Effectiveness of a rural sanitation programme on diarrhoea, soil-transmitted helminth infection, and child malnutrition in Odisha, India: a cluster-randomised trial

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Grantee Final Report
Accepted by 3ie: July 2015

International Initiative for Impact Evaluation

Note to readers

This impact evaluation has been submitted in partial fulfilment of the requirements of grant issued under Open Window 2.

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Suggested citation: Clasen, T, Boisson, S, Routray, P, Torondel, B, Bell, M, Cumming, O, Ensink, J, Freeman, M, Jenkins, M, Odagiri, M, Ray,S, Sinha, A, Suar, M, Schmidt, W, 2015. *Effectiveness of a rural sanitation programme on diarrhoea, soil-transmitted helminth infection, and child malnutrition in Odisha, India: a cluster-randomised trial,* 3ie Grantee Final Report. New Delhi: International Initiative for Impact Evaluation (3ie).

Funding for this impact evaluation was provided by 3ie's donors, which include UKaid, the Bill & Melinda Gates Foundation, Hewlett Foundation and 12 other 3ie members that provide institutional support. A complete listing is provided on the 3ie website.

Acknowledgment

We want to acknowledge 3ie for funding and for technical review and support throughout the study. This study was also funded by the Bill & Melinda Gates Foundation and the Department for International Development-backed SHARE Research Consortium at the London School of Hygiene & Tropical Medicine (LSHTM). We thank the study participants; the Department of Rural Development of the State of Orissa and the Puri District Water and Sanitation Mission; WaterAid, United Artists Association and their collaborating implementers; Loyola Hospital and the Asian Institute of Public Health, Bhubaneswar; and our field staff, laboratory technicians, drivers, and data entry personnel. We appreciate the advice and assistance of Richard Hayes of the LSHTM in analysis of our results, and of Sandy Cairncross for comments on early drafts.

Contents

II. Plain-language executive summary

Background A third of the 2·5 billion people worldwide without access to improved sanitation live in India, as do two-thirds of the 1·1 billion practising open defecation and a quarter of the 1·5 million who die annually from diarrhoeal diseases. We aimed to assess the effectiveness of a rural sanitation intervention, within the context of the Government of India's Total Sanitation Campaign, to prevent diarrhoea, soil-transmitted helminth infection, and child malnutrition.

Methods We did a cluster-randomised controlled trial between May 20, 2010, and Dec 22, 2013, in 100 rural villages in Odisha, India. Households within villages were eligible if they had a child younger than 4 years or a pregnant woman. Villages were randomly assigned (1:1), with a computer-generated sequence, to undergo latrine promotion and construction or to receive no intervention (control). Randomisation was stratified by administrative block to ensure an equal number of intervention and control villages in each block. Masking of participants was not possible because of the nature of the intervention. However, households were not told explicitly that the purpose of enrolment was to study the effect of a trial intervention, and the surveillance team was different from the intervention team. The primary endpoint was 7-day prevalence of reported diarrhoea in children younger than 5 years. We did intention-to-treat and per-protocol analyses. This trial is registered with ClinicalTrials.gov, number NCT01214785.

Findings We randomly assigned 50 villages to the intervention group and 50 villages to the control group. There were 4586 households (24 969 individuals) in intervention villages and 4894 households (25 982 individuals) in control villages. The intervention increased mean village-level latrine coverage from 9% of households to 63%, compared with an increase from 8% to 12% in control villages. Health surveillance data were obtained from 1437 households with children younger than 5 years in the intervention group (1919 children younger than 5 years), and from 1465 households (1916 children younger than 5 years) in the control group. 7-day prevalence of reported diarrhoea in children younger than 5 years was 8·8% in the intervention group and 9·1% in the control group (period prevalence ratio 0·97, 95% CI 0·83–1·12). 162 participants died in the intervention group (11 children younger than 5 years) and 151 died in the control group (13 children younger than 5 years).

Interpretation Increased latrine coverage is generally believed to be effective for reducing exposure to faecal pathogens and preventing disease; however, our results show that this outcome cannot be assumed. As efforts to improve sanitation are being undertaken worldwide, approaches should not only meet international coverage targets, but should also be implemented in a way that achieves uptake, reduces exposure, and delivers genuine health gains.

III. List of tables and figures.

IV. Abbreviations and Acronyms

RCT Randomised control trial

NGO Non-governmental organization

TSC Total Sanitation Campaign

NBA Nirmal Bharat Abhiyan

NGP Nirmal Gram Purashkar

BPL Below poverty line

APL Above poverty line

IEC information, education and communication

UAA United Artist Association

HAZ Height-for-age Z score

WAZ Weight-for-age Z score

KIIT Kalinga Institute of Medical Sciences

WASH Water, Sanitation and Hygiene

ICC Intracluster correlation

GPS Global positioning system

PRA Participatory Rural Appraisal

VWSC Village Water and Sanitation Committee

1. Introduction

Diseases associated with poor sanitation cause a large burden of disease worldwide. Diarrhoea alone causes an estimated 4 billion cases and 1.9 million deaths each year among children under 5 years, or 19% of all under-5 deaths in low income settings (Boschi-Pinto et al., 2008). Other major diseases associated with poor sanitation are soil-transmitted worm infections, trachoma, lymphatic filariasis and schistosomiasis(Cairncross et al., 2010). In contrast to other Millennium Development Goals, sanitation coverage remains low with 2.5 billion people still lacking access to sanitation. Only 6% of rural residents in India have access to improved sanitation, and about 69% practice open defecation(Supply and Sanitation, 2010).

Systematic reviews have suggested that improved sanitation may reduce diarrhoeal diseases by 22% to 36%(Cairncross et al., 2010, Clasen et al., 2010, Esrey et al., 1985, Esrey et al., 1991, Fewtrell et al., 2005, Waddington et al., 2009). The studies included in these reviews were observational or small-scale before/after intervention studies that combined sanitation with water supplies or hygiene. The methodological quality of the studies was generally poor(Cairncross et al., 2010, Esrey et al., 1985, Esrey et al., 1991, Fewtrell et al., 2005, Waddington et al., 2009). To date, there is no randomized controlled trial of sanitation interventions to prevent diarrhoeal diseases(Cairncross et al., 2010, Clasen et al., 2010, Esrey et al., 1985, Esrey et al., 1991, Fewtrell et al., 2005, Waddington et al., 2009). Large RCTs may have been deemed difficult due to logistical constraints, including the long time frame of sanitation campaigns both in terms of construction and the time it takes for behavioural change leading to actual use. Sanitation campaigns are usually conducted by governmental or non-governmental actors. Researchers may have little control over how an intervention is rolled out once it has started. Further, the need for sanitation in dense urban areas (ideally by sewage connections) may be uncontroversial, and can be justified on the basis of non-health benefits alone. An RCT may not greatly influence urban sanitation policy. This may be different in rural settings where the health and social benefits are not always obvious to users and where demand for sanitation is often low(Jenkins and Scott, 2007, Jenkins and Curtis, 2005, WaterAid, 2008). The fraction of diarrhoea preventable by sanitation may be lower in rural compared to dense urban areas. Current large-scale rural sanitation programmes are conducted in the absence of evidence on its health impact.

We conducted a cluster-randomised controlled trial between May 20, 2010, and Dec 22, 2013, in 100 rural villages in Puri, a coastal district of Odisha (formerly Orissa), India. We did this study to assess the effectiveness of a rural household sanitation intervention to prevent diarrhoea, soil-transmitted helminthic infection, and child malnutrition. We aimed to investigate the effect of the intervention as actually delivered by an international implementer and its local partners working in India within the context of the Total Sanitation Campaign—the largest sanitation initiative in the world so far.

Following a baseline survey, 100 villages selected with government cooperation were randomly allocated into two study arms, one to receive the intervention immediately and the other following the end of a 21-month surveillance period.

2. Intervention, theory of change and research hypotheses

Implementation of the intervention was led by Wateraid India, a national affiliate of the UK-based NGO widely recognised for its work in water, sanitation and hygiene (wateraid.org) in collaboration with local NGOs. Implementation followed the government of India’s Total Sanitation Campaign (TSC). The TSC, recently expanded and renamed as Nirmal Bharat Abhiyan (NBA), was set up in 1999 to promote toilet construction and use in rural areas. The TSC programme provided subsidies for latrine construction to households who fall below the poverty line (BPL); it also uses community mobilisation and information, education and communication (IEC) activities to create demand and encourage latrine use(Government of India: Central Rural Sanitation Programme Total Sanitation Campaign. Ministry of Rural Development: Department of Drinking Water Supply, 2007).

2.1 Government of India’s Total Sanitation Campaign

The government of India’s Total Sanitation Campaign (TSC) was initiated in 1999. The programme is implemented at State level under the Rural Development Department. The key components of the programme are: 1) construction and use of individual household latrines, 2) construction of latrines in rural schools, kindergarten and public institutions, 3) provision of low subsidies or ‘incentives’ towards latrine construction to households falling below poverty line (BPL), 4) creation of production centers to provide locally appropriate technologies, and 5) Information, education and communication (IEC) activities designed to generate demand for toilets and encourage use(Government of India: Central Rural Sanitation Programme Total Sanitation Campaign. Ministry of Rural Development: Department of Drinking Water Supply, 2007). In 2003, the government of India launched the Nirmal Gram Purashkar (NGP) initiative to stimulate the campaign by providing financial rewards to Gram Panchayats, block and districts who are ‘open defecation free’. In 2012, the TSC was expanded and renamed as Nirmal Bharat Abhiyan. Under the new scheme, the subsidy amount was increased and was provided not only to BPL households, but also to households above the poverty line (APL) who qualify as ‘poor’(Government of India Ministry for Drinking Water and Sanitation, 2012). Under the programme’s guidelines, NGOs play a key role by conducting IEC activities and capacity building at the community level and by facilitating hardware supply by operating production centres and rural sanitary marts.

2.2. WaterAId

At the village level, the intervention was delivered by WaterAid and a local NGO partner, United Artist Association (UAA). Six local NGOs were contracted to implement the intervention in seven blocks of Puri district in collaboration with local government. WaterAid was responsible for project oversight, technical support on the project implementation and monitoring. WaterAid also provided funding towards latrine construction for poor households who were not eligible for government subsidy. UAA coordinated implementation activities between the six NGOs and with the local government representatives and relevant departments

2.3 Primary outcomes and impacts of interest

-Research question: To assess the effectiveness of a rural household sanitation intervention to prevent diarrhoea, soil-transmitted helminth infection, and child malnutrition.

-Primary outcome: The primary endpoint was 7-day prevalence of reported diarrhoea in children younger than 5 years and the secondary binary health outcomes (all age diarrhoea prevalence, helminths) will be done on an intention-to-treat basis. Continuous secondary health endpoints (HAZ, WAZ) will be analysed using mixed effects linear regression accounting for clustering at village level. We will use geographic data to support a range of exploratory analyses accounting for actual latrine uptake, by geo referencing and mapping for each study household the number and proportion of households with functional latrines within different buffer zones to explore the relative effect of individual and neighbourhood level sanitation coverage.

3. Context

The study is located in Puri, a coastal district in the eastern State of Orissa **(Figure 1)**. More than 50% of the population are recognized by the Indian Government as "below poverty line" (BPL). The area has a tropical climate with a monsoon season from July to September (1500 mm annual rainfall). Puri District is divided into smaller administrative units (Blocks), the unit at which sanitation implementers operate. Agriculture (rice, pulses, vegetables, and livestock) is the main source of income.

In Puri District, sanitation coverage in 2008 was estimated at 15% in rural areas(Government of India, 2008). In the years preceding the trial, several blocks in Puri had received latrines under the Total Sanitation Campaign (TSC), a long term commitment by the Indian Government to increase sanitation in rural areas(Government of India). The study is led by researchers at London School of Hygiene and Tropical Medicine and XIMB, with no direct influence on the type and delivery of the intervention.

From a government list of 385 villages not yet covered by TSC, we selected the first 100 that met the selection criteria ((i) sanitation coverage less than 10%; (ii) improved water supply; and (iii) no other water, sanitation or hygiene interventions anticipated in next 30 months)). We conducted a baseline survey in these villages (Table). Because of the nearly 12-month time for intervention implementation between baseline survey and start of the health outcome surveys, the enrolment procedures had to be repeated in previously enrolled and about 400 of new households (**Figure 2**). Following the baseline survey, 50 villages each were randomly allocated to intervention and control in a parallel trial design (**Figure 2**). The control arm will receive the intervention after trial completion. We also considered a step-wedge design where the intervention roll-out is staggered throughout the follow-up period(Hayes RJ, 2009, Moulton et al., 2007). Step-wedge designs (where only the time point of receiving the intervention is randomised) can be more acceptable to governments and the population than a parallel arm trial. They may also be more robust against unexpected delays in intervention roll-out because follow-up disease surveillance can be started as soon as the first villages have received the intervention. We decided against the step-wedge design because (1) the results of a parallel trial are easier to interpret for policy makers, (2) step-wedge trials require a larger sample size (about 30% or more)(Moulton et al., 2007), and (3) because the NGOs implementing the intervention judged implementation in a parallel trial as feasible.

Figure 1: The study area in seven blocks with administrative boundaries of trial villages (grey).

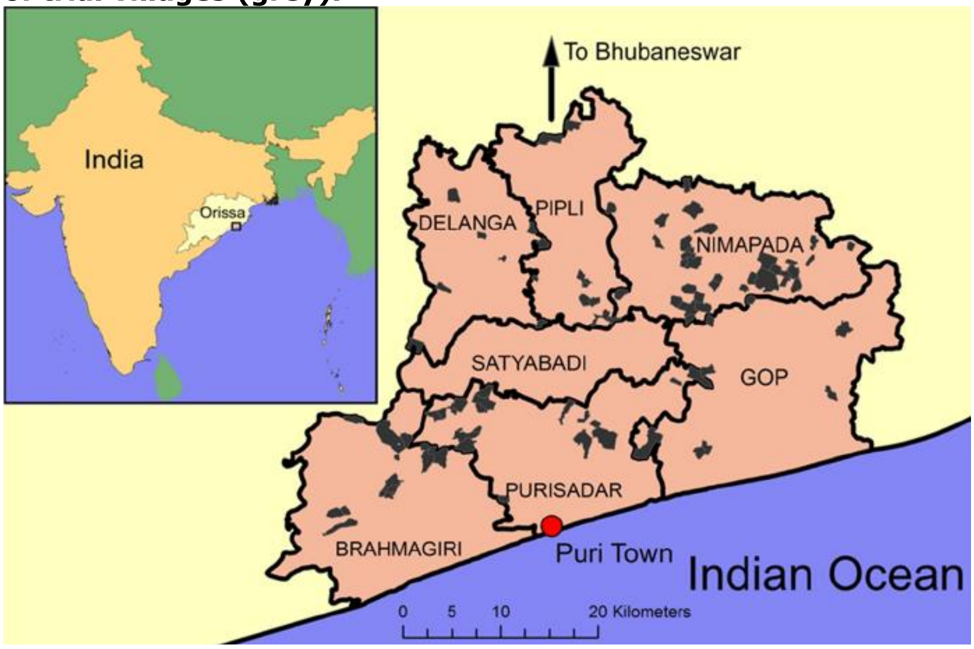
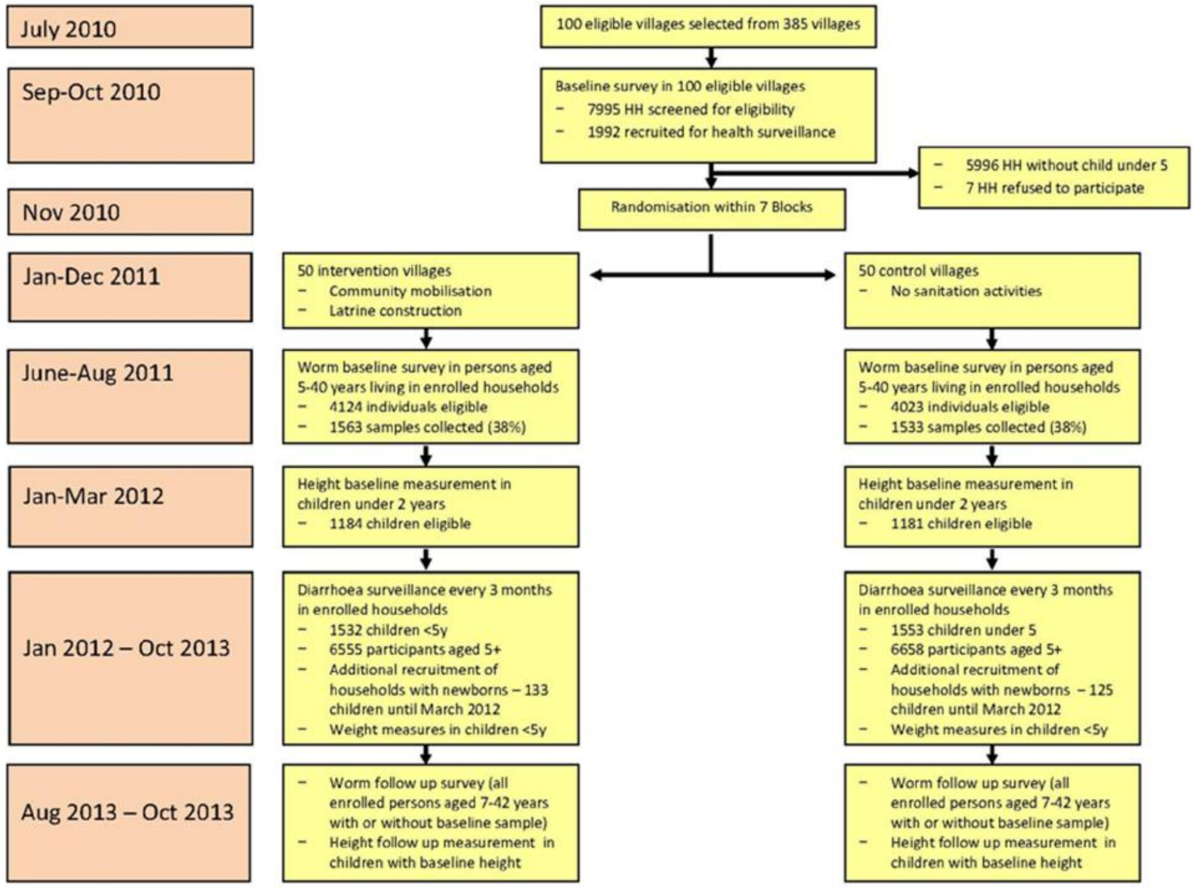
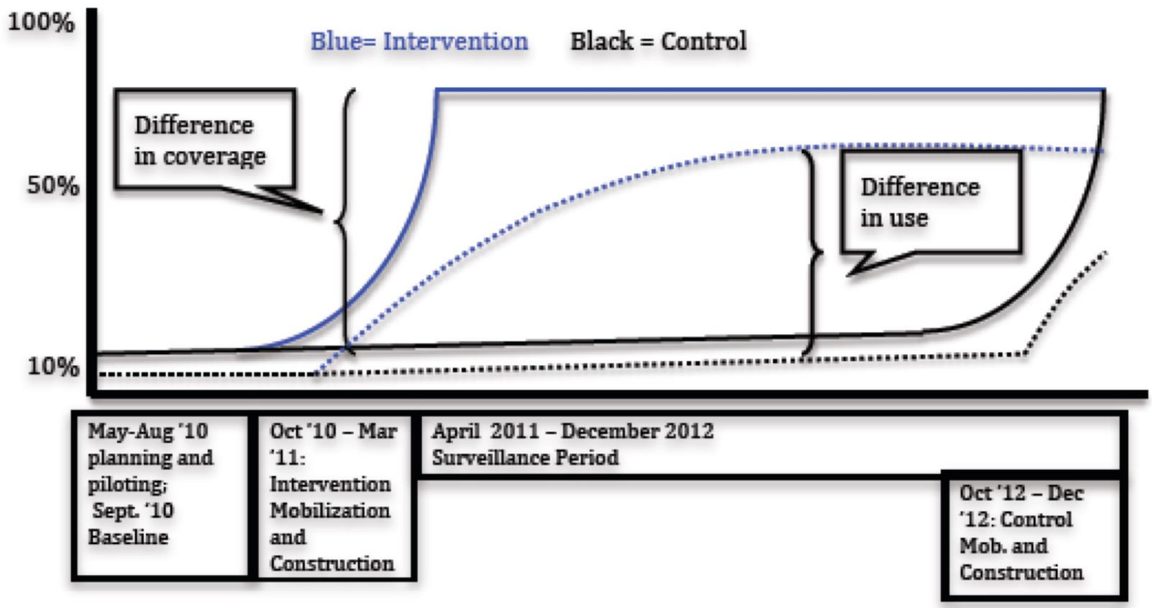


Figure 2: Flow diagram of the study.



4. Timeline

Figure 3: Flow chart.



5. Evaluation: Design, methods and implementation

5.1 Ethics

The study was reviewed and approved by the ethics committee of the London School of Hygiene & Tropical Medicine (London, UK), and by Xavier University and Kalinga Institute of Medical Sciences, KIIT University (both in Bhubaneswar, India). Written informed consent was obtained from the male or female head of household before baseline data collection.

This trial is registered with ClinicalTrials.gov, number NCT01214785.

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Right-to-use pictures: All the subjects that appear in the pictures have provided all necessary permissions.

5.2. Study design and participants

We did this cluster-randomised controlled trial between May 20, 2010, and Dec 22, 2013, in 100 rural villages in Puri, a coastal district of Odisha (formerly Orissa), India(Clasen et al., 2012). Briefly, this trial included villages that were spread across seven of the 11 blocks (an administrative sub district) of the Puri District.

Agriculture is the main source of income in Odisha and half of households are classified as living below the poverty line, according to the Government of India(Government of India, 2008). India ranks among the lowest of states nationally in terms of access to household-level latrines, with 14·1% coverage in rural settings(Ghosh and Cairncross, 2014). Furthermore, Puri District is not covered by any regular deworming programme.

We selected study villages from a list of 385 villages that had not been covered by the Total Sanitation Campaign. Villages were eligible if they had sanitation coverage of less than 10%; had improved water supply; and if no other water, sanitation, or hygiene (WASH) intervention was anticipated in the next 30 months. Households were eligible if they had a child younger than 4 years or if a pregnant woman lived there. We also enrolled households with a new baby born during the surveillance phase. We did a baseline survey between September and October, 2010, to obtain information about household demographic characteristics; socio economic status; water, hygiene, and sanitation conditions; and diarrhoea prevalence.

5.3. Sample size calculation

Sample size calculations for RCTs greatly depend on the design effect, the sample size increase relative to an individually randomised trial. In diarrhoea RCTs, the design effect not only depends on the temporal and spatial variation of diarrhoea between clusters (which can be considerable(Luby et al., 2011)) but also on the number of follow-up surveys and the within-person correlation of diarrhoea, making the design effect difficult to predict(Schmidt et al., 2011). We chose the proportion of days with diarrhoea (longitudinal prevalence) as the outcome for the sample size calculation(Schmidt et al., 2011). Based on data from another ongoing study in Orissa(Boisson et al., 2013), we assumed a mean longitudinal daily prevalence of 4% in children under 5, with a standard deviation of 7.6% assuming 6 follow up visits per child(Schmidt et al., 2010). We assumed a 25% reduction in diarrhoea prevalence as a figure of public health interest and in line with estimates from systematic reviews(Cairncross et al., 2010, Clasen et al., 2010, Esrey et al., 1985, Esrey et al., 1991, Fewtrell et al., 2005, Waddington et al., 2009). Assuming 25 children per cluster, an intracluster correlation (ICC) of 0.025, a design effect of 1.6, and 10% loss to follow-up, 80% power and p=0.05

resulted in 50 clusters per arm. This figure was confirmed using a simulation method developed for the sample size estimation of complex trials(Arnold et al., 2011).

5.4 Randomisation and masking

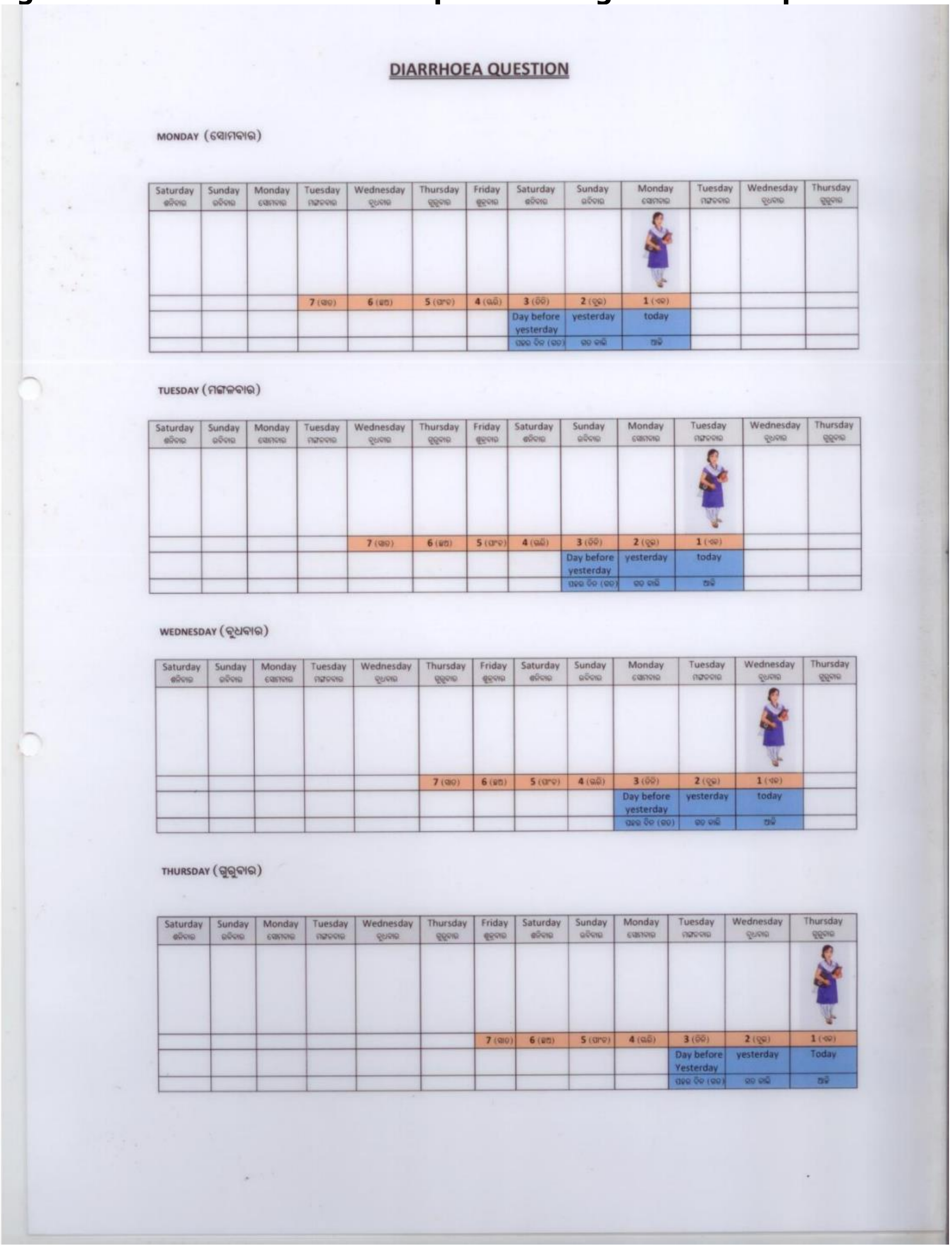
A member of staff who was involved in neither data collection nor intervention delivery randomly assigned villages (1:1), with a computer-generated sequence, to undergo either latrine promotion and construction in accordance with the Total Sanitation Campaign or to receive no intervention (control). Randomisation was stratified by administrative block to ensure an equal number of intervention and control villages in each block. Randomisation achieved a good balance of socioeconomic and water and sanitation-related characteristics(Clasen et al., 2012). Masking of participants was not possible because of the nature of the intervention. However, households were not told explicitly that the purpose of enrolment was to study the effect of a trial intervention, and the surveillance team was different from the intervention team.

5.5. Measures of outcomes:

*Primary outcome***:**

Reported diarrhoea is a subjective outcome. It has been shown that frequent contacts with participants can lead to reporting fatigue leading to a general decline in prevalence over a study(Zwane et al., 2011), and possibly bias(Schmidt and Cairncross, 2009). We restricted the number of diarrhoea follow up visits to nine. Because delays in the latrine construction did not result in reaching the target coverage until January 2012 data from the first two diarrhoea surveys conducted between September and December 2011 will not be included in the primary analysis. We obtained an extension of our research grant that will allow follow up to continue until October 2013. Originally, we chose daily point prevalence over the past three days as the main outcome. However, data from an ongoing study in the area(Boisson et al., 2013) suggested that diarrhoea in children under 5 may be lower than expected. Unable to increase the sample size any further, we switched to seven-day period prevalence as the primary outcome measure to compensate for the potential loss in study power. Using period prevalence as the outcome, we assessed the occurrence of diarrhoea at any time in the last seven days (a binary outcome). Seven day period prevalence is a suitable outcome for interventions expected to primarily reduce incidence rather than disease duration(Schmidt et al., 2011), providing more statistical power than point prevalence data(Schmidt et al., 2010). We defined diarrhoea according to WHO (three or more loose stools in 24 h (WHO, 2009a)), a definition that may be the best compromise between external and internal validity(Schmidt et al., 2011). The diarrhoea questions underwent extensive pilot testing based on local diarrhoea terms. Households are not asked to keep a diary of diarrhoea since the motivation to update diaries varies greatly. However, the fieldworkers use a visual aid showing a simple 10-day calendar to help participants remember the timing of episodes. This approach appeared to reduce reporting errors **(Figure 4).**

Figure 4: Visual Aid tool to help answering diarrhoea questions.



Compliance:
We measured compliance with the intervention with a survey done at the midpoint of the follow-up period. The survey recorded latrine presence and functionality, reported latrine use, and global positioning system (GPS) location of latrines and households. We defined latrine functionality on the basis of the following elements: existence of a roof; latrine not used for storage; pan not broken, not blocked, and not full of leaves or dust; and pit completed. We confirmed present latrine use on the basis of several indicators: smell of faeces, wet pan except when rainy, stain from faeces or urine, presence of soap, presence of water bucket or can, presence of a broom or brush for cleaning, or presence of slippers.

Environmental exposure:
We measured the effect of the intervention on environmental exposure to faecal pathogens through typical transmission pathways by testing for the presence of faecal indicator bacteria in source and household drinking water, on children's and mothers' hands and on children's toys, and by monitoring fly density.

Water
20% of participating households were randomly selected at each visit for testing of source and household microbial drinking water quality. Samples were collected from sources and storage vessels with sterile 125 mL Whirl-Pak bags (Nasco Ft, Atkinson, WI, USA), transported in a cooler to the laboratory, and processed within 4 h of collection with the membrane filtration technique and a portable incubator, in accordance with standard methods(Apha). Samples were tested for thermo tolerant coliforms—an indicator of faecal contamination(WHO, 2011).

Hand-rinses
To assess hand contamination, we obtained hand rinse samples(Pickering et al., 2010) 26 from mothers and children younger than 5 years from a subsample of 360 households (about six households from 30 intervention and 30 control villages) and assayed them for thermotolerant coliforms. Furthermore, we provided sterile balls to children younger than 5 years from the same 360 households, encouraged them to play with the toys in their household settings for 1 day, rinsed them in 300 mL of sterile water, and assayed the water for thermotolerant coliforms(Vujcic et al., 2014).

Flies
Finally, we monitored density of synanthropic flies (*Musca domestica* and *M sorbens)* by installing 24h fly traps for 3 consecutive nights in food preparation areas of a subsample of 572 households from 32 intervention and 32 control villages.

Household visits were done every 3 months between June, 2011, and October, 2013. Because of delays in latrine construction resulting in the target coverage not being met until January, 2012, the first three rounds of diarrhoea surveys after the baseline survey were not included in the primary analysis, resulting in a total of seven rounds of data collection.
*Soil-transmitted helminth infection***:**
We measured prevalence of three common soil transmitted helminth worms—*Ascaris lumbricoides*, *Trichuris trichiura,* and hookworm spp—by collecting stool samples from study participants aged 5–40 years (living in households with a child younger than 5 years). Baseline measurement was done in June and July, 2011, with subsequent sampling done after the last follow-up round. On the same day of collection, samples were transported to the laboratory and processed with the ethyl-acetate sedimentation method(Truant et al., 1981), and eggs were quantified with microscopy. After baseline stool collection, one 400 mg dose of albendazole (200 mg for children), a broad-spectrum anthelmintic, was given to individuals enrolled for stool sampling (except women in their first trimester of pregnancy), in accordance with WHO recommendations.
A problem specific to sanitation interventions could be that the availability of a latrine may influence the willingness of participants to give a stool sample. Pilot testing suggested that people going for open defecation may be reluctant to be seen carrying a stool sample back to the house. However, the proportion of samples collected was similar in intervention and control (44% vs. 43%), as was the baseline total worm prevalence (17.6 vs 17.0%), indicating no evidence of bias.

Anthropometrics:

A baseline measure of weight (in children younger than 5 years) and recumbent length or height (in those younger than 2 years) was taken in January, 2012 following standard procedures for anthropometric assessment(Gibson, 2005). The same children, and those born during the study, were measured again in October, 2013. Weight was measured with Seca 385 scales, with 20 g increments for weight lower than 20 kg and increments of 50 g for weight between 20 kg and 50 kg. We measured recumbent length of children younger than 2 years with Seca 417 boards with 1 mm increments. We measured height of children aged 2 years and older with a Seca 213 stadiometer. All children < 5 years will be weighed at each diarrhoea surveillance visit. Height and weight will be converted into z-scores (HAZ, WAZ)(WHO, 2009b) design. We assume that only a strong reduction in the exposure to faecal pathogens will lead to a measurable impact of the intervention on HAZ. It is unclear whether the "real-life" intervention evaluated in this study will achieve this during the timeframe of the follow-up. HAZ is often regarded as the better nutrition marker than WAZ, because inappropriate nutrition may increase weight without making the child healthier. This is less of a concern in a sanitation intervention aiming at improving nutritional status by reducing gastrointestinal infections, because any weight gain due to fewer infections may be regarded as beneficial. We measure WAZ repeatedly in each child as an indicator of recent diarrhoea(Biran et al., 2009) design. Back-checks on weight and height measurements were done in roughly 5% of households selected at random (Ulijaszek and Kerr, 1999). The repeated measure was carried out within 1 hour of previous weight measurement. In a small number of households, participants refused weight measurements because of the fear that a child may lose weight by placing it on a scale.

6. Programme or policy: Design, methods and implementation

6.1 Intervention Organisation

At the village level, the intervention was delivered by WaterAid and a local NGO partner, United Artist Association (UAA). Six local NGOs were contracted to implement the intervention in seven blocks of Puri district in collaboration with local government. WaterAid was responsible for project oversight, technical support on the project implementation and monitoring. WaterAid also provided funding towards latrine construction for poor households who were not eligible for government subsidy.

UAA coordinated implementation activities between the six NGOs and with the local government representatives and relevant departments. Implementing NGOs were assigned between four and twelve villages each. NGOs were selected based their experience with similar community-based projects in the selected areas. Each NGO appointed one cluster coordinator and village motivators on the basis of one motivator being responsible for two villages. Cluster coordinators were responsible for overseeing implementation of the programme in all assigned villages. Village motivators were recruited from the project area to facilitate mobilisation activities and coordinate latrine construction logistics in villages.

Cluster coordinators were typically employees of the NGO while village motivators were often recruited specifically for the project for the duration of one year. Village motivators did not necessarily have extensive experience in community mobilisation or in water, hygiene and sanitation projects. They reported progresses to cluster coordinators on a weekly basis and provided monthly reports.

In February 2011, training sessions were held for village-level implementers. A total of 25 village motivators and 6 cluster coordinators appointed by the NGOs attended a 3-day residential training course organised by UAA. The training covered the key elements of the Total Sanitation Campaign, an introduction to

Participatory Rural Appraisal (PRA) concept and tools, communication techniques, technical aspects of latrine construction, roles and responsibilities, and work plan. The training consisted of classroom presentations and group discussions with a half-day field practice on Participatory Rural Appraisal (PRA) and a visit to the production centres. Each NGO selected two 'Master' masons who would be responsible for latrine construction and supervision and training of local masons in their allocated villages. Masons received a five-day training course on latrine construction.

6.2. Hardware

The latrine design consisted of a pour-flush latrine with a single pit and a Y-joint for diversion to a future second pit. At the start of the programme, the contribution of the programme towards latrine construction was set at INR2200 (then approximately US$33). This amount covered the costs of three pit liner rings and cover plate, two bags of cement, one Y-connector, one connector pipe, one ceramic pan set, and one door. This amount also included the cost for transporting the material to the village and 1.5 days of mason's time. Sand, bricks, stones and two days of labour were to be covered by the household. Village motivators maintained a register containing the material and corresponding costs contributed by each household along with the head of household signature. The value of the contribution made by each household varied but was mostly equivalent to the subsidy amount of INR2200. Construction material such as pipe, pan set, Y-connector, cement were purchased from external suppliers and stored at a central production centres set up at one of the implementing NGOs. The doors were made at the central production centre while the rings and cover plates were produced at 'satellite centres' located nearer or within the intervention villages. **(Figure 5)**

Figure 5: Toilet example.

6.3. Community mobilisation

Details of the key components of community mobilisation along with the time frame for each activity are provided in **(Table 1)**. In brief, the approach consisted of initial meetings with community leaders to explain the programme, a baseline assessment of the water, hygiene and sanitation and socio-economic profile of the village, the formation of Village Water and Sanitation Committee (VWSC), and a combination of community-level events and door-to-door household visits to encourage construction and use of toilets. Additional IEC activities included wall paintings, school rallies and the formation of adolescent girls groups to disseminate sanitation messages among families and neighbours.

Table 1: Key components of the community mobilisation process and timing of activities.

Component	Description	Dates
Introductory meetings	NGO cluster coordinator and village motivator meet with local government representatives, key opinion leaders and members of existing community-based organisations such as Self-Help Groups to explain details about the programme.	Feb-Apr 2011
Baseline survey	A second or third meeting is organise the following week to meet with key leaders and provide further details on the programme and collect preliminary information on the village structure, socio-economic profile and water, hygiene and sanitation conditions. During this visit, the village motivator may visit households door-to-door to prepare a list of households with details on BPL status to estimate number of beneficiaries per village. Whenever possible, the BPL list is verified against BPL list maintain at the Gram Panchayat office.	Feb-Apr 2011
Village Water and Sanitation Committee (VWSC)	The committee is typically composed of 10-15 members. The VWSC includes local government representatives, schoolteacher, kindergarten (*Anganwadi*) worker, community health worker (*Accredited Social Health Activist, ASHA*), villager elders, Self-help group members. At least a third of committee members should be women and lower socio-economic groups and schedule castes should be represented. The role of the VWSC is to inform community members about the programme and encourage participation, develop an action plan for their village, help with the identification of beneficiaries, liaise with NGO staff and community members to resolve any potential conflicts and issues, support latrine construction logistics such as material procurement and storage, and record keeping. VWSC members attend a 2-day training organised by the implementing NGO and meet once a month thereafter to review progresses with the village motivator and local masons and to discuss and resolve issues arising during the implementation.	Feb-Apr 2011
Participatory Rural Appraisal	Transect walk: The village motivator gathers community members in a public place in the village and walk through the village with community members to identify and discuss sanitation related issues, visit open defecation sites, village water sources etc. Village mapping exercise: The village motivator stimulate discussion about sanitation issues by encouraging community members to draw a map of the village on the ground and use stones, leaves and colour powder to show village landmarks, houses with and without latrines, defecation sites, and water sources. Wealth ranking exercise: village motivator organises a meeting with community leaders and VWSC members at a central location in the village and	Feb – Apr 2011

	encourage discussions to help them identify poorest households in their village.	
Door-to-door household visits	Village motivators visit households door-to-door on a weekly basis to explain the programme, encourage participation, and follow-up on latrine construction progresses.	Feb 2011 – Mar 2012
Wall paintings	Wall paintings are located at the entrance of the village or visible location. Paintings typically include the F-diagram showing the transmission pathways for diarrhoea pathogens, breakdown of latrine construction costs and NGO contact details for transparency, and the map of the village as drawn during mapping exercise. One painting planned in each village.	Jan -Mar 2012
School Rally	School-aged children are assembled at the village school and walk through the village with placards while chanting slogans about sanitation. One school rally planned to take place in each village.	Jan-Mar 2012
Adolescent girls group or *'Kumari committee'*	Adolescent girls groups engaged in communicating about good sanitation practices among family and friends, organise village cleaning campaigns. Group members attend a 2-day training organised by the NGO.	Mar 2012

6.4. Monitoring system:

The process evaluation component was designed based on the framework developed by Linnan and Steckler(Steckler et al., 2002) . The key objectives of this evaluation were to 1) provide information on the context in which the intervention was implemented 2) document how the intervention was delivered 3) assess exposure to the intervention among the target population, and 4) explore associations between household exposure to community mobilisation activities and construction of latrines. Process evaluation data were collected through review of key documentation, quantitative surveys, direct observations, and semi-structured interviews with NGOs staff and community members. After an initial review of implementation guidelines and reports on the Total Sanitation Campaign, we met with the implementing NGOs to obtain detailed accounts on what the intervention consisted of at their level of operation. This information was used to develop the data collection tools. Between March 2011 and March 2012, a team of four trained enumerators and one supervisor visited each of the 50 intervention villages approximately every 6–8 weeks, resulting in six data collection rounds for each village. At each visit, field enumerators conducted the following activities: 1) they interviewed NGO village motivators to obtain information on the campaign activities conducted in the village 2) they reviewed documentation maintained by the village motivators and village water and sanitation committee (VWSC) members such as activity log books, meetings notes, household contribution registers, and construction material stock registers 3) they visited each household to observe and record latrine construction status. Latrine construction status was categorised as 'completed' and 'under construction'. A latrine was classified as 'completed' when it met the specification provided by WaterAid. A completed latrine had walls over 1.5 meters, a door, an unbroken and unblocked toilet pan, and a functional pan-pipe-pit connection. Latrine classified as 'under construction' were latrines that were left unfinished or latrine that were completed, but subsequently damaged. Between January and

March 2013, latrine coverage was assessed in both intervention and control villages. Between January and June 2012, a survey was conducted among a random sample of 10% of households in each of the 50 control and 50 intervention villages (approximately 400 households in each arm). The male or female head of household or if absent, a household member over sixteen years of age present at the time of visit was asked questions to measure their level of awareness about community mobilisation events undertaken within their village. For each intervention village where a village water and sanitation committee had been formed, we obtained a list of the VWSC members along with basic demographic characteristics. Approximately 10% of VWSC members or two members per village were randomly selected from the list and administered a short questionnaire to assess their involvement in the programme activities such as meetings, attendance to training, and awareness of their role and responsibilities as VWSC members. The sample size for both household and VWSC member surveys was based on logistical considerations.

For each village, a list of households and VWSC members was available. A sample was randomly selected from the list using the random generator function in Stata 13. Questionnaires and interview guides were developed in English, translated into Oriya and back-translated into English to ensure accuracy of translation. Quantitative data were analysed in Stata 13 (Stata corp, College Station, TX). We compared levels of awareness of key mobilisation activities between control and intervention villages. We first calculated village-level proportions of households who reported they had heard or participated in a given activity. We calculated the means of the village proportions for intervention and control groups and compared them using the Student't-test. Within intervention villages, we explored associations between village level percent awareness of or participation in mobilisation activities and village-level coverage using linear regression.

7. Impact analysis and results of the key evaluation questions

7.1.Statistical analyses

The primary outcome was 7-day prevalence of reported diarrhoea in children younger than 5 years. 7-day prevalence was recorded for all household members on the basis of reports from the primary caregiver(Schmidt et al., 2010, Schmidt et al., 2011). We defined diarrhoea
with the WHO definition of three or more loose stools in 24 h(Organization, 1995). In secondary analyses, we stratified the primary analysis by age, household size, population density (defined as the number of people living within 50 m, on the basis of
GPS survey) and below-poverty-line status. The sample size was based on the proportion of days with diarrhoea (longitudinal prevalence) of children younger than 5 years. We assumed a mean longitudinal daily prevalence of 4% (SD 7·6) in this population, with the assumption of six follow-up visits per child(Schmidt et al., 2010). We assumed a 25% reduction in diarrhoea prevalence as a figure of public health interest and in line with estimates from systematic reviews(Esrey et al., 1991, Wolf et al., 2014, Clasen et al., 2010, Engell and Lim, 2013). With an assumed 25 children per cluster, an intracluster correlation of 0·025, a design effect of 1·6, and 10% loss to follow-up, 80% power and a p value of 0·05 resulted in 50 clusters per study group. This figure was confirmed with a simulation method developed for the sample-size estimation of complex trials(Arnold et al., 2011). We calculated prevalence ratios of diarrhoea and soil-transmitted helminth infection in intervention and control villages with log-binomial models (binomial distribution, log-link). Village-level clustering was accounted for by generalised estimating equations with robust SEs. We converted height and weight into height-for-age and weight-for-age *Z* scores(Organization,

2007) and calculated mean differences in these scores with random-effects linear regression, adjusted for baseline values and accounting for village-level clustering. Negative binomial regression was used to calculate rate ratios of count data (soil-transmitted helminth eggs and flies), by aggregation of counts at village level, and with use of the number of samples in a village as exposure. Due to zero inflation and right truncation of bacterial counts of thermotolerant coliforms assays, we grouped these counts into log categories (0, 1–10, 11–100, etc., per 100 mL) and compared them between intervention and control groups with ordered logistic regression (with robust SEs to account for village-level clustering), which calculates the odds ratio of being in a higher category.

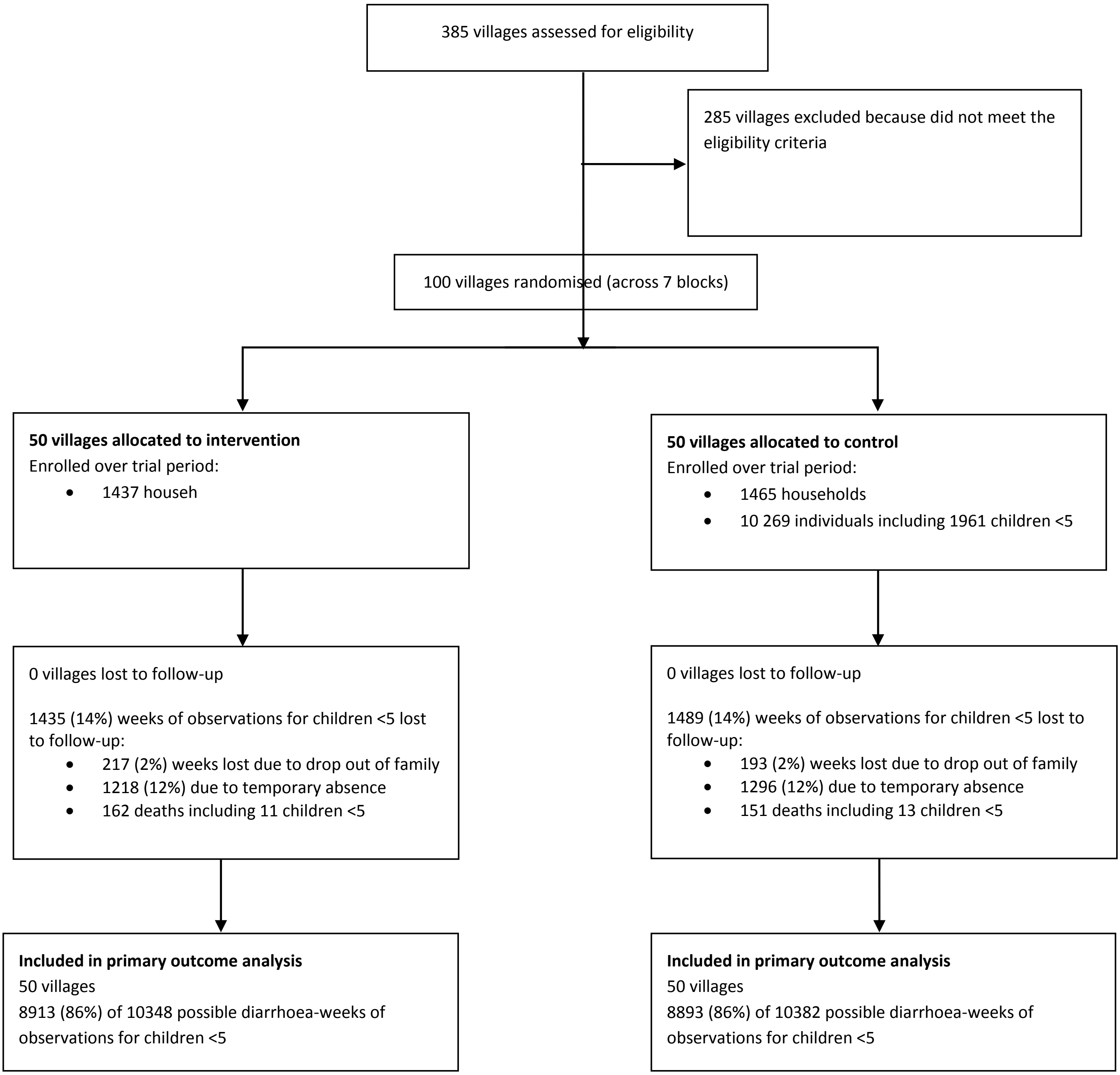
Because only 33% of follow-up stool samples were from individuals who had also given a baseline sample, the analysis of worm infection focused on follow-up samples.

In addition to the primary intention-to-treat analysis, we did a per-protocol analysis for village-level and household-level compliance for all health outcomes. For this purpose, a village was defined as compliant if 50% or more households had a functional latrine at the midpoint of follow-up. Households were defined as compliant with the protocol if they had a functional latrine at midpoint (intervention group) or not (control). To reduce the potential for bias inherent in per-protocol analyses, we adjusted for baseline diarrhoea. No per-protocol analysis was done for soil-transmitted helminth infection, as only a few baseline samples could be matched to follow-up samples, and baseline samples from five villages (four from the control group) were lost, making adjustments for baseline values unreliable. We did analyses with STATA (version 10).

7.2. Results of evaluation:

(Figure 6) shows the trial profile. We randomly assigned 50 villages to the intervention group and 50 villages to the control group. There were 4586 households (24 969 individuals) in intervention villages and 4894 households (25 982 individuals) in control villages; 1437 households from the intervention group and 1465 households from the control group met the eligibility criteria and were enrolled for health surveillance **(Figure 6)**. For diarrhoea surveillance, 10 014 individuals, including 1919 younger than 5 years were enrolled in the intervention at some point during surveillance, as were 10 269 individuals (n=1961 younger than 5 years) in the control group. Baseline and follow-up weight-for-age *Z*-score measures were available for 1462 individuals (n=650 younger than 2 years) in the intervention group and 1490 individuals (n=637 younger than 2 years) in the control group. Baseline and follow-up height-for-age *Z*-score measures were available for 350 individuals (71% of children measured at baseline) in the intervention group and 337 (74%) children in the control group. The proportion of worm samples obtained at baseline was similar in the intervention and control groups (1521 [44%] of 3457 *vs* 1438 [43%] of 3344), and worm samples at follow-up were obtained from 2231 (52%) of 4255 in the intervention group and 2063 (47%) of 4379 in the control group.

Figure 6: Trial profile.



In the intervention villages, the mean proportion of households with a latrine increased from 9% at baseline to 63% at follow-up (**Table 2**). At follow-up, 11 of 50 intervention villages had functional latrine coverage of 50% or greater, and seven had coverage of less than 20%. In the control villages, mean household-level coverage increased from 8% at baseline to 12% at follow-up (**Table 2**). At follow-up, two of 50 control villages had coverage with functional latrines greater than 30% (none had coverage of 50% or greater), and 41 had coverage of less than 20%. Because households with more individuals were more likely to have a functional latrine, the total proportion of the people with access to a functional latrine was higher than the household-level coverage (**Table 2**). 1729 (63%) of 2732 households with any latrine in the intervention group reported that household members were using the latrine; of these, 1690 (98%) of 1724 reported that women were using it, 1364 (79%) of 1725 reported that men were using it, and 903 (79%) of 1140 households with children reported that children were using it.

Table 2: Latrine coverage at village level at baseline and post-intervention.

	Intervention villages mean % (SD, range)	Control villages mean % (SD, range)	%Difference (95% CI)
Baseline household latrine coverage (any latrine)*	9 (8, 0-32)	8 (6, 0-27)	+1 (-2–4)
Households with any latrine	63 (18, 15-90)	12 (11, 0-47)	+51 (45–57)
Households with functional latrine†	38 (17, 8-80)	10 (9, 0-37)	+28 (23–34)
Households with functional latrine and signs of current use‡	36 (16, 7-76)	9 (8, 0-37)	+27 (22–32)
Functional latrines by number of people in household			
<5	32 (16, 15-71)	6 (7, 0–26)	+25 (20–30)
5-8	41 (19, 6-82)	12 (11, 0–47)	+29 (23–35)
>9	51 (29, 0-100)	19 (22, 0–100)	+32 (22–42)
Functional latrines by BPL status*			
BPL card	47 (26, 0-100)	10 (18, 0–100)	+37 (28–46)
No BPL card	40 (21, 0-77)	17 (22,0–100)	+23 (15–32)
People with access to functional latrine‡	46 (18, 6-81)	15 (12, 0-48)	+30 (24–37)

All values calculated from village-level data, based on 4585 intervention and 4895 households surveyed at study midpoint, except *calculated using status data from baseline survey (973 intervention and 1001 control households with children <5); †defined as *all* of the following: 1) any cover, 2) Not used for storage, 3) Pan not broken, not blocked and not full of leaves/dust, 4) Pit completed; ‡ defined as *any* of the following: 1) Smell, 2) Pan wet except when rainy, 3) Stain (faeces, urine), 4) Soap present, 5) Water bucket/can present, 6) Broom, brush for cleaning present, 7) Slippers present

The intervention had no effect on overall faecal contamination of water stored in the households of study participants (**Table 3**). No evidence showed that latrine construction affected contamination of wells. We recorded a trend for reduced contamination of the hands of mothers and children younger than 5 years in the intervention group (12% and 15% reduction, respectively, in the odds of being in a higher category of contamination), and on the sentinel toy (17% reduction of odds), compared with participants in the control group; however, this finding was not significant (**Table 3**). Similarly, there were numerically, but not significantly, fewer synanthropic flies in the intervention group than in the control group (**Table 3**).

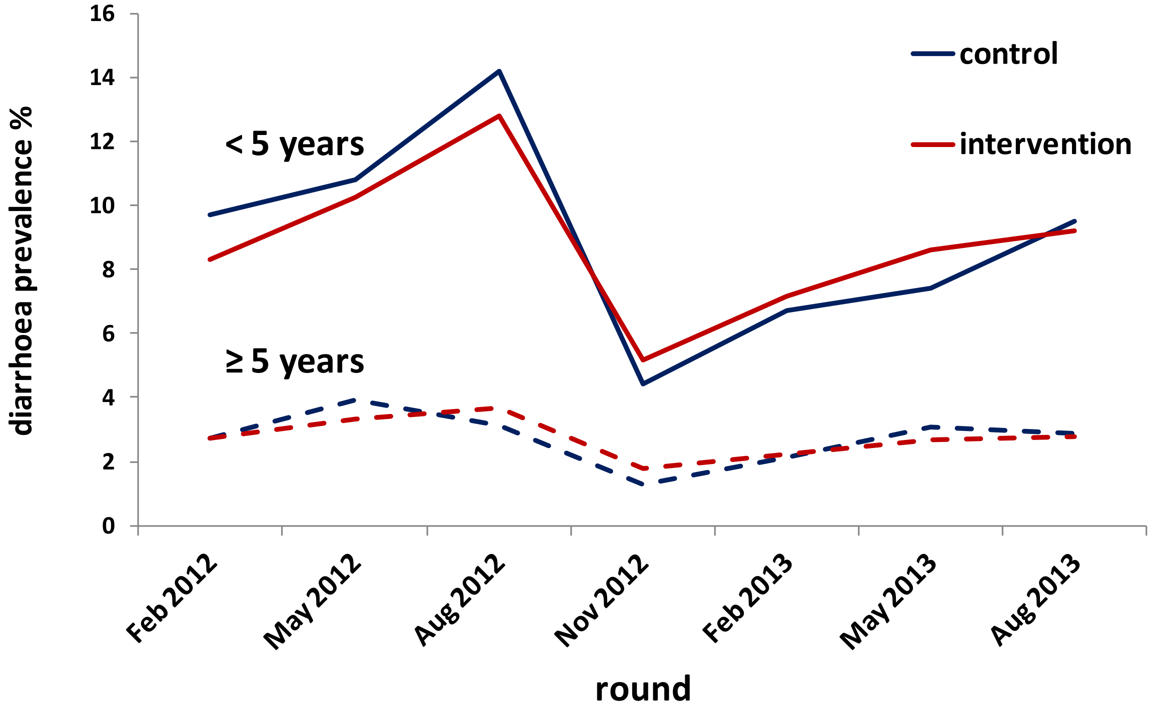
Table 3: Effect of intervention on water quality, hand contamination, and flies (intention-to treat analysis).

	Denominator		median bacterial colony / fly count		Effect size	95% CI
	Intervention	control	intervention	Control		
Water quality						
Household water	2406*	2505*	60	60	1.06‡	0.89–1.24
Source water	1951*	1918*	1	1	1.08‡	0.90–1.30
Hand contamination						
Mothers	175†	177†	205.8	469	0.88‡	0.49–1.58
Children <5	172†	167†	107	107	0.85‡	0.47–1.55
Sentinel toy	164†	162†	1.5	3	0.83‡	0.50–1.40
Total synanthropic flies	288*	284*	12	13	0.73§	0.46–1.16

*Number of households; †number of individuals; ‡Odds ratio from ordered logistic regression(categories: 0;1-10;11-100;101-1000;1001-10000;>10000 colony forming unit per 100ml of water, two hands or toy). 95%CI adjusted for clustering by use of robust standard errors, proportionality of odds tested with likelihood ratio test (all p>0.3); § rate ratio from negative binomial regression (counts aggregated at village level).

Reported 7-day diarrhoea prevalence in children younger than 5 years was 8·8% in the intervention group and 9·1% in the control group (**Figure 7**), with a decline in late 2012, corresponding to the cold and dry season.

Figure 7: 7-day prevalence of diarrhoea in children younger than 5 years (solid lines) and individuals aged 5 years and older (dashed lines) over seven rounds of follow up, by intention status.



No evidence showed that the intervention was protective against diarrhoea in children younger than 5 years, or against diarrhoea in all age groups (**Table 4**).

Table 4: Effect of the intervention on diarrhoea prevalence.

	Denominator (individuals)		Diarrhoea prevalence†		Prevalence ratio	95% CI
	intervention	control	intervention	control		
Intention-to-treat analysis						
By age						
Children <5 years	1919	1961	8.8	9.1	0.97	0.83–1.12
All ages	10014	10269	3.8	3.7	1.02	0.88–1.18
By household size*						
0/4	388	441	8.3	8.3	0.98	0.74–1.30
5/8	917	942	8.6	10.0	0.90	0.76–1.07
>9	614	578	9.2	7.8	1.09	0.88–1.36
By BPL status*						
Has BPL card	561	626	8.4	8.7	0.95	0.77–1.18
No BPL card	777	757	8.9	7.8	1.10	0.90–1.36
By population density (residents of all ages within 50m radius)*						
0/100	637	655	9.3	8.1	1.07	0.86–1.33
101/200	669	611	9.7	10.0	0.93	0.72–1.20
>200	456	554	8.4	8.8	0.95	0.76–1.18
*Per-protocol analysis**						
Villages with functional latrine coverage ≥50%						
Crude	299	1409	8.6	9.1	0.92	0.75–1.15
Adjusted‡	299	1409	-	-	0.98	0.78–1.24
Households with functional latrine						
Crude	612	1211	7.5	8.6	0.90	0.74–1.08
Adjusted‡	612	1211	-	-	0.95	0.79–1.13

Table shows results from log-binomial models, clustering by village accounted for by use of GEE; *Children <5; †crude mean village-level diarrhoea prevalence; ‡adjusted for baseline village level diarrhoea prevalence and baseline individual diarrhoea prevalence (calculated combining diarrhoea data from the baseline survey and the first two rounds that were done before October 2011).

No effect of the intervention was detected when the population was stratified by household size, population density, or below-poverty-line status (**Table 4**). The per-protocol analysis did not suggest an effect of the intervention on diarrhoea in children younger than 5 years, neither from village-level coverage nor from presence of a functional latrine in an individual household (**Table 4**). The baseline mean village-level prevalence of diarrhoea was highly correlated with follow-up village-level prevalence (r^2 0·79 in children younger than 5 years). The baseline total worm prevalence was similar between the groups (17·6% *vs* 17·0%). No evidence showed that the intervention reduced prevalence or egg counts of all soil-transmitted helminth infections, or of *A lumbricoides, T trichiura,* or hookworm (**Table 5**). At follow-up, 576 (87%) of 662 prevalent soil-transmitted helminth infections were due to hookworm and 6963 (84%) of 8288 identified eggs were hookworm eggs. The intervention had no effect on mean weight-for-age *Z* score in children younger than 5 years, or in those younger than 2 years, at baseline (**Table 5**). Findings from the per-protocol analysis suggest evidence for an increase in weight-for-age *Z* score in compliant villages and households (**Table 5**). The primary analysis showed no effect on mean height-for-age *Z* score in children younger than 2 years at baseline, and the per-protocol analysis suggested no major effects (**Table 5**). 162 participants died in the intervention group (11 children younger than 5 years) and 151 died in the control group (13 children younger than 5 years). The intracluster correlation coefficient for diarrhoea due to village-level clustering of diarrhoea (with exclusion of correlation due to repeated measurements) was 0·02 for children younger than 5 years and 0·01 for all age groups.

The coefficients for weight-for-age and height-for-age *Z* score at follow-up were both 0·06. The coefficients for combined prevalence of soil-transmitted helminth infection was 0·09.

Table 5: Effect of the intervention on anthropometric measures and worm infection.

	Denominator (individuals)		Mean z-score / STH prevalence/ mean STH egg count		Effect size	95% CI
	intervention	control	intervention	Control		
STH infection						
Intention-to-treat analysis						
STH prevalence	2231	2063	16.0	16.4	0.97‡	0.72–1.32
STH egg counts/gram	2151	2002	10.2	9.4	1.08§	0.62–1.88
Hookworm prevalence	2231	2063	14.1	15.6	0.90‡	0.66–1.22
Hookworm egg counts / gram	2151	2002	8.7	9.1	0.96§	0.54–1.68
Ascaris prevalence	2229	2063	0.7	0.3	2.04‡	0.38–10.91
Ascaris egg counts / gram	2150	2000	0.9	0.5	1.85§	0.07–48.75
Trichuris prevalence	2229	2063	2.6	0.6	3.89‡	1.38–10.92
Trichuris egg counts / gram	2149	2002	0.9	0.1	9.90§	1.98–46.62
Weight-for-age z score*						
Intention-to-treat analysis						
Children <5 years at baseline	1462	1490	-1.48	-1.43	0.02†	-0.04–0.08
Children < 2 years at baseline	650	637	-1.46	-1.32	-0.01†	-0.12–0.09
Per-protocol analysis (children <5 at baseline)						
Villages with functional latrine coverage ≥50%	324	1490	-1.36	-1.43	0.10†	0.003–0.20
Households with functional latrine	683	1274	-1.32	-1.50	0.12†	0.05–0.20
Height-for-age z score*						
Intention-to-treat analysis	350	337	-1.56	-1.36	-0.10†	-0.22–0.02
Per-protocol analysis						
Villages with functional latrine coverage ≥50%	75	337	-1.45	-1.37	-0.04†	-0.24–0.16
Households with functional latrine	161	294	-1.42	-1.39	-0.06†	-0.27–0.15

*Children with z-score >5 and <-5 excluded from analysis; † random effects linear regression ‡ log-binomial models, clustering by village accounted for by use of GEE; § negative binomial regression of sum of village level egg counts with number of samples in village as exposure

7.3. Results of process documentation:

Community mobilisation

Information on VWSC formation and composition was obtained for 48 villages. Information was missing for two villages where NGOs encountered delays in implementation due to political issues within the communities.

In most villages, committees were established after one or two meetings between February and June 2011.

The mean number of members in each committee was 12 (range 5 to 16) and 40% of VWSC members were women. Committees included local government representatives (11%), Self-help group members (16%), kindergarten or community health workers (13%), and teachers (2%).

The remaining were key opinion leaders or community members who volunteers to be part of the committee. Two VWSC members per village were invited to participate in a 2-day training at the NGO office. Each training course had approximately 20–25 participants. The key objectives of the training were to 1) discuss the problems associated with lack of sanitation, 2) explain the objectives of the TSC programme including discussions on latrine construction logistics and contribution costs to ensure transparency, and 3) help committee members to prepare an action plan for their village. The NGO used pile sorting exercises with colour cards to display different behaviours and asks the audience to categorise the behaviours as good or bad and to explain the reasons why. This was followed by a discussion on existing defecation practices in the village and by learning a song on sanitation. The second day covered roles and responsibilities and development of an action plan. In 37 villages, mapping exercise activities reportedly took place. In six villages, the village motivator reported that no community-level participatory mapping exercise was conducted and information could not be obtained for seven villages. Important differences were noted in the way village motivators described how the mapping exercise was done. In half of the 37 villages, village motivators would describe the mapping exercise as a participatory process where they called on people to a central location in the village and engaged villagers in discussions to draw a map on the floor using colour powder and point out key landmarks in the village, houses, open defecation fields, households with latrines and water sources. The number of participants reported to attend ranged between 15 and 20, and most were VWSC members. In two villages, the motivator reported that 30–45 people attended the event although most people left within one hour. The mapping exercise was typically completed within a half-day including waiting time to gather community members. In three villages, the mapping exercise was reported to have taken 3 days. None of the village motivators mentioned using tools such as faeces counts or standing in open defecation areas as are used in community-led total sanitation (CLTS) programmes. In the remaining villages, village motivators reported that the mapping exercise was conducted with the help of two to three VWSC members and consisted of walking around the village and simply sketching a map of the village on a piece of paper.

Village motivators reported weekly door-to-door household visits. They explained the advantages of having a latrine, provided details of the programme including contribution amounts and construction logistics. They used behaviour change messages provided to them during their initial training. The communication strategy did not focus on a well-defined set of key messages. Instead, sanitation messages were varied and included themes such as inconvenience (at night, time wasted to walk to open defecation sites), women safety and privacy, shame, health, loss of school and work days from being sick, cost of treatment for intestinal infections. Some village motivators carried with them a picture of the latrine design but were not provided with any other communication tools to engage householders in discussions during visits.

According to NGO staff, wealth ranking exercises consisted of organising a meeting with VWSC members and asking them to identify and make a list of households in the village that were considered as poor but did not owned a BPL card. Provision of financial assistance to some but not all households was a frequent source of tensions between the NGOs and communities. As a result, implementers decided to provide a subsidy to all households in intervention villages to prevent delays in the implementation.

As of the last process documentation visit in March 2012, school rallies were recorded to have taken place in 31 villages. School rallies were conducted once during the first quarter of 2012 among children in primary school and included approximately 25–35 students. Village motivators provided teachers with slogans and songs about sanitation and prizes for students who successfully recited them. Children were then given placards and marched through the village while chanting slogans on the merits of sanitation. Wall paintings were observed in 28 villages, although this number is likely to be an underestimation because paintings were being produced during the time of the last visit. Wall paintings typically showed the F-diagram representing the transmission pathways for faecal pathogens**(Figure 8)**. The NGO also included the cost breakdown for latrine construction in order to make the process transparent to the community. Adolescent girls groups or 'Kumari committees' were reported to be formed in 31 villages. In 6 villages, no groups were formed as of the last visit and no information was available for the remaining 13 villages. A training course was organised by the implementing NGOs.

Figure 8: F-Diagram by WaterAid.

The content of the course or the actual role of those committees as described by village motivators was vague. Some mentioned that the groups would become engaged in micro-finance activities while others mentioned that the role of the committee was to discourage open defecation, engage in village cleaning activities, and to raise awareness about the issue of sanitation among their family members and neighbours. Village motivators were unclear about the structure of those committees, what they were actually supposed to do and how.

Exposure to intervention: Levels of awareness among community members

Overall, the percentage of households who had heard about the total sanitation campaign was significantly higher in intervention than in control villages (91% versus 49%, respectively, $p < 0.001$). Perceived benefits associated with having a latrine were broadly similar across intervention and control villages (**Table 6. Apendix A**). In intervention villages, households heard about the campaign mostly from NGOs (64%) or VWSC members (17%) while in control villages, respondents heard about it from neighbours (30%), NGOs (20%), ward member

(15%) or family (12%) and friends (10%). Almost none of the households in intervention villages recalled any form of participatory activities such as transect walk and mapping exercise (6%) or wealth ranking (0%). The proportions were similar in the control villages. However, intervention households were more aware of VWSCs than controls (51% versus 9%, $p < 0.001$).

Awareness of Kumari committees was higher among intervention villages (23% versus 8%, $p < 0.01$). Overall, 36% and 43% of intervention and control households remembered school rallies being conducted in their village. Wall paintings and household visits regarding sanitation over the past three months were also more commonly cited among intervention households (44% versus 7%, $p < 0.001$ and 65% versus 3%, $p < 0.001$, respectively). Among the topic being discussed during home visits, intervention households remembered contribution amounts (70%) and latrine construction logistics (52%) the most. Much less remembered discussions around use (26%) and benefits of latrines (20%).

Awareness among VWSC members

Overall, 57% of VWSC members reported that they were invited to participate in a training course provided by the NGO and 69% of those reported attending the training (**Table 7**).

Table 7: Awareness of mobilisation activities among members of village water and sanitation committee of intervention villages (n=170).

	n	%
Respondent is female	91	53
Mean age of respondent (SD)	44 (12)	
Know the name of other VWSC members		
President	88	52
Secretary	41	24
ASHA	90	52
Anganwadi	85	50
Invited for training	97	57
Attended training	67	69
Topics remember being discussed at training		
Learned about the benefits of having a latrine	44	66
How to motivate people to build a latrine	30	47
Latrine cost and contribution amounts	21	31
How to motivate people to use latrine	18	27
Instruction on how to construct latrine	11	16
Perceived role as VWSC member		
Encourage households to construct toilets	90	54
Oversee latrine construction work	36	21
Encourage households to use toilets	14	8
Conduct meetings	11	7
Don't know	50	30
Who organises VWSC meetings		
VM	141	89
Other VWSC members	17	9
Number of VWSC meetings remembered being held		
0-4	79	46
5-9	56	33
10+	29	17
Don't know	6	3
Attended the last VWSC meeting	94	55
Remember being discussed at last meeting		
Discuss benefits of having a latrine	48	29
Instruction on how to construct latrine	28	17
Latrine cost breakdown and contribution amounts	34	21
How to motivate people to build a latrine	36	22
How to motivate people to use latrine	23	14
How often is the village motivator present at those meetings		
Always	150	93
Sometimes	5	3
Rarely	1	1
Never	5	3
Ever conducted household visits	102	60
Frequency of visits		

1-4	39	38
5-9	18	17
10+	41	40
Don't know	5	5
Remember discussing during those visits		
Instruction on how to construct latrine	86	51
Latrine cost breakdown and contribution amounts	76	45
Benefits of having a latrine	65	39
How to use and maintain a latrine	30	17

The topic most remembered was about the benefits of using the latrine (66%) followed by sessions on communication techniques to motivate other villagers to build a latrine (47%). 54% of VWSC members saw their role as encouraging people to construct toilets, but only 21% described being involved in overseeing latrine construction logistics. Even fewer (8%) mentioned their role was about encouraging toilet use. Almost a third didn't know what their role as VWSC members was. VWSC meetings almost always took place in the presence of the village motivator (89%). Almost half (45%) reported not attending the last VWSC meeting and 40% never conducted door-to-door household visits in relation with the programme. We explored if there was any association between awareness of or participation in different mobilisation activities and latrine coverage among households and members of the village water and sanitation committee in intervention villages. There were some evidence that latrine coverage was higher among villages where a larger proportion of households remembered seeing wall paintings (p = 0.05), reported a home visit by the village motivator during the past month (p = 0.02), and among villages where village water and sanitation committee members reported that five or more VWSC meetings were held since the start of the programme (p = 0.04)
(**Table 8**). There was no apparent association between reported awareness of or participation in other activities and latrine coverage.

Table 8: Association between village-level coverage in March 2012 and awareness of or participation in mobilisation activities in the 50 intervention villages.

	Regression Coefficient*	95%CI	p-value
Household awareness (n=408)			
Heard about sanitation campaign	0.203	(-0.306; 0.712)	0.43
Heard or participated in transect walk/ mapping exercise	0.637	(-0.104; 1.379)	0.09
Heard or participated in wealth ranking exercise	1.530	(-2.261; 5.321)	0.42
Heard of village water and sanitation committee	0.181	(-0.660; 0.428)	0.15
Heard of kumari committee	0.233	(-0.051; 0.518)	0.11
Heard or seen school children rally	0.230	(-0.025; 0.482)	0.07
Seen wall paintings	0.171	(0.001; 0.341)	0.05
Village motivator visited their house in the past month	0.216	(-0.000; 0.431)	0.05
VWSC members awareness (n=170)			
VWSC members attended NGO training	0.001	(-0.181; 0.183)	0.99
≥ 5 VWSC meetings held since the start of the programme	0.178	(0.010; 0.346)	0.04
VWSC attended the last VWSC meeting	0.060	(-0.164; 0.284)	0.59
VWSC member ever conducted household visits	0.025	(-0.205; 0.254)	0.83
VWSC member conducted ≥ 5 household visits	0.058	(-0.156; 0.272)	0.59

*Regression coefficients express increase in latrine coverage in percent with every additional percent increase in awareness of or participation in activities among respondents in a village

8. Discussion

Our findings show no evidence that this sanitation programme in rural Odisha reduced exposure to faecal contamination or prevented diarrhoea, soil transmitted helminth infection, or child malnutrition. These results are in contrast with systematic reviews that have reported significant health gains from rural household sanitation interventions (panel)(Esrey et al., 1991, Wolf et al., 2014, Clasen et al., 2010, Engell and Lim, 2013, Ziegelbauer et al., 2012, Stocks et al., 2014, Strunz et al., 2014). However, they are consistent with another trial of a sanitation project implemented within the context of the Total Sanitation Campaign in the Indian state of Madhya Pradesh(Patil et al., 2014). Insufficient coverage and use of latrines seem to be the most likely causes for the absence of effect, because no evidence showed that the intervention reduced faecal exposure. Although mean coverage of latrines increased substantially in the intervention villages, more than a third of village households (on average) remained without a latrine after the intervention. About twice that many had no functional latrine that was used at the midpoint of the surveillance period. Latrine functionality is an objective measure of some use by the household; however, it cannot discern use by individual householders. Other evidence exists to show suboptimum use of latrines constructed as part of the Total Sanitation Campaign, particularly by men and children(Arnold et al., 2010, Barnard et al., 2013) and for the disposal of child faeces(Clasen et al., 2014). Although we detected no effect of the intervention at coverage of 50% or higher with functional latrines, that level of coverage and inconsistent use still represents high levels of continued open defecation and thus a substantial opportunity for continued exposure to faecal pathogens at the village level. Another possible explanation for our negative findings is that improvements in household sanitation alone are insufficient to mitigate exposure to faecal–oral pathogens. Hands can be contaminated by anal cleansing of oneself or a child that is not followed by handwashing with soap, and food can be contaminated during production or preparation. Animal faeces could also be contributing to the disease burden—a possibility that we are exploring in our substudy of microbial source tracking(Clasen et al., 2012). Exposure to rotavirus or zoonotic agents such as *Cryptosporidium* spp, both of which have been reported to be a major cause of severe to moderate diarrhoea in India, might only be partly prevented by sanitation(Kotloff et al., 2013). Another explanation could be that the latrines themselves were ineffective at containing excreta; however, no evidence showed that latrines contaminated water sources. Additionally, the 14-month construction period and 18-month surveillance period might not be long enough to eliminate the risk of pre-intervention faeces in the environment. Some soil-transmitted helminth eggs and protozoan cysts can persist for extended periods outside a host, and some enteropathogenic bacteria can multiply in suitable environments(Feachem et al., 1983). All these possible explanations are important areas for further research. For now, however, increasing of village-level coverage and use would seem to be a priority. The levels achieved in our study are not unusual under the Total Sanitation Campaign and thus cannot be dismissed as an aberration(Arnold et al., 2010, Barnard et al., 2013, Pattanayak et al., 2009). From 2001 to 2011, only two of 509 districts in India increased latrine coverage by more than 50%(Ghosh and Cairncross, 2014). Changes to the Total Sanitation Campaign (which has been renamed the Nirmal Bharat Abhiyan) increase and extend subsidies for construction beyond households below the poverty line to specified vulnerable groups(Hueso and Bell, 2013). However, most households above the poverty line still do not qualify for subsidies and must build their own latrines. Although the Total Sanitation Campaign includes incentives through the Nirmal Gram Puraskar scheme to encourage village-wide open-defecation-free status, most villages do not qualify. Other approaches to rural sanitation, including community-led total sanitation, emphasise 100% latrine coverage in each village. An important limitation of our study relates to the 18-

month follow-up period. The potential health effect of rural sanitation (especially with regard to slow-reacting outcomes such as worm infection and stunting) might not be measurable within this time. This drawback raises questions about the feasibility of sanitation trials, especially because a more successful programme (e.g., using sanitation marketing and enhanced community mobilisation) might take 5–10 years to be implemented in areas with a low initial demand—a period during which investigators would encounter difficulties in withholding an intervention from a control group(Schmidt, 2014). Although we recorded no evidence for bias caused by self-reported or carer-reported diarrhoea data, this possibility is a further limitation(Schmidt et al., 2011). The per-protocol analyses were adjusted for baseline values, but residual confounding is possible. Even with the potential for residual confounding, the per-protocol analysis showed no consistent effects in villages or households with higher compliance, except for weight-for-age *Z* score, which was not consistent with the absence of effect on height-for-age score. Compliance with the intervention might be related not only to child weight-for-age *Z* score at baseline, but also independently to the rate of decline in weight-for-age score in the first 2 years of life, which we noted in our study area. Household sanitation could provide other benefits, including convenience, dignity, privacy, and safety. Latrine use was nearly five times higher for women than for men or children. However, our results show that the health benefits generally associated with sanitation cannot be assumed simply by construction of latrines. As efforts to expand sanitation coverage are undertaken worldwide, approaches need to not only meet coverage-driven targets, but also achieve levels of uptake that could reduce levels of exposure, thereby offering the potential for genuine and enduring health gains.

9. Specific findings for policy and practice

The intervention did not show an effect on the measured child health outcomes of self-reported diarrhoea, prevalence of soil-transmitted infections or under-nutrition. Our findings raise questions about the health effect of sanitation initiatives that focus on increasing latrine construction but do not end open defecation or mitigate other possible sources of exposure.

Although latrine coverage increased substantially in the study villages to levels targeted by the underlying campaign, many households did not build latrines and others were not functional at follow-up. Even householders with access to latrines did not always use them, particularly among men and children. Combined with other possible exposures, such as no hand washing with soap or safe disposal of child faeces, suboptimum coverage and use may have vitiated the potential health effect generally reported from improved sanitation. These results are consistent with those from another trial(Patil et al., 2014). Although the sanitation campaign in India has been modified to address some of these challenges, the programme still focuses mainly on the building of latrines—the main metric for showing progress towards sanitation targets.

Although these efforts should continue, sanitation strategies can optimise health gains by ensuring full latrine coverage and use, ending open defecation, and minimising other sources of exposure.

Appendix A: Table 6: Awareness of mobilisation activities among intervention and control households (n=807).

	Intervention (n=408)		Control (n=399)		Difference	p-value*
	N	%	N	%	%	
Mean age of respondent (sd)	45 (15)		41 (14)			
Respondent is female	249	61	222	56	5	
Perceived benefits of having a toilet						
Convenient when it rains or during floods	187	46	193	48	-2	0.61
Time saving from walking to OD sites	241	59	189	47	12	0.02
Health benefits	141	35	114	29	6	0.18
Safety	128	31	131	33	-2	0.82
Prevent contaminating the environment	70	17	87	22	-5	0.15
Convenient at night	118	29	138	35	-6	0.47
Convenient for elderly	46	11	48	12	-1	0.73
Convenient for children	47	12	75	19	-7	0.01
Convenient when sick	19	5	55	14	-9	0.02
Convenient for disabled person	4	1	6	2	-1	0.51
Safer for women	71	17	92	23	-6	0.04
Give privacy to women	82	20	84	21	-1	0.98
Cost saving	2	0	15	4	-4	<0.01
Status improved	8	2	16	4	-2	0.04
Shame	16	4	0	0	4	<0.01
Good for married women	17	4	1	0	4	<0.01
Heard about sanitation campaign	373	91	194	49	42	<0.001
Heard about campaign from (n=567)						
NGO	238	64	38	20	44	<0.001
VWSC	63	17	0	0	17	<0.001
Ward member	21	6	30	15	-9	<0.01
Anganwadi worker	12	3	16	8	-5	0.09
ASHA	23	6	0	0	6	0.02
School teacher	3	1	0	0	1	0.09
Adolescent girls committee	3	1	0	0	1	0.19
Self-help group	5	1	9	5	-4	0.06
Neighbours	34	9	59	30	-21	<0.001
Family	10	3	23	12	-9	<0.01
Friends	1	0	19	10	-10	<0.001
Heard or seen village walk or mapping exercise	26	6	38	10	-4	0.04
Heard of wealth ranking exercise	1	0	5	1	-1	0.09
Heard of village water and sanitation committee	207	51	37	9	42	<0.001
Can cite name of at least one VWSC member	169	41	26	7	34	<0.001
Can explain what VWSC members do	138	34	8	2	32	<0.001
Heard of adolescent girls group	93	23	33	8	15	<0.01
Heard or seen school children rally	147	36	173	43	-7	0.10
Seen wall paintings	178	44	28	7	37	<0.001
Remember content of wall painting (n=206)						
Transmission of diarrhoea	103	57	6	21	36	<0.01
Latrine cost breakdown	104	57	2	8	49	0.01

Village map	68	38	3	11	27	0.24
Received home visit about sanitation in past 3 mo	242	65	12	3	230	<0.001
Person who came at last visit						
NGO staff	257	63	11	3	60	<0.001
VWSC member	13	3	0	0	3	0.2145
Ward member	4	1	7	2	-1	0.0023
Anganwadi worker	4	1	1	0	1	0.4559
ASHA	12	3	0	0	3	0.3551
SHG member	25	6	2	1	5	0.9694
Remember being discussed during last visit						
Contribution amount	285	70	4	1	69	0.001
Latrine construction logistics	211	52	10	3	49	0.04
How to use and maintain latrine	108	26	2	1	25	0.91
Benefits of having a latrine	80	20	1	0	20	0.88
Inform about meetings	37	9	0	0	9	0.66
Kumari committee	2	0	0	0	0	0.12

*p-values calculated using the t-test on village-level percent awareness of or participation in mobilisation activities

References

APHA, A. Wef. 2005. *Standard Methods for the Examination of Water and Wastewater. 21st ed. American Public Health Association. Washington, DC. Part,* 8000**,** 94-100.

ARNOLD, B. F., HOGAN, D. R., COLFORD, J. M. & HUBBARD, A. E. 2011. Simulation methods to estimate design power: an overview for applied research. *BMC medical research methodology,* 11**,** 94.

ARNOLD, B. F., KHUSH, R. S., RAMASWAMY, P., LONDON, A. G., RAJKUMAR, P., RAMAPRABHA, P., DURAIRAJ, N., HUBBARD, A. E., BALAKRISHNAN, K. & COLFORD, J. M. 2010. Causal inference methods to study nonrandomized, preexisting development interventions. *Proceedings of the National Academy of Sciences,* 107**,** 22605-22610.

BARNARD, S., ROUTRAY, P., MAJORIN, F., PELETZ, R., BOISSON, S., SINHA, A. & CLASEN, T. 2013. Impact of Indian Total Sanitation Campaign on Latrine Coverage and Use: A Cross-Sectional Study in Orissa Three Years following Programme Implementation. *PloS one,* 8**,** e71438.

BIRAN, A., SCHMIDT, W. P., WRIGHT, R., JONES, T., SESHADRI, M., ISAAC, P., NATHAN, N., HALL, P., MCKENNA, J. & GRANGER, S. 2009. The effect of a soap promotion and hygiene education campaign on handwashing behaviour in rural India: a cluster randomised trial. *Tropical medicine & international health,* 14**,** 1303-1314.

BOISSON, S., STEVENSON, M., SHAPIRO, L., KUMAR, V., SINGH, L. P., WARD, D. & CLASEN, T. 2013. Effect of household-based drinking water chlorination on diarrhoea among children under five in Orissa, India: a double-blind randomised placebo-controlled trial. *PLoS medicine,* 10**,** e1001497.

BOSCHI-PINTO, C., VELEBIT, L. & SHIBUYA, K. 2008. Estimating child mortality due to diarrhoea in developing countries. *Bulletin of the World Health Organization,* 86**,** 710-717.

CAIRNCROSS, S., HUNT, C., BOISSON, S., BOSTOEN, K., CURTIS, V., FUNG, I. C. & SCHMIDT, W.-P. 2010. Water, sanitation and hygiene for the prevention of diarrhoea. *International journal of Epidemiology,* 39**,** i193-i205.

CLASEN, T., BOISSON, S., ROUTRAY, P., CUMMING, O., JENKINS, M., ENSINK, J. H., BELL, M., FREEMAN, M. C., PEPPIN, S. & SCHMIDT, W.-P. 2012. The effect of improved rural sanitation on diarrhoea and helminth infection: design of a cluster-randomized trial in Orissa, India. *Emerging themes in epidemiology,* 9**,** 7.

CLASEN, T., BOISSON, S., ROUTRAY, P., TORONDEL, B., BELL, M., CUMMING, O., ENSINK, J., FREEMAN, M., JENKINS, M. & ODAGIRI, M. 2014. Effectiveness of a rural sanitation programme on diarrhoea, soil-transmitted helminth infection, and child malnutrition in Odisha, India: a cluster-randomised trial. *The Lancet Global Health*.

CLASEN, T. F., BOSTOEN, K., SCHMIDT, W. P., BOISSON, S., FUNG, I., JENKINS, M. W., SCOTT, B., SUGDEN, S. & CAIRNCROSS, S. 2010. Interventions to improve disposal of human excreta for preventing diarrhoea. *Cochrane Database Syst Rev,* 6.

ENGELL, R. E. & LIM, S. S. 2013. Does clean water matter? An updated meta-analysis of water supply and sanitation interventions and diarrhoeal diseases. *The Lancet,* 381**,** S44.

ESREY, S. A., FEACHEM, R. G. & HUGHES, J. M. 1985. Interventions for the control of diarrhoeal diseases among young children: improving water supplies and excreta disposal facilities. *Bulletin of the World Health organization,* 63**,** 757.

ESREY, S. A., POTASH, J. B., ROBERTS, L. & SHIFF, C. 1991. Effects of improved water supply and sanitation on ascariasis, diarrhoea, dracunculiasis, hookworm infection, schistosomiasis, and trachoma. *Bulletin of the World Health organization,* 69**,** 609.

FEACHEM, R., BRADLEY, D., GARELICK, H. & MARA, D. 1983. Sanitation and Disease: Health Aspects of Wastewater and Excreta Management. John Wiley & Sons, Chichester.

FEWTRELL, L., KAUFMANN, R. B., KAY, D., ENANORIA, W., HALLER, L. & COLFORD JR, J. M. 2005. Water, sanitation, and hygiene interventions to reduce diarrhoea in less developed countries: a systematic review and meta-analysis. *The Lancet infectious diseases,* 5**,** 42-52.

GHOSH, A. & CAIRNCROSS, S. 2014. The uneven progress of sanitation in India. *Journal of Water, Sanitation and Hygiene for Development,* 4**,** 15-22.

GIBSON, R. S. 2005. *Principles of nutritional assessment*, Oxford university press.

GOVERNMENT OF INDIA. Available: http://ddws.gov.in/TSC.

GOVERNMENT OF INDIA 2008. Puri – Fact Sheet. In District Level Household and Facility survey (DLHFS-3). Mumbai: International Institute for Population Science.

GOVERNMENT OF INDIA MINISTRY FOR DRINKING WATER AND SANITATION 2012. Guidelines on Nirmal Bharat Abhiyan (NBA). *In:* HTTP://WWW.MDWS.GOV.IN/SITES/UPLOAD_FILES/DDWS/FILES/PDFS/FINAL%20GUIDELINES%20(ENGLISH).PDF., A. (ed.).

GOVERNMENT OF INDIA: CENTRAL RURAL SANITATION PROGRAMME TOTAL SANITATION CAMPAIGN. MINISTRY OF RURAL DEVELOPMENT: DEPARTMENT OF DRINKING WATER SUPPLY 2007.

HAYES RJ, M. L. 2009. Cluster Randomised Trials. *Boca Raton: Chapman & Hall/CRC.*

HUESO, A. & BELL, B. 2013. An untold story of policy failure: the Total Sanitation Campaign in India. *Water Policy,* 15**,** 1001-1017.

JENKINS, M. W. & CURTIS, V. 2005. Achieving the 'good life': Why some people want latrines in rural Benin. *Social science & medicine,* 61**,** 2446-2459.

JENKINS, M. W. & SCOTT, B. 2007. Behavioral indicators of household decision-making and demand for sanitation and potential gains from social marketing in Ghana. *Social science & medicine,* 64**,** 2427-2442.

KOTLOFF, K. L., NATARO, J. P., BLACKWELDER, W. C., NASRIN, D., FARAG, T. H., PANCHALINGAM, S., WU, Y., SOW, S. O., SUR, D. & BREIMAN, R. F. 2013. Burden and aetiology of diarrhoeal disease in infants and young children in developing countries (the Global Enteric Multicenter Study, GEMS): a prospective, case-control study. *The Lancet,* 382**,** 209-222.

LUBY, S. P., AGBOATWALLA, M. & HOEKSTRA, R. M. 2011. The variability of childhood diarrhea in karachi, pakistan, 2002–2006. *The American journal of tropical medicine and hygiene,* 84**,** 870-877.

MOULTON, L. H., GOLUB, J. E., DUROVNI, B., CAVALCANTE, S. C., PACHECO, A. G., SARACENI, V., KING, B. & CHAISSON, R. E. 2007. Statistical design of THRio: a phased implementation clinic-randomized study of a tuberculosis preventive therapy intervention. *Clinical Trials,* 4**,** 190-199.

ORGANIZATION, W. H. 1995. The treatment of diarrhoea: a manual for physicians and other senior health workers. *The treatment of diarrhoea: a manual for physicians and other senior health workers; The treatment of diarrhoea: a manual for physicians and other senior health workers.* World Health Organization.

ORGANIZATION, W. H. 2007. Anthro for personal computers, version 2, 2007: Software for assessing growth and development of the world's children. *Geneva: WHO*.

PATIL, S. R., ARNOLD, B. F., SALVATORE, A. L., BRICENO, B., GANGULY, S., COLFORD JR, J. M. & GERTLER, P. J. 2014. The effect of India's total sanitation campaign on defecation behaviors and child health in rural Madhya Pradesh: a cluster randomized controlled trial. *PLoS medicine,* 11**,** e1001709.

PATTANAYAK, S. K., YANG, J.-C., DICKINSON, K. L., POULOS, C., PATIL, S. R., MALLICK, R. K., BLITSTEIN, J. L. & PRAHARAJ, P. 2009. Shame or subsidy revisited: social mobilization for sanitation in Orissa, India. *Bulletin of the World Health Organization,* 87**,** 580-587.

PICKERING, A. J., BOEHM, A. B., MWANJALI, M. & DAVIS, J. 2010. Efficacy of waterless hand hygiene compared with handwashing with soap: a field study in Dar es Salaam, Tanzania. *The American journal of tropical medicine and hygiene,* 82**,** 270-278.

SCHMIDT, W.-P., ARNOLD, B. F., BOISSON, S., GENSER, B., LUBY, S. P., BARRETO, M. L., CLASEN, T. & CAIRNCROSS, S. 2011. Epidemiological methods in diarrhoea studies—an update. *International journal of epidemiology,* 40**,** 1678-1692.

SCHMIDT, W.-P. & CAIRNCROSS, S. 2009. Household water treatment in poor populations: is there enough evidence for scaling up now? *Environmental science & technology,* 43**,** 986-992.
SCHMIDT, W.-P., GENSER, B., BARRETO, M. L., CLASEN, T., LUBY, S. P., CAIRNCROSS, S. & CHALABI, Z. 2010. Sampling strategies to measure the prevalence of common recurrent infections in longitudinal studies. *Emerging themes in epidemiology,* 7**,** 5.
SCHMIDT, W. P. 2014. The elusive effect of water and sanitation on the global burden of disease. *Tropical Medicine & International Health,* 19**,** 522-527.
STECKLER, A. B., LINNAN, L. & ISRAEL, B. 2002. *Process evaluation for public health interventions and research*, Jossey-Bass San Francisco.
STOCKS, M. E., OGDEN, S., HADDAD, D., ADDISS, D. G., MCGUIRE, C. & FREEMAN, M. C. 2014. Effect of water, sanitation, and hygiene on the prevention of trachoma: a systematic review and meta-analysis. *PLoS medicine,* 11**,** e1001605.
STRUNZ, E. C., ADDISS, D. G., STOCKS, M. E., OGDEN, S., UTZINGER, J. & FREEMAN, M. C. 2014. Water, sanitation, hygiene, and soil-transmitted helminth infection: a systematic review and meta-analysis. *PLoS medicine,* 11**,** e1001620.
SUPPLY, W. U. J. M. P. F. W. & SANITATION 2010. Progress on Sanitation and Drinking-Water—2010 Update. World Health Organization Geneva, Switzerland.
TRUANT, A. L., ELLIOTT, S. H., KELLY, M. T. & SMITH, J. H. 1981. Comparison of formalin-ethyl ether sedimentation, formalin-ethyl acetate sedimentation, and zinc sulfate flotation techniques for detection of intestinal parasites. *Journal of clinical microbiology,* 13**,** 882-884.
ULIJASZEK, S. J. & KERR, D. A. 1999. Anthropometric measurement error and the assessment of nutritional status. *British Journal of Nutrition,* 82**,** 165-177.
VUJCIC, J., RAM, P. K., HUSSAIN, F., UNICOMB, L., GOPE, P. S., ABEDIN, J., MAHMUD, Z. H., SIRAJUL ISLAM, M. & LUBY, S. P. 2014. Toys and toilets: cross-sectional study using children's toys to evaluate environmental faecal contamination in rural Bangladeshi households with different sanitation facilities and practices. *Tropical Medicine & International Health,* 19**,** 528-536.
WADDINGTON, H., SNILSTVEIT, B., WHITE, H. & FEWTRELL, L. 2009. *Water, sanitation and hygiene interventions to combat childhood diarrhoea in developing countries*, International Initiative for Impact Evaluation Delhi.
WATERAID 2008. Feeling the Pulse. In A Study of the Total Sanitation Campaign in Five States. Edited by India W. New Delhi. London, UK: WaterAid.
WHO. 2009a. Available: http://www.who.int/topics/diarrhoea/en/.
WHO 2011. Guidelines for drinking water quality. *In:* ORGANIZATION., T. E. G. W. H. (ed.).
WHO, U. 2009b. WHO child growth standards and the identification of severe acute malnutrition in infants and children; A joint statement by the World Health Organization and the United Nations Children's Fund. *Geneva, Switzerland: WHO*.
WOLF, J., PRÜSS-USTÜN, A., CUMMING, O., BARTRAM, J., BONJOUR, S., CAIRNCROSS, S., CLASEN, T., COLFORD, J. M., CURTIS, V. & FRANCE, J. 2014. Assessing the impact of drinking water and sanitation on diarrhoeal disease in low-and middle-income settings: systematic review and meta-regression. *Tropical Medicine & International Health*.
ZIEGELBAUER, K., SPEICH, B., MÄUSEZAHL, D., BOS, R., KEISER, J. & UTZINGER, J. 2012. Effect of sanitation on soil-transmitted helminth infection: systematic review and meta-analysis. *PLoS medicine,* 9**,** e1001162.
ZWANE, A. P., ZINMAN, J., VAN DUSEN, E., PARIENTE, W., NULL, C., MIGUEL, E., KREMER, M., KARLAN, D. S., HORNBECK, R. & GINÉ, X. 2011. Being surveyed can change later behavior and related parameter estimates. *Proceedings of the National Academy of Sciences,* 108**,** 1821-1826.