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## An empirical analysis based on a cluster randomized control trial

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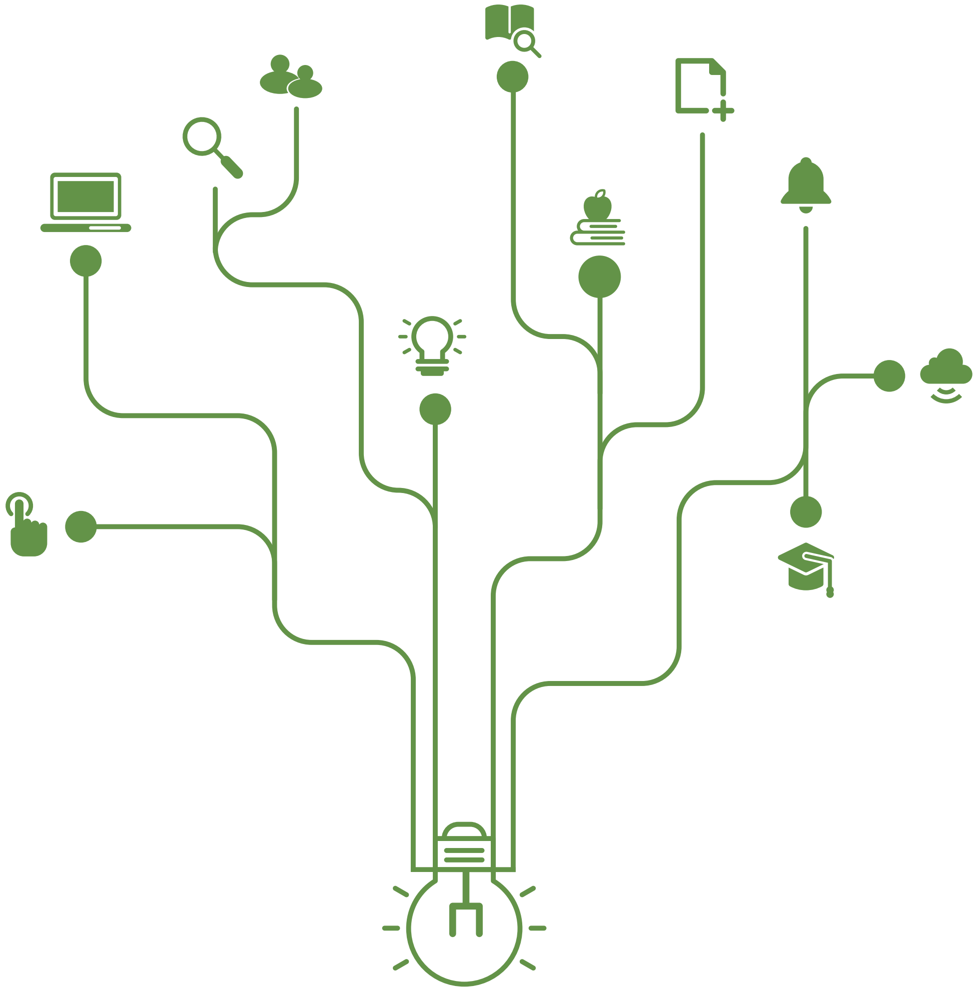

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# Cost-effectiveness of community-led total sanitation (CLTS) intervention in rural areas of Ethiopia: An empirical analysis based on a cluster randomized control trial

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# Abstract

**Background** Diarrhoeal disease is the second leading cause of death in children under five years old. It accounted for 81 million disability-adjusted life-years (DALYs) for all-ages in 2017. A significant proportion of diarrhoeal disease can be prevented through safe drinking water and adequate sanitation and hygiene. Ensuring access to sanitation for all by 2030 is set by the Sustainable Development Goals (SDGs); however, in 2017 above 1.7 billion people (22%) lacked basic sanitation facilities, and still, more than 494 million people were defecating in the open. Understanding the cost-effectiveness of CLTS intervention is crucial for policy direction towards alleviating mortality and morbidity of diarrhoeal diseases.

**Methods** We conducted a cost-effectiveness analysis of CLTS intervention in comparison to the ordinary sanitation approach (no intervention state) in two districts of Ethiopia. We used a model to determine cost-effectiveness in terms of incremental costs of CLTS over its incremental effects (ICER). To do so we followed societal perspective with a bottom-up approach to estimate costs, and DALY is used to estimate the health effect (the losses in healthy life years because of diarrheal disease).

**Findings** We found that CLTS intervention is cost-effective with an ICER value of Int'l $616.25 (95% CI: Int'l $3663.36, Int'l $388.91) per DALY averted. Our Monte Carlo simulation analysis of 10,000 draws also showed that ICER was not above the threshold under any plausible circumstances.

**Interpretation** Our study showed that the ICER value for CLTS is less than the national per capita GDP of Ethiopia which makes CLTS a very cost-effective intervention according to WHO standard/guideline. This implies that diarrhea prevention or WASH-related interventions should include a CLTS section for effective management of diarrhea-related diseases.

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# 1. INTRODUCTION

Diarrhea accounted for 81 million disability-adjusted life-years (DALYs) for all-ages in 2017 [1]. It is the fourth-leading cause of under-5 DALYs [2]. Unsafe sanitation caused 774,000 deaths out of 1.6 million diarrhea-specific deaths in 2017[3, 4]. Ensuring access to sanitation for all by 2030 is set by the Sustainable Development Goals (SDGs); however, according to the JMP 2021 progress report above 1.7 billion people (22%) lacked basic sanitation facilities and still, more than 494 million people were defecating in the open [5]. The progress of improvement in sanitation has been slowest in Sub-Saharan Africa [72]. While 90% of the population in North Africa has access to improved sanitation facilities, only 30% of the population in sub-Saharan African countries have access to these facilities [73]. And about 69% of Africa's population, particularly those in urban slums and rural areas have no access to even basic sanitation [73].

Diarrhea is among the major causes of child mortality in Ethiopia. The EDHS 2019 mini-report displayed that 28.5% of the population were reported defecating in the open and only 10.8% of the population have access to at least basic sanitation facilities [74]. Community-led total sanitation interventions, which encourage and motivate collective behavior changes, were considered a fundamental shift of sanitation interventions toward a community-level approach from an individual or household level approach [7]. Globally more than 60 countries have been implementing CLTS and over 20 of them (including Ethiopia) adopted it as their national policy [8]. To accelerate sanitation coverage, the Government of Ethiopia (GoE) developed the National Strategy Improved Hygiene and Sanitation recognizing sanitation and hygiene promotion as an essential component in disease prevention, environmental protection, and socio-economic advancement [71].

Most of the existing economic analyses of sanitation improvements are based on a hypothetical assumption and do not share the details of modeling, equations, or calculation methods for outcomes or parameters such as DALY [ref]. A recent study on CLTS intervention compared cost-effectiveness between four different types of interventions; however, it did not incorporate the health outcomes measured in terms of the DALYs averted [53]. These previous studies point to the pressing need for contextualized evidence based on real-world sanitation improvements [13-18]. In this study, we aim to analyze the cost-effectiveness of a CLTS intervention in rural areas of Ethiopia. We estimated the incremental cost per quality-adjusted life-year (QALY) relying primarily on empirical data from a clustered randomized control trial.

## 2. METHODS

### 2.1 Study Design

A cluster-randomized trial was carried out in the Gurage zone in the two districts (Cheha, and Enemor Ena Ener) having 48 intervention gotts (villages). The trial area is located in the Southern Nations, Nationalities, and Peoples' Region state (SNNPR) in Ethiopia, and was conducted period between 10 January 2015 to 20 February 2017. We take a village as our randomization unit and the improvement intervention for latrine was carried out at the village level. Both the intervention and the control arm received the latrine improvement intervention in the first and second phases respectively. During the first phase of the intervention, latrine improvement was implemented in the intervention arm (24 villages), and the 24 villages in the control arm received the intervention in the second phase. In the first phase, the control arm received no other intervention except the routine health extension workers (HEWs) activities. Health extension workers are government-trained women whose major role is to improve the knowledge and skills of households and communities to handle preventable diseases and get access to clinics and hospitals' primary health services in the community [23,75].

To determine the cost-effectiveness of CLTS intervention we compute the ratio of its incremental cost per its effect. A societal perspective is used/adapted from the RCT trials in estimating the intervention cost [24]. Analyses are conducted based on 2017 international dollars (Int'l $). For calculating YLD and YLL in the base-case analysis we used the estimates: 0.105, 66.6 years, and 2.6 days (0.0071years) as the values for disability weight, life expectancy, and disability duration, respectively.

To reach the final ICER value we followed the following steps, as it is displayed in Table 5 of the result section. First, we add the result of YLD (a) and YLL(b), 2) to get the total DALY (tdP) from premature death averted (c) we multiplied the sum of YLD (a) and YLL (b) (i.e.: a+b) by the number of premature death averted (c). 3) Similarly, to get the total DALY averted (tdD) from diarrhea cases avoided (d), we multiplied YLD (a) by the number of diarrhea cases avoided (d). 4) Fourth the total DALY (TD) averted for each age group and gender is obtained by summing the DALYs averted premature death and the DALYs averted diarrhea cases avoided. 5) Fifth, the total DALYs averted (717.79) as a result of the CLTS intervention is found by adding the total DALYs obtained under each age group and gender. 6) finally, to get the ICER value we divide the total cost (444,899) by total DALY averted.

The study was approved by National Research Ethics Review Committee under the Ministry of Science and Technology, Federal Democratic Republic of Ethiopia (NRERC 3.10/032/2015; July

29, 2015) and the London School of Hygiene & Tropical Medicine (LSHTM Ethics Ref: 16260; February 22, 2019). The trial was registered as an International Standard Randomized Controlled Trial (ISRCTN82492848). For latrine improvement, the procedures of CLTS containing pre-triggering, triggering, and follow-up were performed in the intervention villages from November 2015 to October 2016.

## 2.2. Study setting

Cheha and Enemore Ena Ener districts are the study areas of the project which are situated 185 km southwest of the capital city. The 2007 national population and housing census/statistics of the districts showed that the total population of Cheha and Enemore Ena Ener districts was 115,951 and 167,770, respectively [76]. These districts are mostly rural, having a farming land size of 90% of the total mass. Crop production and livestock farming are the main income sources in the areas. The major cash crops of the area include coffee, chat, and oilseeds. Above 80 % of the population in the area belong to the Guraghe ethnic group. Muslim and Ethiopian Orthodox Christians constitute the majority of the population with a share of 64 % and 33 % respectively.

## 2.3. Study Population

A total of forty-eight (48) villages were purposely selected out of the 212 screened villages from the two districts based on water and sanitation coverage. All households in the selected villages who have one or more under-5 children were listed and 25 HHs were selected randomly from each village using SPSS (version 21). The criteria for inclusion are: (1) A household having an under-5 child, and (2) A household who signed informed consent and is willing to participate in the study. Prior selection of participants was made before allocating villages to the intervention or control groups to address the issue of allocation concealment. And the criteria for exclusion of subjects was if a household (a caregiver) did not have any child under-5 or/and a caregiver who did not want to be registered in the trial or refused to sign on the informed consent.

## 2.4. Intervention Procedure

At the initial step of CLTS, a triggering process is conducted in each of these villages by a team of trained CLTS facilitators. The facilitators were a group of health centers' health professionals, district health officials, and HEWs working in health posts. CLTS triggering had been carried out by these facilitators in the 24 villages between February and March 2016.

During the triggering process, different participatory methods were used by the facilitators to enable the village members to understand the effects that practices of open defecation have on health in their villages. The methods include transect walk, mapping sanitation, and feces deposition calculation. In the process, village members were enabled to understand their defecation practices by arousing human emotions (shame and disgust). From every village, CLTS promoters (one or two depending on the village size) were recruited. After triggering, these promotors together with CLTS facilitators conducted household visits and community conversations to follow-up activities and motivate villagers to construct improved latrines. Triggering in CLTS normally took half a day for each village. For the construction of their own latrines, individual households were not provided with any financial or material subsidies according to the core CLTS principle. As a result, in the process of constructing latrines, household members took the responsibility of the following main activities: (1) digging a pit-hole; (2) slab and pit-hole cover construction; (3) walls, door, and roof construction; and (4) installation of hand-washing facilities. The labor cost for latrine construction incurred by the community member was approximately US$5.95 per household (125 Birr as of October 23, 2015).

If the purchase of local materials (stone, thatch, wood, and the likes) and latrine construction were to be carried out by two adults working together, it is estimated that ten full days of labor were needed for an improved latrine construction per household.

## 2.5. Sampling Method

The incidence density expected value, $E\ (s2)$, is given by

$$E(s2) = \lambda Av(1/yj) + \sigma 2c = \lambda Av\ (1/\ yj) + k2\lambda 2,$$

where $\lambda$ represents the true mean rate, $yj$ corresponds to jth cluster child-weeks of follow-up, $Av\ ()$ implies the overall clusters mean, $\sigma 2c$ between-cluster variance of the true rates, and $k$ is the rates coefficient of variation. The preliminary survey showed that the overall diarrheal rate in the 48 gotts was 0.18 (or 18 cases per 100 child-weeks). The observed diarrhea rates empirical standard deviation was 0.092189, and the reciprocal child-weeks average per neighborhood was 0.001667. Hence, k was estimated as:

$\sigma 2 = 0.0921892 - 0.18 \times 0.001667 = 0.008199$, and therefore, $k = \surd\ (0.008199/0.18) = 0.213422$.

We assumed that in the control gotts the diarrhea rate remained constant at $\lambda 0 = 0.18$, and we required 90 % power ($z\beta = 1.28$) if 21% of the diarrhea rate is reduced by the intervention. Assuming 24 weeks of follow-up for 25 children (600 child-weeks of observation in each gott), for each treatment group the number of neighborhoods required is given by $c = 1 + (1.96 + 0.28)2[(0.18 + 0.1422)/600 + 0.\ 2134222(0.\ 182 + 0.\ 14222)]/\ (0.18 - 0.1422)2 = 22.55$.

## 2.6. Cost Measurement

We used an incremental cost analysis to compare the cost of CLTS intervention with that of the routine sanitation promotions. The routine sanitation promotions refer to the ones which took place in the control area by HEWs. We used the estimated cost of CLTS intervention from the previous empirical study [18]. We followed societal perspective in measuring the cost of all resources in CLTS intervention (including implementation, maintenance, and other resultant costs). For the capital and recurrent costs, we adapted the reference case definitions [25]. Both household survey results and the project's financial records were used as a source of data [26]. We categorized costs into four: initial investment, local investments, program costs, and recurrent costs. Program costs include the management costs, CLTS promoters' and facilitators' training costs, community education costs, and CLTS promoters' incentives. The local investment includes the time spent by community members and local actors on latrine construction and CLTS activities. It also includes the materials purchased for latrine construction by the households. Estimation of the costs of local investments is made using a bottom-up approach while estimation of the costs of the program is made using a top-down approach.

Maintenance, operations, and hygiene education costs are included in the recurrent cost which in the base case is estimated to be 10% of annualized capital costs. Independent accountant audited the project's financial records. Since in this setting 10 years is the average estimated useful life of an improved latrine, for estimating costs and effects the same number of years is considered as the time horizon. A pit latrine is estimated to have a lifespan of ten years assuming that it has a pit depth of two (2) meters and it serves a HH of six members according to UNICEF [27]. Eight (8) years is estimated to be the lifespan of a basic latrine and twenty (20) years for a safely managed latrine according to Hutton [28].

## 2.7. Effect measurement

### 2.7.1. Health Effect

We investigated the effect of CLTS on child diarrhea reduction. We measured the longitudinal prevalence in terms of the number of days with diarrhea. We followed children for one hundred forty (140) days in both the intervention and control groups to record the daily diarrheal cases. Three (3) months after the CLTS triggering, June 3 was the first day for starting daily diarrhea records.

### 2.7.2. Economic Effect

We translated the health effects generated from the intervention through diarrhea reduction into economic effects. We followed the guidelines of the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) [32].

#### Disability-adjusted life year (DALY)

The DALY metric is used to measure the losses in healthy life years. We calculate DALYs simply as the sum of YLDs and YLLs:

$$\text{DALYs} = \text{YLDs} + \text{YLLs}$$

To calculate DALY, we used the values of some parameters from previous studies [35,36]. The two studies estimated that the average age of death for under-five children is 2(two). We followed a similar assumption to estimate the average age of death for other age groups. We estimated premature deaths averted and diarrheal cases avoided based on the trial [35]. We took the average disability weight (D=0.105) for diarrheal diseases episodes from WHO 2004 report [37] [24,38].

#### Years lived with disability (YLDs)

The years lived with disability are the number of years that a subject lives with some disease [41]. YLD is calculated as follows:

$$\text{YLDs}\,[r, k, \beta] = D\left\{\frac{KCe^{ra}}{(r+\beta)^2}\left\{e^{-(r+\beta)\,(L+a)}[-(r+\beta)\,(L+a) - 1] - e^{-(r+\beta)\,a}\,[-(r+\beta)\,a - 1]\right] + \frac{1-K}{r}\,(1 - e^{-rL})\right\}\right\}$$

Where: r = discount rate; K = age weighting modulation factor; β = parameter from the age weighting function; C = constant; a = age of onset of disability; L = duration of disability; D = disability weight. We calculated the number of YLDs lost per incident per age group and gender and then summed up the results.

For instance, we used 0.105 for disability weight (D), which means that a person would prefer having perfect health only for one (1) year and then dying as roughly equivalent to living 1.12 years (1/ (1- 0.105) years) with a health condition of D = 0.105 then die [44,45]. We used the value of β as 0.04, which implies a similar age pattern [46, 33]. We used diarrhea estimates (incidence, duration, and mortality) from our previous empirical study. We estimated diarrhea incidence, average duration, and diarrhea mortality from our previous empirical study [18]. The total number of deaths and diarrheal cases avoided by trial per each age group by gender is mentioned somewhere in this paper. For other parameters such as k, r= 0.03, K= 1, β= 0.04 and C, we referred to the GBD study [33,42]

## Years of life lost (YLLs)

Years of life lost (YLLs) is a measure of the loss of life related to premature death because of a specific cause happening at a particular age. We calculated YLLs using the age of death estimate and the Ethiopian life expectancy at the age at which death happens.

It is calculated as follows:

$$\text{YLLs}[r, k, \beta] = \frac{KCe^{ra}}{(r+\beta)^2}\left\{e^{-(r+\beta)(L+a)}[-(r+\beta)(L+a) - 1] - e^{-(r+\beta)a}[-(r+\beta)a - 1]\right] + \frac{1-K}{r}(1 - e^{-rL})\}$$

Where: r = discount rate; K = age weighting modulation factor; β = parameter from the age weighting function; C = constant; a = age of death; L = standard expectation of life at age a. Age-specific social roles are captured by age weighting which gives less weight to children and older adults than the working-age people. We used the Ethiopia life expectancy at birth 66.7 years for males and 70.4 years for females in the year 2017 [48]. For parameter values, we referred to the GBD study (r= 0.03, K= 1, β= 0.04, and C= 0.1658) [33].

**Incremental Costs Effectiveness Ratio (ICER)**

In this study, we compared CLTS intervention to the routine sanitation activities, taking into consideration the extra amount we need to pay to avert extra DALY by choosing CLTS intervention over the routine sanitation intervention being currently done by HEWs. The cost-effectiveness criteria of the ICER value, we referred to the WHO-CHOICE framework for low- and middle-income countries, which is 1 to 3 times the per capita GDP [24, 77]. An intervention is considered: cost-effective if it is less than 3 times the GDP per capita per DALY averted; very cost-effective if it is less than 1 times; and not cost-effective for more than 3 times [42, 50].

## 2.8. Sensitivity Analyses

We used probabilistic and one-way sensitivity analysis. In one-way analysis, we re-calculated DALYs and ICERs by taking the upper and lower limit of the parameter values for disability weight, life expectancy, disability duration, discount rate, and intervention effect. We executed 10,000 Monte Carlo simulations with varying model parameters over a range of plausible values. In the base case, the effects of CLTS intervention are assumed to sustain over the time horizon. The reasonable parameter range applied in one-way sensitivity analysis and the parameter distributions of each variable in the probabilistic sensitivity analysis is described in the Supplementary Table. For the probabilistic and one-way analyses, we provided cumulative frequency distributions and a tornado plot, respectively.

## 3. RESULTS

In the trial, the intervention group consisted of 1,737 and the control group of 1,795 households. There were 1301 under-5 children, 3804 school-age children (aged 5-14), and 4608 people aged 15 or above. When a child encountered diarrhea in the household, 63% of the caregivers reported seeking health care (among them 56% brought their children to health facilities, 4% preferred home care and 3% took their children to traditional healers or drugstores). An average of 5 days of hospitalization was reported only for 5% of the children with diarrhea.

The proportion (percentage points/pp) of open defecation declined by 3 pp among school-age children (5-14) and 4pp among the people aged 15 or above. Switching from open defecation to latrine utilization could help people save 9 minutes for each round trip. Households switching from using a neighbor’s latrine to their own enabled 20 pp of people aged 15 or above to save 5 min per round trip. During the ten years after the CLTS intervention, the number of diarrhea cases avoided was 20,374 among children under-5, 16,084 among children aged 5-14, and 15,154 among the people aged 15 or above. A total of twenty-two premature deaths would be averted in the 10-years time horizon. Around 64% of the premature deaths averted and 40% of the diarrhea cases avoided took place among children aged under-5. We got these results from our previous empirical study [52]. Table 1 presents all this detail.

Table 1. Health effect from the CLTS intervention (10 years time horizon).

| Age Groups | Health Effects | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Diarrhea cases avoided | | | | Premature deaths averted | | | |
| | Male | Female | Total | % | Male | Female | Total | % |
| Under-5 | 9718 | 10,656 | 20,374 | 39.48 | 7 | 7 | 14 | 63.64 |
| 5-14 | 8268 | 7,816 | 16,084 | 31.16 | 2 | 1 | 3 | 13.64 |
| ≥15 | 7138 | 8,016 | 15,154 | 29.36 | 2 | 3 | 5 | 22.73 |
| SUM | 25124 | 26,488 | 51,612 | 100 | 11 | 11 | 22 | 100 |

To measure the effect of the intervention, the treatment participants in both groups were follow-upped for 140days. According to the report from the diarrhoeal calendar in the 140 follow-up days, there were 481 diarrhoeal days (202 cases) and 773 diarrhoeal days (293 cases) in the intervention and control groups respectively. The incidence and the longitudinal ratios were 0.70 and 0.71 with the 95% confidence interval of 0.46-0.99 and 0.46-0.99 respectively as shown in the table. When we see the effect of the intervention on diarrhoea duration, children with 1-day diarrhoeal duration were 90(45%) in the intervention and 124(41%) in the control. Children with more than 4 days of diarrhoea duration were 11(5%) and 29% (10%) in the intervention and control group respectively. The mean days of diarrhoea duration were 2.4 in the intervention and 2.6 in the control. To measure the effect of CLTS on the secondary outcome, we counted the number of the newly constructed improved latrine. As a result, after triggering the mean proportion of households with an improved latrine increased from 0.0% to 35.0% and from 0.5% to 2.8% in the intervention and control villages respectively. The details are displayed in Table 2.

Table 2. Effect of CLTS intervention on incidence, longitudinal prevalence, and duration of diarrhoea.

|  | Intervention group | Control group |
|---|---|---|
| Baseline characteristics of the intervention and control groups |  |  |
| Initial number of caregivers/children before screening | 539 | 531 |
| Number of caregivers/children after screening | 455 | 451 |
| Caregiver’s gender(female) | 446 | 446 |
| Household head’s gender (male) | 427 | 435 |
| Child’s sex (female) | 226 | 224 |
| Having household latrine | 341 | 364 |
| Effect of CLTS intervention on the incidence and longitudinal prevalence of diarrhoea |  |  |
|  | Intervention | Control |
| Total No. of children (after 140 days of follow-up) | 409 | 433 |
| Total episodes | 202 | 298 |
| Total days of diarrhoea | 481 | 773 |
| Incidence ratio* | 0.7 (95%ci: 0.46-0.99, p=0.04) |  |
| Incidence ratio† | 0.64(95%ci: 0.43-0.94, p=0.03) |  |
| longitudinal prevalence ratio* | 0.71(95%ci: 0.52-0.97, p=0.03) |  |
| longitudinal prevalence ratio† | 0.69(95%ci: 0.51-0.95, p=0.02) |  |
| Effects of the CLTS intervention on diarrhoea duration |  |  |
| 1 day | 90 (45%) |  |
| 2 days | 56(28%) |  |
| 3 days | 32 (16%) |  |
| 4 days | 13 (6%) |  |
| More than 4 days | 11 (5%) |  |
| Mean duration (days) | 2.4 | 2.6 |
| Mean difference days* | -0.2(95%ci: -0.8 - 0.4, p=0.50) |  |
| Mean difference days† | -0.3(95%ci: -0.9 - 0.3, p=0.40) |  |

* Adjusted for clustering effect and stratification

†Adjusted for clustering effect and stratification, caregiver’s age, child’s age, and sex, and type of water source

Table 3 presents the summary of both the intervention and control groups. The table displays the baseline characteristics of the treatment and control groups; the effect of CLTS intervention on the incidence, longitudinal prevalence of diarrhea, and duration of diarrhea. At the start of the intervention before the screening, there were 539 and531 caregivers/children in the treatment and control groups respectively. Later after screening the number reduced to 455 in the intervention group and 451 in the control group.

To measure the effect of the intervention, the treatment participants in both groups were follow-upped for 140days. According to the report from the diarrheal calendar in the 140 follow-up days, there were 481 diarrheal days (202 cases) and 773 diarrheal days (293 cases) in the intervention and control groups respectively. The incidence and the longitudinal ratios were 0.70 and 0.71 with the 95% confidence interval of 0.46-0.99 and 0.46-0.99 respectively as shown in the table. When we see the effect of the intervention on diarrhea duration, children with 1-day diarrheal duration were 90(45%) in the intervention and 124(41%) in the control. Children with more than 4 days of diarrhea duration were 11(5%) and 29% (10%) in the intervention and control group respectively. The mean days of diarrhea duration were 2.4 in the intervention and 2.6 in the control. To measure the effect of CLTS on the secondary outcomes, we counted the number of the newly constructed improved latrines. As a result, after triggering the mean proportion of households with an improved latrine increased from 0.0% to 35.0% and from 0.5% to 2.8% in the intervention and control villages respectively.

Table 3. Summary of the treatment and control groups

| | Intervention group | Control group |
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| Baseline characteristics of the intervention and control groups | | |
| Initial number of caregivers/children before screening | 539 | 531 |
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| Total No. of children (after 140 days of follow-up) | 409 | 433 |
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| Effects of the CLTS intervention on diarrhea duration | | |
| 1 day | 90 (45%) | |
| 2 days | 56(28%) | |
| 3 days | 32 (16%) | |
| 4 days | 13 (6%) | |
| More than 4 days | 11 (5%) | |
| Mean duration (days) | 2.4 | 2.6 |
| Mean difference days* | -0.2(95%ci: -0.8 - 0.4, p=0.50) | |
| Mean difference days† | -0.3(95%ci: -0.9 - 0.3, p=0.40) | |

* Adjusted for clustering effect and stratification

†Adjusted for clustering effect and stratification, caregiver's age, child's age, and sex, and type of water source

Table 4 presents CLTS intervention costs. Costs were divided into two: the initial costs, and the operational and maintenance costs. The initial costs consisted of implementation and management costs of the project, and community and local stakeholders' investment, which accounts for about 54% (Int'l$238,425) and 42% (Int'l $186,690) out of the total cost respectively. Recurrent costs take a substantial share (94% Int'l $223,845) from the project implementation and management costs. Some of the project implementation costs are related to CLTS introduction, training, community campaign, meetings, and workshops. While staffs' salary, stationery, fuel, office, and monitoring and evaluation costs are the major project management costs. Similarly, in terms of time and material, recurrent costs constitute 55% (Int'l $102,353) of the total initial costs incurred by local stakeholders and community members. CLTS follow-up and CLTS triggering costs took the major share of the recurrent costs of the initial costs. Initial cost covered about 96% (Int'l $425,115) of the total cost whereas operation and maintenance cost take the remaining 4% (Int'l $19,784).

Table 4. Costs of CLTS intervention (Int'l).

| **Costs** | **Initial costs** | | | | | | | **Education, operation and maintenance** costs for **latrine lifespan** | | | **Total** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Project implementation and management | | | Community and local stakeholders Investment | | | Initial costs subtotal | | | | |
| | Recurrent | Capital | Subtotal | Recurrent | Capital | Subtotal | | Operation and maintenance | Education | Subtotal | |
| **Amount** | 223,845 | 14,580 | 238,425 | 102,353 | 84,337 | 186,690 | 425,115 | 9,892 | 9,892 | 19,784 | 444,899 |
| **Subtotal %** | 94 | 6 | 100 | 55 | 45 | 100 | | 50 | 50 | 100 | |
| **Total %** | 54% | | | 42% | | | 96% | 4% | | | 100% |

Table 5 summarizes the results for the calculated YLD, YLL, DALY per each age group for the base case scenario and the ICER value of our intervention. The incremental cost is Int'l $444,899 and the incremental outcome is 717.79 DALY averted for the base case, and the ICER is Int'l $616.25. The DALYs averted from premature mortality is high (67.11%) in under-5 age groups, while above half of the DALYs averted from avoided diarrheal cases were found among those aged 15 or above.

Table 5. The calculated YLD, YLL, and DALY per age group (the base case scenario).

| Age Groups | Sex | YLD (a) | YLL (b) | Premature Death Averted (c) | Diarrhea cases avoided (d) | DALY Averted (Premature death) tdP= [(a+b)*c] | % | DALY Averted (Diarrhea cases avoided) tdD=(a*d) | % | Total DALY per age Groups TD=[(a+b)*c+(a*d)] | % |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **<5** | Male | 0.00012 | 32.92983 | 7 | 9718 | 230.510 | | 1.162 | | 231.671 | |
| | Female | 0.00012 | 33.19897 | 7 | 10656 | 232.394 | | 1.274 | | 233.667 | |
| | **(M&F)** | | | **14** | **20374** | **462.903** | 66.66 | **2.436** | 8.34 | **465.339** | 64.31 |
| **5 - 15** | Male | 0.000656 | 35.87741 | 2 | 8268 | 71.756 | | 5.426 | | 77.182 | |
| | Female | 0.000656 | 35.96655 | 1 | 7816 | 35.967 | | 5.129 | | 41.096 | |
| | **(M&F)** | | | **3** | **16084** | **107.723** | 15.51 | **10.555** | 36.14 | **118.278** | 16.35 |
| **>15** | Male | 0.00107 | 23.63327 | 2 | 7138 | 47.269 | | 7.639 | | 54.907 | |
| | Female | 0.00107 | 25.49304 | 3 | 8016 | 76.482 | | 8.578 | | 85.061 | |
| | **(M&F)** | | | **5** | **15154** | **123.751** | 17.82 | **16.217** | 55.52 | **139.968** | 19.34 |
| **Grand total** | | | | **22** | **51612** | **694.378** | **100.00** | **29.208** | **100** | **723.585** | **100.00** |
| **Total cost (f)** | **444,899** | | | | | | | | | | |
| **ICER (f/©)** | **614.85** | | | | | | | | | | |

Figure 1 shows the outputs of one-way sensitivity analyses. The largest changes in ICER were yielded by the effects of the CLTS intervention on diarrhea. The ICER with low effectiveness (lower limit of 95% confidence interval) was Int'l $3663.36, and the ratio with high effectiveness increased to Int'l $388.91. The changes in response to variation in other parameters in the ICER were minimal.

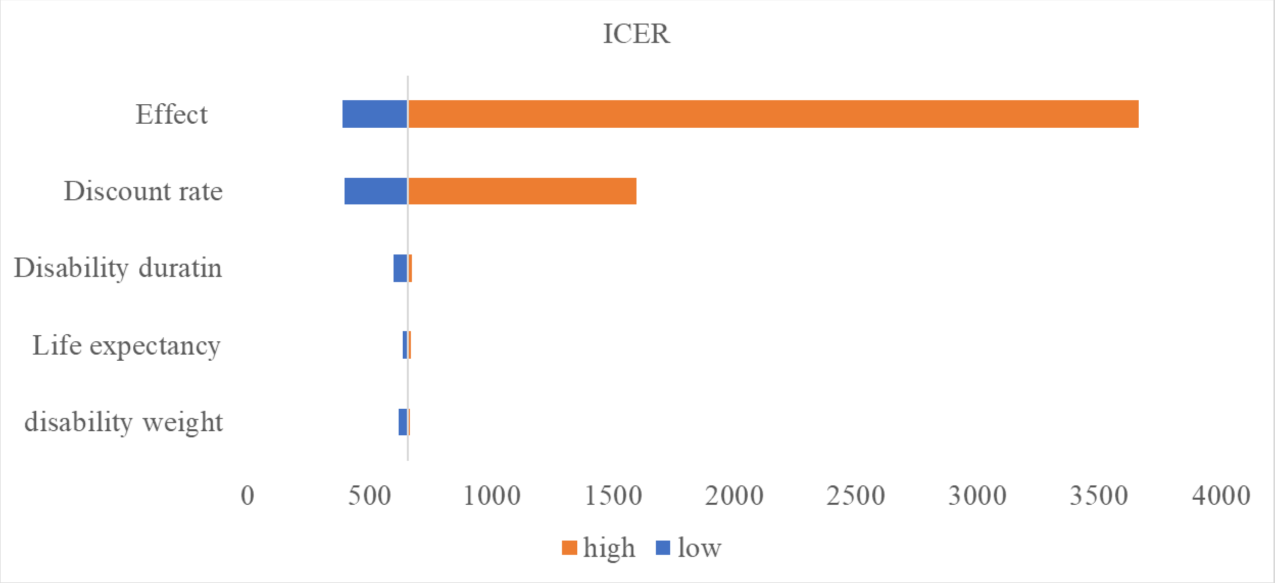

**Figure 1.** Results of the one-way analyses.

Figure 2 shows the results of Monte Carlo simulations with the cumulative density functions of ICERs of 10,000 draws. The 5th and 95th percentile of ICERs were Int’l $923 and Int’l $362. The Monte Carlo analysis outputs showed that the ICER was not above the threshold under any plausible circumstances.

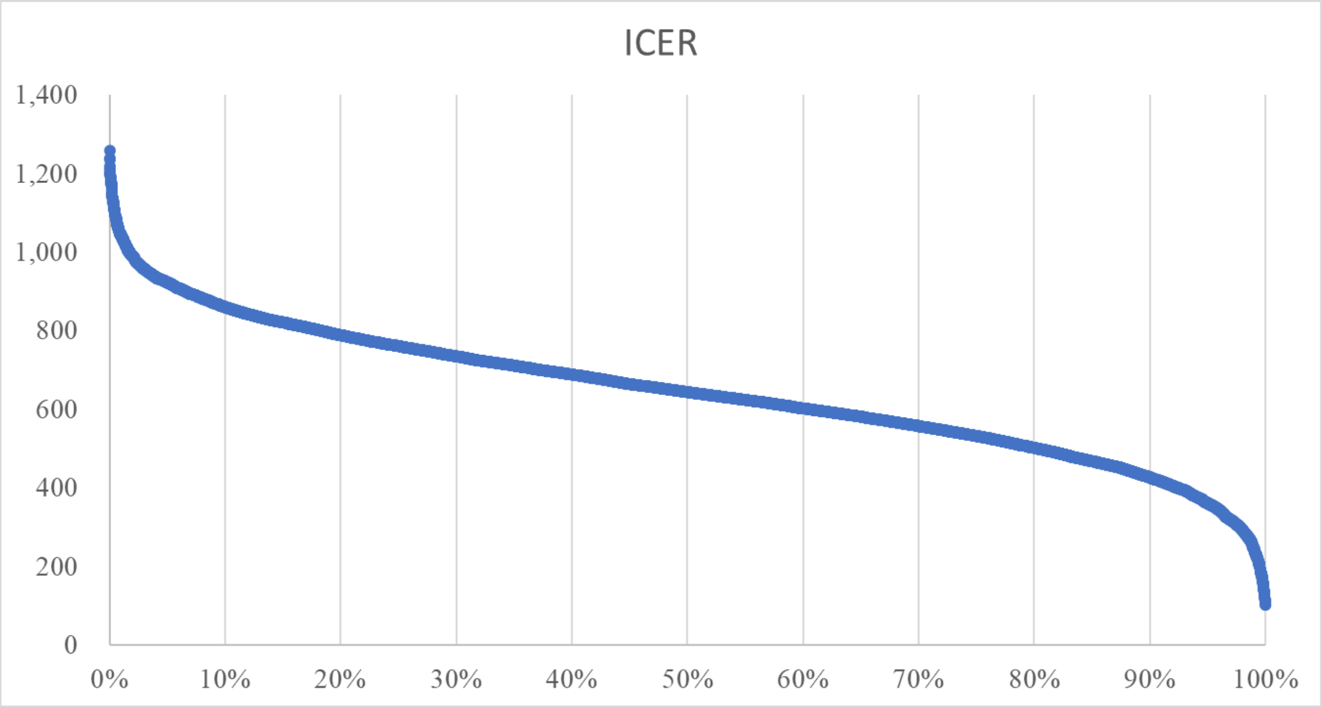

**Figure 2.** Cumulative density functions of ICERs (Monte Carlo analysis, x-axis: cumulative percentage, and y-axis: ICER).

## 4. Discussion

The ICER value which is less than the GDP per capita of Ethiopia (Int’l $2021.56 in 2017) indicates that CLTS interventions are highly cost-effective compared to the routine sanitation promotion delivered by HEWs [51]. To our knowledge, this is the first study to assess the cost-effectiveness of CLTS measuring as a ratio of cost to DALY averted based on the randomized control trial. We took many parameters values including the baseline conditions and the effects of the CLTS intervention from the empirical data.

The recent economic evaluation of CLTS by Crocker and colleagues explored four different types of interventions in five regions in Ethiopia and Ghana. One of the findings in their study is that the CLTS interventions were more effective in the regions of low baseline coverage of latrine, which implies that the cost-effectiveness of sanitation intervention varies depending on the context [53]. The health effect of CLTS intervention was highest (71.9%) in under-5 children in terms of the total averted premature death DALY and was most substantial (55.5%) in people older than 15 (>15) in terms of the total averted diarrhea cases DALY. The aggregated CLTS effect (total DALYs avoided) is most profound in under 5 (<5) children. We found the CLTS interventions are very attractive considering the cost-effectiveness of other interventions done in Ethiopia: the ICER of calcium supplementation for maternal and neonatal health $3080 per DALY averted [54]; combined interventions of long-lasting insecticidal nets (LLINs) and indoor residual spraying (IRS), $1403 [55]; multidrug-resistant tuberculosis (MDR-TB) treatment taken at the hospital/ treatment initiative center (TIC), $1,641 [56]; and an inhaled oxytocin product (IHO) for the prevention of postpartum hemorrhage (PPH), $1880 [57].

A recent study [62] in Ethiopia to estimate the cost-effectiveness of 159 interventions for Ethiopia’s essential health service package (EHSP) showed that 104 interventions (65%) have an average cost-effective ratio (ACER) of less than US$500 per healthy life years (HLY) and 119 (75%) have an ACER of less than US$1000 per HLY gained. To mention some of the interventions WASH, tuberculosis, nutrition, mental health, malaria, and breast cancer had the ACER (USD per HLY) of 122, 143, 262, 1045, 1163, and 2157 ACER respectively. The average cost-effectiveness of the intervention was calculated as the ratio of the total cost of the intervention to total HLYs gained from the intervention [42,62]. Apart from diarrhea, there are many other diseases like trachoma and schistosomiasis caused by poor hygiene and sanitation [67]. Also, undernutrition can be indirectly caused by the lack of access to sanitation [68]. Though the outcomes mentioned above can be ideally included in the CEA of a sanitation intervention, we only include the effect analysis of diarrhea because of the absence of relevant empirical data. Hence this leaves a future potential research spot for those interested in further carrying out CEA in the area.

Our study has several limitations. First, we did not conduct clinical diagnosis for ascertainment of diarrhea but relied on caregivers' reports and records of child diarrhea. Second, we were not able to mask the CLTS interventions because enumerators were able to recognize their latrine construction and identify whether the households or community belong to the intervention or control. To overcome the social desirability bias, we directly observed latrine construction.

## Conclusion

There is a huge gap in the study of the cost-effectiveness of CLTS intervention, we tried to fill this gap by providing an analysis based on empirical evidence and a model. Based on the RCT trial our analysis showed that CLTS is very cost-effective with an ICER value of $616.25. The key determinant factor in stating that CLTS intervention is cost-effective is the prevalence of diarrhea in the study areas. From this, we can generalize that CLTS could be very effective if implemented in other districts/regions of the country. Diarrhea prevention or WASH-related interventions which include CLTS components can bring about effective management of diarrhea-related diseases. Our CEA study may not fully fit to present adequate direction to policymakers on efficient decision making (informing policies and project planning) because we constrained our analysis on only two outcomes of CLTS; however, CLTS has other benefits like improved solid waste management and handwashing practices which leaves potential area for future studies.

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## Supplementary

In one-way sensitivity analysis, we used different parameter estimates from various sources. For example: concerning the diarrhoeal disability weight in the base case we used the value (D = 0.105). While we used the values D= 0.074 and D= 0.247 in the lower (mild diarrhoeal) and upper (severe diarrhoeal) cases, respectively. For the life expectancy parameter, the values for the base case (Ethiopian life expectancy at birth), lower case (the average life expectancy), and upper case (the highest life expectancy- Japanese age) were used from three sources IHME, World Bank (WB), and Murray CJL (1994) respectively. Similarly, we used estimates from various sources for other parameters too. The detail is illustrated in Table S1.

Table S1. One-way sensitivity analysis parameter range and assumptions.

| Parameter | Range | Value | Total DALY | ICER | Remark |
|---|---|---|---|---|---|
| Disability weight (DW) | Base case: Source: [37] | 0.105 | 721.947 | 616.25 | The rise in DW results in decline to ICER |
| | Lower case: Source: [78] | 0.074 | 713.32 | 623.70 | |
| | Upper case: Source: [78] | 0.247 | 761.45 | 584.28 | |
| Life Expectancy (LE) | Base case: Source: [48] | (M=66.7, F=70.4) | 721.947 | 616.25 | The rise in LE results in decline to ICER |
| | Lower case: Source: [79] | (M=65.87, F=65.87) | 713.187 | 623.82 | |
| | Upper case: Source: [80] | (M=80, F= 82.5) | 749.55 | 593.55 | |
| Disability Duration (DD) (days) | Base case: Source: [40] | 2.6 | 721.947 | 616.25 | The rise in DD results in rise to ICER |
| | Lower case: We used the lowest possible diarrhoea duration. | 1 | 722.00 | 616.20 | |
| | Upper case: Source: [39]. | 8.4 | 721.76 | 616.41 | |
| Discount rate (r) | Base case: Source: [24]. | 3% | 721.947 | 616.25 | The rise in r results in decline to ICER |

| | | | | | |
|---|---|---|---|---|---|
| | Lower case: Source: [26] | 1% | 1160.24 | 383.45 | |
| | Upper case: Source: [26] | 8% | 321.55 | 1383.61 | |
| CLTS Effect on the longitudinal prevalence of diarrhoea | Base case: Source: [81] | 30% reduction | 721.947 | 616.25 | The rise in CLTS Effect results in decline to ICER |
| | Lower case: Source: [81] | 5% reduction | 120.43 | 3694.25 | |
| | Upper case: Source: [81] | 48% reduction | 1155.12 | 385.15 | |

As seen in the supplementary table (Table S2) the monitoring/follow-up cost after the triggering constituted above 54% of the CLTS implementation recurrent cost while staff salary and benefits covered above 74% of CLTS management recurrent cost. Both CLTS implementation and CLTS management recurrent costs covered 18% and 32% of the total cost respectively, together they constituted above 50%. The investment recurrent costs by community members and local stakeholders made up 23% of the total. The investment capital costs by community members and local stakeholders covered 19% of the total CLTS intervention cost.

Table S2. Presents CLTS initial implementation and management costs, and community members' and local stakeholders' initial investments.

| **Costs** | **Value (Int'l $)** | **Information source** |
|---|---|---|
| **CLTS implementation Recurrent costs** | | |
| **CLTS sensitization, training, and implementation cost** | 11,366 | Trial data |
| IEC Materials | 9,000 | Trial data |
| Material incentives | 3,840 | Trial data |
| Monitoring/follow-up after the CLTS triggering | 43,204 | Trial data |
| Meeting/workshop | 4,800 | Trial data |
| Other costs | 7,350 | Trial data |
| Subtotal | 79,560 | Trial data |
| **CLTS Management Recurrent costs** | | |
| Staff salary and benefits (local & ex-pat) | 107,640 | Trial data |

| | | |
|---|---|---|
| Fuel | 12,000 | Trial data |
| Monitoring and evaluation | 8,925 | Trial data |
| Office and translator | 7,200 | Trial data |
| Other costs (stationary & Report printing) | 8520 | Trial data |
| Subtotal | 144,285 | Trial data |
| **CLTS Management Capital costs** | 14580 | Trial data |
| Motorcycle & Vehicle | 14580 | Trial data |
| Total | 238,425 | Trial data |
| **Community members' and local stakeholders' investment Recurrent costs** | | |
| CLTS training | 4371 | Trail data |
| CLTS promotor training | 817 | Trail data |
| CLTS orientation | 312 | Trail data |
| CLTS triggering | 24655 | Trail data |
| CLTS follow up | 60125 | Trail data |
| Review meeting | 12073 | Trail data |
| Subtotal | 102353 | Trail data |
| **Community members' and local stakeholders' investment Capital cost** | | |
| Latrine construction (time cost) | 70107 | Trail data |
| Latrine construction (cement) | 1968 | Trail data |
| Latrine construction (handwashing facility) | 12263 | Trail data |
| Subtotal | 84338 | Trail data |
| Total | 186691 | Trail data |
| **Life span operation, maintenance, and education costs** | | |
| Operation and maintenance | 9892 | Trail data |
| Education for the lifespan of a latrine | 9892 | Trail data |
| Subtotal | 19784 | Trail data |
| Grand total | 444,900 | Trail data |

Adjusted for clustering effect and stratification the relative risk was 0.68 and 0.97 at the 3-month and 5-month follow-up period, respectively. And it has decreased in the subsequent follow periods to reach at 0.75 at the 10-month of follow-up. While adjusted for clustering effect, district/stratification, baseline prevalence of diarrhoea, caregiver’s age, child’s age, and sex, and type of water source, the RR was 0.73 at the 10-months follow-up time. Table S4 below shows the result.

Table S4. Relative Risk of diarrhoea in the intervention and control groups.

| Follow-up months | CLTS | Control | Relative Risk* | 95% CI | P | Relative Risk† | 95% CI | P |
|---|---|---|---|---|---|---|---|---|
| 3 | 11.8% (51/433) | 17.2% (72/419) | 0.68 | 0.45 - 1.03 | 0.07 | 0.58 | 0.42 - 0.80 | 0.001 |
| 5 | 17.3% (68/394) | 17.5% (72/412) | 0.97 | 0.68 - 1.39 | 0.89 | 1.02 | 0.72 - 1.47 | 0.9 |
| 9 | 10.5% (44/418) | 11.8% (53/451) | 0.87 | 0.51 - 1.48 | 0.62 | 0.82 | 0.48 - 1.41 | 0.48 |
| 10 | 7.7% (34/439) | 9.9% (42/426) | 0.75 | 0.35 - 1.62 | 0.46 | 0.73 | 0.35 - 1.52 | 0.4 |
| Overall | | | 0.83 | 0.60 - 1.15 | 0.26 | 0.78 | 0.58 - 1.07 | 0.12 |

* Adjusted for clustering effect, and district/stratification.

† Adjusted for clustering effect, district/stratification, baseline prevalence of diarrhoea, caregiver’s age, child’s age, and sex, and type of water source.