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Effectiveness of a rural sanitation programme on diarrhoea, soil-transmitted helminth infection and malnutrition in India

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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 20 May 2010 and 22 December 2013, in 100 rural villages in Odisha, India. Households within villages were eligible if they had a child younger than four 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 seven-day prevalence of reported diarrhoea in children younger than five years. We did intention-to-treat and per-protocol analyses. This trial is registered with ClinicalTrials.gov, no. NCT01214785.

Findings

We randomly assigned 50 villages to the intervention group and 50 villages to the control group. There were 4,586 households (24,969 individuals) in intervention villages and 4,894 households (25,982 individuals) in control villages. The intervention increased mean village-level latrine coverage from 9 per cent of households to 63 per cent, compared with an increase from 8 per cent to 12 per cent in control villages. Health surveillance data were obtained from 1,437 households with children younger than five years in the intervention group (1,919 children younger than five years), and from 1,465 households (1,916 children younger than five years) in the control group. Seven-day prevalence of reported diarrhoea in children younger than five years was 8.8 per cent in the intervention group and 9.1 per cent in the control group. In the intervention group, 162 participants died (11 children younger than five years) and 151 died in the control group (13 children younger than five 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.

Contents

List of figures and tables

Abbreviations and acronyms

APL	above poverty line
ASHA	Accredited Social Health Activist
BPL	below poverty line
GPS	global positioning system
HAZ	height-for-age Z-score
IEC	information, education and communication
KIIT	Kalinga Institute of Industrial Technology
NBA	Nirmal Bharat Abhiyan
NGO	non-governmental organisation
NGP	Nirmal Gram Purashkar
PRA	Participatory Rural Appraisal
RCT	randomised controlled trial
SHG	self-help group
TSC	Total Sanitation Campaign
UAA	United Artists' Association
WASH	Water, Sanitation and Hygiene
WAZ	weight-for-age Z-score
WHO	World Health Organization
VWSC	Village Water and Sanitation Committee
XIMB	Xavier Institute of Management, Bhubaneswar

1. Introduction

Diseases associated with poor sanitation cause a large burden of disease worldwide. Diarrhoea alone affects an estimated four billion children aged under five each year, and causes 1.9 million deaths per year in this group, equal to 19 per cent of all under-five deaths in low-income settings (Boschi-Pinto *et al*. 2008). Other major diseases associated with poor sanitation include 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 six per cent of rural residents in India have access to improved sanitation, and about 69 per cent practice open defecation (Supply and Sanitation 2010).

Systematic reviews have suggested that improved sanitation may reduce diarrhoeal diseases by 22–36 per cent (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 or 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 randomised controlled trial (RCT) 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 & Scott 2007; Jenkins & Curtis 2005; WaterAid 2008). The fraction of diarrhoea preventable by sanitation may be lower in rural areas compared with dense urban areas. Current large-scale rural sanitation programmes are conducted in the absence of evidence of their health impact.

We conducted a cluster-RCT between 20 May 2010 and 22 December 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 (TSC) – 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 and research hypotheses

Implementation of the intervention was led by WaterAid India, a national affiliate of the UK-based non-governmental organisation (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 TSC. The TSC, expanded and renamed as Nirmal Bharat Abhiyan (NBA) during the period in which this evaluation was done, 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 TSC is implemented at state level under the Rural Development Department. The key components of the programme are:

- construction and use of individual household latrines
- construction of latrines in rural schools, kindergartens and public institutions
- provision of low subsidies or 'incentives' towards latrine construction to households falling BPL
- creation of production centres to provide locally appropriate technologies, and
- IEC activities designed to generate demand for toilets and encourage use.

In 2003, the Government of India launched the Nirmal Gram Puraskar (NGP) initiative to stimulate the campaign by providing financial rewards to Gram Panchayats (blocks and districts) who are 'open defecation free'. In 2012, the TSC was expanded and renamed as NBA. 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 and implementing partners

At the village level, the intervention was delivered by WaterAid and a local NGO partner, United Artists' 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 a government subsidy. UAA coordinated implementation activities between the six NGOs and with the local government representatives and relevant departments.

Implementing NGOs were assigned 4–12 villages each. NGOs were selected based on 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 a duration of one year. Village motivators did not necessarily have extensive experience in community mobilisation or in water, hygiene and sanitation projects. They reported progress 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 six cluster coordinators appointed by the NGOs attended a three-day residential training course organised by UAA. The training covered the key elements of the TSC, an introduction to the 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 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.

2.3 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 INR2,200 (then approximately US$33). This amount covered the costs of three pit liner rings and a 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 a 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 the household's signature. The value of the contribution made by each household varied but was mostly equivalent to the subsidy amount of INR2200. Construction materials such as pipe, pan set, Y-connector and cement were purchased from external suppliers and stored at 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 1).

Figure 1: Toilet example

2.4 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 Committees (VWSC), and a combination of community-level events and door-to-door household visits to encourage the 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 (SHGs) to explain details about the programme.	Feb–Apr 2011
Baseline survey	A second or third meeting is organised 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 the BPL list maintained 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, schoolteachers, kindergarten (*anganwadi*) workers, community health workers Accredited Social Health Activist (ASHA), village elders and SHG members. At least a third of the 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 two-day training event organised by the implementing NGO, and meet once a month thereafter to review progress 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 walks through the village with community members to identify and discuss sanitation related issues, visit open defecation sites, village water sources and so on. Village mapping exercise: the village motivator stimulates discussion about sanitation issues by encouraging community members to draw a map of the village on the ground and use stones, leaves and coloured powder to show village landmarks,	Feb–Apr 2011

	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 encourage discussions to help them identify the 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 progress.	Feb 2011 – Mar 2012
Wall paintings	Wall paintings are located at the entrance of the village or another prominent 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 the 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'	Groups of adolescent girls are engaged to communicate good sanitation practices among family and friends and organise village cleaning campaigns. Group members attend a two-day training course organised by the NGO.	Mar 2012

2.5 Primary outcomes and impacts of interest

The study assessed the effectiveness of a rural household sanitation intervention to prevent diarrhoea, soil-transmitted helminth infection and child malnutrition.

The primary endpoint outcome was seven-day prevalence of reported diarrhoea in children younger than five years, and the secondary binary health outcomes were all-age diarrhoea prevalence and helminth infections. All analyses were done on an intention-to-treat basis. Continuous secondary health endpoints (health-for-age (HAZ) and weight-for-age (WAZ) Z-scores) were analysed using mixed-effects linear regression accounting for clustering at village level. We used geographic data to support a range of exploratory analyses accounting for actual latrine uptake by geo referencing and mapping 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 and timeline

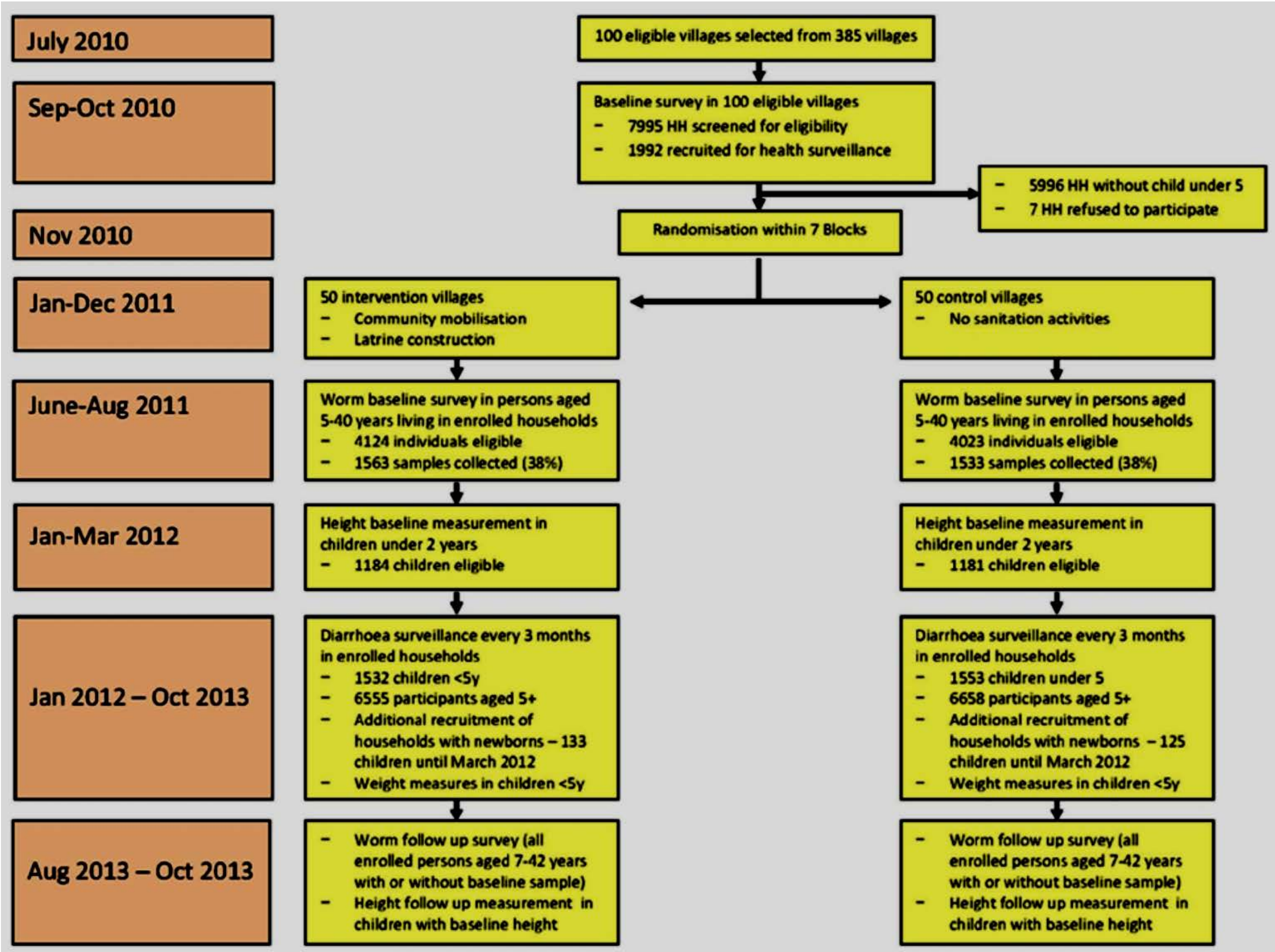
The study was located in Puri, a coastal district in the eastern state of Odisha (formerly Orissa). More than 50 per cent of the population are recognised by the Indian government as BPL. The area has a tropical climate with a monsoon season from July to September (1,500 mm annual rainfall). Puri District is divided into smaller administrative units (blocks), the unit at which sanitation implementers operate.

In Puri District, sanitation coverage in 2008 was estimated at 15 per cent in rural areas (Government of India, 2008). In the years preceding the trial, several blocks in Puri had received latrines under the 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 & Tropical Medicine and the Xavier Institute of Management, Bhubaneswar (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: (1) sanitation coverage less than 10 per cent; (2) improved water supply; and (3) no other water, sanitation or hygiene interventions anticipated in the next 30 months. We conducted a baseline survey in these villages. Because it took nearly 12 months to implement the intervention after the baseline surveys and before the start of the health outcomes surveys, the enrolment procedures had to be repeated in previously enrolled and approximately 400 new participating households (Figure 2). Following the baseline survey, 50 villages each were randomly allocated to intervention and control in a parallel trial design. The control arm received the intervention after trial completion.

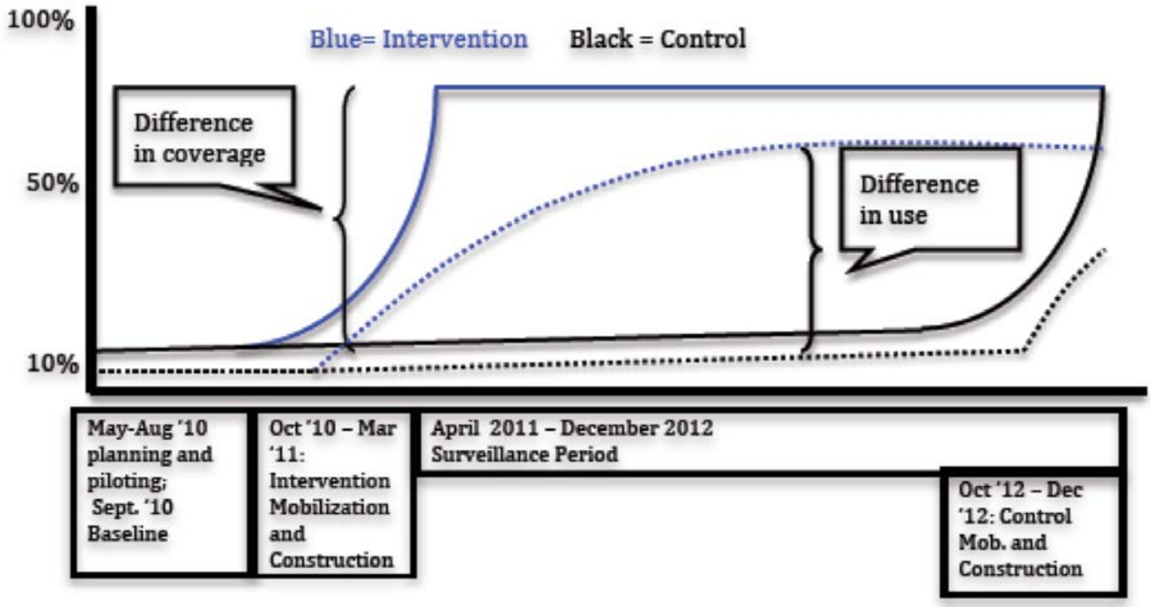
We also considered a step-wedge design where the intervention roll-out is staggered throughout the follow-up period (Hayes & Moulton 2009; Moulton *et al*. 2007). Step-wedge designs (where only the time point of receiving the intervention is randomised) can be more acceptable to governments and the population 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 per cent or more) (Moulton *et al*. 2007); and (3) because the NGOs implementing the intervention judged implementation in a parallel trial as feasible.

Figure 2: Flow diagram of the study.



The study was conducted between May 2010 and December 2012 (Figure 3). Following a piloting phase, the baseline survey was conducted in treatment and control sites in September 2010. Latrine construction in treatment sites was done between October 2010 and March 2011. Surveillance of intermediate (use) and endpoint outcomes (morbidity and mortality) was carried out between April 2011 and October 2012, after which time community mobilisation and latrine construction were carried out in the control sites.

Figure 3: Implementation timeline



4. Evaluation design, methods and implementation

4.1 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 the 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.

4.2 Study design and participants

We did this cluster-randomised controlled trial between 20 May 2010 and 22 December 2013, in 100 rural villages in Puri, a coastal district of Odisha, 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 (rice, pulses, vegetables and livestock) is the main source of income in Odisha, and half of households are classified as living BPL (Government of India 2008). India ranks among the lowest of countries in terms of access to household-level latrines, with 14.1 per cent coverage in rural settings (Ghosh & 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 TSC. Villages were eligible if they had sanitation coverage of less than 10 per cent; 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 four years or if a pregnant woman lived there. We also enrolled households with a 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; WASH conditions; and diarrhoea prevalence.

4.3 Sample size calculation

Sample size calculations for cluster RCTs greatly depend on the design effect, the sample size increase relative to an individually randomised trial. In RCTs measuring diarrhoeal outcomes, 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 Odisha (Boisson *et al*. 2013), we assumed a mean longitudinal daily prevalence of 4 per cent in children under five, with a standard deviation of 7.6 per cent assuming six follow-up visits per child (Schmidt *et al*. 2010). We assumed a 25 per cent 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 *etal*. 2009). Assuming 25 children per cluster, an intra-cluster correlation of 0.025, a design effect of 1.6,10 per cent loss to follow-up, 80 per cent 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).

4.4 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 be assigned to either latrine promotion and construction in accordance with the TSC, 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 socio-economic and water- and sanitation-related characteristics (Clasen *et al*. 2012). Masking of participants was not possible because of the nature of the intervention, but 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.

4.5 Measures of outcomes

4.5.1. 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 & Cairncross 2009). Household visits were done every three months between June 2011 and October 2013. We restricted the number of diarrhoea follow-up visits to nine. Because of delays in the latrine construction, the target coverage was not reached until January 2012, so data from the first two diarrhoea follow-up surveys, conducted between September and December 2011, were not included in the primary analysis. We obtained an extension of our research grant that allowed follow-up to continue until October 2013.

Originally, we chose daily point prevalence over the past three days as the main outcome. Data from an ongoing study in the area (Boisson *et al*. 2013) suggested that diarrhoea in children under five may be lower than expected, however. 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 primarily to 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 as being three or more loose stools in 24 hours (World Health Organization 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 were not asked to keep a diary of diarrhoea since the motivation to update diaries varies greatly. Instead, the fieldworkers used a visual aid showing a simple 10-day calendar to help participants remember the timing of episodes (Figure 7). This approach appeared to reduce reporting errors**.**

4.5.2. Compliance

We measured compliance with the intervention using 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, blocked or 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 and presence of slippers.

4.5.3. 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

Twenty per cent 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-Pakbags (Nasco, Fort Atkinson, WI), transported in a cooler to the laboratory and processed within four hours of collection with the membrane filtration technique and a portable incubator, in accordance with standard methods (Eaton *et al*. 2005). Samples were tested for thermotolerant coliforms – an indicator of faecal contamination (WHO 2011).

Handrinses

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

Flies

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

4.5.4. Soil-transmitted helminth infection

We measured prevalence of three common soil-transmitted helminth worms – *Ascaris lumbricoides*,*Trichuris trichiura* and hookworm species – by collecting stool samples from study participants aged 5–40 years (living in households with a child younger than five 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), abroad-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 villages (44 per cent versus 43 per cent), as was the baseline total worm prevalence (17.6 per cent versus 17 per cent), indicating no evidence of bias.

4.5.5. Anthropometrics

A baseline measure of weight (in children younger than five years) and recumbent length or height (in those younger than two 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 50g for weight between 20 kg and 50 kg. We measured the recumbent length of children younger than two years with Seca 417 boards with 1mm increments. We measured the height of children aged two years and older with a Seca 213 stadiometer. All children under five years were weighed at each diarrhoea surveillance visit. Height and weight were converted into HAZ and WAZ scores (WHO 2009b). We assumed that only a strong reduction in the exposure to faecal pathogens would lead to a measurable impact of the intervention on HAZ or WAZ, since it was unclear whether the 'real-life' intervention evaluated in this study would 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 sanitation interventions aimed at improving nutritional status by reducing gastrointestinal infections, because any weight gain due to fewer infections may be regarded as beneficial. We measured WAZ repeatedly in each child as an indicator of recent diarrhoea (Biran *et al*. 2009). Back-checks on weight and height measurements were done in roughly five per cent of households selected at random(Ulijaszek & Kerr 1999). The repeated measure was carried out within one 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.

4.6 Statistical analyses

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 standard errors (SEs). We calculated mean differences in HAZ and WAZ 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 in the thermotolerant coliform assays, we grouped these counts into log categories (0, 1–10, 11–100 and so on 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 per cent 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 per cent 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 and 13, StataCorp LP, College Station, TX).

4.7 Process data collection

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 NGO staff and community members. After an initial review of implementation guidelines and reports on the TSC, we met with the implementing NGOs to obtain detailed accounts of 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 VWSC members, such as activity log books, meeting notes, household contribution registers and construction material stock registers; and (3) they visited each household to observe and record latrine construction status. Latrine construction status was categorised as ‘completed’ or ‘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. Latrines classified as 'under construction' were latrines that were left unfinished or 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 per cent 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 16 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 VWSC had been formed, we obtained a list of the VWSC members along with basic demographic characteristics. Approximately10 per cent 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 at 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. 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 of or participated in a given activity. We calculated the means of the village proportions for intervention and control groups and compared them using Student's t-test. Within intervention villages, we explored associations between village level percentage awareness of or participation in mobilisation activities and village-level coverage using linear regression.

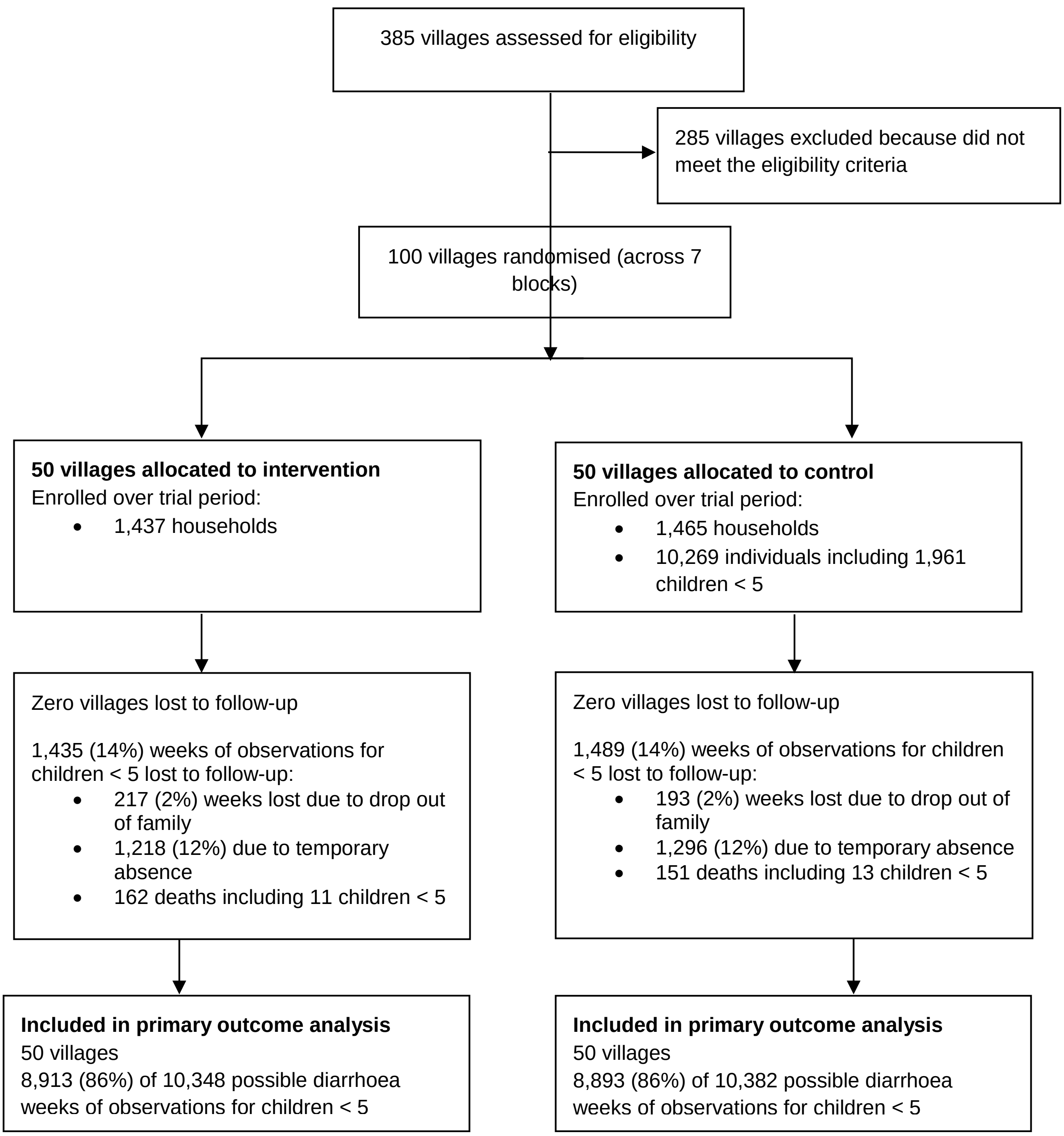
5. Impact analysis and results of the key evaluation questions

5.1 Results of evaluation

Figure 4 shows the trial profile. We randomly assigned 50 villages to the intervention group and 50 villages to the control group. There were 4,586 households (24,969 individuals) in intervention villages and 4,894 households (25,982 individuals) in control villages; 1,437 households from the intervention group and 1,465 households from the control group met the eligibility criteria and were enrolled for health surveillance. For diarrhoea surveillance, 10,014 individuals, including 1,919 younger than five years, were enrolled in the intervention at some point during surveillance, as were10,269 individuals (n = 1,961 younger than five years) in the control group.

Baseline and follow-up WAZ measures were available for 1,462 individuals (n = 650 younger than two years) in the intervention group and 1,490 individuals (n = 637 younger than two years) in the control group. Baseline and follow-up HAZ measures were available for 350 individuals (71 per cent of children measured at baseline) in the intervention group and 337 (74 per cent) children in the control group. The proportion of worm samples obtained at baseline was similar in the intervention and control groups (1,521 [44 per cent] of 3,457 versus1,438 [43 per cent] of 3,344), and worm samples at follow-up were obtained from 2,231 (52 per cent) of 4,255 in the intervention group and 2,063 (47 per cent) of 4,379 in the control group.

Figure 4: Trial profile



In the intervention villages, the mean proportion of households with a latrine increased from 9 per cent at baseline to 63 per cent at follow-up (Table 2). At follow-up, 11 of 50 intervention villages had functional latrine coverage of 50 per cent or greater, and seven had coverage of less than 20 per cent. In the control villages, mean household-level coverage increased from 8 per cent at baseline to 12 per cent at follow-up (Table 2). At follow-up, two of 50 control villages had coverage with functional latrines greater than 30 per cent (none had coverage of 50 per cent or greater), and 41 had coverage of less than 20 per cent. Because households with more individuals were more likely to have a functional latrine, the total proportion of people with access to a functional latrine was higher than the household-level coverage (Table 2). Out of 2,732 households with a latrine in the intervention group, 1,729 (63 per cent) reported that household members were using it; of these, 1,690 (98 per cent) of 1,724 reported that women were using it, 1,364 (79 per cent) of 1,725 reported that men were using it and 903 (79 per cent) of 1,140 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)

Notes: All values calculated from village-level data, based on 4,585 intervention and 4,895 households surveyed at study midpoint, except *calculated using status data from baseline survey (973 intervention and 1,001 control households with children < 5); †defined as *all* of the following: (1) any cover, (2) not used for storage, (3) pan not broken, blocked or full of leaves or 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 or can present, (6) broom or brush for cleaning present or (7) slippers present.

SD = standard deviation; CI = confidence interval.

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 five years in the intervention group (12 per cent and 15 per cent reduction, respectively, in the odds of being in a higher category of contamination), and on the sentinel toy (17 per cent 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).

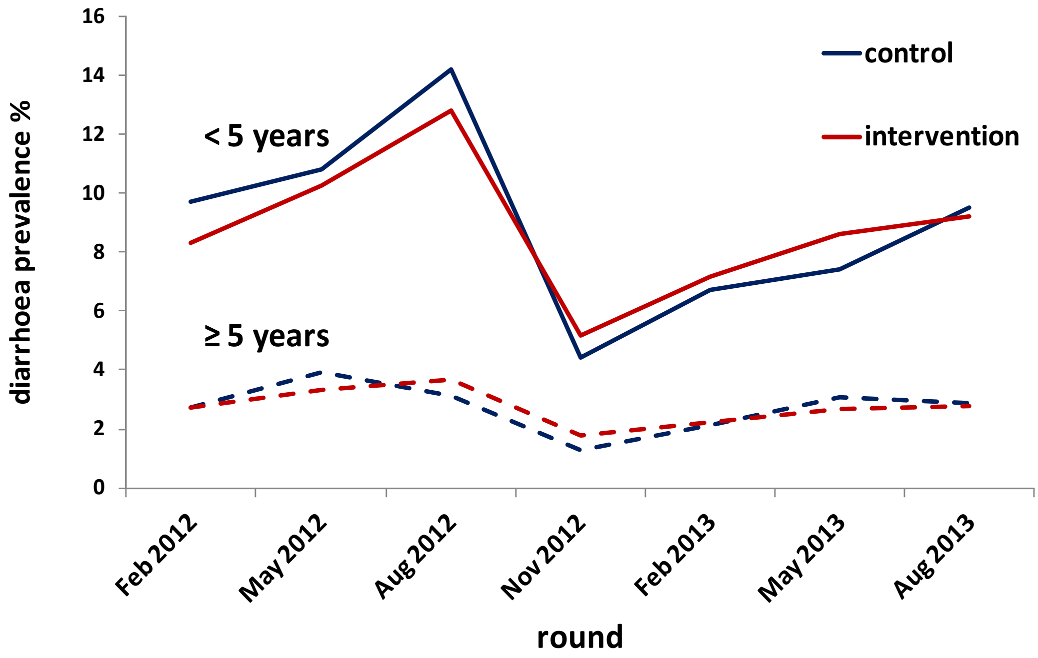
Table 3: Effect of intervention on water quality, hand contamination and flies (intentionto treat analysis)

	Denominator		median bacterial colony/fly count		Effect size	95% CI
	Intervention	Control	Intervention	Control		
Water quality						
Household water	2,406*	2,505*	60	60	1.06‡	0.89–1.24
Source water	1,951*	1,918*	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

Notes: *Number of households; †number of individuals; ‡odds ratio from ordered logistic regression (categories: 0; 1–10; 11–100; 101–1,000; 1,001–10,000; >10,000 colony forming units per 100 ml of water, two hands or toy). Ninety-five per cent 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 seven-day diarrhoea prevalence in children younger than five years was 8.8 per cent in the intervention group and 9.1 per cent in the control group (Figure 5), with a decline in late 2012, corresponding to the cold and dry season.

Figure 5: Seven-day prevalence of diarrhoea in children younger than five years (solid lines) and individuals aged five 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 five 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	1,919	1,961	8.8	9.1	0.97	0.83–1.12
All ages	10,014	10,269	3.8	3.7	1.02	0.88–1.18
By household size*						
< 5	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*						
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 50 m 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	1,409	8.6	9.1	0.92	0.75–1.15
Adjusted‡	299	1,409	-	-	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

Notes: Table shows results from log-binomial models, clustering by village accounted for by use of generalised estimating equation; *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 BPL status (Table 4). The per-protocol analysis did not suggest an effect of the intervention on diarrhoea in children younger than five 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 five years).

The baseline total worm prevalence was similar between the groups (17.6 per cent versus 17 per cent). No evidence showed that the intervention reduced the 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 per cent) of 662 prevalent soil-transmitted helminth infections were due to hookworm and 6,963 (84 per cent) of 8,288 identified eggs were hookworm eggs.

The intervention had no effect on mean WAZ in children younger than five years, or in those younger than two years, at baseline (Table 5). Findings from the per-protocol analysis suggest evidence for an increase in WAZ in compliant villages and households (Table 5). The primary analysis showed no effect on mean HAZ in children younger than two years at baseline, and the per-protocol analysis suggested no major effects (Table 5). In the intervention group, 162 participants died (11 children younger than five years) and 151 died in the control group (13 children younger than five years).

The intra cluster 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 five years and 0.01 for all age groups. The coefficients for WAZ and HAZscores 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	2,231	2,063	16.0	16.4	0.97‡	0.72–1.32
STH egg counts/gram	2,151	2,002	10.2	9.4	1.08§	0.62–1.88
Hookworm prevalence	2,231	2,063	14.1	15.6	0.90‡	0.66–1.22
Hookworm egg counts/gram	2,151	2,002	8.7	9.1	0.96§	0.54–1.68
Ascaris prevalence	2,229	2,063	0.7	0.3	2.04‡	0.38–10.91
Ascaris egg counts/gram	2,150	2,000	0.9	0.5	1.85§	0.07–48.75
Trichuris prevalence	2,229	2,063	2.6	0.6	3.89‡	1.38–10.92
Trichuris egg counts/gram	2,149	2,002	0.9	0.1	9.90§	1.98–46.62
Weight-for-age Z-score*						
Intention-to-treat analysis						
Children < 5 years at baseline	1,462	1,490	–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	1,490	–1.36	–1.43	0.10†	0.003–0.20
Households with functional latrine	683	1,274	–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

Notes: *Children with Z-scores> 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.

STH = soil-transmitted helminth infection.

5.2 Results of process documentation

5.2.1. 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 was12 (range 5 to 16) and 40 per cent of VWSC members were women. Committees included local government representatives (11 per cent), SHG members (16 per cent), kindergarten (*anganwadi*) or community health (ASHA) workers (13 per cent) and teachers (2 per cent); SHGs are local microfinance groups, often run by women.

The remaining members were key opinion leaders or residents who volunteered to be part of the committee. Two VWSC members per village were invited to participate in a two-day training event 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 coloured cards to display different behaviours and asked 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 people to a central location in the village and engaged villagers in discussions to draw a map on the floor using coloured 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 three 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 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 on a piece of paper.

Village motivators reported weekly door-to-door household visits. They explained the advantages of having a latrine and 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's safety and privacy, shame, health, loss of school and work days from being sick and cost of treatment for intestinal infections. Some village motivators carried with them a picture of the latrine design but they 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 own a BPL card. Provision of financial assistance to some but not all households was a frequent source of tension 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 schools 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 6). The NGOs also included the cost breakdown for latrine construction in order to make the process transparent to the community.

Figure 6: Wall diagram showing transmission pathways for faecal pathogens

Source: Wall diagram by Wateraid

Adolescent girl groups (Kumari committees) were reported to be formed in 31 villages. In six 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. The content of the course or the actual role of the committees as described by village motivators was vague. Some mentioned that the groups would become engaged in microfinance 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 the Kumari committees, what they were actually supposed to do or how.

5.2.2. Exposure to intervention: levels of awareness among community members

Overall, the percentage of households who had heard about the TSC was significantly higher in intervention than in control villages (91 per cent versus 49 per cent, respectively,

$p < 0.001$). Perceived benefits associated with having a latrine were broadly similar across intervention and control villages (Table 6). In intervention villages, households heard about the campaign mostly from NGOs (64 per cent) or VWSC members (17 per cent) while in control villages, respondents heard about it from neighbours (30 per cent), NGOs (20 per cent), ward members (15 per cent) or family (12 per cent) and friends (10 per cent). Almost none of the households in intervention villages recalled any form of participatory activities such as a transect walk and mapping exercise (6 per cent) or wealth ranking (0 per cent). The proportions were similar in the control villages. Intervention households were more aware of VWSCs than controls (51 per cent versus 9 per cent, $p < 0.001$), however.

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
Kumari 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 Kumari committee	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 three months	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
Information about meetings	37	9	0	0	9	0.66
Kumari committee	2	0	0	0	0	0.12

Note: *p-values calculated using the t-test on village-level percentage awareness of or participation in mobilisation activities.

Awareness of Kumari committees was higher among intervention villages (23 per cent versus 8 per cent, p < 0.01). Overall, 43 per cent and 36 per cent of intervention and control households respectively 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 per cent versus 7 per cent,

p < 0.001and 65 per cent versus 3 per cent, p < 0.001, respectively). Among the topics being discussed during home visits, intervention households remembered contribution amounts (70 per cent) and latrine construction logistics (52 per cent) the most. Many less remembered discussions around use (26 per cent) and benefits of latrines (20 per cent).

5.2.3. Awareness among VWSC members

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

Table 7: Awareness of mobilisation activities among members of village water and sanitation committees 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 remembered 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		
Village motivator	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
Topics remembered 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
Topics remembered being discussed 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 per cent) followed by sessions on communication techniques to motivate other villagers to build a latrine (47 per cent). Fifty-four per cent of VWSC members saw their role as encouraging people to construct toilets, but only 21 per cent described being involved in overseeing latrine construction logistics. Even fewer (8 per cent) mentioned that their role was about encouraging toilet use. Almost a third didn't know what their role as a VWSC member was. VWSC meetings almost always took place in the presence of the village motivator (89 per cent). Almost half (45 per cent) reported not attending the last VWSC meeting and 40 per cent never conducted door-to-door household visits.

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 VWSC in intervention villages. There was 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 where VWSC members reported that five or more VWSC meetings had been 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: 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 of or participated in transect walk/ mapping exercise	0.637	(–0.104; 1.379)	0.09
Heard of or participated in wealth ranking exercise	1.530	(–2.261; 5.321)	0.42
Heard of VWSC	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
Attended the last VWSC meeting	0.060	(–0.164; 0.284)	0.59
Ever conducted household visits	0.025	(–0.205; 0.254)	0.83
Conducted ≥ 5 household visits	0.058	(–0.156; 0.272)	0.59

Note: *Regression coefficients express increase in latrine coverage in per cent with every additional per cent increase in awareness of or participation in activities among respondents in a village.

6. 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 (Esrey *et al*. 1991; Wolf *et al*. 2014; Clasen *et al*. 2010; Engell & Lim 2013; Ziegelbauer *et al*. 2012; Stocks *et al*. 2014; Strunz *et al*. 2014). They are consistent, however, with another trial of a sanitation project implemented within the context of the TSC in the 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 in use 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 sub optimum use of latrines constructed as part of the TSC, 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 per cent 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 sub-study of microbial source tracking (Clasen *et al*. 2012). Exposure to rotavirus or zoonotic agents such as *Cryptosporidium*, both of which have been reported to be a major cause of moderate-to-severe 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 village-level coverage and use would seem to be apriority.

The levels achieved in our study are not unusual under the TSC 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 per cent (Ghosh & Cairncross 2014). Changes to the TSC (which has been renamed the Nirmal Bharat Abhiyan) increased and extended subsidies for construction beyond households below the poverty line to specified vulnerable groups (Hueso & Bell 2013); however, most households above the poverty line still do not qualify for subsidies and must build their own latrines.

Although the NBA 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 per cent latrine coverage in each village. An important limitation of our study relates to the18-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 byself-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 WAZ, which was not consistent with the absence of effect on HAZ. Compliance with the intervention might be related not only to child WAZ at baseline, but also independently to the rate of decline in WAZ in the first two 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. Nevertheless, our results show that the health benefits generally associated with sanitation cannot be assumed simply from the 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.

7. Specific findings for policy and practice

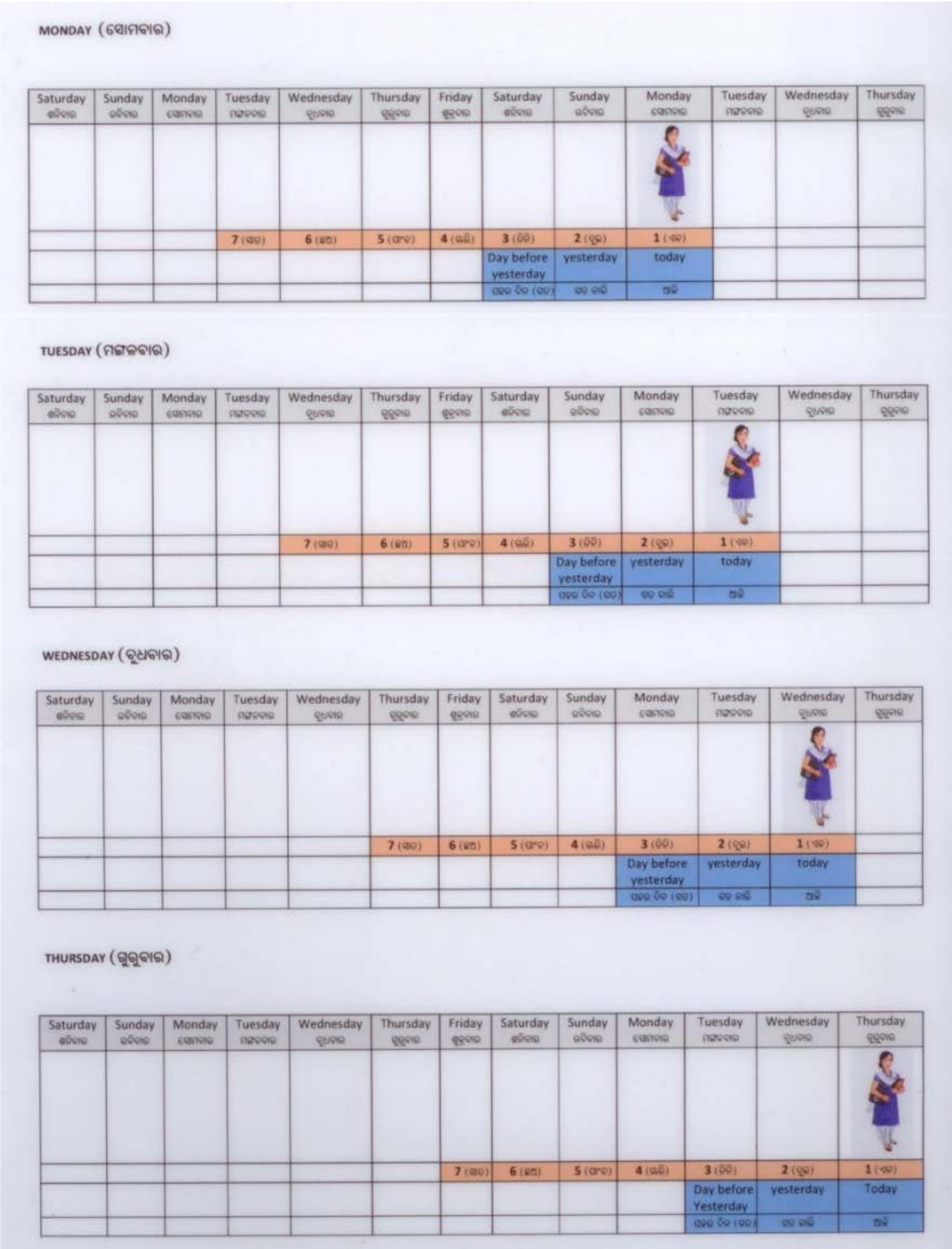
The intervention did not show an effect on the measured child health outcomes of self-reported diarrhoea, prevalence of soil-transmitted infections or under-nutrition. Our findings raise questions about the health effects of sanitation initiatives that focus on increasing latrine construction but do 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 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 effects 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: Tools used is the survey

Figure 7: Visual aid tool to help answering diarrhoea questions



Source: Authors

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The research team conducted a cluster-randomised evaluation in 100 villages of Odisha, India to test the effectiveness of a rural sanitation intervention that is part of the Government of India's Total Sanitation Campaign. Randomly selected households were offered assistance to construct latrines to prevent open defecation and soil-transmitted diseases. Researchers also tracked cases of diarrhoea reported in children younger than five years. They found no evidence that this sanitation programme 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. The results also show that the health benefits generally associated with sanitation cannot be assumed simply by latrine construction.

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