



(RESEARCH ARTICLE)



EFFECT OF AN INTEGRATED ENVIRONMENTAL MANAGEMENT INTERVENTION ON MALARIA PARASITAEMIA PREVALENCE AMONG ADULTS IN THE ADA WEST AND NORTH TONGU DISTRICTS, GHANA: A CLUSTER-RANDOMISED CONTROLLED TRIAL WITH PRE- AND POST-INTERVENTION SURVEYS

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ABSTRACT

Malaria control in Ghana's coastal savannah is constrained by outdoor biting and insecticide resistance, yet controlled evidence on environmental management is scarce. This study estimated the effect of an integrated environmental management (IEM) package on malaria parasitaemia among adults. A parallel two-arm cluster-randomised controlled trial was conducted from July to December 2024, with randomisation stratified by district: three sub-district clusters in Ada West District received the intervention, and four in North Tongu District served as controls. The six-month package combined habitat modification, habitat manipulation, targeted larviciding with *Bacillus sphaericus*, and community

health education, while control clusters continued routine malaria control. Independent samples of 700 adults per arm were tested with an HRP2/pLDH rapid diagnostic test at baseline and end-line. The primary contrast was the difference-in-differences (DiD) in prevalence. Parasitaemia fell from 51.9% (95% CI 48.2–55.5) to 42.6% (39.0–46.3) in the intervention arm and rose from 62.3% (58.6–65.8) to 65.1% (61.5–68.6) in the control arm. The DiD was –12.1 percentage points (95% CI –19.4 to –4.9; $p = 0.001$), and the ratio of odds ratios was 0.61 (0.45–0.82). The effect remained statistically significant when variances were inflated for intra-cluster correlation coefficients below 0.009, but not above. The IEM package was associated with a substantial reduction in adult parasitaemia against a rising control-arm trend. Because only two district strata were randomised and the control district had recent flood exposure, the estimate is best regarded as an upper bound to be confirmed in trials with more clusters.

Keywords: Malaria parasitaemia; Environmental management; Larval source management; Cluster-randomised trial; Difference-in-differences; Ghana

1 INTRODUCTION

Malaria remains one of the most consequential infectious diseases worldwide. In 2024, an estimated 282 million cases and 610,000 deaths occurred, with the WHO African Region accounting for approximately 94% of cases and 95% of deaths [1]. Climatic variability increasingly destabilises transmission across Africa [2], and the disease imposes heavy direct and indirect costs on households and the health system [3,4]. In Ghana, the burden is unevenly distributed: the 2019 Malaria Indicator Survey recorded parasite prevalence of 2% among children aged 6–59 months in the Greater Accra Region but 20% in the neighbouring Volta Region [5], and the national strategic plan targets the elimination of malaria from the lowest-burden districts of Greater Accra by 2028 [6].

The principal vector control tools in Ghana, insecticide-treated nets and indoor residual spraying, act inside dwellings, and their reach is limited by vector behaviour and resistance. Across Ghana's ecological zones, including a coastal savannah site, about 80% of resting *Anopheles gambiae* s.l. were collected outdoors [7], and human landing catches showed biting divided almost equally between indoor and outdoor settings [8]. *Anopheles gambiae* s.l. from southern Ghana is resistant to all four classes of public health insecticides, with high-intensity pyrethroid resistance that erodes the efficacy of long-lasting insecticidal nets [9]. Dug-out wells are the most productive larval habitats in the coastal savannah [10], and annual entomological inoculation rates of 37.4 to 100.1 infective bites per person have been recorded in island communities on the Volta Lake [11]. Where vectors rest and bite outdoors and tolerate indoor insecticides, interventions targeting aquatic stages are particularly important [12,13].

Environmental management comprises the planning, implementation, and monitoring of activities that modify or manipulate environmental factors to prevent vector propagation and reduce human–vector contact; it includes permanent habitat modification, recurrent habitat manipulation, and larviciding [14,15]. The evidence for these measures is encouraging but uneven. Community-based microbial larviciding reduced infection prevalence in urban Dar es Salaam [16], larviciding added to insecticide-treated nets reduced new infections in the western Kenya highlands [17], and larviciding with *Bacillus thuringiensis israelensis* in Burkina Faso produced reductions in vector density that were reproducible across intervention years and extended to co-occurring mosquito species [18,19]. By contrast, a factorial cluster-randomised trial in Malawi found no additional effect of community-driven larval source management on transmission or prevalence when added to high net coverage [20], although community-led delivery proved affordable [21]. The World Health Organization issues only a conditional recommendation for larviciding, restricted to settings where habitats are few, fixed, and findable, and makes no recommendation on habitat modification or manipulation because the evidence is insufficient [15]; the corresponding Cochrane reviews describe the evidence as sparse, heterogeneous, and of low certainty [14,22]. An expert consensus has since called for larval source management to occupy a central place in African vector control [13], yet controlled evaluations from the coastal savannahs of West Africa remain scarce.

The Ada West District illustrates this problem. In a region targeted for elimination [6], reported malaria cases in the district rose from 3,511 in 2018 (33.3% of outpatient attendance) to 6,826 in 2023 (51.8%), despite sustained deployment of conventional interventions [23]. The district lies in the coastal savannah adjoining the Volta Region, with a predominantly outdoor transmission ecology and abundant man-made breeding habitats, making it an informative setting to test whether a structured environmental management package can reduce parasitaemia. This paper reports the first objective of a cluster-randomised trial: to estimate and compare the baseline and end-line prevalence of malaria parasitaemia among adults in the intervention and control arms and thereby to estimate the effect of an integrated environmental management (IEM) package on parasitaemia.

2 MATERIAL AND METHODS

2.1 Study design

We conducted a parallel, two-arm cluster-randomized controlled trial in which sub-district clusters were the units of randomisation and intervention delivery, and individual adults were the units of observation. We conducted independent cross-sectional surveys in all clusters at baseline (T_0), immediately before implementation, and at end-line (T_1), six months after implementation began. We chose cluster allocation because habitat modification, habitat manipulation, larviciding, and community education act on shared environmental resources and the entire population; therefore, individual allocation would invite contamination between arms [24]. The trial is reported in accordance with the CONSORT 2025 statement [25] and its extension to cluster-randomized trials [26], and the intervention is described using the TIDieR checklist [27].

2.2 Study setting

The intervention arm was the Ada West District in the south-eastern Greater Accra Region, which lies in the coastal savannah and is bounded by the Volta estuary, lagoons, coastal wetlands, and salt pans. Livelihoods are dominated by fishing, irrigated vegetable farming, salt extraction, and livestock rearing, each of which brings residents into sustained contact with aquatic habitats. The control arm was the North Tongu District, across the Volta River in the Volta Region, which shares a bimodal rainfall regime, riverine hydrology, and a predominantly agrarian livelihood structure. The study areas had populations of 89,789 (intervention) and 93,360 (control). The Volta River provides a physical barrier that limits contamination between the arms; however, the two districts lie on either side of a steep regional transmission gradient [5], and North Tongu was heavily affected by the flooding that followed the 2023 Akosombo Dam spillage [28].

2.3 Clusters, randomisation and allocation concealment

We enrolled all seven eligible sub-district clusters in the two districts: Sege, Bornikope, and Anyamam in Ada West and Battor, Juapong, Volo, and Dorfor in North Tongu. Clusters were eligible if they lay entirely within the study district, contained at least one aquatic habitat in which *Anopheles* immature stages were detected during baseline dipping, remained accessible to sanitation teams throughout the rainy season, and were overseen by a single sub-district health team; sub-districts sharing a contiguous water body with a cluster in the opposite arm were excluded. Allocation used restricted randomisation stratified by district. The clusters were grouped into two district strata, and an independent statistician at the University of Port Harcourt, with no other role in the study, randomised the strata to the two arms using a computer-generated sequence and a pre-specified seed. The sequence was kept in a sealed envelope until the trial inception meeting, which took place after cluster enrolment and household listing had been completed. Because all clusters within a district received the same allocation, the number of independently randomised units was two, and district and arm are confounded by design; this was accepted to control contamination across the Volta River and is addressed in the analysis and interpretation [24].

2.4 Participants and sampling

The study population comprised permanent residents aged 18 years or older who had lived in the cluster for at least six months and who provided written informed consent. We excluded individuals who reported antimalarial treatment within the preceding 28 days to limit misclassification of parasitological status. We used a three-stage design at each survey wave: we included all eligible clusters, selected households by systematic random sampling from community enumeration lists, with the sampling interval set as the ratio of listed households to the cluster sample size, and selected one consenting adult per household using a Kish grid. The end-line sample was drawn independently of the baseline sample, giving a repeated cross-sectional design.

2.5 Sample size

The sample size was calculated using the formula for comparing two independent proportions [29]: $n = (Z_{\alpha/2} + Z_{\beta})^2 \times [p_1(1 - p_1) + p_2(1 - p_2)] / (p_1 - p_2)^2$, with a two-sided α of 0.05 ($Z_{\alpha/2} = 1.96$), 95% power ($Z_{\beta} = 1.645$), a pre-intervention proportion of $p_1 = 0.536$ derived from district surveillance data [23], and a post-intervention proportion of $p_2 = 0.436$, representing an absolute reduction of 10 percentage points. This gave 643 participants per arm, which we increased to 715 per arm to allow for 10% non-response; we tested 700 adults per arm (97.9% of the target) at each wave. A cluster-based calculation [24] with a between-cluster coefficient of variation of 0.15 would have required approximately 24 clusters per arm, which exceeded the number of eligible sub-districts in the two districts (three and four); the residual within-cluster correlation was therefore addressed at the analysis stage.

2.6 Intervention and control condition

The IEM package comprised four components delivered over six months (Table 1). Habitat modification removed or permanently altered water bodies, habitat manipulation rendered habitats temporarily unsuitable for larval development, targeted larviciding treated the habitats in which *Anopheles* immature stages were found, and community health education addressed transmission, habitat recognition, net use, prompt care-seeking, and intermittent preventive treatment in pregnancy with sulfadoxine–pyrimethamine (IPTp-SP). Delivery was embedded in the existing municipal sanitation and Environmental Sanitation Day structures rather than in parallel project systems. Fidelity was monitored through fortnightly delivery logs that recorded the habitats treated, the quantity of larvicide applied, the sanitation activities completed, and the education sessions held; a cluster was classed as adherent when it delivered at least 80% of planned activities. Control clusters continued to receive the routine national package of long-lasting insecticidal net (LLIN) distribution, IPTp-SP, case management, and health promotion, without any environmental management component, and the package was offered to control communities after end-line data collection.

Table 1: Description of the integrated environmental management package following the TIDieR checklist

Component	Procedures and materials	Provider	Dose and schedule
Habitat modification	Landfilling of pits and depressions, land levelling, construction and rehabilitation of drains, permanent covering of water-holding structures	Municipal sanitation teams with community labour	Once at inception, with remedial works as required
Habitat manipulation	Container emptying, vegetation clearance, desilting of canals, removal of debris and blockages, flushing	Community volunteers under Environmental Sanitation Day structures	Fortnightly for six months
Targeted larviciding	<i>Bacillus sphaericus</i> (Vectolex® WDG) applied to habitats identified as productive by systematic larval surveillance	Trained community-owned resource persons	Fortnightly to productive habitats
Community health education	Structured sessions on transmission, habitat recognition, net use, prompt care-seeking and IPTp-SP	District health promotion officers and trained volunteers	Monthly community sessions plus household contact

Note. Delivered in all three intervention clusters from July to December 2024. Larvicide applicators were resident adults literate in English or Dangme who completed two days of training on habitat identification, dosing, application, and personal protection, with competency confirmed by supervised field application. IPTp-SP, intermittent preventive treatment in pregnancy with sulfadoxine–pyrimethamine; TIDieR, Template for Intervention Description and Replication.

2.7 Outcome and data collection

The primary outcome was malaria parasitaemia, defined as a positive result on the Abbott Bioline™ Malaria Ag P.f/Pan rapid diagnostic test (RDT), which detects histidine-rich protein 2 (HRP2) and pan-*Plasmodium* lactate dehydrogenase (pLDH), irrespective of symptoms. The combination assay was chosen to preserve detection where *pfhrp2* and *pfhrp3* gene deletions compromise HRP2-only tests [1]. Trained field officers tested finger-prick capillary blood according to the manufacturer's instructions, with a standardised buffer volume and a fixed 15-minute reading time. Outcome assessors held a health-related qualification, were recruited from outside both study districts, were rotated between clusters, and used study identifiers that did not encode arm allocation. Participants with positive results were referred for treatment under national guidelines at no cost. A structured questionnaire administered on tablets through KoboToolbox collected sociodemographic, housing, and LLIN data. The questionnaire was pretested in a non-study community with a similar ecology ($n = 40$) and achieved a content validity index of 0.87 after review by three specialists in epidemiology, entomology, and public health.

2.8 Statistical analysis

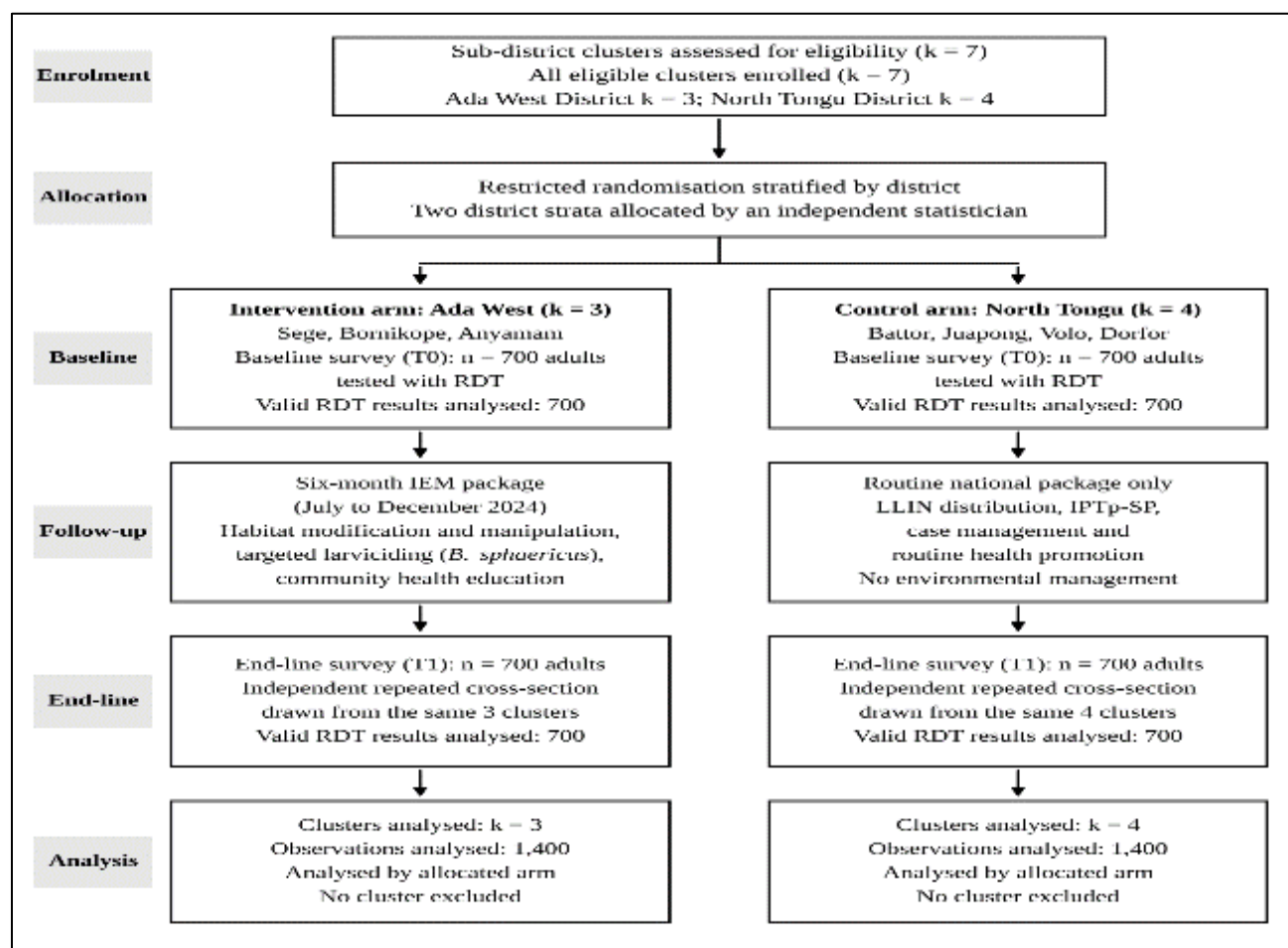
Participant characteristics were summarised by arm as counts and percentages, and balance was assessed using standardised mean differences (SMDs), with values of 0.10 or less taken to indicate adequate comparability; baseline differences were not tested for significance [25,26]. Prevalence was estimated for each arm and wave with Wilson 95% confidence intervals (CIs), and within-arm changes were estimated as differences in proportions between independent samples. The primary effect measure was the difference-in-differences (DiD), $(P_{I,T1} - P_{I,T0}) - (P_{C,T1} - P_{C,T0})$, where P is prevalence, I and C denote the intervention and control arms, and T_0 and T_1 denote baseline and end-line; the DiD removes time-invariant differences between arms under the assumption of parallel trends [30]. It was estimated as the arm-by-wave interaction in a binomial regression model with an identity link. Relative effects were estimated as the ratio of odds ratios (logit link) and the ratio of risk ratios (log link) from the same model, so that absolute and relative

measures are reported together [25]. We analysed participants by the intervention arm to which their cluster was allocated, and the analysis population included all participants with a valid rapid diagnostic test (RDT) result.

With seven clusters and two randomised strata, cluster-level permutation inference is uninformative: the unrestricted permutation set contains $C(7,3) = 35$ allocations, so the smallest attainable two-sided exact p-value is $2/35 = 0.057$, and the stratified set contains only two allocations [24,31,32]. Clustering was therefore addressed through a pre-specified sensitivity analysis in which the variance of each arm-wave prevalence was inflated by the design effect, $DE = 1 + (m - 1)\rho$, where m is the mean number of participants per cluster per wave (233.3 in the intervention arm and 175.0 in the control arm) and ρ is the intra-cluster correlation coefficient (ICC). The ICC varied across the range reported for *Plasmodium* prevalence in cluster trials, 0.001 to 0.082 [33], and the ICC at which the DiD lost statistical significance was identified. This approach is conservative because it ignores the positive correlation between baseline and end-line cluster means, which they DiD removes. All tests were two-sided at $\alpha = 0.05$. Analyses were performed in Python 3.13

3 RESULTS

3.1 Participant flow and characteristics



Note. The end-line sample was drawn independently from the baseline sample (repeated cross-sectional design). IEM, integrated environmental management; IPTp-SP, intermittent preventive treatment in pregnancy with sulfadoxine-pyrimethamine; LLIN, long-lasting insecticidal net; RDT, rapid diagnostic test.

Figure 1: CONSORT flow diagram of clusters and participants in the trial

All seven clusters were retained from allocation to analysis, and we tested 700 adults per arm at each survey wave, yielding 2,800 RDT results for the analysis (Figure 1). No cluster was excluded, and no participant was reassigned to the arms.

Table 2: Baseline characteristics of respondents by study arm

Characteristic	Category	Intervention, n (%)	Control, n (%)	SMD
Sex	Female	306 (43.7)	307 (43.9)	0.003
	Male	394 (56.3)	393 (56.1)	
Age group (years)	18–34	306 (43.7)	333 (47.6)	0.077
	> 34	394 (56.3)	367 (52.4)	
Occupation	Skilled manual	387 (55.3)	374 (53.4)	0.037
	Unskilled manual	313 (44.7)	326 (46.6)	
Place of residence	Rural	426 (60.9)	424 (60.6)	0.006
	Urban	274 (39.1)	276 (39.4)	
Married	No	286 (40.9)	310 (44.3)	0.069
	Yes	414 (59.1)	390 (55.7)	
Education	Graduate	158 (22.6)	144 (20.6)	0.049
	Undergraduate or below	542 (77.4)	556 (79.4)	
NHIS enrolment	No	212 (30.3)	209 (29.9)	0.009
	Yes	488 (69.7)	491 (70.1)	
Household size	> 3 members	388 (55.4)	408 (58.3)	0.058
	≤ 3 members	312 (44.6)	292 (41.7)	
Monthly income (GH¢)	< 2,000	362 (51.7)	340 (48.6)	0.063
	≥ 2,000	338 (48.3)	360 (51.4)	
Roof	Grass thatch	215 (30.7)	223 (31.9)	0.025
	Iron sheet	485 (69.3)	477 (68.1)	
Wall	Mud	224 (32.0)	221 (31.6)	0.009
	Permanent	476 (68.0)	479 (68.4)	
Floor	Cement	492 (70.3)	502 (71.7)	0.031
	Earth	208 (29.7)	198 (28.3)	
Eaves	Closed	409 (58.4)	409 (58.4)	0.000
	Open	291 (41.6)	291 (41.6)	
Window/door screens	No	256 (36.6)	236 (33.7)	0.060
	Yes	444 (63.4)	464 (66.3)	
Rooms in dwelling	≥ 5	407 (58.1)	371 (53.0)	0.104
	< 5	293 (41.9)	329 (47.0)	
LLIN ownership	No	148 (21.1)	135 (19.3)	0.046
	Yes	552 (78.9)	565 (80.7)	
LLIN used the previous night ^a	Yes	422 (76.6)	442 (78.2)	0.039

Note. n = 700 per arm; percentages are within the arm. SMD, standardised mean difference (0.10 or less indicates adequate balance); NHIS, National Health Insurance Scheme; GH¢, Ghana cedi; LLIN, long-lasting insecticidal net. ^a Among LLIN owners (intervention n = 551; control n = 565).

The two arms were closely comparable at baseline (Table 2). Males made up 56.3% of respondents in the intervention arm and 56.1% in the control arm, about three in five respondents lived in rural settlements (60.9% and 60.6%), and roughly seven in ten were enrolled in the National Health Insurance Scheme (69.7% and 70.1%). Housing characteristics were similarly distributed, with iron-sheet roofs in 69.3% and 68.1% of dwellings and window or door

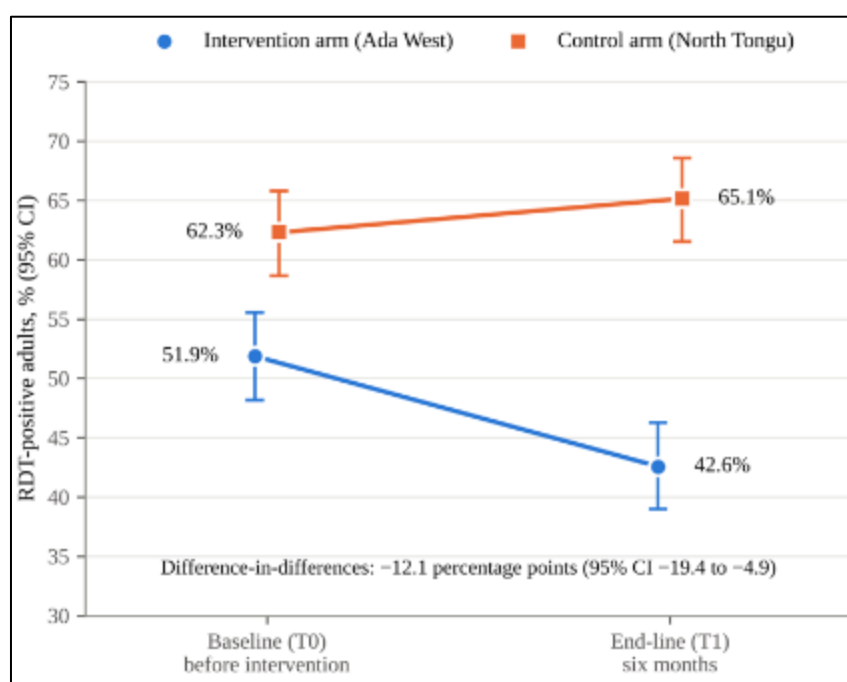
screens in 63.4% and 66.3%. LLIN ownership was 78.9% in the intervention arm and 80.7% in the control arm, and 76.6% and 78.2% of owners, respectively, reported sleeping under a net the previous night. All SMDs were 0.10 or less, except for the number of rooms in the dwelling (0.104), which indicates that the arms were balanced on measured characteristics.

3.2 Prevalence of parasitaemia at baseline and end-line

Table 3: Malaria parasitaemia (RDT-positive) at baseline and end-line by study arm, with effect estimates

Measure	Intervention (Ada West)	Control (North Tongu)	Between-arm contrast (95% CI)	p-value
<i>Baseline (T₀)</i>				
Cases/tested	363/700	436/700		
Prevalence, % (95% CI)	51.9 (48.2–55.5)	62.3 (58.6–65.8)	RD -10.4 (-15.6 to -5.3)	< 0.001
Risk ratio, I/C (95% CI)			0.83 (0.76–0.91)	
<i>End-line (T₁)</i>				
Cases/tested	298/700	456/700		
Prevalence, % (95% CI)	42.6 (39.0–46.3)	65.1 (61.5–68.6)	RD -22.6 (-27.7 to -17.5)	< 0.001
Risk ratio, I/C (95% CI)			0.65 (0.59–0.72)	
<i>Change from baseline to end-line</i>				
Absolute change, pp (95% CI)	-9.3 (-14.5 to -4.1)	2.9 (-2.2 to 7.9)	DiD -12.1 (-19.4 to -4.9)	0.001
p-value for change	< 0.001	0.266		
Relative change, %	-17.9	4.6		
OR, T ₁ vs T ₀ (95% CI)	0.69 (0.56–0.85)	1.13 (0.91–1.41)	ROR 0.61 (0.45–0.82)	0.001
RR, T ₁ vs T ₀ (95% CI)	0.82 (0.73–0.92)	1.05 (0.97–1.13)	RRR 0.78 (0.68–0.90)	< 0.001

Note. Outcome: malaria parasitaemia (positive HRP2/pLDH RDT). Prevalence CIs are Wilson intervals. The p-value column refers to the between-arm contrast. The DiD, ROR, and RRR are the arm-by-wave interaction terms from binomial regression with identity, logit, and log links. CI, confidence interval; DiD, difference-in-differences; I, intervention; C, control; OR, odds ratio; pp, percentage points; RD, risk difference (pp); RDT, rapid diagnostic test; ROR, ratio of odds ratios; RR, risk ratio; RRR, ratio of risk ratios.



Note. Points show prevalence and error bars show 95% Wilson confidence intervals (n = 700 per arm per wave).

Figure 2: Prevalence of malaria parasitaemia among adults at baseline and end-line by study arm

At baseline, parasitaemia was 51.9% (363/700; 95% CI 48.2–55.5) in the intervention arm and 62.3% (436/700; 58.6–65.8) in the control arm, a between-arm difference of –10.4 percentage points (95% CI –15.6 to –5.3) that reflects the regional transmission gradient between the districts (Table 3). By end-line, the prevalence in the intervention arm fell to 42.6% (298/700; 39.0–46.3), an absolute reduction of 9.3 percentage points (95% CI 4.1 to 14.5; $p < 0.001$) and a relative reduction of 17.9%. In the control arm, the prevalence rose to 65.1% (456/700; 61.5–68.6), an increase of 2.9 percentage points (95% CI –2.2 to 7.9; $p = 0.266$). Therefore, the arms diverged over the intervention period (Figure 2), and at end-line, the risk of parasitaemia in the intervention arm was 0.65 times that in the control arm (95% CI 0.59–0.72).

After accounting for the baseline imbalance, the DiD was –12.1 percentage points (95% CI –19.4 to –4.9; $z = -3.29$; $p = 0.001$). On the relative scale, the ratio of odds ratios was 0.61 (95% CI 0.45–0.82; $p = 0.001$) and the ratio of risk ratios was 0.78 (95% CI 0.68–0.90; $p < 0.001$), which indicates that the risk of parasitaemia declined by approximately 21% more in the intervention arm than the trend in the control arm would predict.

3.3 Sensitivity of the effect to intra-cluster correlation

Table 4: Difference-in-differences in malaria parasitaemia under assumed intra-cluster correlation coefficients

Assumed ICC (ρ)	DE, intervention	DE, control	DiD (pp)	95% CI (pp)	p-value
0 (unadjusted)	1.00	1.00	–12.1	–19.4 to –4.9	0.001
0.001	1.23	1.17	–12.1	–20.1 to –4.2	0.003
0.005	2.16	1.87	–12.1	–22.4 to –1.8	0.021
0.008	2.86	2.39	–12.1	–23.9 to –0.4	0.043
0.009	3.09	2.57	–12.1	–24.3 to 0.1	0.051
0.010	3.32	2.74	–12.1	–24.8 to 0.5	0.060
0.020	5.65	4.48	–12.1	–28.5 to 4.2	0.145
0.050	12.62	9.70	–12.1	–36.4 to 12.1	0.326
0.082	20.05	15.27	–12.1	–42.7 to 18.4	0.435

Note. Outcome: Malaria parasitaemia (positive RDT). $DE = 1 + (m - 1)\rho$, with $m = 233.3$ (intervention) and 175.0 (control) participants per cluster per wave. The range of ρ follows the published values for *Plasmodium* prevalence [33]. CI, confidence interval; DE, design effect; DiD, difference-in-differences; ICC, intra-cluster correlation coefficient; pp, percentage points.

Inflating the variance for clustering widened the CI of the DiD without changing the point estimate (Table 4). The DiD remained statistically significant for ICCs up to 0.008 (95% CI –23.9 to –0.4; $p = 0.043$) and lost significance at an ICC of approximately 0.009 ($p = 0.051$). At the upper end of the published range ($\rho = 0.082$), the 95% CI extended from –42.7 to 18.4 percentage points ($p = 0.435$).

4 DISCUSSION

In this cluster-randomised trial in the coastal savannah and Lower Volta of Ghana, adult parasitaemia declined by 9.3 percentage points in clusters that received the IEM package and rose by 2.9 percentage points in control clusters over the same six months. The resulting DiD of 12.1 percentage points, equivalent to a relative reduction of about one fifth beyond the control-arm trend, indicates that a community-delivered package directed at aquatic habitats was associated with lower parasitaemia in a setting where indoor tools are constrained by outdoor resting, near-equal indoor and outdoor biting, and multi-class insecticide resistance [7–9].

The absolute effect should be read against the intensity of transmission. Prevalence exceeded 40% in both arms at both waves, consistent with the high inoculation rates documented on the adjoining Volta Lake islands [11] and facility data from the neighbouring Shai-Osudoku District likewise document a persistent burden [34]. Because the relationship between the entomological inoculation rate and parasite prevalence saturates at high intensity [35], a large reduction in vectorial capacity is expected to produce a proportionally smaller fall in prevalence. In semi-immune adults, much of the infection measured in community surveys is asymptomatic and can persist for months without treatment [36,37], so six months is a short window in which to observe the clearance of established infections. HRP2 antigen also remains detectable for weeks after parasites are cleared [38], so RDT positivity lags behind changes in infection. For these reasons, the end-line survey may understate the change in transmission achieved by the intervention.

The direction of the effect differed from that reported in the most closely comparable recent trial. In Malawi, community-driven larval source management added to the national programme produced no further reduction in transmission or prevalence, but the inoculation rate fell to very low levels in all arms during follow-up, which left little residual transmission for a supplementary measure to avert [20]. The present trial was conducted where transmission was intense and largely outdoors, so a larger fraction of transmission fell beyond the reach of indoor tools [12,13]. The findings are more concordant with community-based microbial larviciding in urban Dar es Salaam [16] and with larviciding combined with insecticide-treated nets in the western Kenya highlands [17], where habitats were accessible and application was regular and supervised, and with the reproducible reductions in vector density achieved by biological larviciding in Burkina Faso [18,19]. They are also consistent with evidence that bacterial larvicides are effective and operationally feasible where habitats can be located and treated [39]. Both Cochrane reviews rated the existing evidence as of low certainty and heterogeneous [14,22]; the present estimate adds a controlled result from an under-represented ecology, but its certainty is limited by the design constraints discussed below.

The baseline imbalance, with prevalence 10.4 percentage points higher in the control arm, is expected when only two strata are randomised across a regional transmission gradient [5] and within a region where malaria is spatially heterogeneous [40]. An end-line-only comparison would have overstated the effect (–22.6 versus –12.1 percentage points), which is why the DiD was the primary contrast [30]. Because both arms were surveyed at the same points in the seasonal cycle, seasonal change is removed by the DiD, but the estimate still requires parallel trends. The increase in prevalence in the control arm is plausibly linked to the aftermath of the Akosombo Dam spillage, which flooded North Tongu, displaced households, interrupted routine services, and enlarged the surface area of standing water [28]. If the control district experienced a flood-related increase that the intervention district did not, the DiD was biased away from the null. Therefore, the estimate is best regarded as an upper bound, and the divergence of the arms is more secure than the magnitude.

Two further features of the design temper causal inference. First, because allocation was at the level of two district strata, any unmeasured district-level determinant of malaria risk is inseparable from the effect of the intervention [24]. Second, the sensitivity analysis shows that statistical significance depends on weak intra-cluster correlation: the DiD remained significant only for ICCs below approximately 0.009, whereas published values for *Plasmodium* prevalence range from 0.001 to 0.082 [33]. With so few clusters, neither individual-level models nor cluster-level permutation tests can recover this information [31,32], and only a trial with more randomised clusters can establish the precision of the effect.

The study has several strengths. It used a concurrent control arm and concealed random allocation, measured a parasitological outcome with assessors recruited from outside the study districts, identifiers that did not encode arm, used a combination RDT that is robust to *pfhrp2* deletion, achieved complete testing of the planned samples, and reported absolute and relative effects with an explicit quantification of the sensitivity to clustering. Its limitations, beyond those discussed above, should be stated. The RDT does not detect submicroscopic infections [36] and can remain positive after parasite clearance [38]. The study included only adults; therefore, the results may not transfer to children, in whom clinical disease is concentrated. The package was delivered as a whole; therefore, we cannot separate the contribution of each component. Adult vector density, sporozoite rates, and inoculation rates were not measured; therefore, the pathway from larval control to human infection was inferred rather than observed. The follow-up period was six months; therefore, the durability of the effect beyond the period of supported delivery is unknown. Finally, implementers and participants could not be blinded, although the primary outcome was objectively measured.

These findings support the evaluation of environmental management as a complement to indoor vector control in Ghana's coastal savannah and Lower Volta districts, where outdoor transmission and insecticide resistance limit current tools. This aligns with the call to elevate larval source management in Africa [13], the conditions the WHO attaches to larviciding [15], and Ghana's elimination targets for Greater Accra [6]. Evidence that community-led delivery is affordable [21] suggests that the main questions are operational rather than financial. A larger trial with more randomised clusters per arm, follow-up for at least one full transmission year, and entomological endpoints is needed to confirm the effect size.

5 CONCLUSION

In the Ada West and North Tongu Districts of Ghana, a six-month community-delivered IEM package that combined habitat modification, habitat manipulation, targeted larviciding with *Bacillus sphaericus*, and community health education was associated with a decline in adult malaria parasitaemia from 51.9% to 42.6%, while prevalence in the control district rose from 62.3% to 65.1%, which gave a difference-in-differences of 12.1 percentage points. The direction of effect was consistent across absolute and relative measures, but its magnitude is best treated as an upper bound, because only two district strata were randomised; the control district was exposed to post-flood transmission, and statistical significance was retained only under weak intra-cluster correlation. Integrated environmental

management merits a place in malaria control in Ghana's coastal savannah as a complement to indoor tools, and a multi-cluster trial with longer follow-up and entomological endpoints should confirm the effect.

STATEMENTS ON COMPLIANCE WITH ETHICAL STANDARDS

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Disclosure of conflict of interest

The authors declare no conflicts of interest regarding this manuscript

Statement of ethical approval

The Research Ethics Committee of the University of Port Harcourt (UPH/CEREMAD/REC/MM119/089) approved the study prior to its commencement. The researchers obtained administrative clearance from the District Health Administrations and District Assemblies of both districts and from the traditional authorities of each cluster. This study was conducted in accordance with the Declaration of Helsinki.

Statement of informed consent

We obtained written informed consent from all participants before administering the questionnaire and conducting rapid diagnostic testing. For non-literate participants, consent was documented via thumbprints in the presence of an impartial third-party witness. Because the intervention modified shared environmental resources, we secured additional gatekeeper permissions from the relevant district authorities and community leaders. Furthermore, we convened community assemblies in each cluster before implementation to inform stakeholders and document community-level agreements.

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