

# **Health Education Model Led by Community Health Volunteers**

**NCT06312462**

**24-August-2025**

## **Study Protocol and Statistical Analysis Plan**

### **Study Design and Sampling**

A repeated cross-sectional design compared the impact of CHVs-led (CBPR-based) health education versus traditional health education on schistosomiasis-related KAP over 12 months (February 2024 - February 2025). The CBPR approach included: (1) Needs assessment using baseline surveys; (2) Co-design of interventions with community stakeholders; (3) Implementation led by trained CHVs; and (4) Mixed-methods evaluation combining infection rates and questionnaires(Figure 1). The process emphasized cultural adaptation, community ownership, and continued improvement to ensure sustainable interventions.

### **Cluster Sampling Implementation**

A three-stage cluster sampling method was implemented:

1. School selection: Three public primary schools were randomly selected from distinct geographical regions of Pemba Island, matched for demographic characteristics (student population, gender ratio, and age distribution).
2. Cluster formation: Within each school, grades 4–6 (ages 8–16 years) were designated as natural clusters, reflecting the target population exposed to schistosomiasis transmission.
3. Participant inclusion: All students meeting eligibility criteria within selected grades were enrolled, minimizing selection bias through complete enumeration within clusters.

Intervention allocation:

- Intervention group: One school received CBPR-based education led by CHVs.

- Control group A and B: Two schools received standard health education from PHCs providers.

## **Eligibility Criteria**

- Inclusion:
  - (1) Grades 4 – 6 students aged 8 – 16.
  - (2) Written parental/guardian consent and student assent.
  - (3) Permanent residency in the school's catchment area for  $\geq 2$  years.
- Exclusion:
  - (1) Severe cognitive or communication impairments affecting questionnaire completion.
  - (2) Temporary enrollment (e.g., visiting students).
  - (3) Missing consent documentation or incomplete questionnaires.

## **Study design**

Baseline data were collected in February 2024, followed by a six-month intervention period. Post-intervention data were collected in August 2024, and a follow-up survey was conducted in February 2025 to assess the sustainability of the intervention effects. During the survey, face-to-face questionnaires were administered by CHVs to assess students' KAP related to schistosomiasis. Additionally, the research team distributed sterile wide-mouth plastic containers labeled with unique student identification numbers for morning urine sample collection. Each student provided approximately 30–50 mL of urine under teacher supervision to ensure proper collection procedures. The questionnaires, translated into Kiswahili, were pre-tested and validated. The questionnaire covered KAP of schistosomiasis transmission, exposure, and prevention. And include a survey on students' satisfaction with CHVs in the second questionnaire.

## **Laboratory procedures**

The collected urine samples were transported to the China-Zanzibar Pathogen Biology Laboratory located in Pemba Island for analysis. In the laboratory, trained technicians performed urine filtration and microscopic

examination to detect *Schistosoma haematobium* eggs. The egg counts were manually recorded on paper by the technicians and subsequently entered into a Microsoft Excel database using a double-data-entry method to ensure accuracy.

### Recruitment and Training of CHVs

Six CHVs were recruited from local communities. To ensure the quality of the intervention, CHVs participated in a two-day training workshop led by public health experts. The training covered:

- **Basic knowledge of schistosomiasis:** Life cycle, transmission routes, clinical symptoms, diagnosis, and treatment.
- **Health education skills:** Effective use of educational materials (e.g., slides, videos, microscopes), communication techniques, and interactive teaching methods.
- **Practical training:** Microscopic observation of Schistosoma eggs and intermediate host snails, role-playing, and feedback sessions.
- **Assessment:** CHVs were evaluated through written tests and simulated teaching sessions. Only those who passed the assessment were allowed to participate in the intervention.

### Structured health education sessions

The 6-month intervention (February-August 2024) featured (Table 1):

Table 1 CBPR-Integrated Schistosomiasis structured health education sessions.

Session	Core Content	CEPEM Components	Duration	Framework Alignment
1	<p>Schistosomiasis life cycle &amp; transmission</p> <ul style="list-style-type: none"> <li>• Using local water source photos</li> <li>• Analyzing common exposure behaviors (laundry, farming)</li> </ul>	<p>Community Embedding</p> <ul style="list-style-type: none"> <li>• Culturally-grounded case studies</li> <li>• Trust capital utilization</li> </ul>	2 hours	CHVs as Cultural Insiders

---

	Microscopic			
	observation of host			
	snails			
2	• Local snail specimens	Participatory Methodology	2.5 hours	Interactive Sessions
	• High-risk	• Hands-on learning		
	transmission zone			
	identification			
	Pathological impacts			
	on organs	Systems		
3	• Anatomical model demonstration	Reinforcement		Household-
	• Symptom self-check	• Household practice extension	2 hours	School Linkage
	forms			
	Prevention knowledge			
	games	Participatory		
4	• Schistosomiasis quiz	Methodology	1.5 hours	Peer-Led
	• Risk behavior simulation	• Peer-facilitated learning		Learning
	Preventive measures			
	poster exhibition	Systems		
5	• Safe water source guidelines	Reinforcement		Infrastructure
	• Hygiene practice visualization	• Infrastructure advocacy	2 hours	Advocacy
	Key message reinforcement	Community		
6	• Educational booklet distribution	Embedding		Trust Capital
		• Community	1 hours	Utilization
		resource mobilization		

---

---

- Core knowledge

- retention test

---

## Traditional Intervention

The control group schools A and B received traditional health education delivered by PHCs providers, following the standard health education practices recommended by the Ministry of Health Tanzanian, Tanzania. The health education content focused on general disease prevention and hygiene promotion, key topics included:

- Avoiding consumption of untreated water (e.g., “Do not drink untreated water from rivers, lakes, or ponds”).
- Promoting proper sanitation practices (e.g., “Do not defecate in open areas”).
- Encouraging safe recreational activities (e.g., “Avoid swimming or playing in cercaria-infested water bodies”).

## Statistical analysis

The data were double-entered into Microsoft Excel, systematically organized, coded, and verified for accuracy before being imported into IBM SPSS Statistics 26.0 for analysis. *S. haematobium* egg counts were stratified into light intensity (1–49 eggs/10 ml of urine) or heavy-intensity ( $\geq 50$  eggs/10 ml of urine) infection, based on WHO guidelines . For the KAP questionnaire: Knowledge scores were calculated based on correct responses (1 point per correct answer, maximum 10 points). Attitudes were evaluated using a 5-point Likert scale with a maximum score of 55 points. Behavioral patterns were scored according to frequency (1-3 points per item), totaling a maximum of 30 points. All scores were converted into percentage equivalents and categorized as "good" (80-100%), "moderate" (60-80%), or "poor" (<60%) . Satisfaction ratings were quantified with 1 point for "dissatisfied," 2 points for "neutral," and 3 points for "satisfied," yielding a maximum satisfaction score of 6 points.

Demographic and KAP data were analyzed descriptively: continuous variables were expressed as Mean  $\pm$  SD (normally distributed) or median [IQR] (non-normal). A two-way repeated-measures ANOVA with Bonferroni correction assessed temporal

effects (baseline/post-intervention/follow-up) and group differences. For ordinal data violating ANOVA assumptions (normality/homoscedasticity via Q-Q plots/Levene's test), the Kruskal-Wallis test was applied.