) | 0·87 (0·37 - 2·09) |
| Campylobacter                 |            |                  |           |          |
| Control                       | 14/109 (13%) | 4/48 (8·3%) | ·· | ·· |
| Intervention                  | 8/99 (8·1%) | 5/55 (9·1%) | 1·76 (0·38 - 8·09) | 2·57 (0·55 - 11·96) |
| C. difficile                  |            |                  |           |          |
| Control                       | 13/109 (12%) | 7/48 (15%) | ·· | ·· |
| Intervention                  | 10/99 (10%) | 9/55 (16%) | 1·37 (0·42 - 4·45) | 1·49 (0·46 - 4·89) |
| E. coli o157                  |            |                  |           |          |
| Control                       | 4/109 (3·7%) | 0/48 (0·0%) | ·· | ·· |
| Intervention                  | 2/99 (2%) | 0/55 (0·0%) | 7·56 (0·42 - 140) | 51·8 (1·01 - 2700) |
| STEC                          |            |                  |           |          |
| Control                       | 0/109 (0·0%) | 0/48 (0·0%) | ·· | ·· |
| Intervention                  | 3/99 (3%) | 1/55 (1·8%) | ·· | ·· |
| Y. enterocolitica             |            |                  |           |          |
| Control                       | 0/109 (0·0%) | 0/48 (0·0%) | ·· | ·· |
| Intervention                  | 0/99 (0·0%) | 0/55 (0·0%) | ·· | ·· |
| V. cholerae                   |            |                  |           |          |
| Control                       | 0/109 (0·0%) | 0/48 (0·0%) | ·· | ·· |
| Intervention                  | 0/99 (0·0%) | 0/55 (0·0%) | ·· | ·· |
| Any Protozoa                  |            |                  |           |          |
| Control                       | 14/109 (13%) | 10/48 (21%) | ·· | ·· |
| Pathogen               | Intervention | Control | Odds Ratio (95% CI) |
|------------------------|--------------|---------|--------------------|
| **Intervention 22/99 (22%)** | 7/55 (13%)   | 0.41 (0.12 - 1.44) | 0.51 (0.15 - 1.78) |
| **Giardia**            |              |         |                    |
| Control 12/109 (11%)   | 8/48 (17%)   |         |                    |
| Intervention 16/99 (16%) | 6/55 (11%)   | 0.51 (0.14 - 1.83) | 0.59 (0.16 - 2.17) |
| **Cryptosporidium**    |              |         |                    |
| Control 2/109 (1.8%)   | 2/48 (4.2%)  |         |                    |
| Intervention 8/99 (8.1%) | 1/55 (1.8%)  | 0.12 (0.01 - 2.49) | 0.25 (0.01 - 6.02) |
| **E. histolytica**     |              |         |                    |
| Control 0/109 (0%)     | 1/48 (2.1%)  |         |                    |
| Intervention 1/99 (1%)  | 0/55 (0.0%)  |         |                    |
| **Any virus**          |              |         |                    |
| Control 15/109 (14%)   | 12/48 (25%)  |         |                    |
| Intervention 21/99 (21%) | 8/55 (15%)   | 0.40 (0.14 - 1.11) | 0.44 (0.16 - 1.19) |
| **Norovirus GI/GII**   |              |         |                    |
| Control 12/109 (11%)   | 8/48 (17%)   |         |                    |
| Intervention 15/99 (15%) | 7/55 (13%)   | 0.55 (0.17 - 1.79) | 0.57 (0.18 - 1.82) |
| **Adenovirus 40/41**   |              |         |                    |
| Control 4/109 (3.7%)   | 4/48 (8.3%)  |         |                    |
| Intervention 3/99 (3%)  | 2/55 (3.6%)  | 0.56 (0.06 - 5.05) | 0.91 (0.09 - 9.49) |
| **Rotavirus A**        |              |         |                    |
| Control 0/109 (0%)     | 0/48 (0.0%)  |         |                    |
| Intervention 3/99 (3%)  | 0/55 (0.0%)  |         |                    |
| **Coinfection, ≥2 GPP pathogens** |          |         |                    |
| Control 23/109 (21%)   | 13/48 (27%)  |         |                    |
| Intervention 25/99 (25%) | 13/55 (24%)  | 0.75 (0.30 - 1.86) | 0.86 (0.37 - 1.98) |
| **Trichuris**          |              |         |                    |
| Control 10/93 (11%)    | 3/25 (12%)   |         |                    |
| Intervention 10/92 (11%) | 4/32 (13%)   | 1.04 (0.21 - 5.01) | 0.98 (0.23 - 4.29) |
| **Ascaris**            |              |         |                    |
| Control 12/93 (13%)    | 1/25 (4%)    |         |                    |
| Intervention 9/92 (9.8%) | 3/32 (9.4%)  | 2.87 (0.30 - 27.85) | 3.10 (0.30 - 32.51) |
| **Coinfection, ≥2 STH** |          |         |                    |
| Control 5/93 (5.4%)    | 1/25 (4%)    |         |                    |
| Intervention 6/92 (6.5%) | 3/32 (9.4%)  | 1.90 (0.16 - 22.73) | 1.76 (0.15 - 20.98) |

Analysis includes children <1 year old at baseline and children born into the study after baseline and <1 year old at the time of the 24-month visit. Results are presented as prevalence (n/N (%)). Pathogen outcomes adjusted for child age and sex, caregiver’s education, and household wealth index, reported diarrhoea also adjusted for baseline presence of a drop-hole cover and reported use of a tap on compound grounds as primary drinking water source. Models did not converge due to sparse data.
|                                | Prevalence | Prevalence ratio |
|--------------------------------|------------|------------------|
|                                | Baseline   | 12-month         | unadjusted | adjusted† |
| **Any bacterial or protozoan infection** |            |                  |            |          |
| Control                        | 161/207 (78%) | 187/207 (90%)   | ::         | ::        |
| Intervention                   | 174/227 (77%) | 205/227 (90%)   | 1.01 (0.90 - 1.14) | 1.00 (0.89 - 1.13) |
| **Any STH infection**          |            |                  |            |          |
| Control                        | 67/132 (51%)  | 80/132 (61%)     | ::         | ::        |
| Intervention                   | 63/154 (41%)  | 91/154 (59%)     | 1.22 (0.92 - 1.61) | 1.16 (0.87 - 1.55) |
| **Diarrhoea**                  |            |                  |            |          |
| Control                        | 36/277 (13%)  | 17/277 (6.1%)    | ::         | ::        |
| Intervention                   | 42/279 (15%)  | 34/279 (12%)     | 1.71 (0.78 - 3.77) | 1.71 (0.79 - 3.70) |
| **Any Bacteria**               |            |                  |            |          |
| Control                        | 141/207 (68%) | 165/207 (80%)   | ::         | ::        |
| Intervention                   | 142/227 (63%) | 168/227 (74%)   | 1.01 (0.85 - 1.20) | 1.00 (0.84 - 1.18) |
| **Shigella**                   |            |                  |            |          |
| Control                        | 89/207 (43%)  | 129/207 (62%)    | ::         | ::        |
| Intervention                   | 90/227 (40%)  | 141/227 (62%)    | 1.08 (0.86 - 1.36) | 1.06 (0.84 - 1.34) |
| **ETEC**                       |            |                  |            |          |
| Control                        | 63/207 (30%)  | 79/207 (38%)     | ::         | ::        |
| Intervention                   | 71/227 (31%)  | 82/227 (36%)     | 0.92 (0.61 - 1.39) | 0.93 (0.62 - 1.40) |
| **Campylobacter**              |            |                  |            |          |
| Control                        | 20/207 (9.7%) | 17/207 (8.2%)   | ::         | ::        |
| Intervention                   | 13/227 (5.7%) | 15/227 (6.6%)   | 1.37 (0.53 - 3.54) | 1.32 (0.50 - 3.47) |
| **C. difficile**               |            |                  |            |          |
| Control                        | 15/207 (7.3%) | 3/207 (1.4%)    | ::         | ::        |
| Intervention                   | 8/227 (3.5%)  | 3/227 (1.3%)     | 1.88 (0.32 - 11.13) | 2.00 (0.34 - 11.84) |
| **E. coli O157**               |            |                  |            |          |
| Dataset                  | Control     | Intervention | Odds Ratio  | 95% CI      | 95% CI      |
|--------------------------|-------------|--------------|-------------|-------------|-------------|
| Control                  | 12/207 (5.8%) | 10/227 (4.4%) | 0.84 (0.28 - 2.53) | 0.85 (0.28 - 2.55) |
| Intervention             | 9/227 (4%)   | 10/227 (4.4%) | 0.84 (0.28 - 2.53) | 0.85 (0.28 - 2.55) |
| STEC                     | Control     | Intervention | Odds Ratio  | 95% CI      | 95% CI      |
| Control                  | 6/207 (2.9%) | 4/227 (1.8%)  | 0.11 (0.01 - 1.31) | 0.11 (0.01 - 1.32) |
| Intervention             | 6/227 (2.6%) | 4/227 (1.8%)  | 0.11 (0.01 - 1.31) | 0.11 (0.01 - 1.32) |
| Y. enterocolitica        | Control     | Intervention | Odds Ratio  | 95% CI      | 95% CI      |
| Control                  | 0/207 (0.0%) | 0/227 (0.0%)  | ··          | ··          |
| Intervention             | 1/227 (0.4%) | 0/227 (0.0%)  | ··†         | ··†         |
| V. cholerae              | Control     | Intervention | Odds Ratio  | 95% CI      | 95% CI      |
| Control                  | 0/207 (0.0%) | 0/227 (0.0%)  | ··          | ··          |
| Intervention             | 1/227 (0.4%) | 0/227 (0.0%)  | ··†         | ··†         |
| Any Protozoa             | Control     | Intervention | Odds Ratio  | 95% CI      | 95% CI      |
| Control                  | 129/207 (62%) | 162/227 (71%) | 1.17 (0.93 - 1.46) | 1.16 (0.92 - 1.46) |
| Intervention             | 117/227 (52%) | 159/227 (70%) | 1.17 (0.93 - 1.46) | 1.16 (0.92 - 1.46) |
| Giardia                  | Control     | Intervention | Odds Ratio  | 95% CI      | 95% CI      |
| Control                  | 129/207 (62%) | 162/227 (71%) | 1.17 (0.93 - 1.46) | 1.16 (0.92 - 1.46) |
| Intervention             | 117/227 (52%) | 159/227 (70%) | 1.17 (0.93 - 1.46) | 1.16 (0.92 - 1.46) |
| Cryptosporidium          | Control     | Intervention | Odds Ratio  | 95% CI      | 95% CI      |
| Control                  | 2/207 (0.97%) | 5/227 (2.2%)  | 1.44 (0.21 - 9.82) | 1.45 (0.22 - 9.72) |
| Intervention             | 10/227 (4.4%) | 5/227 (2.2%)  | 1.44 (0.21 - 9.82) | 1.45 (0.22 - 9.72) |
| E. histolytica           | Control     | Intervention | Odds Ratio  | 95% CI      | 95% CI      |
| Control                  | 0/207 (0.0%) | 5/227 (2.3%)  | 1.44 (0.21 - 9.82) | 1.45 (0.22 - 9.72) |
| Intervention             | 2/227 (0.88%) | 7/227 (3.1%)  | 1.44 (0.21 - 9.82) | 1.45 (0.22 - 9.72) |
| Any virus                | Control     | Intervention | Odds Ratio  | 95% CI      | 95% CI      |
| Control                  | 23/207 (11%) | 23/227 (10%)  | ··          | ··          |
| Intervention             | 31/227 (14%) | 23/227 (10%)  | ··          | ··          |
| Norovirus GI/GII         | Control     | Intervention | Odds Ratio  | 95% CI      | 95% CI      |
| Control                  | 22/207 (11%) | 22/207 (11%)  | ··          | ··          |
| Pathogen                | Control                  | Intervention             | Odds Ratio (95% CI) |
|-------------------------|--------------------------|--------------------------|--------------------|
| **Intervention 23/227 (10%)** | 17/227 (7.5%)            | 0.67 (0.29 - 1.54)       | 0.69 (0.30 - 1.57) |
| Adenovirus 40/41         | Control                  | 7/207 (3.4%)             | 3.56 (0.46 - 27.25) | 3.59 (0.46 - 27.90) |
|                         | Intervention             | 6/227 (2.6%)             |                    |                    |
| Rotavirus A              | Control                  | 1/207 (0.48%)            |                    |                    |
|                         | Intervention             | 4/227 (1.8%)             |                    |                    |
| Coinfection, ≥2 GPP pathogens | Control                  | 114/207 (55%)            |                    |                    |
|                         | Intervention             | 115/227 (51%)            |                    |                    |
| Trichuris                | Control                  | 49/132 (37%)             |                    |                    |
|                         | Intervention             | 53/154 (34%)             |                    |                    |
| Ascaris                  | Control                  | 40/132 (30%)             |                    |                    |
|                         | Intervention             | 35/154 (23%)             |                    |                    |
| Coinfection, ≥2 STH      | Control                  | 22/132 (17%)             |                    |                    |
|                         | Intervention             | 25/154 (16%)             |                    |                    |

Analysis includes children with complete observations at baseline and 12-month visits. Results are presented as prevalence (n/N (%)). *Pathogen outcomes adjusted for child age and sex, caregiver’s education, and household wealth index, reported diarrhoea also adjusted for baseline presence of a drop-hole cover and reported use of a tap on compound grounds as primary drinking water source. †‡ Models would not converge due to sparse data.
| Condition                        | Prevalence | Prevalence ratio |
|---------------------------------|------------|-----------------|
|                                 | Baseline   | 24-month        | unadjusted       | adjusted†          |
| **Any bacterial or protozoan infection** |            |                 |                  |                   |
| Control                         | 131/166 (79%) | 155/166 (93%)  | ··                | ··                 |
| Intervention                     | 151/192 (79%) | 175/192 (91%)  | 0.98 (0.87 - 1.10) | 0.98 (0.87 - 1.10) |
| **Any STH infection**            |            |                 |                  |                   |
| Control                         | 48/95 (51%)  | 65/95 (68%)     | ··                | ··                 |
| Intervention                     | 38/106 (36%) | 62/106 (58%)    | 1.20 (0.84 - 1.70) | 1.25 (0.87 - 1.78) |
| **Diarrhoea**                    |            |                 |                  |                   |
| Control                         | 25/196 (13%) | 20/196 (10%)    | ··                | ··                 |
| Intervention                     | 34/221 (15%) | 20/221 (9·1%)  | 0.72 (0.33 - 1.58) | 0.69 (0.31 - 1.50) |
| **Any Bacteria**                 |            |                 |                  |                   |
| Control                         | 109/166 (66%) | 138/166 (83%)  | ··                | ··                 |
| Intervention                     | 120/192 (63%) | 153/192 (80%)  | 1.00 (0.84 - 1.21) | 1.01 (0.83 - 1.21) |
| **Shigella**                     |            |                 |                  |                   |
| Control                         | 66/166 (40%) | 121/166 (73%)  | ··                | ··                 |
| Intervention                     | 79/192 (41%) | 136/192 (71%)  | 0.93 (0.71 - 1.22) | 0.93 (0.71 - 1.22) |
| **ETEC**                         |            |                 |                  |                   |
| Control                         | 47/166 (28%) | 47/166 (28%)    | ··                | ··                 |
| Intervention                     | 58/192 (30%) | 52/192 (27%)    | 0.90 (0.55 - 1.46) | 0.85 (0.52 - 1.39) |
| **Campylobacter**                |            |                 |                  |                   |
| Control                         | 16/166 (9·6%) | 12/166 (7·2%)  | ··                | ··                 |
| Intervention                     | 13/192 (6·8%) | 14/192 (7·3%)  | 1.44 (0.56 - 3.72) | 1.52 (0.60 - 3.83) |
| **C. difficile**                 |            |                 |                  |                   |
| Control                         | 9/166 (5·4%)  | 4/166 (2·4%)    | ··                | ··                 |
| Intervention                     | 8/192 (4·2%)  | 1/192 (0·52%)   | 0.28 (0.03 - 2.95) | 0.26 (0.03 - 2.59) |
| **E. coli O157**                 |            |                 |                  |                   |
|                     | Control     | Intervention | p value 1 | p value 2 |
|---------------------|-------------|--------------|-----------|-----------|
| STEC                | 7/166 (4.2%)| 9/166 (5.4%) | 0.69 (0.14 - 3.40) | 0.59 (0.12 - 2.93) |
| Y. enterocolitica   | 2/166 (1.2%)| 7/166 (4.2%) | 0.66 (0.07 - 6.20) | 0.58 (0.07 - 4.89) |
| V. cholerae        | 0/166 (0.0%)| 0/166 (0.0%) | 0.57 (0.06 - 5.38) | 0.55 (0.06 - 4.93) |
| Any Protozoa       | 89/166 (54%)| 121/166 (73%)| 0.93 (0.73 - 1.19) | 0.90 (0.69 - 1.15) |
| Giardia            | 86/166 (52%)| 120/166 (72%)| 0.93 (0.73 - 1.18) | 0.89 (0.69 - 1.15) |
| Cryptosporidium    | 5/166 (3%)  | 3/166 (1.8%) | 0.57 (0.06 - 5.38) | 0.55 (0.06 - 4.93) |
| E. histolytica     | 0/166 (0.0%)| 0/166 (0.0%) | 0.57 (0.06 - 5.38) | 0.55 (0.06 - 4.93) |
| Any virus          | 21/166 (13%)| 18/166 (11%) | 0.86 (0.37 - 1.97) | 0.95 (0.41 - 2.19) |
| Norovirus GI/GII   | 15/166 (9%) | 15/166 (9%)  |           |           |
| Pathogen                          | Intervention | Control   | Odds Ratio (CI) | Adj. OR (CI)  |
|----------------------------------|--------------|-----------|-----------------|--------------|
| **Adenovirus 40/41**             | 26/192 (14%) | 17/192 (8.8%) | 0.65 (0.25 - 1.69) | 0.74 (0.28 - 1.90) |
| **Control**                      | 6/166 (3.6%) | 1/166 (0.6%)  |                  |              |
| **Intervention**                 | 5/192 (2.6%) | 5/192 (2.6%)  | 6.12 (0.48 - 78.34) | 6.01 (0.49 - 73.94) |
| **Rotavirus A**                  | 1/166 (0.6%) | 2/166 (1.2%)  |                  |              |
| **Control**                      | 1/192 (0.52%) | 1/192 (0.52%) | 6.12 (0.48 - 78.34) | 6.01 (0.49 - 73.94) |
| **Intervention**                 | 1/192 (0.52%) | 1/192 (0.52%) | 6.12 (0.48 - 78.34) | 6.01 (0.49 - 73.94) |
| **Coinfection, ≥2 GPP pathogens**| 89/166 (54%) | 120/166 (72%) |                  |              |
| **Control**                      | 102/192 (53%) | 132/192 (69%) | 0.96 (0.77 - 1.19) | 0.95 (0.76 - 1.19) |
| **Trichuris**                    | 39/95 (41%)  | 62/95 (65%)  |                  |              |
| **Control**                      | 32/106 (30%) | 57/106 (54%)  | 1.11 (0.74 - 1.67) | 1.16 (0.77 - 1.75) |
| **Intervention**                 | 27/95 (28%)  | 34/95 (36%)  |                  |              |
| **Ascaris**                      | 18/95 (19%)  | 31/95 (33%)  |                  |              |
| **Control**                      | 13/106 (12%) | 16/106 (15%)  | 0.71 (0.30 - 1.70) | 0.72 (0.31 - 1.69) |
| **Intervention**                 | 19/106 (18%) | 21/106 (20%)  | 0.88 (0.43 - 1.79) | 0.89 (0.44 - 1.79) |

Analysis includes children with complete observations at baseline and 24-month visits. Results are presented as prevalence (n/N (%)). Pathogen outcomes adjusted for child age and sex, caregiver’s education, and household wealth index, reported diarrhoea also adjusted for baseline presence of a drop-hole cover and reported use of a tap on compound grounds as primary drinking water source. Models would not converge due to sparse data.
Table 12: Sensitivity analysis assessing impact of independent upgrading of control sanitation facilities on effect estimates.

|                                | 12-month adjusted prevalence ratio | 24-month adjusted prevalence ratio |
|--------------------------------|-----------------------------------|-----------------------------------|
|                                | Main analysis, all children*       | Excluding controls with upgraded sanitation† | Main analysis, all children*       | Excluding controls with upgraded sanitation† |
| Any bacterial or protozoan infection | 1·05 (0·95 – 1·16), n=1509         | 1·05 (0·96 – 1·16), n=1490         | 0·99 (0·91 – 1·09), n=1536         | 1·00 (0·91 – 1·10), n=1502 |
| Any STH infection               | 1·11 (0·89 – 1·38), n=1239         | 1·11 (0·89 – 1·38), n=1225         | 0·95 (0·77 – 1·17), n=1161         | 0·94 (0·76 – 1·16), n=1148 |
| Diarrhoea                       | 1·69 (0·89 – 3·21), n=1594         | 1·76 (0·91 – 3·39), n=1575         | 0·84 (0·47 – 1·51), n=1502         | 0·81 (0·45 – 1·48), n=1471 |

Infection outcomes adjusted for child age and sex, caregiver’s education, and household wealth index, diarrhoea also adjusted for baseline presence of a drop-hole cover and reported use of a tap on compound grounds as primary drinking water source.
Table 13: Consort 2010 Checklist Extension for Cluster Trials.

| Section/Topic | Item No | Standard Checklist item | Extension for cluster designs | Page No * |
|---------------|---------|-------------------------|-------------------------------|-----------|
| Title and abstract |        |                         |                               |           |
| 1a | Identification as a randomised trial in the title | Identification as a cluster randomised trial in the title | N/A | |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | See table 2 | 3-4 | |
| Introduction |        |                         |                               |           |
| Background and objectives | 2a | Scientific background and explanation of rationale | Rationale for using a cluster design | 5-6 |
| 2b | Specific objectives or hypotheses | Whether objectives pertain to the cluster level, the individual participant level or both | 6 | |
| Methods |        |                         |                               |           |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Definition of cluster and description of how the design features apply to the clusters | 6 |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A | | |
| Participants | 4a | Eligibility criteria for participants | Eligibility criteria for clusters | 7,8 |
| 4b | Settings and locations where the data were collected | | 6-7 | |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Whether interventions pertain to the cluster level, the individual participant level or both | 7-8 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, | Whether outcome measures pertain to the cluster level, the individual participant level or both | 10 |
including how and when they were assessed

| 6b | Any changes to trial outcomes after the trial commenced, with reasons | N/A |

**Sample size**

| 7a | How sample size was determined | Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intraclass correlation (ICC or $k$), and an indication of its uncertainty |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines | N/A |

**Randomisation:**

**Sequence generation**

| 8a | Method used to generate the random allocation sequence | N/A |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Details of stratification or matching if used | N/A |

**Allocation concealment mechanism**

| 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both | N/A |

**Implementation**

| 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Replace by 10a, 10b and 10c |
| 10a | Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions | 7 |
| 10b | Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling) | 8 |
| 10c | From whom consent was sought (representatives of the cluster, or | 8 |
| Section | Question | Code | Description |
|---------|----------|------|-------------|
| Blinding | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 11a | 8 |
| Blinding | If relevant, description of the similarity of interventions | 11b | 7-8 |
| Statistical methods | Statistical methods used to compare groups for primary and secondary outcomes | 12a | 11-12 |
| Statistical methods | Methods for additional analyses, such as subgroup analyses and adjusted analyses | 12b | 12 |
| Results | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | 13a | Figure 1 |
| Results | For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome | 13a | Figure 1 |
| Results | For each group, losses and exclusions after randomisation, together with reasons | 13b | Figure 1 |
| Results | For each group, losses and exclusions for both clusters and individual cluster members | 13b | Figure 1 |
| Recruitment | Dates defining the periods of recruitment and follow-up | 14a | 12 |
| Recruitment | Why the trial ended or was stopped | 14b | N/A |
| Baseline data | A table showing baseline demographic and clinical characteristics for each group | 15 | 16-17 |
| Baseline data | Baseline characteristics for the individual and cluster levels as applicable for each group | 15 | |
| Numbers analysed | For each group, number of participants (denominator) included in each analysis and | 16 | Figure 1, 19-20 |
whether the analysis was by original assigned groups

| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome | 18-20 |
|-------------------------|-----|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|-------|
| 17b                     |     | For binary outcomes, presentation of both absolute and relative effect sizes is recommended                                                                                                       |                                                                                                                                  | 18-20 |

| Ancillary analyses      | 18  | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory                                                      |                                                                                                                                  | 22-25 |

| Harms                   | 19  | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms<sup>2</sup>)                                                                                           |                                                                                                                                  | N/A   |

Discussion

| Limitations             | 20  | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses                                                                                           |                                                                                                                                  | 26, 28-30 |

| Generalisability        | 21  | Generalisability (external validity, applicability) of the trial findings                                                                                                                            | Generalisability to clusters and/or individual participants (as relevant)                                                        | 30-31 |

| Interpretation          | 22  | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence                                                                                         |                                                                                                                                  | 26, 30-31 |

Other information

| Registration            | 23  | Registration number and name of trial registry                                                                                                                                                    |                                                                                                                                  | 12 |

| Protocol                | 24  | Where the full trial protocol can be accessed, if available                                                                                                                                    |                                                                                                                                  | 33 |

| Funding                 | 25  | Sources of funding and other support (such as supply of drugs), role of funders                                                                                                                 |                                                                                                                                  | 32-33 |
