Effect of a community-led sanitation intervention on child diarrhoea and child growth in rural Mali: a cluster-randomised controlled trial

Amy J Pickering, Habiba Djebbari, Carolina Lopez, Massa Coulibaly, Maria Laura Alzua

Summary

Background Community-led total sanitation (CLTS) uses participatory approaches to mobilise communities to build their own toilets and stop open defecation. Our aim was to undertake the first randomised trial of CLTS to assess its effect on child health in Koulikoro, Mali.

Methods We did a cluster-randomised trial to assess a CLTS programme implemented by the Government of Mali. The study population included households in rural villages (clusters) from the Koulikoro district of Mali; every household had to have at least one child aged younger than 10 years. Villages were randomly assigned (1:1) with a computer-generated sequence by a study investigator to receive CLTS or no programme. Health outcomes included diarrhoea (primary outcome), height for age, weight for age, stunting, and underweight. Outcomes were measured 1·5 years after intervention delivery (2 years after enrolment) among children younger than 5 years. Participants were not masked to intervention assignment. The trial is registered with ClinicalTrials.gov, number NCT01900912.

Findings We recruited participants between April 12, and June 23, 2011. We assigned 60 villages (2365 households) to receive the CLTS intervention and 61 villages (2167 households) to the control group. No differences were observed in terms of diarrhoeal prevalence among children in CLTS and control villages (706 [22%] of 3140 CLTS children *vs* 693 [24%] of 2872 control children; prevalence ratio [PR] 0·93, 95% CI 0·76–1·14). Access to private latrines was almost twice as high in intervention villages (1373 [65%] of 2120 *vs* 661 [35%] of 1911 households) and reported open defecation was reduced in female (198 [9%] of 2086 *vs* 608 [33%] of 1869 households) and in male (195 [10%] of 2004 *vs* 602 [33%] of 1813 households) adults. Children in CLTS villages were taller (0·18 increase in height-for-age *Z* score, 95% CI 0·03–0·32; 2415 children) and less likely to be stunted (35% *vs* 41%, PR 0·86, 95% CI 0·74–1·0) than children in control villages. 22% of children were underweight in CLTS compared with 26% in control villages (PR 0·88, 95% CI 0·71–1·08), and the difference in mean weight-for-age *Z* score was 0·09 (95% CI –0·04 to 0·22) between groups. In CLTS villages, younger children at enrolment (<2 years) showed greater improvements in height and weight than older children.

Interpretation In villages that received a behavioural sanitation intervention with no monetary subsidies, diarrhoeal prevalence remained similar to control villages. However, access to toilets substantially increased and child growth improved, particularly in children <2 years. CLTS might have prevented growth faltering through pathways other than reducing diarrhoea.

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See Comment page e659

Woods Institute for the Environment, and Department of Civil and Environmental Engineering, Stanford University, Stanford, CA, USA (A J Pickering PhD); **Aix-Marseille School of Economics, Aix-Marseille University, Centre National de la Recherche Scientifique (CNRS) and École des Hautes Études en Sciences Sociales (EHESS), Marseille, France** (Prof H Djebbari PhD); **CEDLAS-CONICET-Universidad Nacional de La Plata, La Plata, Argentina** (C Lopez MA, Prof M L Alzua PhD); **and Great Mali, Bamako, Mali** (M Coulibaly PhD)

Correspondence to: Dr Amy J Pickering, Woods Institute for the Environment, Stanford University, Stanford, CA 94503, USA **amyjanel@stanford.edu**

Introduction

1 billion people in the world still practise open defecation.[1] Of the 2·5 billion people without access to an improved sanitation facility, 70% live in rural areas.[1] Target 10 of the Millennium Development Goals is to "halve, by 2015, the proportion of people without sustainable access to safe drinking water and basic sanitation".[2] Progress in gaining access to improved sanitation has been the slowest in sub-Saharan Africa, where sanitation coverage has only increased by 5% between 1990 and 2012.[1]

Community-led total sanitation (CLTS) uses participatory methods to eliminate the practise of open defecation in rural communities and promote building of toilets. CLTS focuses on mobilisation of communities to change their own behaviour and therefore does not give hardware or financial subsidies to assist households in constructing latrines.[3] The approach aims to sustainably change behaviour through the elicitation of strong emotional drivers such as shame, disgust, pride, and dignity that trigger collective action in the community to stop open defecation.[4] Communities that successfully eliminate open defecation and achieve universal latrine coverage are rewarded with open defecation free certification, typically presented by government officials during a ceremony to post a sign declaring the community's status.

Critiques of CLTS include the use of shame to motivate behaviour,[5] little support for poor households who cannot

Panel: Research in context

Evidence before this study

Recent meta-analyses have identified a scarcity of high quality data for the causal effect of improved rural sanitation on child diarrhoea and child growth. Before the start of this study in 2011, no randomised controlled trial evaluating the health effects of a rural sanitation intervention had been published. During the course of this study, two randomised controlled trials of rural sanitation interventions were done in India by Patil and colleagues (2014) and Clasen and colleagues (2014); both trials reported no significant effect on child diarrhoea prevalence, parasite infections, or child growth. These trials included latrine hardware subsidies and few behavioural change components. The authors cited low use of toilets as a potential explanation for no effect on health; Patil and colleagues reported only slight decreases in open defecation (a 10 percentage point decrease among adults, down from 84%) whereas Clasen and colleagues noted that about half of newly built toilets were dysfunctional or unused. Although these studies provide valuable information about the effectiveness of rural sanitation interventions in India, they cannot rule out low use of toilets as an explanation for the negative results.

Added value of this study

We describe a randomised controlled trial of a rural sanitation intervention in sub-Saharan Africa and we report no effect of the intervention on child diarrhoeal prevalence in this setting. Contrary to previous trials in rural India, low use of latrine hardware is not a likely explanation for the observed absence of an effect on diarrhoea. Our study also presents rigorous evidence that a community-led sanitation programme with a strong behavioural component can lead to increased access and use of sanitation facilities, without financial subsidies. Additionally, this paper provides new evidence that reduced open defecation in rural sub-Saharan Africa can improve child growth.

Implications of all the available evidence

Our findings together with previous studies do not show that improved access to sanitation prevents child diarrhoea in rural settings. At the same time, our study provides evidence that increased toilet use might contribute to improved growth outcomes for children younger than 2 years, and justifies future research into the biological mechanism through which this health benefit could occur. Differences in intervention uptake (eg, village-level open defecation prevalence), population density, and climate could help explain why child growth outcomes improved in this study in Mali but not among children enrolled in rural sanitation trials in India.

afford to build latrines, and the promotion of simple and unimproved sanitation facilities. The reward (certification) system is typically reliant on compliance reporting from the communities themselves or the implementing organisation, both of which might be incentivised to make false declarations of programme success.[4] Since its inception in 1999, in Bangladesh, CLTS is being implemented in 50 countries with at least 15 incorporating CLTS into their national policy. This level of scale-up has been called into question in view of the few independent evaluations of CLTS and no published randomised controlled trials of the programme.

The health effects of rural sanitation interventions are not well characterised. Although observational evidence shows that networked sewers can reduce diarrhoea and enteric parasite infections in cities,[6–8] the evidence of health effects from interventions promoting the construction and use of latrines in rural settings is scarce. Two randomised controlled trials of rural sanitation interventions have been completed; both were recently undertaken in India and included hardware subsidies in addition to restricted behavioural change programmes.[9,10] The trials reported the programme to have no significant effects on child diarrhoea prevalence, parasite infections, or child growth. Other non-randomised sanitation intervention studies, also in India, have not shown beneficial health effects.[11,12] However, a cross-sectional analysis of data from 112 districts in India reported that higher rates of open defecation were strongly associated with increased risk of child stunting.[13] A potential explanation for the seemingly contradicting evidence from observational and intervention studies is that supply-driven interventions can have low uptake by households. Particularly in India, evidence shows individuals prefer open defecation even with latrines available.[14] One of the rural sanitation trials in India recorded about half of newly built latrines were dysfunctional or unused.[9]

The aim of this study was to explore the effectiveness of a CLTS intervention on coverage and quality of household sanitation facility, defecation behaviour, and child health in a rural setting in sub-Saharan Africa.

Methods

Study design

We did a cluster-randomised trial in villages of the Koulikoro region in rural Mali of a CLTS intervention implemented by the government (the Koulikoro directorate of sanitation) in collaboration with UNICEF; the unit of randomisation (clusters) was the villages. Data collection was completed by an independent organisation, Great Mali, with training and support by study investigators. The study protocol was approved by the National University of La Plata (Buenos Aires, Argentina; protocol number 0001/2011 FCE-UNLP), and Stanford University's (Stanford, CA, USA; protocol number 21209) human subjects and Institutional Review Boards.

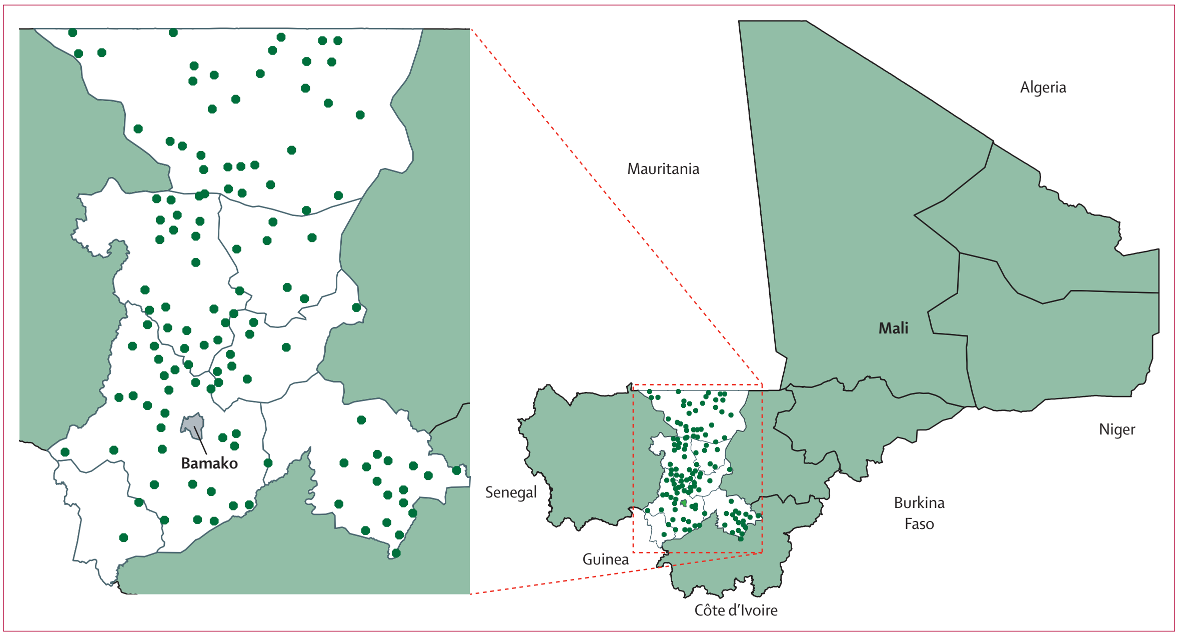

Figure 1: **Map of Koulikoro region (white) in Mali**
Every circle represents one study village.

Participants

The study was undertaken in rural villages that met the government's eligibility criteria to receive the CLTS programme: a village could not have previously received the CLTS programme; latrine coverage was less than 60%; and the village population included 30–70 households (figure 1). A total of 402 villages were identified as eligible in Koulikoro. Study villages were randomly selected, one at a time following a protocol that ensured a 10 km buffer between all villages. The buffer was used to prevent potential programme contamination of the intervention into the control population. Households with young children (at least one child aged <10 years) were enrolled in the study. Verbal informed consent was obtained from all survey respondents. Written consent was not obtained because it could have discouraged participation in the study because of low literacy in the study population.

Randomisation and masking

Randomisation occurred after baseline data collection was complete. One of the study investigators (MLA) used a computer-generated algorithm that randomly assigned villages (1:1) to treatment and control groups. Other investigators remained masked to cluster assignment until all data collection was complete. The algorithm generated a random number for each village, which was then used to sort villages and assigned the first 60 to the intervention group and the remaining 61 to the control group. The randomisation was repeated until balance (defined by a t test value <1 generated by an independent samples t test) was achieved between the two groups for mean village access to a private latrine and mean level of village cooperation as measured by an experimental game (presented in a separate manuscript[15]). Balance was achieved after five iterations. Because of the nature of the intervention, participants were not masked to treatment status. Field staff were not informed of village treatment status, but could have inferred this during the follow-up from the presence of signage showing village certification of an open defecation free status.

Procedures

Programme staff employed by the government's Department of Sanitation in the district of Koulikoro did the CLTS triggering sessions. Programme facilitators completed the following activities during a triggering session: welcomed the community and completed introductions; drew a map on the ground of defecation areas in the village; calculated the quantity of faeces produced by the village per year; calculated expenditures on health-care costs; led a walk to view open defecation areas in the village, known as the so-called walk of shame; showed flies landing on fresh faeces and then on food; asked individuals to commit to building latrines and stop the practise of open defecation; helped form a village sanitation committee; and explained the CLTS open defecation free competition rules and set a target date for the village to become free from open defecation. A cameraman travelled with each facilitation team and filmed the triggering session as well as the public commitments made by each villager to comply with the intervention.

CLTS programme staff subsequently visited each village every 2–4 weeks to monitor the village's progress

See Online for appendix

until certification was granted (see appendix for village eligibility criteria for certification). The programme provided no subsidies for latrine building and encouraged latrine designs built with local and available materials (appendix).[3]

A village census, gathering of household survey data, and child anthropometric measurements were done at baseline. Follow-up data, including anthropometric measurements of children younger than 5 years, were collected 24 months after baseline (an average of 18 months after intervention completion). Both data collection rounds took place during the dry season (March–June) in Mali.

Enumerators completed in-home interviews with the female primary carer of the youngest child in the household. Field staff asked carers to report whether, during the past 2 days and in the past 2 weeks, each child younger than 5 years had three or more loose or watery stools in 24 h, vomit, fever, cough, congestion, or difficulty breathing. Additionally, a stool image chart was used as a secondary method to identify loose or watery stools (appendix).[16] We also measured self-reported all-cause and cause-specific mortality among the study population. Every household was asked to report the age and sex of any household member that had died in the past 12 months and the cause of death. We measured sanitation access and defecation behaviour with indicators collected by participant self-report as well as enumerator direct observations of sanitation facilities (appendix).

For the **data from DHS** see http://dhsprogram.com/data/

Pairs of anthropometrists measured the height and weight of all children younger than the age of 5 years at baseline and at follow-up among study households. All weight and height measurements were taken in triplicate and the median measurement was used for analysis. Children with height-for-age *Z* scores (HAZ) less than –2 were classified as stunted and those with HAZ less than –3 were regarded as severely stunted. Children with weight-for-age *Z* scores (WAZ) less than –2 were regarded as underweight and children with WAZ less than –3 were regarded as severely underweight.

A field team gathered and processed source water and household stored drinking water samples from a subset of households in every village. Water samples were processed by the IDEXX Quanti-Tray/2000 method (IDEXX Laboratories, Westbrook, ME, USA) using Colilert-18 media to enumerate the most probable number of *Escherichia coli* per 100 mL of water sample (appendix).

Outcomes

The primary outcome of the trial was prevalence of reported child diarrhoea (defined as three or more loose or watery stools per 24 h). Child growth (height-for-age, stunting prevalence, weight-for-age, and underweight prevalence) was measured as a secondary outcome. Child growth was chosen as an objective (not self-reported) and broad indicator of child enteric infections.[17,18] Respiratory illness was a prespecified additional outcome because the CLTS programme includes messages about improved hand hygiene and previous work has shown that recent diarrhoeal illness can make children more susceptible to respiratory illness.[19] Additionally, enumerators recorded earache and bruising as negative control outcomes to assess potential differential reporting bias between intervention groups.[20] Mortality was not a prespecified outcome; however, we asked households to report all-cause and diarrhoea-related mortality.

Many additional outcomes were measured to better understand the pathways through which the CLTS programme could affect child health outcomes, and to assess the effect of the programme on sanitation access, quality of latrines, and defecation behaviour. We did direct observations of sanitation facilities and household interviews to assess indicators of behavioural change. Drinking water source and household stored water were sampled to understand whether higher densities of pit latrines in villages would negatively or positively affect groundwater microbial quality.[21]

Statistical analysis

The study sample size was constrained by the number of treatment villages the implementers thought was feasible to undertake the intervention during the study timeline. We used data from the Demographic and Health Surveys (DHS) Program for the Koulikoro region collected during the dry season (February–May) in 2001 to calculate a baseline prevalence of diarrhoea (20·5%) and an intracluster correlation coefficient (ICC) of 0·029 (2006 DHS data were not used because they were taken during the rainy season in Koulikoro). We estimated the study had 80% power to detect a 25% reduction in diarrhoea, assuming at least 26 children per cluster (village), and defined significance at a p value of 0·05.

We did an intention-to-treat analysis for all outcomes. We used Poisson regression to estimate the prevalence ratio among children younger than 5 years in the intervention group compared with the control group for diarrhoea, other illness symptoms, stunting, underweight, and mortality. We used ordinary least squares linear regression to estimate mean differences between intervention and control groups for HAZ and WAZ. We estimated standard errors and confidence intervals using robust standard errors (the Huber-White Sandwich estimator) to account for correlated outcomes at the village level. The same model structures were used to test for differences in baseline characteristics between households present at follow-up (panel households) and those lost to follow-up, and to estimate mean differences in prevalence of defecation and hygiene behaviours between groups at follow-up. We did not adjust p values based on multiple comparisons because many of our health outcomes were strongly correlated.[22]

Adjusted models of anthropometric outcomes include child age in months to improve precision, and include every child's baseline measurements to condition on baseline growth status. Two subgroup analyses of anthropometric outcomes were done of children aged younger than 2 years (prespecified), and children younger than 1 year at baseline (not prespecified). The random assignment of villages and all statistical analyses were done with Stata software (version 12). Two investigators (AJP and MLA) independently replicated the primary analysis. The trial is registered at ClinicalTrials.gov, number NCT01900912.

Role of the funding source

The funder 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

Participants were recruited between April 12, and June 23, 2011 (before the rainy season) in Koulikoro. The baseline census identified 5833 households in the study villages. After exclusion of households without any children younger than 10 years (1283 households) and those that declined to participate (18 households), 4532 households were randomly assigned by village (clusters) into CLTS intervention (2365 households) or the control (2167 households) group receiving no intervention (figure 2). The study population included 6862 children younger than 5 years at baseline (mean 56·7 [SD 22·1] children per village). Follow-up data and anthropometric measurements were gathered from March 27, to May 31, 2013. At follow-up, 4031 households were enrolled and successfully matched with observations from baseline households. 6413 children who were younger than 5 years were included at follow-up from baseline households. Baseline characteristics of baseline households present at follow-up were similar to those lost to follow-up (appendix).

Table 1 shows baseline characteristics of participants by control and intervention groups. Access to sanitation and an improved water source were similar across groups. Baseline diarrhoeal and respiratory illness symptoms were at higher prevalence in villages assigned to the CLTS intervention (table 1). Anthropometric mean measurements and distributions of children younger than 5 years were similar at baseline between CLTS intervention and control groups (table 1, appendix). With our baseline data, we estimated we could detect a 0·19 difference in HAZ and a 0·15 difference in WAZ between treatment groups at follow-up.

During the study, in March, 2012, the Malian Government was overthrown by a military coup, between baseline and follow-up data collection. Most violence occurred outside the study region, however, these events delayed the follow-up data collection by 6 months to ensure safety of field staff. The government did not pause the CLTS intervention activities during the coup; although it is likely the certification process would have been completed earlier in the absence of the conflict.

According to the National Directorate of Sanitation and Pollution Control in the Malian Ministry of the Environment and Sanitation, open defecation free certification was achieved in 58 (97%) of 60 villages assigned to receive the CLTS intervention. At follow-up, 1999 (95%) of 2094 households in CLTS villages reported that an organisation had come to promote building of latrines, compared with 197 (10%) of 1884 control villages. 183 (93%) of 197 respondents in control villages identified a sanitation promotion organisation other than the CLTS programme. 1692 (85%) of 2001 respondents in CLTS villages reported attending the triggering event; 1660 (84%) of 1980 reported at least one female household member, 1434 (72%) of 1981 reported at least one male household member, and 1423 (72%) of 1977 reported that children attended (appendix).

For more about the **Malian Ministry of the Environment and Sanitation** see http://www.environnement.gov.ml/

Access to a private latrine almost doubled in CLTS villages, rising from 790 (33%) of 2365 households at baseline to 1373 (65%) of 2120 households in the intervention group at follow-up, compared with the control group access of 765 (35%) of 2167 households at

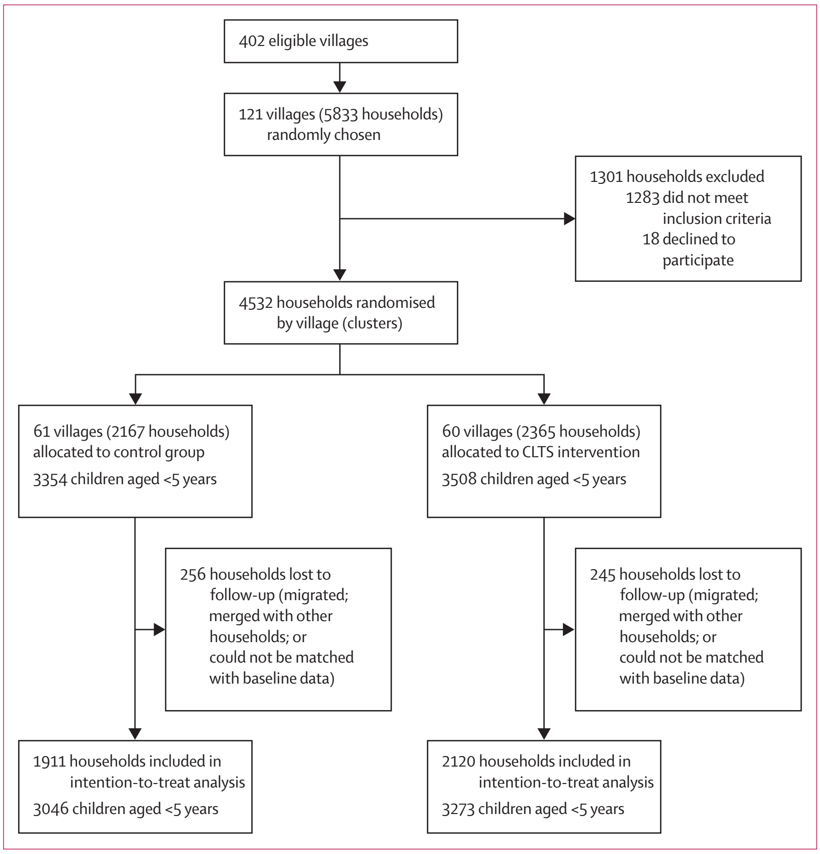

Figure 2: **Trial profile**
CLTS=community-led total sanitation.

baseline and 661 (35%) of 1911 households at follow-up. Village-level mean latrine access increased independent of baseline levels (appendix). Among households ranked in the lowest quartile by a household asset index (whereby households scored one point for each asset owned; appendix), latrine ownership rose more steeply as a result of CLTS; latrine ownership increased by 39 percentage points (95% CI 29–48) among these households versus 26 percentage points among wealthier households (95% CI 19–33). Self-reported open defecation rates decreased by 23 percentage points among adult women (71% reduction), by 24 percentage points (71%) among adult men, by 43 percentage points (49%) among children aged 5–10 years, and by 43 percentage points (51%) among children younger than 5 years (table 2, appendix). Of those households with access to a private latrine (2034 [50%] of 4031 households), 1972 (98%) of 2018 households reported the latrine as the prime defecation location for female adults and 1915 (98%) of 1960 households reported the latrine as the prime defecation location for adult males. Mothers reported that children younger than 5 years were significantly more likely to use a child potty as the main defecation location in CLTS villages than in control villages (table 2).

We reported no difference in child diarrhoea prevalence between intervention and control groups with either a 2-day (22% *vs* 24%) or 2-week recall period (31% *vs* 32%; ICC 0·056). The prevalence of other gastrointestinal and respiratory illness symptoms were also similar between groups; the only significant difference was a reduction in the prevalence of bloody stools in intervention villages (table 3) measured with a 2-week recall period. We noted no difference between groups in the prevalence of earache and bruising (negative control variables that would not be expected to be affected by the intervention; table 3, appendix).

Children younger than 5 years in intervention villages were taller than were children in control villages by a mean of 0·18 in HAZ (95% CI 0·03–0·32) at follow-up (ICC 0·072). Stunting prevalence was lower in children in intervention villages than control villages (table 4). No differences in WAZ scores (ICC 0·070) and reduction in the proportion of children underweight were observed between control and intervention villages (table 4). Children were less likely to be severely underweight in intervention villages than in control villages (table 4). Effects on child growth were more pronounced for younger children (<2 years) than older children (2 to <5 years; figure 3). With restriction of the analysis to children younger than 2 years of age at enrolment, those in CLTS villages had a mean HAZ higher by 0·24, and were less likely to be stunted and less likely to be severely underweight than children in control villages (table 4). Children aged younger than 1 year at baseline showed the largest improvements in height and weight (table 4, figure 3). Model specifications adjusting for baseline measurements and child age in months gave similar results (table 4).

694 deaths were reported in the last 12 months of the trial in study households for all age groups (331 in control, 363 in intervention); 16% of all households

	Control		CLTS		p value
	Data available (N)	Data (n [%])	Data available (N)	Data (n [%])	
Household characteristics					
Number of household members	2166	7·7 (4·2)*	2365	7·6 (3·7)*	0·655
Age of children <5 years (months)	3472†	25·6 (17·0)*	3702†	25·2 (17·0)*	0·319
Child is breastfed	3326†	1323 (40%)	3475†	1455 (42%)	0·083
Asset index	2166	0·5 (0·1)*	2363	0·5 (0·1)*	0·908
Living in poorest quartile	2166	687 (32%)	2363	753 (32%)	0·970
Owns mobile phone	2165	954 (44%)	2363	883 (37%)	0·049
Household head has ≥1 year of school education	1974	369 (19%)	2178	403 (19%)	0·931
Household head can read and write	2035	643 (32%)	2221	687 (31%)	0·825
Access to private latrine	2167	765 (35%)	2365	790 (33%)	0·873
Soap observed at latrine	1434	40 (3%)	1508	46 (3%)	0·721
Water observed at latrine	1436	61 (4%)	1508	92 (6%)	0·222
Flies observed in latrine	1437	824 (57%)	1507	1043 (69%)	0·009
Faeces observed on latrine floor	1436	63 (4%)	1506	151 (10%)	0·001
Cover over the latrine	1437	731 (51%)	1510	832 (55%)	0·423
Uses improved water source	2102	869 (41%)	2270	1011 (45%)	0·639
Main water source <5 min walk	2156	1519 (70%)	2357	1672 (71%)	0·896
Treated water in past 7 days	2106	955 (45%)	2272	1024 (45%)	0·958
L of water used per person per day	2102	44·8 (36·7)*	2269	43·0 (43·7)*	0·542
Household stored water quality (log MPN *Escherichia coli* per 100 mL)	425	2·2 (1·0)*	419	2·1 (1·0)*	0·117
Source water quality (log MPN *E coli* per 100 mL)	190	2·4 (1·3)*	205	2·2 (1·4)*	0·148
Illness in children <5 years (2-day recall)					
Diarrhoea‡	3354†	0·18 (0·38)*	3508†	0·21 (0·41)*	0·121
Blood in stool	3353†	0·02 (0·14)*	3507†	0·02 (0·15)*	0·530
Vomiting	3362†	0·04 (0·16)*	3512†	0·05 (0·22)*	0·222
Fever	3360†	0·17 (0·38)*	3513†	0·23 (0·42)*	0·014
Congestion	3363†	0·20 (0·40)*	3509†	0·29 (0·45)*	0·001
Cough	3363†	0·19 (0·40)*	3510†	0·27 (0·45)*	0·001
Difficulty breathing	3355†	0·03 (0·16)*	3506†	0·06 (0·24)*	<0·001
Anthropometrics of children <5 years					
Height-for-age *Z* score	3141†	–1·18 (1·6)*	3268†	–1·18 (1·6)*	0·982
Weight-for-age *Z* score	3154†	–1·27 (1·4)*	3268†	–1·27 (1·4)*	0·998
Stunted	3141†	0·30 (0·46)*	3268†	0·3 (0·46)*	0·879
Severely stunted	3141†	0·12 (0·33)*	3268†	0·12 (0·33)*	0·985
Underweight	3154†	0·28 (0·45)*	3268†	0·28 (0·45)*	0·847
Severely underweight	3152†	0·11 (0·31)*	3268†	0·10 (0·31)*	0·826

p values were calculated with robust standard errors to account for clustering by village. We created the asset index in which households scored one point for each asset owned (appendix). Children with height-for-age *Z* scores (HAZ) less than –2 were classified as stunted and those with HAZ less than –3 were regarded as severely stunted. Children with weight-for-age *Z* scores (WAZ) less than –2 were regarded as underweight and children with WAZ less than –3 were regarded as severely underweight. CLTS=community-led total sanitation. MPN=most probable number. *Mean (SD). †Number of children. ‡Defined as three or more loose or watery stools per 24 h.

Table 1: **Baseline characteristics of intervention and control households**

	Control		CLTS		Overall	
	Number of households	n (%)	Number of households	n (%)	Difference (percentage points)	95% CI
Sanitation access						
Access to own latrine	1911	611 (34·6%)	2120	1373 (64·8%)	30·2%	22·7 to 37·6
Share latrine with other households	664	361 (54·4%)	1372	494 (36·0%)	–18·4%	–27·4 to –9·4
Child uses potty	1630	251 (15·4%)	1762	890 (50·5%)	35·1%	27·9 to 42·4
Satisfied with sanitation	1885	955 (50·7%)	2092	1495 (71·5%)	20·8%	12·9 to 28·7
Women have privacy	1880	1392 (74·0%)	2091	1772 (84·7%)	10·7%	1·9 to 19·5
Women feel safe at night	1880	1556 (82·8%)	2091	1937 (92·6%)	9·9%	2·2 to 17·5
Latrine observations*						
Potty in latrine	1276	68 (5·3%)	1897	188 (9·9%)	4·6%	0·1 to 8·2
Latrine has concrete slab	1280	281 (22·0%)	1898	361 (19·0%)	–2·9%	–10·7 to 4·8
Soap in latrine	1280	62 (4·8%)	1898	294 (15·5%)	10·6%	7·1 to 14·2
Water in latrine	1280	59 (4·6%)	1898	483 (25·4%)	20·8%	15·4 to 26·2
Flies in latrine	1280	740 (57·8%)	1898	875 (46·1%)	–11·7%	–20·3 to –3·1
Faeces on latrine floor	1280	128 (10·0%)	1898	189 (10·0%)	0·0%	–5·1 to 5·1
Water or urine on latrine floor	1280	891 (69·6%)	1898	1272 (67·0%)	–2·6%	–9·4 to 4·3
Latrine hole covered	1280	321 (25·1%)	1897	1313 (69·2%)	44·1%	36·5 to 51·7
Human faeces in compound	1885	212 (11·2%)	2094	114 (5·4%)	–5·8%	–9·2 to –2·4
Animal faeces in compound	1884	1639 (87·0%)	2093	1604 (76·6%)	–10·4%	–16·4 to –4·4
Clear path to latrine	1272	997 (78·4%)	1884	1537 (81·6%)	3·2%	–2·7 to 9·1
Latrine appears used	1274	1202 (94·3%)	1889	1815 (96·1%)	1·7%	–0·5 to 3·9
Reported open defecation						
Adult women	1869	608 (32·5%)	2086	198 (9·5%)	–23·0%	–33·5 to –12·6
Adult men	1813	602 (33·2%)	2004	195 (9·7%)	–23·5%	–33·7 to –13·2
Children (5–10 years)	1239	1079 (87·1%)	885	392 (44·3%)	–42·6%	–50·3 to –35·0
Children (<5 years)	1632	1361 (83·4%)	1762	718 (40·8%)	–42·8%	–53·2 to –32·3
Water						
Stored water reported treated	1884	896 (47·6%)	2088	1255 (60·1%)	12·5%	1·1 to 23·9
log MPN *Escherichia coli* per 100 mL in stored water	432	2·1 (1·1)†	457	2·0 (1·0)†	–0·15%	–0·4 to 0·09
log MPN *E coli* per 100 mL in source water	195	2·1 (1·4)†	162	1·9 (1·4)†	–0·24%	–0·58 to 0·10
Hand hygiene						
Daily handwashes with soap	1878	1·9 (1·5)†	2090	2·4 (1·6)†	0·5%	0·3 to 0·7
Mother has clean palms*	1882	240 (12·8%)	2085	300 (14·4%)	1·6%	–2·5 to 5·7
Reports handwashing important after using toilet	1911	752 (39·4%)	2120	1182 (55·8%)	16·4%	9·9 to 22·9

95% CIs account for robust standard errors at the village level. CLTS=community-led total sanitation. MPN=most probable number. *Observed. †Mean (SD).

Table 2: **Effect of CLTS on sanitation, hygiene, and water characteristics**

reported at least one death in the past 12 months (303 [16·1%] of 1887 households in control, 329 [15·7%] of 2097 households in intervention). Diarrhoea was reported as the cause of 7% of all deaths (50 of 670 deaths with known causes). Households in CLTS villages were less likely to have a death by diarrhoea than control villages (PR 0·46, 95% CI 0·26–0·83; 34 total diarrhoeal deaths in control group *vs* 16 total diarrhoeal deaths in CLTS). 331 (48%) of all deaths were of children aged younger than 5 years. Households in CLTS and control groups were equally likely to report a death of a child younger than 5 years (PR 0·95, 95% CI 0·71–1·27). CLTS households were less likely to report a child death by diarrhoea than control households (PR 0·47, 95% CI 0·23–0·98; 11 child diarrhoeal deaths in CLTS *vs* 23 child diarrhoeal deaths in control; table 3).

Latrines at CLTS households were more than twice as likely to have a cover over the hole of the pit, and less likely to have flies observed inside the latrine. CLTS households were half as likely to have piles of human faeces noted in the courtyard, and animal faeces were also less likely to be present in the courtyard than in courtyards at the control households (table 2). Field staff indicated almost all latrines seemed to be in regular use in CLTS and control villages, and had clear footpaths to the latrine (table 2). At follow-up, more than two-thirds of all latrines had water from anal washing or urine on the latrine floor, suggesting they had been very recently used. Latrines in

	Baseline				Follow-up				Prevalence ratio (95% CI)	p value
	Control		CLTS		Control		CLTS			
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)		
2-day recall										
Diarrhoea*	3354	0·178 (0·383)	3508	0·212 (0·409)	2872	0·241 (0·428)	3140	0·225 (0·418)	0·93 (0·76–1·14)	0·486
Loose stool, by chart†	2721	0·277 (0·463)	2735	0·288 (0·468)	2420	0·165 (0·380)	2646	0·141 (0·370)	0·85 (0·71–1·03)	0·106
Blood in stool	3353	0·021 (0·143)	3507	0·024 (0·153)	2866	0·014 (0·117)	3133	0·012 (0·108)	0·85 (0·53–1·35)	0·481
Vomiting	3362	0·044 (0·206)	3512	0·053 (0·224)	2874	0·045 (0·207)	3148	0·038 (0·190)	0·84 (0·63–1·11)	0·221
Fever	3360	0·171 (0·376)	3513	0·227 (0·419)	2881	0·207 (0·405)	3150	0·206 (0·405)	1·00 (0·81–1·23)	0·993
Congestion	3363	0·200 (0·400)	3509	0·290 (0·454)	2881	0·351 (0·478)	3149	0·358 (0·479)	1·02 (0·88–1·18)	0·822
Cough	3363	0·194 (0·396)	3510	0·274 (0·446)	2882	0·263 (0·440)	3151	0·269 (0·469)	1·02 (0·86–1·23)	0·791
Difficulty breathing	3355	0·025 (0·156)	3506	0·060 (0·238)	2882	0·037 (0·189)	3149	0·021 (0·144)	0·57 (0·32–1·01)	0·056
Earache	3355	0·026 (0·158)	3510	0·035 (0·184)	2882	0·025 (0·157)	3149	0·025 (0·155)	0·98 (0·65–1·48)	0·916
Bruising‡	..	..	..	..	2878	0·023 (0·151)	3148	0·018 (0·132)	0·76 (0·38–1·55)	0·455
2-week recall										
Diarrhoea*	3349	0·251 (0·434)	3494	0·287 (0·452)	2869	0·320 (0·467)	3130	0·312 (0·463)	0·98 (0·82–1·17)	0·787
Blood in stool	3338	0·037 (0·188)	3495	0·046 (0·208)	2853	0·034 (0·180)	3111	0·023 (0·149)	0·68 (0·48–0·97)	0·031
Vomiting	3350	0·073 (0·260)	3499	0·098 (0·297)	2864	0·081 (0·273)	3135	0·076 (0·265)	0·93 (0·74–1·18)	0·562
Fever	3352	0·264 (0·441)	3506	0·311 (0·463)	2875	0·288 (0·453)	3140	0·285 (0·451)	0·99 (0·82–1·19)	0·902
Congestion	3355	0·280 (0·449)	3503	0·363 (0·481)	2881	0·444 (0·497)	3141	0·449 (0·497)	1·01 (0·88–1·16)	0·858
Cough	3352	0·270 (0·444)	3500	0·348 (0·477)	2877	0·341 (0·474)	3140	0·349 (0·477)	1·02 (0·87–1·21)	0·782
Difficulty breathing	3343	0·040 (0·197)	3494	0·081 (0·273)	2866	0·052 (0·223)	3132	0·032 (0·177)	0·62 (0·37–1·03)	0·065
Mortality										
All-cause mortality	2165§	0·118 (0·323)	2364	0·104 (0·305)	1887	0·081 (0·027)	2097	0·076 (0·266)	0·95 (0·71–1·27)	0·716
Diarrhoeal-related mortality	2165§	0·011 (0·105)	2364	0·011 (0·102)	1887	0·011 (0·105)	2097	0·005 (0·072)	0·47 (0·23–0·98)	0·044

Mean proportions shown for illness symptoms reported by respondent for 2-day and 2-week recall periods. Mortality estimates show number and percentage of households reporting a death of a child younger than 5 years in the past 12 months. n=number of children <5 years (unless stated otherwise). CLTS=community-led total sanitation. *Defined as three or more loose or watery stools per 24 h. †Image selection of six or seven on stool chart, not including exclusive breastfeeding children. ‡Not measured at baseline. §Number of households.

Table 3: **Comparisons of mean prevalence of gastrointestinal and respiratory illness symptoms among children aged 5 years and younger at baseline and follow-up in intervention and control households**

CLTS villages were more likely to be stocked with soap and water for hygiene purposes than control villages (table 2). The prevalence of sharing of latrines with other households was lower in CLTS villages than control villages (table 2); CLTS village latrines were shared by a mean of 2·7 (SD 1·1) households, compared with a mean of 3·1 (1·2) households in control villages. The type of latrine used by study households was similar across groups, with households mainly using pit latrines without a concrete slab (table 2; see appendix for details about how latrines were built). 1383 (73%) of 1899 latrines in CLTS villages were located within 10 m of the household, compared with only 710 (56%) of 1278 in control villages.

Households more likely to report being satisfied with their overall sanitation situation in CLTS villages than in control villages (table 2), and ranked their main defecation location as better in terms of cleanliness, functionality, privacy, and comfort (appendix). Women in CLTS villages

	Follow-up				Effect size or prevalence ratio							
	Control		CLTS		Unadjusted				Adjusted			
	n	Mean	n	Mean	n	PR	95% CI	p value	n	PR	95% CI	p value
Children <5 years at baseline												
Height-for-age *Z* score (SD)	1132	–1·77 (1·2)	1283	–1·60 (1·2)	2415	0·18*	0·03 to 0·32	0·022	2162	0·17*	0·04 to 0·31	0·012
Weight-for-age *Z* score (SD)	1145	–1·36 (1·0)	1307	–1·27 (1·0)	2452	0·09*	–0·04 to 0·22	0·155	2178	0·09*	–0·03 to 0·20	0·138
Stunted	1132	0·41	1283	0·35	2415	0·86	0·74 to 1·00	0·047	2162	0·85	0·75 to 0·98	0·020
Severely stunted	1132	0·16	1283	0·12	2415	0·78	0·60 to 1·02	0·067	2162	0·75	0·57 to 1·01	0·056
Underweight	1145	0·26	1307	0·22	2452	0·88	0·71 to 1·08	0·226	2178	0·87	0·72 to 1·05	0·141
Severely underweight	1145	0·08	1307	0·05	2452	0·65	0·46 to 0·93	0·020	2178	0·65	0·44 to 0·95	0·028
Children <2 years at baseline												
Height-for-age *Z* score (SD)	746	–1·92 (1·2)	830	–1·68 (1·2)	1576	0·24*	0·08 to 0·40	0·004	1384	0·24*	0·09 to 0·40	0·002
Weight-for-age *Z* score (SD)	756	–1·45 (1·2)	846	–1·30 (1·1)	1602	0·15*	0·00 to 0·31	0·051	1395	0·16*	0·01 to 0·31	0·030
Stunted	746	0·46	830	0·38	1576	0·83	0·72 to 0·96	0·014	1384	0·80	0·69 to 0·92	0·002
Severely stunted	746	0·19	830	0·15	1576	0·77	0·58 to 1·01	0·060	1384	0·74	0·55 to 1·00	0·046
Underweight	756	0·29	846	0·24	1602	0·84	0·68 to 1·05	0·134	1395	0·81	0·66 to 1·00	0·052
Severely underweight	756	0·09	846	0·06	1602	0·65	0·43 to 0·96	0·031	1395	0·65	0·43 to 1·01	0·053
Children <1 year at baseline												
Height-for-age *Z* score (SD)	381	–1·98 (1·3)	431	–1·70 (1·2)	812	0·29*	0·09 to 0·48	0·004	674	0·25*	0·07 to 0·44	0·008
Weight-for-age *Z* score (SD)	388	–1·55 (1·1)	436	–1·29 (1·1)	824	0·26*	0·07 to 0·47	0·007	691	0·25*	0·07 to 0·43	0·008
Stunted	381	0·49	431	0·39	812	0·80	0·68 to 0·94	0·008	674	0·80	0·68 to 0·94	0·008
Severely stunted	381	0·22	431	0·15	812	0·69	0·50 to 0·96	0·027	674	0·71	0·51 to 0·98	0·038
Underweight	388	0·34	436	0·25	824	0·73	0·57 to 0·94	0·015	691	0·70	0·54 to 0·89	0·004
Severely underweight	388	0·12	436	0·06	824	0·45	0·27 to 0·76	0·003	691	0·44	0·24 to 0·81	0·008

Models include individuals measured at baseline and at follow-up. Height-for-age *Z* scores (HAZ) and weight-for-age *Z* scores (WAZ) are modelled with linear regression; stunting and underweight are modelled with Poisson regression. All models include robust SEs to account for clustering at the village level; adjusted models include baseline measurements and child age in months. Children with HAZ less than –2 were classified as stunted and those with HAZ less than –3 were regarded as severely stunted. Children with WAZ less than –2 were regarded as underweight and children with WAZ less than –3 were regarded as severely underweight. n=number of children. CLTS=community-led total sanitation programme. PR=prevalence ratio. *Effect size.

Table 4: **Effect of CLTS on child growth among children aged younger than 5, 2, and 1 years at enrolment**

were more likely to feel they had privacy when defecating and to feel safe defecating at night (table 2). CLTS households were more likely, compared with control village households, to agree that to practise open defecation was regarded as shameful (86% *vs* 72%; an increase of 14 percentage points, 95% CI 9–20). Latrine use seemed to be more of a social norm in CLTS villages; 48% of respondents in control villages agreed with the statement “the majority of people in my community do not use latrines for defecation”, compared with only 14% in CLTS villages (reduction of 34 percentage points, 95% CI –44 to –24).

CLTS households were more likely to report treating their stored drinking water (table 2). Of those households treating their water, the predominant method was straining it through a cloth (1904 [89%] of 2151 CLTS and control households). Faecal contamination in drinking water sources and in household stored water was not significantly different between control and intervention households at follow-up (table 2).

Female respondents in CLTS villages reported a high daily frequency of handwashing with soap compared with respondents from control villages (table 2). Individuals in CLTS households were more likely to state that washing

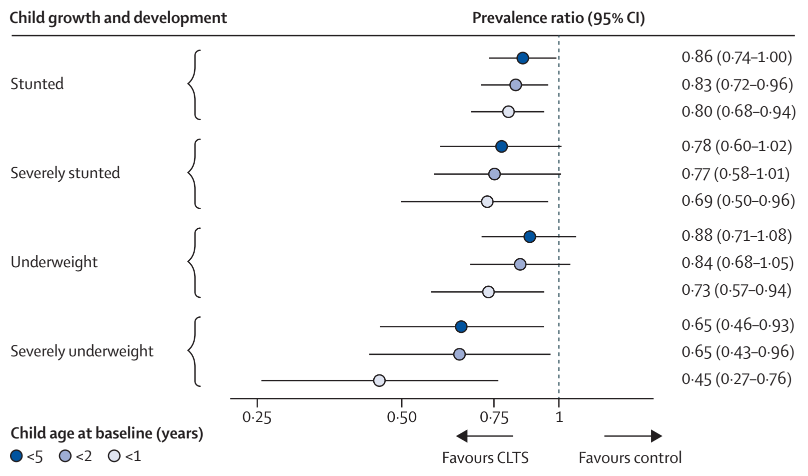

Figure 3: **Prevalence ratio of child stunting and underweight in CLTS group at follow-up compared with control, by child age at baseline enrolment**

Errors bars show 95% CIs generated by Poisson regression. Models include robust standard errors to account for clustering at the village level. CLTS=community-led total sanitation.

their hands after defecation (unprompted) was important, in comparison to households in control villages (table 2). However no significant difference was reported in the percentage of female caregivers with presence of visible dirt on palms between the two groups (table 2).

Discussion

This study reported no evidence that the CLTS intervention reduced child diarrhoeal illness, although the reduced prevalence of bloody stools in CLTS villages might suggest a reduction in severe diarrhoea. The absence of an effect on diarrhoea is consistent with our finding that drinking water quality was similar across groups (control and intervention). Evaluations of rural sanitation programmes in India have also reported no effect on diarrhoea or water quality, although these programmes also had limited success in changing defecation behaviours.[9–11] By contrast, we noted high use of latrines and safe management practices of child faeces in Mali.

Diarrhoeal illness was only measured at one timepoint during the dry season, thus it is possible that improved access to sanitation could have increased or reduced the risk of diarrhoeal illness during the rainy season.[23] Diarrhoeal risk has been previously documented to differ by season and to be affected by recent precipitation events;[24] however, diarrhoea prevalence is typically higher during the dry season in sub-Saharan Africa.[25] Although sanitation access in CLTS villages increased by 30 percentage points, universal coverage was not achieved; it is possible that sanitation coverage must be above a certain threshold to adequately prevent transmission of diarrhoeal pathogens within rural communities, however there is inadequate evidence from previous research to support this hypothesis.

Our data suggest that CLTS intervention reduced stunting by 6 percentage points and improved child height by 0·18 HAZ of children at follow-up. The increase in child height was driven exclusively by improvements in children aged younger than 2 years at enrolment (0·24 HAZ). An even larger effect (0·29 HAZ) was noted with restriction of the sample to children younger than 1 year at enrolment (table 4, figure 3). These findings are consistent with the window of opportunity to prevent long-term stunting in those aged younger than 2 years,[26] and suggest that preventing early exposure to faecal contamination could be crucial to achieve improvements in child health. Future trials need to assess whether the association between reduced open defecation and child growth reported in this study can be replicated.

Improvements in child growth were noted despite the fact that the programme did not significantly reduce diarrhoeal illness in children. A possible explanation for this finding is that increased latrine use might have reduced the prevalence of intestinal worm infections, which can cause malnutrition and stunted growth in children;[27] however, sanitation intervention studies in India reported no effect on worm infections.[9,10] Another possible explanation is that the CLTS programme reduced child exposure to faecal contamination, through reduction in open defecation and possible improvements in hand hygiene behaviours. Lower levels of environmental faecal contamination could potentially contribute to less environmental enteropathy (also termed environmental enteric dysfunction) among children, a subclinical disorder characterised by poor nutrient absorption in the gut and associated with stunting in children.[28] Environmental enteropathy has been shown to be associated with a contaminated environment; a study in rural Bangladesh showed that children from households with improved sanitation and a clean household were less likely to have biomarkers of environmental enteropathy.[29] Randomised controlled trials are ongoing in rural Kenya (NCT01704105), Bangladesh (NCT01590095), and in Zimbabwe (NCT01824940) to assess whether or not improved sanitation can reduce child environmental enteropathy or parasite infections in conjunction with improved child growth.[30]

Although mortality was not a prespecified analysis, households reported diarrhoea-related under-5 child mortality to be significantly lower in intervention villages than in control villages. We did not use verbal autopsy to measure cause-specific mortality; therefore, some deaths due to diarrhoea could have been misclassified. Differential misclassification between groups is a possibility if CLTS households refrained from reporting deaths due to diarrhoea. Additionally, the total number of diarrhoeal-related deaths recorded in this study was low; only 23 diarrhoea-related under-5 deaths in the control group and 11 diarrhoea-related under-5 deaths in the CLTS group.

Most latrines constructed during the programme were not classified as improved facilities according to WHO and UNICEF's Joint Monitoring Program, and thus do not count towards the Millennium Development Goal Target 10.[1] Encouraging construction of simple latrines with local materials is in line with the CLTS guidelines, designed to reduce barriers against their construction, such as cost or scarce technical expertise.[3] In Mali, latrines are built out of mud-brick—a mixture of clay, sand, water, and grain husks that is also used to construct houses and mosques. We noted no negative effect on source water quality in CLTS villages, suggesting the construction and use of unimproved latrines did not contaminate the groundwater used for drinking.

This study has several important limitations. We relied on respondent self-reporting to measure defecation behaviours, illness symptoms, and mortality; these outcomes are thus subjected to reporting bias. Notably, we showed no significant difference in prevalence of negative control illness outcomes between groups. Diarrhoeal prevalence was high across both intervention and control groups (it is possible that the indicator was not specific enough to capture an effect on gastrointestinal illness). Additionally, all follow-up data was gathered at only one timepoint during the dry season in Mali. Finally, we did not measure child parasite infections or biomarkers of environmental enteropathy. Future research is warranted to understand if improved sanitation could improve child height through these pathways.

Our study provides new evidence that a behavioural intervention can substantially increase access to sanitation facilities in a rural setting without financial subsidies. Access to a private latrine almost doubled to 65% of households in CLTS villages, self-reported open defecation was reduced to less than 10% in adult men and women, and management of child faeces improved (child potty use increased by 35 percentage points). The programme increased access to private latrines particularly among poor households; poor households were three times more likely to have a private latrine in intervention villages than in control villages. These findings justify scale-up of the CLTS programme in rural Mali and suggest that the CLTS approach can be effective in improving access to sanitation.

Contributors

AJP, HD, and MLA contributed to the study design. MC managed the data collection. AJP, CL, and MLA did the data analysis. AJP wrote the first draft of the manuscript. All authors contributed to editing and revising the manuscript.

Declaration of interests

We declare no competing interests.

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