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Effectiveness of community-led total sanitation and health education against helminth infections in Côte d'Ivoire: a cluster-randomised factorial trial with 38 months of follow-up

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Abstract

Background

Parasitic infections remain an important public health problem in low- and middle-income countries. Preventive chemotherapy is the main strategy to control helminthiasis, but rapid reinfection occurs in settings that lack clean water, sanitation and hygiene. This study aimed to assess the effectiveness of community-led total sanitation (CLTS) with or without health education on infections with soil-transmitted helminths, schistosomes and intestinal protozoa.

Methods

We conducted a longitudinal, repeated cross-sectional cluster-randomised trial within 56 communities in Côte d'Ivoire. Households that had at least one child aged 5–15 years were eligible. After a baseline parasitological and knowledge, attitudes, practice and behaviour (KAPB) questionnaire survey, villages were randomly assigned 1:1:1:1 to one of the four groups: (i) CLTS; (ii) health education; (iii) both interventions combined; and (iv) no intervention. All communities received annual preventive chemotherapy. Two follow-up surveys at 17 and 38 months post-intervention assessed the effects of the interventions on primary (infection with any soil-transmitted helminth species) or secondary (infection with schistosomes and intestinal protozoa) outcomes. The primary analysis compared the effect of CLTS on hookworm infection status.

Results

Participants were recruited in August and September 2014. Fifty-four localities with 1,246 households including 5,230 participants were randomised, as follow: 13 villages to CLTS, 14 villages to health education, 13 villages to both and 14 villages to no intervention. No significant differences were observed in terms of hookworm prevalence in CLTS and control villages for both follow-up surveys: (i) follow-up at 17 months [59/1,552 (3.8%) vs 69/1,594 (4.3%); odds ratio (OR) = 0.87, 95% confidence interval (CI) 0.45 to 1.68, p = 0.69] and follow-up at 38 months [26/1,212 (2.1%) vs 24/1,278 (1.9%); OR 1.15, 95% CI 0.60 to 2.17, p = 0.68]. Subgroup analysis using localities that achieved at least 75% latrine coverage vs no-CLTS localities, revealed no specific differences in reinfection.

Conclusions

Our study highlights that the effectiveness of CLTS interventions in preventing helminth and intestinal protozoa infections varies. CLTS may be effective if the baseline prevalence is high but the synergistic effect when combined with regular preventive chemotherapy appears to be limited in this setting.

Trial Registration

ISRCTN53102033

Background

Parasitic infections are common, particularly in resource-limited setting, where personal hygiene and access to clean water and sanitation (safe disposal of human faeces and urine) is often poor[1, 2]. It is estimated that more than a billion people are affected by soil-transmitted helminthiasis (STH), schistosomiasis and intestinal protozoa infections (e.g. amoebiasis and giardiasis), causing an estimated 3.5 million disability-adjusted life years[3, 4].

The global control strategy for helminthiasis is preventive chemotherapy through regular administration of deworming drugs to entire populations at risk. Albendazole or mebendazole against soil-transmitted helminthiasis and praziquantel against schistosomiasis are the current drugs of choice[5]. However, preventive chemotherapy does not protect patients from reinfections[6]. The optimal strategy to control the transmission of these diseases is based on three pillars: (i) large-scale deworming to gradually reduce the infection burden; (ii) improved water, sanitation and hygiene (WASH) to reduce environmental contamination with infectious stages; and (iii) health education to alter behaviour to reduce environmental contamination and risk of infection. Integrated approaches combining several pillars of control hold promise for improving the cost-effectiveness of interventions and thus ensuring the sustainability of control activities in resource-constrained settings.

Community-led total sanitation (CLTS) represents a participatory approach that has been developed as a strategy to reduce the incidence of diarrhoea and intestinal infections by putting an end to open defecation and maintaining this status within communities[7]. In a pilot study carried out in the Taabo health and demographic surveillance system (HDSS) in Côte d'Ivoire, the impact on parasitic infections and attitudes and practices towards WASH of an intervention package, including CLTS and health education, was tested in nine communities within the Taabo HDSS between 2011 and 2012[8]. Promising effects on hookworm prevalence and intensity as well as lower follow-up infection rates with intestinal protozoa in communities receiving the intervention were observed. However, this study was conducted at small scale and was limited by its design, as it lacked a randomised controlled trial set-up to address potential baseline discrepancies between group assignments and a short interval between baseline and follow-up assessment.

In August 2013, a project was launched in 56 communities in the south-central part of Côte d'Ivoire with the aim to assess and quantify the effect of preventive chemotherapy, combined with either CLTS, or health education, or both measures combined, on reinfection with soil-transmitted helminths, schistosomes and intestinal protozoa, using a cluster randomised controlled trial (RCT) design[9]. Additionally, the effect of the interventions on the

incidence of diarrhoea was determined. Here we present the impact data on the parasitic infections that were assessed at three different timepoints during the overall trial duration of 38 months.

Methods

Study area and population

The study was implemented in 56 communities in three departments in the south-central part of Côte d'Ivoire (i.e. Taabo, Djékanou and Toumodi). People are mainly engaged in subsistence agriculture, whereas rubber, cocoa and coffee are farmed as cash crops.

Initially, the study was planned to comprise 56 localities in the department of Taabo alone, because of the presence of an HDSS that monitored a population of about 42,000 people when the trial was launched[10]. However, the number of appropriately sized communities according to implementation of CLTS in the Taabo department was lower than expected, and hence, the study was extended into the adjacent departments of Djékanou and Toumodi to obtain the required number of localities. To that end, our study involved 40 localities in Taabo, nine in Djékanou and seven in Toumodi.

Factorial cluster randomised trial design

Randomisation occurred after baseline data collection was completed. Sample size calculation was done using the Web-based sample calculator for cluster randomised trials presented elsewhere[11], assuming a baseline hookworm prevalence of 30% according to previous studies in the region[12,13], a prevalence reduction of 50% after implementation of interventions[8], an intra-cluster correlation of 0.4. The high correlation within the community was assumed because of the participatory nature of the interventions. Assuming a dropout rate of 30% at each follow-up we estimated that 40 clusters with 152 individuals per cluster are required to achieve 80% power at the 5% significance level. In Côte d'Ivoire, the average number of people per household in the study area is 7[12] (our assumption was 2 adults and 5 children). For a sample size of 152 children per community, we therefore included 30 households per community.

The communities were selected based on their population size. We intended to include communities with at least 30 households and a population size not exceeding 600 individuals because this is the optimal recommended size for implementation of the CLTS intervention[7]. Given the demographic characteristics of the study area, somewhat smaller communities (slightly less than 30 households) and villages exceeding 600 individuals were also included. The selection of up to 30 households per community was done at random, according to the World Health Organization's (WHO) Expanded Programme on Immunization (EPI) method[14]. Our main target group were children aged 5-15 years, on whom sample size calculation was based. Additionally, whenever possible, 1 pre-school-aged child (<5 years) and 1 adolescent or adult (>15 years) from each household were also selected. All the 3 categories of participants underwent parasitological examinations. Household heads (or their spouses/partners) were administered a questionnaire for knowledge, attitudes, practices and beliefs (KAPB), whereas direct observations in each household were done to check for the presence, use and maintenance of latrines as well as potential open defecation and waste disposal sites in close proximity. The trial communities were assigned by restricted randomisation to 1 of 4 intervention arms with 14 communities per intervention arm based on baseline hookworm (the most prominent soil-transmitted helminth species identified in the area) prevalence and population size[15,16]. The control and 3 intervention arms are as follows: (i) control arm; (ii) CLTS; (iii) health education; and (iv) CLTS and health education, resulting in a 2 × 2 factorial design. In addition, all villages received annual preventive chemotherapy.

Figure 1 shows the study area with the 56 selected communities, stratified by study arm. Interventions started right after randomisation of the communities.

Assessments

A first follow-up parasitological and KAPB questionnaire survey was carried out 17 months after the baseline cross-sectional survey. A second follow-up survey was scheduled another 21 months later. At the end of the CLTS intervention, the communities were visited and inspected using standardised forms. Transects were done to assess whether open defecation and waste disposal spots were visible and all households were inspected for the availability of latrines. An overview of the activities during the study (from August 2014 to November 2017) is provided in Figure 2.

Interventions

The interventions were implemented after the baseline cross-sectional survey[15]. The CLTS intervention was started in the communities of intervention arms 2 and 4. Only after these communities had commenced building latrines, the health education was launched in the communities of intervention arms 3 and 4 to avoid interference with the methodological approach of the CLTS intervention in arm 4. Preventive chemotherapy was done according to ongoing activities of the national control programme. These activities consist of community-based yearly mass administration of ivermectin and albendazole (against lymphatic filariasis) and yearly administration of praziquantel and albendazole (against schistosomiasis and soil-transmitted helminthiasis) to at-risk groups, adhering to WHO guidelines[5].

Implementation of interventions

Community-led total sanitation

The CLTS approach is based on participatory rural appraisal that emphasises that the learning effect is considerably higher if knowledge is acquired through self-experience and self-reflexion. Before the intervention, CLTS facilitators were trained and instructed during a 1-week workshop by certified national CLTS facilitators from the Ministry of Sanitation, UNICEF and a Swiss-based nongovernmental organization (FAIRMED; Bern, Switzerland). Communities were contacted, and a first community meeting organised. During this meeting, the ignition process of CLTS was started, which could include the following

components according to Kar and Chambers[7]: (i) transect walk ("walk of shame") through the open defecation areas and water points; (ii) defecation map, mapping of defecation areas and defecation mobility; (iii) identifying the dirtiest neighbourhoods; (iv) calculation of faeces amount and medical expenses; and (v) triggering disgust pathways of faecal contamination (glass of water, faeces to food exercise, flow diagrams of faecal-oral routes, etc.). These components were used to initiate the ignition moment (we are eating each other's faeces!). When talking about faeces, the term "caca" was employed, as "caca" had been identified as the most suited and culturally accepted term by CLTS facilitators in Côte d'Ivoire. Subsequently, two more steps were pursued that include the identification of natural leaders and the monitoring and sustaining of open defecation-free status or the process towards an open defecation-free community. Although CLTS encourages the communities to build basic sanitary facilities (i.e, latrines), to change one's hygiene behaviour, and to alter people's waste disposal practices, it does not impose standard designs and does not provide subsidies. Hence, for toilet construction, most communities used readily available local material, so that toilets were more affordable and accessible for rural communities. When a given community decided to go towards open defecation-free status, an implementation plan of community-based basic sanitation and hygiene services was elaborated. This community was frequently visited by the community development agents to ensure that the implementation of the different actions was done according to protocol.

Health education

Once communities implementing CLTS were well advanced with the construction of latrines, communities of intervention arms 3 and 4 were visited by the research team, and a first health education session was offered for the entire community. These sessions were informed by results from the preceding focus group discussions (FGDs) of the formative social science research that aimed to identifying knowledge gaps and related key health messages. In each community, interested community members (up to 10) were identified (mostly by the village chief and other village authorities) and invited to form a community health theatre group. In a further visit, the community theatre group received an additional health education session by the team and was coached to develop its own sketch to deliver hygiene and health messages in front of the community. In a final visit, the theatre group presented the sketch to the community, and during this visit, the animated cartoon called "Koko et les lunettes magiques" was screen played to children, although adults were also invited to watch[17]. After the theatre and screening of the cartoon, people were grouped into elderly, adult women, adult men and school-aged children, and discussions about health and hygiene topics were pursued to determine their understanding.

Preventive chemotherapy

After the baseline cross-sectional survey[15], appropriate treatment was offered to all individuals in the targeted communities, regardless of their infection status and participation in the baseline survey in May/June 2015 (albendazole) and August 2015 (praziquantel). All members of the 56 communities received a single oral dose of albendazole (400 mg for participants aged >2 years and 200 mg for children aged 1–2 years, respectively) against STH. A single 40 mg/kg oral dose of praziquantel against schistosomiasis was administered to community members aged 5 years and above in localities where the prevalence of schistosomiasis was ≥5%, while individual case treatment was applied in localities with lower prevalences. Drug administration was implemented by the national control programme, in collaboration with personnel from local health districts and our research team. These treatments were repeated after follow-up surveys 1 (October 2016) and 2 (December 2017).

Outcome measure

The primary outcome of the trial was infection status with any soil-transmitted helminth, particularly hookworm infection, as determined by the Kato-Katz method[18]. Secondary outcomes were other parasitic infections (i.e. *Schistosoma* spp., and intestinal protozoa) and KAPB with regard to hygiene and intestinal parasitic infections. Particular emphasis was placed on hookworm infection because of its endemicity across Côte d'Ivoire and the moderate to high prevalence in the study area[8,12,15].

Parasitological surveys

Prior to any intervention, a baseline cross-sectional parasitological survey was conducted in the 56 communities from August to September 2014[15]. The status of infection with helminths and intestinal protozoa was assessed by microscopic examination of stool and urine samples. Follow-up surveys were done 17 months (February 2016) and 38 months (November 2017) after interventions, using the same quality-controlled methods.

In each study community, project-associated community health workers (CHWs) provided participants with two plastic containers for stool and urine collection, the day before the field team's visit. All participating household members were invited to return filled containers the next morning (between 08:00 and 12:00 hours). Stool and urine samples were transferred to laboratories at the general hospitals of Taabo and Djékanou, the community health centre at Kpouèbo, or a mobile field laboratory set up at the dispensary of Léléblé.

Participants' infection status with soil-transmitted helminths (*A. lumbricoides*, hookworm and *Trichuris trichiura*), *Schistosoma mansoni* and pathogenic intestinal protozoa (*G. intestinalis* and *Entamoeba histolytica*/*E. dispar*), as determined in stool samples, and *Schistosoma haematobium*, determined in urine samples, were recorded. From each stool sample, duplicate Kato-Katz thick smears were prepared, using a standard template holding 41.7 mg of faeces[18]. The slides were allowed to clear for 30–45 min before examining under a microscope by experienced laboratory technicians. Helminth eggs were counted and recorded for each species separately. A portion of stool (1–2 g) was preserved in 10 ml of sodium acetate-acetic acid-formalin (SAF) solution for further diagnostic work-up. Urine samples that were positive for microhaematuria from reagent strip testing (Hemastix, Siemens Healtheare; Zurich, Switzerland) were subjected to a filtration method for quantification of *S. haematobium* eggs[19].

SAF-preserved stool samples were transferred to a laboratory at the Université Félix Houphouët-Boigny (Abidjan, Côte d'Ivoire). An ether concentration method was employed and samples examined for helminths and intestinal protozoa by experienced laboratory technicians. The number of species-specific helminth eggs was recorded, whereas intestinal protozoa cysts and trophozoites were recorded semi-quantitatively[20].

For quality control, 10% of the slides were randomly selected and re-examined on the same day by a third technician. In case of conflicting results (negative vs. positive or a difference in the number of egg counts of more than 10%), the slides were re-examined a third time and the results discussed until agreement was reached.

The same diagnostic approaches were used for each of the three assessment time points.

KAPB questionnaire survey

Household's KAPB were assessed, using a combination of direct observations and interviews using a tablet-based structured questionnaire. All the components of the KAPB study were conducted in parallel to the baseline and follow-up parasitological surveys. It was directed at household heads and included questions on demographic factors (e.g. age, sex, ethnicity and educational attainment), socioeconomic indicators (e.g. possession of household assets) and reported or observed WASH indicators (e.g. sources of water for household use, open defecation, use of latrines and waste disposal in close proximity to the house). In addition, interviewees were asked about their knowledge of health risks associated with open defecation, signs and symptoms of parasitic infections, and how such infections can be prevented and treated.

Statistical analysis

Parasitological data were double-entered in Microsoft Excel and cross-checked in EpiInfo version 3.5.4 (Centers for Disease Control and Prevention; Atlanta, USA). Questionnaire data were collected using Open Data Kit (ODK; http://opendatakit.org/), operated on mobile Android devices. Data were uploaded daily on a server based at the Swiss Tropical and Public Health Institute (Swiss TPH; Allschwil, Switzerland). Statistical analyses were performed with R version 4.4.1 and STATA version 14.2 (Stata Corporation; College Station, USA).

We summarised demographic, socioeconomic characteristics and WASH indicators, prevalence of soil-transmitted helminths, schistosomes and pathogenic intestinal protozoa infections at baseline for each of the four arms separately. For continuous variables (e.g. age) and categorical variables (e.g. prevalence of soil-transmitted helminth infections), we reported means (including standard deviation [SD]) and proportions, respectively.

We assessed the effect of the intervention on the occurrence of any soil-transmitted helminth, schistosome and pathogenic intestinal protozoa infections. Our analysis focused on the main effects of the interventions (i.e. CLTS vs non-CLTS and health education vs no health education). To account for the clustered study design, a random effect logistic regression models was used, taking into account the clustering of participants in communities. Effect measures are presented as odds ratios (ORs) and 95% confidence intervals (CIs). The main analysis included only the intervention as fixed effect. The threshold for statistical significance was set at $p < 0.05$. To assess the impact of unsatisfactory intervention adherence, a subgroup analysis was done with communities reaching a minimal latrine coverage of 75% (complier) compared to matching control communities.

Results

Participation in the study

Figure 3 provides an overview of the number of participants who were recruited at baseline, those lost to follow-up and those retained for the final analysis. Study participants were recruited in August and September 2014 in 56 localities in three departments. For the baseline survey, 5,292 participants from 1,267 households were enrolled for the implementation of the study. At the end of this survey, two localities comprising 21 households and 62 participants were not taken into account in the randomisation because no soil-transmitted helminth infection was found. Randomisation took place in 54 localities with 1,246 households including 5,230 participants. Allocations for the interventions were structured as follows: (i) preventive chemotherapy: 14 localities, 300 households, 1,344 participants; (ii) preventive chemotherapy plus CLTS: 13 localities, 312 households, 1,362 participants; (iii) preventive chemotherapy plus health education: 14 localities, 335 households, 1,305 participants; and (iv) all interventions: 13 localities, 299 households, 1,219 participants. Overall, 2084 (39.8%) participants were lost to follow-up at the first and 2740 (52.4%) at the second follow-up survey.

Baseline characteristics

The demographic and socioeconomic characteristics, WASH indicators, prevalence of soil-transmitted helminth, schistosome and pathogenic intestinal protozoa infections at baseline are summarised in Table 1. Across control and all intervention arms, more than 40% of households had between 6 and 10 individuals. The average number of inhabitants was similar in all arms (9-10 people). On average, 4 people were registered per household to participate in the study. In terms of household occupations, over 90% of households were primarily engaged in subsistence agriculture. Least poor households represented less than 25% of the households interviewed, regardless of the intervention arm. Except for the control arm where 18.6% of households were observed to have piped water (tap water), drinking water coverage rates were below 5% in the intervention arms. The proportions of latrines and their usage rates were: (i) control (20.1%, 16.4%); (ii) CLTS (14.9%, 14.2%); (iii) health education (27.2%, 26.2%); and (iv) CLTS plus health education (21.5%, 18.3%). Open defecation was widely reported (>75%) in control and all intervention arms. Less than 20% of the households in the four groups were not defecating in the open during this assessment. Except for *S. mansoni*, participants in the four arms were similar in terms of parasitic infection prevalence. Hookworm was the predominant infection (19.9-22.9%), followed by *G. intestinalis* (12.6-13.4%).

Effect of interventions on health outcomes

Table 2 provides the results for the primary and secondary outcomes. We observed at the first follow-up 17 months post intervention a prevalence in hookworm infections of 4.3% (69/1594) in the non-CLTS arms compared to 3.8% (59/1552) in the CLTS arms (supplementary table 1). This difference lacked statistical significance (OR 0.87, 95% CI 0.45 to 1.68, $p = 0.69$). During the second follow up at 38 months post-intervention, we observed a prevalence of

1.9% (24/1278) in the non-CLTS arms compared to 2.1% (26/1212) in the CLTS arms. This difference was not statistically significant (OR 1.15, 95% CI 0.60 to 2.17, p = 0.68). As regards secondary outcomes, we found no statistically significant differences.

Adherence to CLTS intervention

Figure 4 shows latrine coverage in the study villages at baseline and follow-up survey 1, stratified by study arm. Of the 26 localities in arms 2 and 4, where CLTS had been implemented, 11 had achieved a latrine coverage rate of over 80%. Of these, there were 2 and 4 localities in arms 2 and 4, respectively that achieved 100% coverage. Six and 2 localities in arms 2 and 4, respectively, had coverage rates between 20% and 60%. Low coverage (<20%) was observed in 4 localities, namely one locality in arm 2 and 3 localities in arm 4. No change was recorded in one locality (i.e. Gbamelèkro) of arm 2, as well as in 2 localities (i.e. Ahondo and N'Kloidjo) of arm 4, in terms of latrine coverage (identical latrine rates during both surveys).

Effect of interventions on primary and secondary outcomes in adhering communities

To better elucidate the effect of interventions, we carried out a subgroup analysis using the 11 communities with the best adherence to the CLTS intervention. Those communities had a latrine coverage at follow-up of at least 75%. We matched those to 11 communities in the non-CLTS arms based on baseline latrine coverage and community size. In this analysis, we found no statistically significant difference in the primary outcome (Table 3). Surprisingly, at follow-up survey 2, we observed a higher prevalence of giardiasis in the CLTS intervention group compared to the control group (14.0% vs 2.5%; OR=6.47, 95% CI: 2.49-16.81; p<0.01) (Table 3).

Discussion

Preventive chemotherapy, periodically administering anthelminthic drugs to at-risk populations, is the mainstay of morbidity control and might also reduce environmental contamination. However, there is broad understanding that this strategy alone fails to interrupt transmission. An integrated approach with preventive chemotherapy plus WASH interventions and health education has long been advocated as a means of enhancing the control and elimination of helminthiasis and intestinal protozoa infection[21]. This study was undertaken to assess whether an integrated approach indeed can reduce reinfection patterns of helminths and intestinal protozoa. Our cluster randomised trial conducted in 54 communities in Côte d'Ivoire with a follow-up period of up to 38 months showed no significant impact on reinfection patterns.

Through a local participatory approach, CLTS aims at increasing latrine coverage and use and put an end to open defecation and maintain this status within communities[8, 22, 23]. Along with health education that might reinforce CLTS, the two interventions might induce behaviour change. Initially developed as an approach to reduce the incidence of diarrhoea, these interventions also hold promise to prevent infections due to helminths and intestinal protozoa that share transmission routes as infective stages are excreted in human stool (or urine for *S. haematobium*)[7, 24]·[25]. This study found no evidence that the CLTS intervention (alone or in combination with health education) significantly reduced the incidence of parasitic infections investigated in rural communities compared to standard preventive chemotherapy. Two prior RCTs evaluating a total sanitation programme in India, similarly reported no measurable effect on soil-transmitted helminth post-intervention infection status in the CLTS groups[22, 26], while a slight reduction of *G. intestinalis* infections was noted in the follow-up in rural Madhya Pradesh[22]. In Indonesia, only weak evidence for *A. lumbricoides* intensity reduction was found in children from CLTS receiving communities compared to control communities[27].

Different explanations might explain these observations. The time frame is one. Authors stipulate that to better measure the effect of such interventions on health benefits, long-term research projects should be implemented (i.e. years rather than months)[28, 29]. They support their argument by the fact that faecal-oral pathogens cannot disappear in the environment in a short time. In our study, the time frame may have been too short taking into account the observed low transmission pressure of the primary outcome (i.e. soil-transmitted helminth infection) with low prevalence rates observed at both follow-ups in all intervention arms. Related to the potentially too short assessment intervals are the slow uptake of the intervention and low latrine coverage rates. While certain studies implied minimal coverage rates before starting to include measurements to the analysis,[26] we chose to re-trigger communities with low latrine construction rates and included a second later assessment time point. Yet, we still had quite few communities receiving CLTS remaining under the expected latrine construction goals. A recent study carried out in Ghana (evaluation 10 years after implementation of CLTS) showed that long time frames are necessary to enhance sustainability. This led to a reduction in the number of people not defecating in the open; hence, improvement of sanitation and hygiene, as well as strengthening the application of community rules and regulations regarding WASH[30].

Another factor is the limited potential of CLTS to "clean" the environment from faecal pathogens. Instead of reducing the risk of infection, unimproved latrine types and construction materials as well as inappropriate use may create new infection sources[31]. In the CLTS approach subsidies for materials to construct latrines are not foreseen and each community came up with its own model of a basic latrine that was affordable and feasible for it to be built.

Lastly also the human behaviour factor remains difficult to be controlled for the perceptibility of actions. Behaviour change needs time and besides inappropriate or inconsistent use of latrines, community members may further continue other risky behaviours that foster faecal-oral transmission of pathogens (e.g. contaminated hands from anal cleansing, no handwashing and food contamination during production, preparation or consumption).

Strengths and limitations

The design, methods and approach of the study were robust. RCTs offer the greatest potential for causal inference. In order to ensure homogeneous stratification, villages were randomly allocated to different groups (control, intervention) after the baseline survey. This led to similar baseline characteristics and outcome variables (i.e. parasitic infections) across the four arms. Intensified monitoring and evaluation coupled with remobilisation were undertaken to enhance compliance to the CLTS intervention. Our study provides evidence from two follow-up assessments, the later exceeding the time frame of most

comparable trials assessing the effect of CLTS intervention on parasitic infections[22, 26, 27]. Although embedded in an RCT, the data generated are close to real-life data, as both the preventive chemotherapy was conducted by the usual actors under their conditions and the CLTS intervention was led by national teams as implemented elsewhere in the country.

The limitations of this study come with the complexity of the conduct of a series of different interventions that are executed by a variety of actors and need alignment. Not all interventions always happened in anticipated timeframes and although mitigation strategies and intensified monitoring were put in place, not all receiving communities took up the interventions as planned. Particularly large communities experienced difficulty in adhering to the implementation of the CLTS intervention, and consequently in achieving “open defecation free (ODF)” status. A monitoring system over time could not be put in place after the certification of villages for “ODF” status (post-intervention). In view of this unique and stagnant evaluation of the contamination status with faecal matter and associated pathogens, as well as the lack of environmental analyses, it is not possible to make a definitive appraisal of the true situation. No direct observations of human behaviour were part of this study. Hence, we cannot rule out that community members continued to engage in risky behaviours (e.g. open defecation, not washing hands, unclean food preparation or storage). Another limiting aspect concerns the main study outcome that is infection with any soil-transmitted helminth. Infection rates at the start of the study were relatively low and transmission dynamics appear to be slower than expected in the study area, as reflected by the low reinfection rates in all study arms (including the control arm). These low figures contradicted the hypothesis that communities had returned to their initial prevalence rates at that point in time (i.e. hookworm prevalence > 20%). Our trial was not powered to detect small but from a public health point of view important effects as significant differences. Reassessments in low-to-moderate transmission sites may require longer intervals in-between full intervention uptake and outcome assessment. Additionally, loss to follow-up (40–50%) was higher than anticipated and might have impacted the evaluation of the interventions.

To be able to measure an impact on parasitic diseases from integrated interventions, including WASH compared to standard preventive chemotherapy in settings with lower transmission burden, a study with a much longer time frame may be considered. A more rigid evaluation approach to explore environmental contamination status of the communities (also including built latrines and consumed water and food) is recommended to accompany similar future trials.

Conclusions

Although there were reductions in the prevalence of soil-transmitted helminth infection, in particular hookworm, no statistically significant synergistic effect of the integrative intervention packages compared to standard preventive chemotherapy could be observed during both follow-up surveys. We advocate comprehensive studies that can quantitatively and qualitatively assess the impact of CLTS interventions at the community level over a longer period. As efforts are made to improve coverage of CLTS interventions within rural communities, we emphasise that implementation must be rigorously designed and implemented to achieve the goals of reducing exposure to pathogens and improvement of people’s health and wellbeing.

Abbreviations

CHW Community Health Worker

CI Confidence Interval

CLTS Community-Led total Sanitation

FGD Focus Group Discussion

HDSS Health Demographic Surveillance System

ISRCTN International Standard Randomised Controlled Trial Number

KAPB Knowledge, Attitudes, Practice and Behaviour

ODF Open Defecation Free

ODK Open Data Kit

OR Odds Ratio

RCT Randomised Controlled Trial

SAF Sodium acetate-Acetic acid-Formalin

SD Standard Deviation

STH Soil-Transmitted Helminth

UNICEF United Nations Children's Fund

WASH Water Sanitation and Hygiene

WHO World Health Organisation

Declarations

Ethics Approval and Consent to Participate

Approval of the study protocol was granted by the institutional research commission of the Centre Suisse de Recherches Scientifiques en Côte d'Ivoire (CSRS; Abidjan, Côte d'Ivoire). Ethical clearance for the study was obtained from the Ethics Committee of Basel (EKBB; reference no. 300/13, date of approval: 11 November 2013) and from the ethics committee of the Ministry of Health and Public Hygiene in Côte d'Ivoire (reference no. 76-MSLS-CNER-dkn, date of approval: 28 November 2013). The trial is registered (ISRCTN53102033, date of approval: 26 March 2014 https://www.isrctn.com/ISRCTN53102033).

The purpose and procedures of the study were explained to local authorities (village chiefs) and community members. Written informed consent was obtained from all participants (parents/legal guardians signed for children below the age of 18 years). For illiterate participants, impartial witnessers provided signature. Participation was voluntary and withdrawal from the study was possible anytime without further obligations. Moreover, it was mentioned that preventive chemotherapy was provided to all people in the study area, not just those who decide to participate, free of charge through the National Programme for the Control of Neglected Tropical Diseases.

Consent for publication

Not applicable.

Availability of data and materials

Data collected for the study, anonymised participant data, and a data dictionary defining each field in the set, will be made available to others on reasonable request. De-identified participant data of the requested dataset plus a data dictionary will be made available on reasonable request immediately following publication for at least 1 year. Access will be granted to researchers who provide a methodologically sound proposal. Principal investigators, and collaborators will approve the proposals on the basis of scientific merit. Requests should be directed to the corresponding author. Researchers requesting data will need to sign a data access agreement before they are granted access. Study protocol is available on study registry page (ISRCTN53102033).

Competing interests

We declare no competing interests.

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Authors' Contributions

Gaoussou Coulibaly (data collection, data management, data analysis and interpretation and writing of first draft); Eveline Hürlimann (data management, data collection, coordination, supervision, critical input to manuscript development); Mamadou Ouattara (coordination, data collection, supervision, quality assurance); Kouassi Dongo (coordination, supervision); Jan Hattendorf (randomisation, data analysis and interpretation, critical input to manuscript development); Fabien Zouzou (intervention conduct and monitoring, coordination, supervision); Fidèle K. Bassa, Richard B. Yapi and Naférima Koné (data collection); Véronique A. Koffi (data collection and data management, conduct of intervention); Clémence Esse (conceptualization and conduct of intervention, data collection, coordination, supervision); Jürg Utzinger (project conceptualization, coordination, supervision, critical review to manuscript); Giovanna Raso (project conceptualization, coordination, supervision, fund raising, reporting, project management); Eliézer K. N'Goran (project conceptualization, supervision, coordination). All authors read and approved the final version of the manuscript.

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Tables

Table1. Baseline characteristics of included households in terms of population, occupation, Water, Sanitation and Hygiene (WASH) indicators and parasitic i

	Control		Interventions			
Characteristics			**CLTS**		**CHEP**	
	N	**Mean (SD) or Percent**	**N**	**Mean (SD) or Percent**	**N**	**M**
Household characteristics						
Number of enrolled households	**300**		**312**		**335**	
Number of enrolled children per household						
Age <5 years		0.5 (0.6)		0.3 (0.5)		0.3
Age 5-15 years		3.1 (1.9)		3.2 (2.1)		2.8
Number of enrolled adolescents and adults per households		0.8 (0.4)		0.8 (0.4)		0.8
Number of participants per households		4.5 (2.0)		4.4 (2.3)		3.9
Demography						
N. household questionnaire	**274**		**288**		**294**	
≤5 people	44	16.1%	62	21.5%	61	20
6-10 people	126	46.0%	125	43.4%	145	49
>10 people	104	38.0%	101	35.1%	88	29
Number of people per household		9.9 (5.0)		10.0 (6.0)		9.4
Activities						
Agriculture	247	90.1%	266	92.4%	266	90
Fishing	6	2.2%	10	3.5%	15	5.1
Other occupations*	21	7.7%	12	4.1%	13	4.4
Wealth quartiles						
Most poor	63	23.0%	87	30.2%	86	29
Very poor	68	24.8%	75	26.1%	65	22
Poor	79	28.8%	56	19.4%	75	25
Least poor	64	23.4%	70	24.3%	68	23
Water, Sanitation and Hygiene (WASH) indicators						
Households with tap water	51	18.6%	1	0.3%	0	0.0
Other sources of water for households**	223	81.4%	287	99.7%	294	10
Households with latrines	55	20.1%	43	14.9%	80	27
Use of latrines by households						
Never	216	78.8%	243	84.4%	207	70
Rarely	7	2.6%	1	0.3%	5	1.7
Often	6	2.2%	3	1.0%	5	1.7
Always	45	16.4%	41	14.2%	77	26
Practice of open defecation by households	227	82.8%	220	76.7%	233	79
Defecation in plantation/field						
Never	36	13.1%	32	11.1%	48	16
Rarely	29	10.6%	40	13.9%	41	13
Often	114	41.6%	146	50.7%	149	50
Always	95	34.7%	55	19.1%	56	19
Individual characteristics						

Demography N	**1344**		**1362**		**1305**	
Sex (Number of individuals /Number of participants)						
Male	686	51.0%	676	49.6%	645	49
Female	658	49.0%	686	50.4%	660	50
Age (Number of individuals/Number of participants)						
< 5 years	150	11.2%	104	7.6%	93	7.1
5-15 years	940	69.9%	1002	73.6%	948	72
>15 years	254	18.9%	256	18.8%	264	20
Parasitic infections						
Number individuals with KK result	**1289**		**1290**		**1212**	
Hookworm	281	21.8%	273	21.2%	277	22
Trichuris trichiura	28	2.2%	18	1.4%	24	2.0
Ascaris lumbricoides	6	0.5%	2	0.2%	3	0.2
Schistosoma mansoni	4	0.3%	22	1.7%	87	7.2
Number individuals with UF result	**1336**		**1348**		**1294**	
Schistosoma haematobium	52	3.9%	54	4.0%	43	3.3
Number individuals with ECM result	**1228**		**1227**		**1149**	
Giardia lamblia	157	12.8%	164	13.4%	145	12
Entamoeba histolytica/dispar	75	6.1%	65	5.3%	75	6.5

Abbreviations: PC, Preventive chemotherapy; CLTS, Community-led total sanitation; CHEP, Community health education program; SD, Standard deviation, KK, Kato-katz; UF, Urine filtration, ECM, Ether-concentration method

* Other occupations include: housewife, trader, teacher, animal breeder

** Other sources of water include : Drilling/pump, well, river/backwater/pond

Table 2. Effect of the intervention on primary and secondary outcomes

	Control	CLTS	CHEP	CLTS+CHEP	CLTS Yes vs No OR (95% CI)	P-value
n FU1 (by diagnostic approach)	879*|922"|868^	882*|916"|873^	715*|783|707^	670*|696"|662^		
n FU2 (by diagnostic approach)	689*|757"|689^	659*|721"|653^	589*|662"|587^	553*|606"|552^		
Primary outcome (STH infection status)*						
Hookworm FU1	39 (4.4)	29 (3.3)	30 (4.2)	30 (4.5)	0.87 (0.45-1.62)	0.69
Hookworm FU2	15 (2.2)	10 (1.5)	9 (1.5)	16 (2.9)	1.14 (0.60-2.17)	0.68
Trichuris trichiura FU1	7 (0.8)	6 (0.7)	9 (1.3)	5 (0.7)	ND	
Trichuris trichiura FU2	3 (0.4)	0 (0.0)	0 (0.0)	3 (0.5)	ND	
Ascaris lumbricoides FU1	1 (0.1))	0 (0.0)	1 (0.1)	3 (0.4)	ND	
Ascaris lumbricoides FU2	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	ND	
Secondary outcome (*Schistosoma spp*. & intestinal protozoa infection status)						
***Schistosoma spp*.**						
Schistosoma mansoni FU1*	2 (0.2)	5 (0.6)	23 (3.2)	23 (3.4)	1.15 (0.20-6.79)	0.87
Schistosoma mansoni FU2*	0 (0.0)	6 (0.9)	32 (5.4)	15 (2.7)	0.69 (0.08-5.80)	0.73
Schistosoma haematobium FU1"	13 (1.5)	16 (1.8)	14 (2,0)	26 (3.9)	1.66 (0.48-5.77)	0.42
Schistosoma haematobium FU2"	32 (4.2)	16 (2.2)	19 (2.9)	7 (1.2)	0.47 (0.10-2.28)	0.35
Intestinal protozoa^						
Giardia lamblia FU1	41 (4.7)	51 (5.8)	22 (3.1)	30 (4.5)	1.34 (0.84-2.14)	0.22
Giardia lamblia FU2	67 (9.2)	79 (12.1)	54 (9.2)	64 (11.6)	1.29 (0.96-1.73)	0.10
Entamoeba histolytica FU1	23 (2.6)	22 (2.5)	18 (2.5)	16 (2.4)	0.95 (0.51-1.76)	0.87
Entamoeba histolytica FU2	49 (7.1)	34 (5.2)	40 (6.8)	41 (7.4)	0.89 (0.67-1.17)	0.39

PC, Preventive chemotherapy; CLTS, Community-led total sanitation; CHEP, Community health education program; FU, Follow-up; STH, Soil-transmitted helminth; ND, Not determined

Diagnostic approaches: * Kato-katz; "Urine filtration; ^Ether-concentration method

Table 3. Effect of the intervention on primary and secondary outcomes using complier matching for 11 localities in each CLTS (latrine coverage>75%) and no-CLTS

			CLTS Yes vs No	OR (95% CI)	
	no-CLTS	**CLTS**			**P-value**
n FU1 (by diagnostic approach)	305*|332"|304^	361*|372"|356^			
n FU2 (by diagnostic approach)	239*|273"|238^	293*|318"|293^			
Primary outcome (STH infection status)*					
Hookworm FU1	11 (3.6)	26 (7.2)	2.07 (0.72-5.96)		0.18
Hookworm FU2	4 (1.7)	13 (4.4)	2.72 (0.76-9.76)		0.12
Trichuris trichiura FU1	5 (1.6)	5 (1.4)	ND		
Trichuris trichiura FU2	0 (0.0)	2 (0.7)	ND		
Ascaris lumbricoides FU1	2 (0.7)	0 (0.0)	ND		
Ascaris lumbricoides FU2	0 (0.0)	0 (0.0)	ND		
Secondary outcome (*Schistosoma spp*. & intestinal protozoa infection status)					
Schistosoma spp.					
Schistosoma mansoni FU1*	1 (0.3)	1 (0.3)	ND		
Schistosoma mansoni FU2*	0 (0.0)	1 (0.3)	ND		
Schistosoma haematobium FU1"	9 (2.7)	2 (0.5)	ND		
Schistosoma haematobium FU2"	11 (4.0)	2 (0.6)	ND		
Intestinal protozoa^					
Giardia lamblia FU1	14 (4.6)	16 (4.5)	0.97 (0.42-2.26)		0.95
Giardia lamblia FU2	6 (2.5)	41 (14.0)	6.47 (2.49-16.81)		**<0.01**
Entamoeba histolytica FU1	9 (3.0)	11 (3.1)	2.07 (0.72-5.96)		0.18
Entamoeba histolytica FU2	11 (4.6)	23 (7.8)	2.73 (0.76-9.76)		0.12

CLTS, Community-led total sanitation; FU, Follow-up; STH, Soil-transmitted helminth; ND, Not determined

Diagnostic approaches: * Kato-katz; "Urine filtration; ^Ether-concentration method

Figures

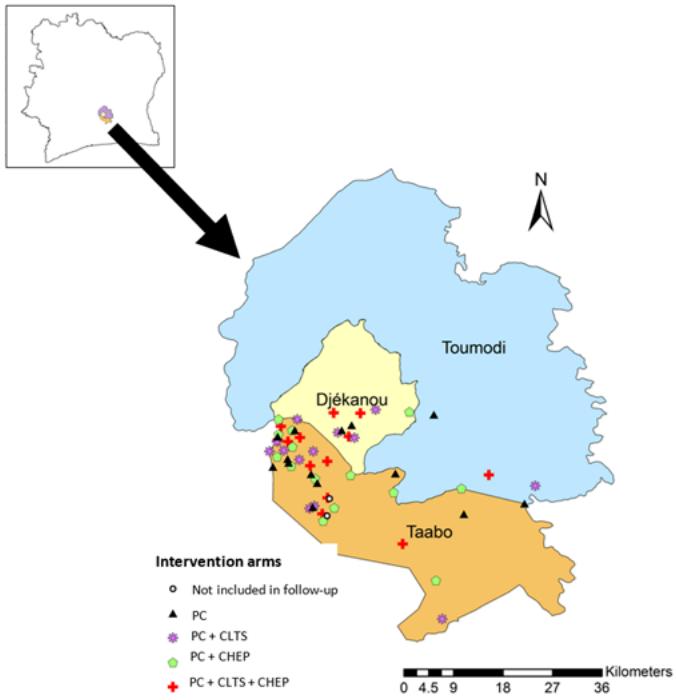


Figure 1

Map displaying randomization in three departments for trial implementation, south-central, Côte d'Ivoire

PC, Preventive chemotherapy; CLTS, Community-led total sanitation; CHEP, Community health education program

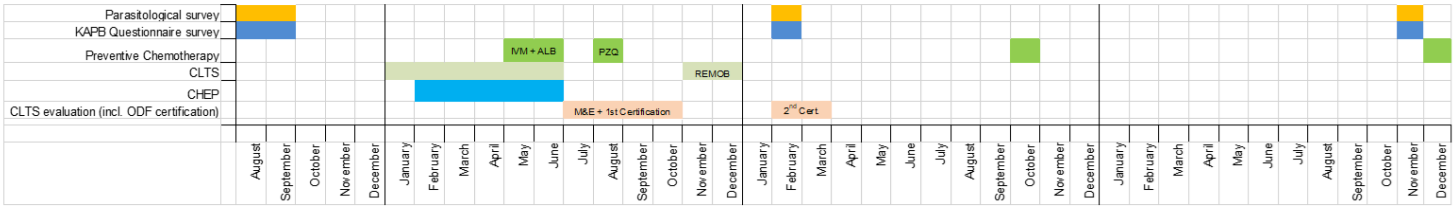


Figure 2

Overview of the trial activities, from August 2014 to November 2017, south-central, Côte d'Ivoire

KAPB, Knowledge–attitudes-practices and beliefs; CLTS, Community-led total sanitation; CHEP, Community health education program; IVM, Ivermectin; ALB, Albendazole; PZQ, Praziquantel; M&E, Monitoring and evaluation; ODF, Open Defecation Free; 1st Certification; First certification; REMOB, Remobilisation; 2nd Cert., Second certification

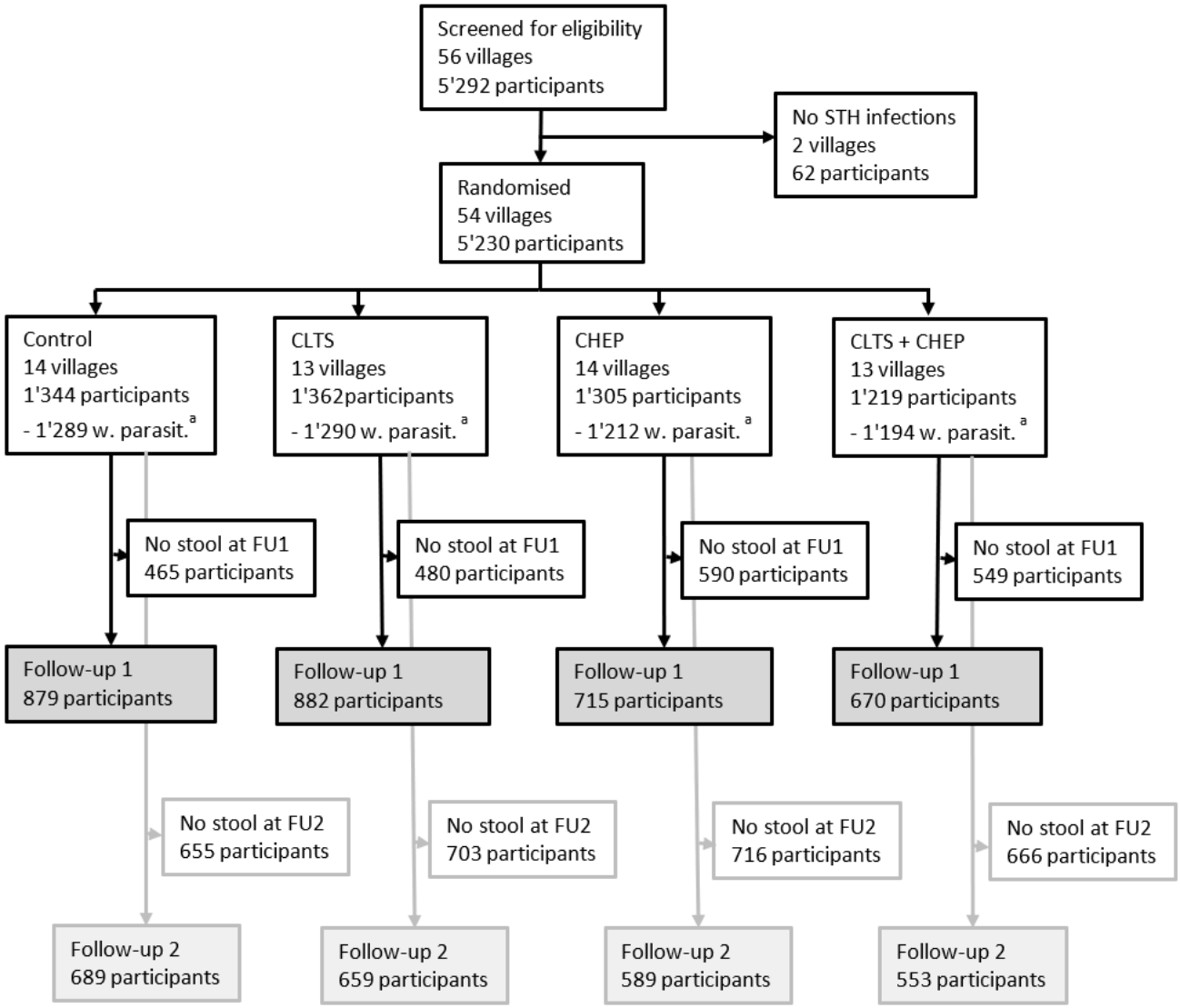


Figure 3

Trial profile: enrollment, intervention allocation, and participation in baseline and follow-up surveys

[a] number of enrolled participants with parasitological assessment at baseline

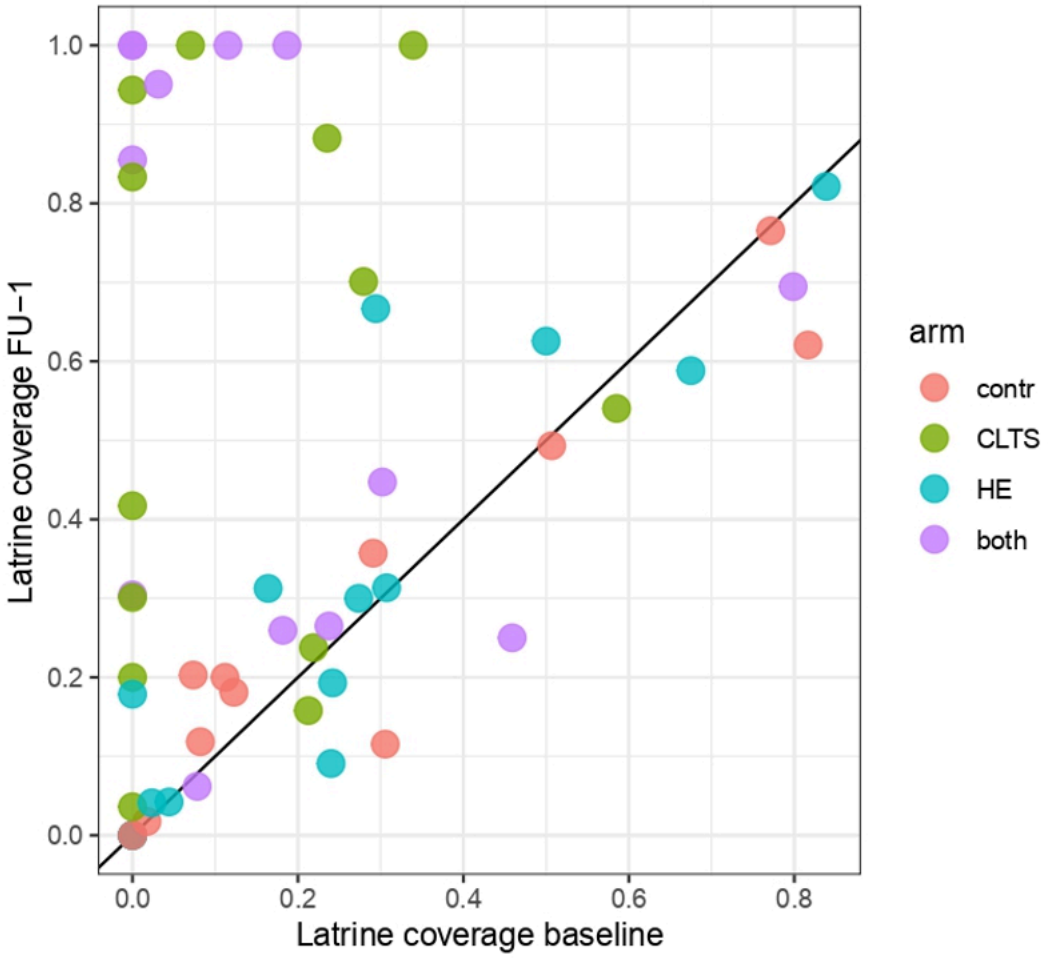


Figure 4

Latrine coverage in 54 study communities at follow-up 1, February 2016, south central Côte d'Ivoire, Symbol size is proportional to village population.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Additionalfile1CONSORT2025checklist.docx
- Additionalfile2StudyProtocolRasoetalJRP2018.pdf
- Additionalfile3studyrecordISRCTN5310203320210304.pdf
- Supplementarytable1.docx