



# Evaluating the Impact of Community-Led Total Sanitation on Childhood Diarrhoea: A Cluster-Randomised Trial Methodology for Rural Mali

Aminata Konaté<sup>1</sup>, Sékou Doumbia<sup>1</sup>, Boubacar Traoré<sup>2</sup>, Mariam Diarra<sup>3</sup>

<sup>1</sup> International Center for Tropical Agriculture (CIAT), Mali

<sup>2</sup> Department of Surgery, Rural Polytechnic Institute (IPR/IFRA) of Katibougou

<sup>3</sup> Department of Public Health, Rural Polytechnic Institute (IPR/IFRA) of Katibougou

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**Correspondence:** [akonat@hotmail.com](mailto:akonat@hotmail.com)

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## Author notes

*Aminata Konaté is affiliated with International Center for Tropical Agriculture (CIAT), Mali and focuses on Medicine research in Africa.*

*Sékou Doumbia is affiliated with International Center for Tropical Agriculture (CIAT), Mali and focuses on Medicine research in Africa.*

*Boubacar Traoré is affiliated with Department of Surgery, Rural Polytechnic Institute (IPR/IFRA) of Katibougou and focuses on Medicine research in Africa.*

*Mariam Diarra is affiliated with Department of Public Health, Rural Polytechnic Institute (IPR/IFRA) of Katibougou and focuses on Medicine research in Africa.*

## Abstract

Childhood diarrhoea remains a leading cause of morbidity and mortality in Mali, with poor sanitation a key risk factor. Community-Led Total Sanitation (CLTS) is a widely implemented participatory approach to ending open defecation, but rigorous evidence of its health impact in the Malian context is limited. This methodology paper describes the design of a cluster-randomised trial to evaluate the impact of CLTS on childhood diarrhoea incidence in rural Mali. The primary objective is to determine whether CLTS reduces the seven-day period prevalence of diarrhoea in children under five years old. A cluster-randomised controlled trial was conducted in the Koulikoro Region. Villages were randomised to either an intervention arm, receiving standard CLTS triggering and follow-up, or a control arm receiving no active sanitation intervention during the trial period. Data on diarrhoea prevalence, sanitation practices, and confounders were collected through repeated household surveys. The sample size was calculated to detect a minimum 30% reduction in diarrhoea prevalence. Analysis follows an intention-to-treat approach using mixed-effects regression models to account for cluster design. As a methodology article, this paper presents no empirical trial results. The findings section outlines the finalised study protocol, confirming that the calculated sample size required 40 village clusters, with approximately 30 households surveyed per cluster, to achieve adequate statistical power. The described methodology provides a robust framework for assessing the health impact of CLTS in a rural Sahelian setting. It addresses common design challenges in sanitation trials, such as contamination and outcome measurement. Future trials of sanitation interventions should consider similar cluster-randomised designs with active control arms. Incorporating process evaluation is recommended to understand implementation fidelity and contextual factors affecting outcomes. Community-Led Total Sanitation,

diarrhoea, cluster-randomised trial, methodology, Mali This paper provides a detailed methodological protocol for a rigorous evaluation of a common public health intervention, which may serve as a reference for researchers designing similar studies in low-resource settings.

**Keywords:** *Community-Led Total Sanitation, cluster-randomised trial, childhood diarrhoea, participatory hygiene promotion, sub-Saharan Africa, rural health, WASH interventions*

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