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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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.

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See Online for podcast interview with Thomas Clasen

Introduction

An estimated 2·5 billion people have no access to improved sanitation.[1] 71% of these people live in rural areas, as do more than 90% of the 1·1 billion who practise open defecation.[1] Even in areas with moderate sanitation coverage, levels of subnational inequity are high.[2] India represents a particular challenge, accounting for roughly a third of the world's population without improved sanitation and two-thirds of the population practising open defecation.[3] There and elsewhere, governments have supported large-scale campaigns to improve coverage of household sanitation, which is often the sole indicator used to measure progress. Poor sanitation is associated with various infectious diseases, including diarrhoea, soil-transmitted helminth infection, trachoma, and schistosomiasis.[4] Diarrhoea accounts for the largest share of sanitation-related morbidity and mortality, causing an estimated 1·4 million deaths annually,[5] including 19% of all deaths of children younger than 5 years in low-income settings.[6] Furthermore, evidence has linked poor sanitation with stunting, environmental enteropathy, and impaired cognitive development—long-term disorders that aggravate poverty and slow economic development.[7]

Although historical efforts to improve sanitation were voted by readers of the *British Medical Journal* as the most important medical advance since 1840,[8] evidence of the health effect of household sanitation in low-income settings is not strong. Investigators of systematic reviews report that improved sanitation can reduce the prevalence of diarrhoeal diseases by 22–36%.[9–12] However, the studies included in these reviews were observational or small-scale trials and of poor methodological quality; most combined household sanitation with water supplies or hygiene. Investigators of recent systematic reviews reported household sanitation to be protective against soil-transmitted helminth infection and trachoma; however, these had the same shortcomings as previous reviews.[13–15] Another review[16] identified no intervention studies of the effect of household sanitation on child anthropometry, although ecological analyses have linked open defecation with stunting in India[17] and other low-income countries.[18]

We did this study to assess the effectiveness of a rural household sanitation intervention to prevent diarrhoea, soil-transmitted helminth 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.[19]

Methods

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. Trial design, setting, and characteristics of the study population have previously been described.[20] Briefly, included villages were spread across seven of the 11 blocks (an administrative subdistrict) 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.[21] India ranks among the lowest of states nationally in terms of access to household-level latrines, with 14·1% coverage in rural settings.[22] 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; socioeconomic status; water, hygiene, and sanitation conditions; and diarrhoea prevalence.

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.

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.[20] 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.

Procedures

The intervention consisted of latrine promotion and construction, in accordance with the Government of India's Total Sanitation Campaign, which combines social mobilisation with a post-hoc subsidy. Implementation was coordinated by WaterAid India (part of WaterAid, an international non-governmental organisation [NGO] working in sanitation) and United Artists Association (an Odisha-based NGO). Six local NGOs were contracted to deliver the intervention in intervention villages in collaboration with local government. Implementation was undertaken between January, 2011, and January, 2012. The Government of India provided subsidies (INR 2200 [US$44] in January, 2011) for the construction of latrines that met specified criteria in below-poverty-line households. The latrine design consisted of a pour-flush latrine with a single pit and Y-joint for a future second pit. Each participating below-poverty-line household was to be provided with a latrine and households contributed sand, bricks, and labour. The subsidy did not cover the cost of full walls, door, and roof. A detailed assessment of the implementation process has been reported elsewhere.[23]

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.

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. 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.[24] Samples were tested for thermotolerant coliforms—an indicator of faecal contamination.[25] To assess hand contamination, we obtained hand rinse samples[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.[27] Finally, we monitored density of synanthropic flies (*Musca domestica* and *M sorbens)* by installing 24 h 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.

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,[28] 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 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. 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. Back-checks on weight and height measurements were done in roughly 5% of households selected at random.[29]

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.[30,31] We defined diarrhoea with the WHO definition of three or more loose stools in 24 h.[32] 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

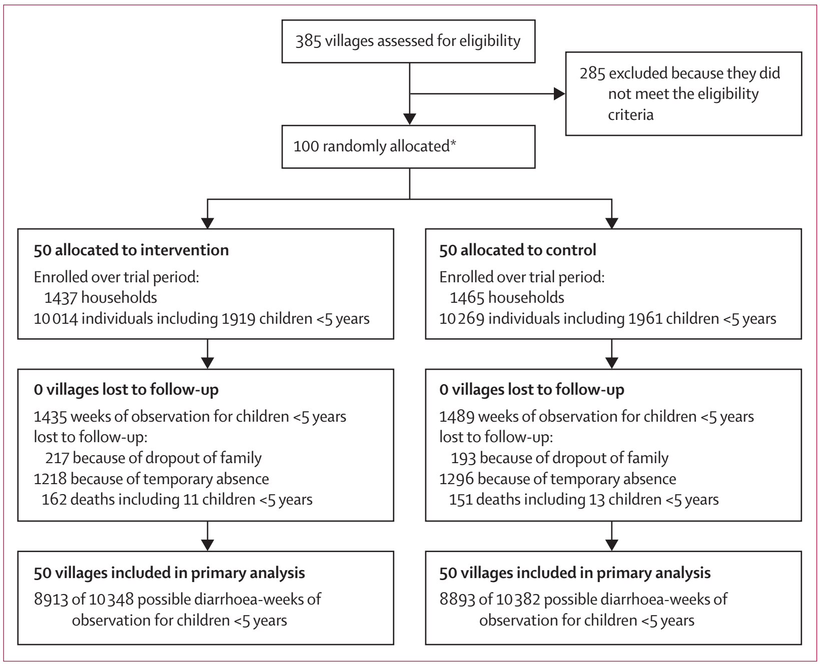

Figure 1: **Trial profile**
*Across seven blocks.

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

Data are mean proportion (SD, range). Values calculated from village-level data, based on 4585 intervention and 4895 control households surveyed at study midpoint. BPL=below poverty line. *Calculated with status data from baseline survey (973 intervention and 1001 control households with children <5 years).

Table 1: **Latrine coverage at village level at baseline and post-intervention**

	Denominator		Median bacterial colony or 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 years	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, 1001–10 000, more than 10 000 colony forming unit per 100 mL of water, two hands, or toy). 95% CI adjusted for clustering by use of robust SEs, proportionality of odds tested with likelihood ratio test (all p>0·3). §Rate ratio from negative binomial regression (counts aggregated at village level).

Table 2: **Effect of intervention on water quality, hand contamination, and flies (intention-to-treat analysis)**

daily prevalence of 4% (SD 7·6) in this population, with the assumption of six follow-up visits per child.[30] We assumed a 25% reduction in diarrhoea prevalence as a figure of public health interest and in line with estimates from systematic reviews.[9–12] 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.[33]

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[34] 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).

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

Role of the funding source

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

Results

Figure 1 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 eligibilty criteria and were enrolled for health surveillance (figure 1). 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.

In the intervention villages, the mean proportion of households with a latrine increased from 9% at baseline to 63% at follow-up (table 1). 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 1). 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 1). 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.

The intervention had no effect on overall faecal contamination of water stored in the households of study participants (table 2). 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 2). Similarly, there were numerically, but not significantly, fewer synanthropic flies in the intervention group than in the control group (table 2).

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 2), with a decline in late 2012, corresponding to the cold and dry season. No evidence showed that the intervention was protective against diarrhoea in children younger than 5 years, or against diarrhoea in all age groups (table 3). No effect of the intervention was detected when the population was stratified by household size, population density, or below-poverty-line status (table 3). The per-protocol

Figure 2: **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 intervention status**

	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	10 014	10 269	3·8%	3·7%	1·02 (0·88–1·18)
By household size†					
0–4 members	388	441	8·3%	8·3%	0·98 (0·74–1·30)
5–8 members	917	942	8·6%	10·0%	0·90 (0·76–1·07)
>9 members	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 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	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 generalised estimating equations. BPL=below poverty line. *Crude mean village-level prevalence of diarrhoea. †Children younger than 5 years. ‡Adjusted for baseline village-level prevalence of diarrhoea and baseline individual diarrhoea prevalence (calculated combining diarrhoea data from the baseline survey and the first two rounds that were done before October, 2011).

Table 3: **Effect of the intervention on diarrhoea prevalence**

	Denominator (individuals)		Mean Z-score, STH prevalence, or 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 to 1·32)
STH egg counts per g	2151	2002	10·2	9·4	1·08† (0·62 to 1·88)
Hookworm prevalence	2231	2063	14·1%	15·6%	0·90* (0·66 to 1·22)
Hookworm egg counts per g	2151	2002	8·7	9·1	0·96† (0·54 to 1·68)
Prevalence of *Ascaris lumbricoides*	2229	2063	0·7%	0·3%	2·04* (0·38 to 10·91)
A lumbricoides egg counts per g	2150	2000	0·9	0·5	1·85† (0·07 to 48·75)
Prevalence of *Trichuris trichiura*	2229	2063	2·6%	0·6%	3·89* (1·38 to 10·92)
T trichiura egg counts per g	2149	2002	0·9	0·1	9·90† (1·98 to 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 to 0·08)
Children <2 years at baseline	650	637	–1·46	–1·32	–0·01§ (–0·12 to 0·09)
Per-protocol analysis (children <5 years at baseline)					
Villages with functional latrine coverage ≥50%	324	1490	–1·36	–1·43	0·10§ (0·003 to 0·20)
Households with functional latrine	683	1274	–1·32	–1·50	0·12§ (0·05 to 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 to 0·16)
Households with functional latrine	161	294	–1·42	–1·39	–0·06§ (–0·27 to 0·15)

STH=soil-transmitted helminth. *Log-binomial models, clustering by village accounted for by use of generalised estimating equations. †Random-effects linear regression. ‡We excluded children with *Z* scores greater than 5 or of 5 and lower. §Negative binomial regression of sum of village-level egg counts with number of samples in village as exposure.

Table 4: **Effect of intervention on anthropometric measures and worm infection**

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 3). 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 4). 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 4). Findings from the per-protocol analysis suggest evidence for an increase in weight-for-age *Z* score in compliant villages and households (table 4). 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 4).

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.

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).[9–15] 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.[35]

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,[36,37] and for the disposal of child faeces.[38] 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

Panel: Research in context

Systematic review

Before undertaking this trial, we did a systematic review of interventions to improve disposal of human excreta for prevention of diarrhoea.[11] We searched the Cochrane Infectious Disease Group Specialized Register; the Cochrane Central Register of Controlled Trials, published in The Cochrane Library; Medline; Embase; Lilacs; the metaRegister of Controlled Trials; and Chinese-language databases available under the Wan-Fang portal, the China National Knowledge Infrastructure. We aimed to identify randomised and quasi-randomised controlled trials comparing interventions for improvement of the disposal of human excreta to reduce direct or indirect human contact with no such intervention. Search terms, other search strategies, eligibility criteria, and other methods are described in the published review. 13 studies from six countries covering more than 33 400 children and adults in rural, urban, and school settings met the review's inclusion criteria. While the studies reported a wide range of effects, 11 of the 13 studies showed that the intervention was protective against diarrhoea. Almost all previous studies combined the sanitation with improvements in water supply, hygiene, or both; as such identification of the contribution of sanitation alone was not possible. Differences in study populations and settings, in baseline sanitation levels, water and hygiene practices, types of interventions, study methods, compliance and coverage levels, and case definitions and outcome surveillance restricted the comparability of results of the studies and rendered a meta-analysis inappropriate. The validity of most individual study results were further compromised by the non-random allocation of the intervention among study clusters, an insufficient number of clusters, scarcity of adjustment for clustering, unclear loss to follow-up, potential for reporting bias, and other methodological shortcomings. Our review provided some evidence that interventions to improve excreta disposal are effective for prevention of diarrhoeal disease. However, this conclusion is based mainly on the consistency of the evidence of beneficial effects. The quality of the evidence is generally poor and does not allow for quantification of any such effect. Rigorous studies in various settings are needed to clarify the potential effectiveness of excreta disposal on diarrhoea. Other systematic reviews have shown sanitation interventions to be protective against diarrhoea.[9–10,12]

Interpretation

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. 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.[35] 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.

are exploring in our substudy of microbial source tracking.[20] 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.[39] 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.[40]

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.[36,37,41] From 2001 to 2011, only two of 509 districts in India increased latrine coverage by more than 50%.[22] 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.[19] 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 (eg, 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.[42]

Although we recorded no evidence for bias caused by self-reported or carer-reported diarrhoea data, this possibility is a further limitation.[31] 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.

Contributors

TC, SB, MB, OC, JE, MF, MJ, AS, and W-PS contributed to the study design. SB, PR and BT managed the study. SB led the substudy of water quality, MO and MJ the substudy of hand contamination, BT the substudy of sentinel toys, and MB the substudy of flies. WS and AS coordinated the assessment of latrine coverage and use. WS was responsible for the analysis of health outcomes. TC, SB, and WS drafted the report. All authors contributed to redrafting the report.

Declaration of interests

We have no competing interests.

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