Insecticide treated eave nets and window screens for malaria control in Chalinze district, Tanzania: a study protocol for a household randomized control trial

Olukayode G. Odufuwa [1,2,4], Sarah Jane Moore [1,2,3], Zawadi Mageni Mboma [1,6], Joseph Muganga[1], Rune Bosselmann[4], Ole Skovmand[5], John Bradley [6].

1. Vector Control Product Testing Unit, Ifakara Health Institute (IHI), Tanzania.

2. Vector Biology unit, Swiss Tropical and Public Health Institute (SwissTPH), Switzerland.

3. University of Basel, Basel, Switzerland.

4. Vegro Aps, Copenhagen, Denmark.

5. Intelligent Insect Control, Montpellier, France.

6. MRC International Statistics and Epidemiology Group, London School of Hygiene and Tropical Medicine (LSHTM), London.

*Corresponding author

Email: oodufuwa@ihi.or.tz; Olukayode.Odufuwa1@lshtm.ac.uk

Abstract

Background: Long-Lasting Insecticidal nets (LLINs) have contributed to the reduction of malaria in sub-Saharan Africa, including Tanzania. However, they rely on daily user behaviour and high coverage which is difficult to maintain. Also, insecticide resistance among malaria vector mosquitoes is contributing to reduced efficacy of control tools. To overcome these problems, we propose to evaluate a new tool for house modification, the dual active ingredient (dual AI) insecticide treated eave nets (ITENs) in combination with insecticide treated window screens (ITWS) for the control of malaria.

Methods: Four hundred and fifty (450) households with intact walls, open eaves without screens or nets on the windows in Chalinze district will be eligible and recruited upon written informed consent. The households will be randomly allocated into two arms: one with ITENs and ITWS installed and the other without. Malaria parasite detection using a quantitative Polymerase Chain Reaction (qPCR) will be conducted shortly after the long rain (June/July, 2022) as the primary outcome and shortly after the short rain (January/February, 2022) as the secondary outcome. Other secondary outcomes include clinical malaria cases, and density of malaria vectors and nuisance after the short rain and long rain. In addition, surveys will be conducted in households with ITENs and ITWS to estimate the intervention's cost during installation, adverse effects after one month of installation, and presence, fabric integrity and user acceptance after six and twelve months of installation. Bioefficacy and chemical content will be evaluated after 12 months of installation.

Discussion: ITENs and ITWS have been shown in Kenya to reduce indoor mosquito density. However, it was not known if the indoor mosquito density reduction translated into reduction of malaria cases. Data from the study will measure the public health value of an additional

intervention for malaria control in areas of mosquito insecticide resistance that does not require daily adherence.

Trial registration: The study is registered on ClinicalTrials.gov.

Keywords: House modification, Malaria, Insecticide-treated nets, Eaves, Windows, Vector-borne diseases, Tanzania.

The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/). The numbers in {brackets} in this protocol refer to SPIRIT checklist item numbers.

Administrative information

Title {1}	Insecticide treated eave nets and window screens for malaria control in Chalinze district, Tanzania: a study protocol for a household randomized control trial.
Trial registration {2a and 2b}	ClinicalTrials.gov
Protocol version {3}	4th November, 2021. V06
Funding {4}	Medical Research Council Joint Global Health Trials MR/T003677/1.
Author details {5a}	Olukayode G. Odufuwa: Ifakara Health Institute (IHI), Tanzania; Swiss Tropical and Public Health Institute (Swiss TPH); London School of Hygiene and Tropical Medicine (LSHTM), London.

	Sarah Jane Moore: Ifakara Health Institute (IHI), Tanzania; Swiss Tropical and Public Health Institute (SwissTPH), Switzerland; University of Basel, Basel, Switzerland. Zawadi Mageni Mboma: Ifakara Health Institute (IHI), Tanzania; Joseph Muganga: Ifakara Health Institute (IHI), Tanzania; Rune Bosselmann: NRS Moon Netting FZE, United Arab Emirates; Ole Skovmand: Intelligent Insect Control, Montpellier, France; John Bradley: London School of Hygiene and Tropical Medicine (LSHTM), London.
Name and contact information for the trial sponsor {5b}	Ifakara Health Institute (IHI), Plot 463, Kiko Avenue Mikocheni. P.O. Box 78 373, Dar es Salaam, Tanzania. Telephone: +255 222 774756 Email: info@ihi.or.tz
Role of sponsor {5c}	Sponsor approved the study design; data collection, data management, analysis plan and protection of human participants through Ifakara Health Institute Institutional review board (IHI-IRB). No ultimate authority exists between the sponsor and funding parties. Decisions are jointly made.

Introduction

Background and rationale {6a}

Long lasting insecticidal nets (LLINs) have contributed to the large reduction of malaria globally, particularly in sub-Saharan Africa in the last decade (1). However, malaria reduction is stalled or reversed in many malaria-endemic countries, including Tanzania. Reasons for this include increasing insecticide resistance of malaria vectors (2), low access to LLIN (3), LLINs not lasting up to three years so they wear out before the next mass distribution (4) and issues on compliance (5). Therefore, additional cost-effective and long-lasting vector control tools are required that will confer protection against insecticide resistant malaria vectors, and that protect every member of the household with minimal user compliance.

The vector control tool for evaluation in this trial is the dual active ingredient (dual AI) Insecticide-Treated Eave nets (ITENs) in combination with Insecticide Treated Window screens (ITWS) for house modification (Figure 1). These can protect everyone in the house by blocking mosquito entry and providing community protection by killing mosquitos that encounter them. The tool is coated with deltamethrin insecticide and piperonyl butoxide (PBO) synergist, both are found in insecticide treated nets that are already in use in the population to control pyrethroid resistant mosquitoes (6). A great advantage is they can be used with other AIs and can be used with AIs that cannot be used on bed nets because they do not come into daily contact with users. These nets are supplied on a roll and, as shown in a study in western Kenya, can be easily applied to houses using locally available tools in just 30 minutes per house (7). The pilot study in Kenya used pyrethroid only ITENs and ITWS among eighty households and showed a 75% reduction of vector densities in the houses using ITENs, ITWS and LLINs when compared to households using LLINs only (7).

This protocol described the activities that will be implemented in a trial designed to investigate the efficacy of ITENs with ITWS on malaria parasite prevalence measured by quantitative polymerase chain reaction (qPCR), and other secondary outcomes.

Figure 1. ITENs being installed. The net is provided on a roll and takes only 30 minutes to install, but lasts more than 4 years in Kenya.

Objectives {7}

The primary objective of the trial is to investigate the efficacy of ITENs with ITWS on malaria parasite prevalence among residents aged 6 months and above, measured by quantitative polymerase chain reaction (qPCR) shortly after long rainy season (June/July 2022), and after the short rainy season (January 2022) as a secondary outcome. Other secondary objectives are to estimate the effect of the interventions on clinical malaria cases, and density of malaria vectors and nuisance (*Culex quinquefasciatus*) mosquitoes after the i) short rainy season (January/February 2022) and ii) long rainy season (June/July 2022). The cost (fabric amount and time duration) of installing the intervention, perceived adverse effects after one month of installation, and physical durability and community acceptance of the tool after 6 months and 12 months installation, as well as chemical durability after 12 months of installation.

Trial design {8}

A household randomized superiority trial of households with ITENs and ITWS compared to those without them, among villages in Chalinze district located in Pwani region, Tanzania (Figure 2). Four hundred and fifty households will be randomly allocated equally into two arms, and will be surveyed twice in the subsequent year: short rainy season (January/February 2022) and long rainy season (June/July 2022). The surveys will assess the malaria prevalence of all participants using quantitative Polymerase Chain Reaction (qPCR) (8); clinical malaria cases defined by fever and malaria rapid diagnostic test (mRDT), SD Bioline; and the density of malaria vectors and nuisance mosquitoes will be measured using Centres for Disease Control (CDC) light traps (9).

In addition, a structured questionnaire will be used to obtain the estimated: i) time and material cost of installing the tool (feasibility) during installation, ii) perceived adverse effects after one month of installation, and iii) community acceptance of ITENs with ITWS. The physical durability of the intervention will be evaluated through physical inspection of the ITENs and ITWS for the continued presence and fabric integrity. Chemical durability will be assessed using samples of netting that will be evaluated for bioefficacy using laboratory reared populations of pyrethroid resistant *An. arabiensis*, *Culex quinquefasciatus, An. funestus* as well as pyrethroid susceptible *Aedes aegypti* mosquitoes, followed by chemical testing according to standard WHO guidelines and procedures (10). In addition, the perception, use and practice of the tool will be examined through Focus Group Discussions.

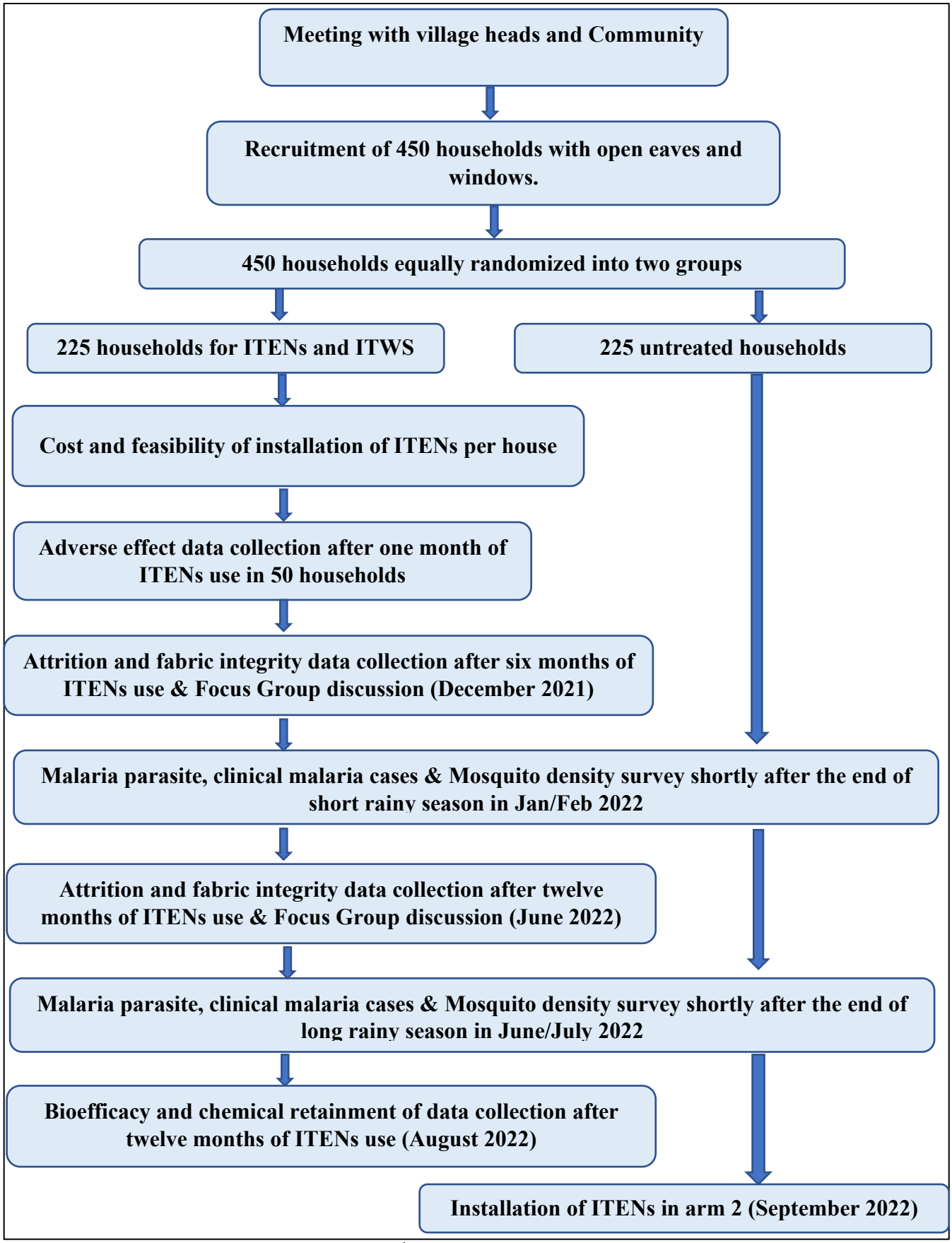

Figure 2: Trial framework

Methods: Participants, interventions and outcomes

Study setting {9}

The trial will be implemented in the villages of Pongwe, Madesa and Mazizi in Chalinze district located in coastal Tanzania. The average rainfall is 1200 to 2100 mm per year and the average temperature is approximately 28°C in the region. The region has two rainfall seasons yearly: the long rainfall from March to May and short rainfall from November to December. The main occupation for majority of the residents in villages of Chalinze is farming. The population of the study area was 13,740 while the average household size in the district was 4.5 (11). The malaria prevalence by PCR in the study area was more than 40% in the survey designed to assess gametocyte in children of age 7 years old and above (Lorenzo Hofer. *pers comm.*). More than sixty percent of houses had window screens and thirteen percent had closed eaves in a study conducted previously in the study area (11). An estimated 1800 people based on the average household size and number of households will be tested for malaria at each survey, thus, nine hundred people per arm will be screened for malaria.

Eligibility criteria {10}

Recruitment for the will be by household. To be eligible, residents must live in a house with strong (intact) walls, having open eaves and unscreened windows. Residents of study houses who are over the age of 6 months will be eligible for the follow up surveys.

Eligibility criteria for individuals who will perform the interventions

Carpenters required to install the ITENs and ITWS. Trained community technicians will be recruited from the participating villages as they are most familiar with the house structures and location. Technicians will i) collect information on the feasibility cost of installing ITENs and ITWS, ii) collect mosquitoes with CDC light traps, iii) assess attrition, fabric integrity, bioefficacy, chemical retainment, and iv) community practice and acceptance of ITENs and ITWS installed in houses. Nurses/clinical officers or clinicians that will withdraw blood samples from household members over 6 months for qPCR analysis and RDTs will also be recruited from the study villages. The purpose of recruiting these individuals from the villages is to utilize their local knowledge and community trust of these individuals as well as to contribute to building the capacity and economy of the villages where the trial will be conducted.

Who will take informed consent? {26a}

Written informed consent in the local language, Kiswahili, will be voluntarily obtained by trained field interviewers recruited from the villages. Informed consent will also be read aloud to non-literates in Kiswahili in the presence of a witness and the participant will be asked to mark a thumb impression on the form and the witness will be asked to sign to obtain acceptance of participation. Consent for household participation will be sought from heads of households that are 18 years of age and above. Additional written informed consent will be sought from individuals prior to malaria testing. Participants under 18 years old will be recruited for malaria testing upon combination of written informed consent from parent/guidance and assent from the child.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Description of use of blood for malaria diagnostic using RDT and qPCR is explained in the written informed consent. Samples will be used only for malaria screening and no samples will be stored for further tests.

Interventions

Explanation for the choice of comparators {6b}

The control arm will consist of houses satisfying the eligibility criteria and that do not receive the intervention. To estimate the additional protection of the intervention given the current malaria control tool in use in the population, houses in the same location without the intervention is ideal.

Intervention description {11a}

Intervention group

The intervention is hardwearing insecticide treated netting that is used to cover the eaves (gaps between the wall and roof) of houses and to screen windows. The insecticides coated in the ITENs and ITWS are deltamethrin at 3g AI/kg, which corresponds to 144 mg/m² and PBO synergist at 10g/kg which corresponds to 480 mg/m², as used in the so-called dual-AI LLIN or "resistance breaking" nets (6). The nets were manufactured by Moon Netting FZCO, United Arab Emirates. The combinations of deltamethrin and PBO synergist has been shown to be efficacious against pyrethroid resistant Anopheline mosquitoes and malaria (12). These nets are supplied on a roll and

attached to the wood around the roof, frame of the windows and on wood between walls using staple guns and hammer. The nets will be used to cover all obvious mosquito entry points including open eaves, windows and holes in house walls of between 10–25 cm diameter.

Criteria for discontinuing or modifying allocated interventions {11b}

Participants are free to withdraw from the study and they will be given the option to either keep the intervention or uninstall the nets from the eaves and windows. If perceived unacceptable adverse effects related to the intervention are reported by the participants, the intervention shall be removed upon the request of the participants by the study team, as this is also discussed in the Informed Consent form (Annex 1).

Strategies to improve adherence to interventions {11c}

ITENs and ITWS are hardwearing insecticide treated netting, thus minimal risk of non-adherence. Houses allocated to the negative arm will have ITENs and IWS installed at the end of the trial.

Relevant concomitant care permitted or prohibited during the trial {11d}

At each survey, clinical officers/nurses/clinicians will withdraw blood samples from all participants with an axillary temperature of 37.5 degrees or over for malaria parasites using a SD Bioline Malaria Ag Pf/Pan rapid diagnostic test (RDT) for point of care as per Tanzania Ministry of Health guidelines, and to establish clinical malaria cases. Any participant (s) that tests positive

using mRDT will be treated using free Artemether Lumefantrine (ALu). This drug is approved by the national guideline for treatment of uncomplicated malaria (13).

Provisions for post-trial care {30}

ITENs & ITWS will be installed in houses randomly selected in the negative control arm at the end of the trial to ensure that all groups have access to the intervention.

Outcomes {12}

Primary outcome

Prevalence of malaria measured by qPCR shortly after long rainy season (June/July, year 2022) in households with ITENs and ITWS installed in comparison to those without.

Secondary outcomes

- Prevalence of malaria measured by qPCR shortly after the short rainy season (January/ February 2022) in households with ITENs and ITWS installed in comparison to those without.
- Prevalence of clinical malaria cases (defined by axillary temperature of 37.5 degrees or above and positive mRDT) shortly after the short rainy season (January/February 2022) and long rainy season (June/July 2022) in households with ITENs and ITWS installed in comparison to those without.
- Density of malaria vectors and nuisance mosquitoes present in houses with ITENs and ITWS installed in comparison to the houses without after the short (January/February 2022) and long (June/July 2022) rainy season measured by CDC light trap.

- The amount of fabric and time cost of installing ITENs and ITWS per house.
- The percentage of adverse effects among technicians and houses with ITENs and ITWS after one month of installation.
- The physical presence and numbers of holes visually observed in ITENs and ITWs after 6 months and 12 months of installation.
- The percentage knockdown and mortality at 24 hours of ITENs and ITWs after 12 months of installation.
- The percentage chemical content of ITENs and ITWs after 12 months of installation.
- The percentage acceptance of ITENs and ITWS in the community using the structured questionnaire.
- The behaviour, practice and use of ITENs and ITWS in the community from FGDs.

Participant timeline {13}

		STUDY PERIOD						
	Enrolment	Allocation	Post allocation					Closeout
TIMEPOINT	May	June, 2021	Aug 2021	Dec, 2021	Jan, 2022	June, 2022	July, 2022	Sept, 22
Eligibility screen/ baseline data	X							
Informed consent /	X							
Allocation								
Installation in the intervention arm		X						
Installation in the control arm								X
ASSESSMENTS								
Perceived adverse effect			X					
50 ul blood from members of above 6 months old					X	X		
Density of malaria vectors and Nuisance mosquitoes					X	X		
Feasibility Cost		X						
Longevity, fabric integrity, community acceptance and practice.				X		X		
Bioefficacy & Chemical retainment						X		

Sample size {14}

With 225 houses per arm was an assumed 4.5 residents per household (14), then if prevalence in the control arm is 20% the study would have 90% power to detect a relative reduction of 30% to a prevalence of 14% assuming a conservative between-house coefficient of variation of 0.5.

Recruitment {15}

Once permission from the District Medical Officer and village heads is obtained, meetings with the village leaders will be convened to discuss the aim and procedures of the trial, and to select the villages where houses that meet eligibility criteria can be found. Once villages are selected, community sensitization will be conducted among all the selected villages to provide information on the purpose of the study to the people, including the adverse consequences of vector-borne diseases, the benefits and risks of using ITENs and ITWS, and caring for the intervention. This will be followed by recruitment of the households through door-to-door process, facilitated by community leaders as key informants to introduce field teams to households.

Assignment of interventions: allocation

Sequence generation {16a}

Household identification numbers stratified by sub-village will be provided to a statistician that will not be in the field during the community enrolment. Simple randomization within blocks of sub-villages to randomly allocate households between two arms will be conducted. Randomization of all study households will be done simultaneously.

Concealment mechanism {16b}

This trial will not have continuous recruitment. All households will be recruited at the start of the study and randomized simultaneously.

Implementation {16c}

After enrollment of all households by trained field workers, the trial statisticians will generate allocation sequence and assign households to interventions through randomization stratified by sub-village.

Assignment of interventions: Blinding

Who will be blinded {17a}

This is an open label trial because intervention can be visually observed.

Procedure for unblinding if needed {17b}

Not Applicable.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Quantitative data such as malaria prevalence, clinical malaria cases, mosquito density, feasibility, cost, adverse effects, attrition, integrity and use practice of the tool will be entered using Open Data Kit (ODK) (15) installed on android tablet computers. Paper data forms will be available to the field team for use in the eventuality of tablet computer failure. Data collected will be uploaded to the IHI secure data repository for data analysis as per the requirement. Qualitative data will be

audio recorded (16). Interviews will be saved in an external hard-drive and locked in a secure file cabinet. Mosquitoes will be collected using CDC light traps to measure the effect of the intervention on the density of malaria vectors and nuisance mosquitoes (9). Blood samples will be collected using New MiniCollect® K2EDTA Capillary Tube, manufactured by Greiner Bio-One, Austria. The blood samples will be kept in cool box before they are transferred to the lab for qPCR analysis. To confirm malaria cases, calibrated ear thermometer will be used to record body temperature of those with positive mRDT. The study personnel, field workers/data collectors are trained on correct data input methods to ensure data integrity.

Plans to promote participant retention and complete follow-up {18b}

Field interviewers recruited to support data collection will be from the study villages. Phases of data collection will involve door to door surveys, with respective sub-village heads guiding field interviewers to households, as participants are more likely to stay in the trial when familiar faces are involved. Achieving complete follow-up in village settings may also be influenced by time of data collection, as most of the study village residents are farmers and are more likely to be in their farms throughout the daytime during cultivation and harvesting season, therefore follow up visits for data collection will occur at a time when participants are available e.g. in the early morning or evening. Data collectors will revisit absent households to ensure completeness of data collection. However, in case of discontinuation by the participants, the information that will be recorded are date, data collectors name, house code, GPS location and consent.

Data management {19}

Data collected using the ODK application installed on tablets will be uploaded onto the IHI secured server and downloaded for analysis. Data collected using paper forms will be double entered into a computer using double-key entry methods to facilitate cross-referencing and validation. The two sets of entries will be compared, and any discrepancies found between the two databases will be resolved by checking the data forms as per analysis plan. Audio recordings and notes taken during the Focus Group Discussions will be stored securely. The data, both in hard copy and digital format, collected will be kept for the purpose of analyses until consideration and clearance of the final report.

Research records for all study participants including history and physical findings, laboratory data, and results of consultations are to be maintained in a secure storage facility for 10 years or until notified by grantee as per Tanzanian ethical guidelines. The grantee will be notified in writing and acknowledgment must be received prior to destruction or relocation of research records. All raw and cleaned data forms will be archived in the project office in a dedicated filing cabinet and all data files will be retained on the IHI central data server in accordance with IHI and Tanzania National guidelines.

Confidentiality {27}

All study related information will be stored securely at IHI. Data collectors are trained on maintaining confidentiality of study participants' information. Households and participants will be given unique identification numbers; thus, participant's study personal information will be anonymized before analysis or if data will be shared based on data sharing agreement. Personal information will only be shared based on written permission of the participant, for purposes of

independent monitoring among representatives of either government and regulatory authorities, and/or site IRBs/ECs.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Trained clinical officers/nurses/clinicians will screen for malaria parasites among all residents of study households by withdrawal of no more than 500µl of blood for dry blood spots that will be transferred to the laboratory at IHI, Kingani for detection of DNA of Plasmodium species (8) using quantitative polymerase chain reaction (qPCR) analysis. Point of care diagnosis for febrile individuals will be SD Bioline Malaria Ag Pf/Pan rapid diagnostic test (RDT) as per Tanzanian guidelines (13).

Used RDT kits will be stored in a locked shipping container at IHI until the data is completed and locked, then the samples will be destroyed on-site in the Clinical Trials facility Incinerator.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

The primary endpoint which is detection of malaria parasitemia through qPCR after the long rainy season (June/July 2022) will be analysed using mixed effects binary logistic regression, with a random effect for household to account for clustering. Analysis of secondary endpoints malaria parasitemia will be tested using qPCR after the short rainy season (January/February 2022) as well

as clinical malaria cases and malaria prevalence shortly after the short rainy season and long rainy will also be analysed following the same approach.

Negative binomial mixed effect model will be performed for mosquito density data, with random effect for household.

The baseline characteristics collected during the survey, including age, sex, education, number of participants, household size, occupation, sleeping spaces, nets per house, nature of houses (wall, roof, and floor), community acceptance of LLINs (use rate and any side effects) and socioeconomic quintiles will be presented by arm.

Principal component analysis (PCA) will be carried out to determine a combination of variables for socioeconomic status to explain the overall observed variation and reduce the complexity of the data, by calculating a weighted score for the socioeconomic status of each household of the population and divided into five quintiles: lowest, low, middle, high and highest.

Proportion of the outcomes (attrition, fabric integrity and community acceptance) will be presented in percentages.

Recorded information during the FGD will be transcribed and grouped into different themes based on inductive thematic analysis of interview summaries. Reports will be illustrated with verbatim quotes of themes and sub-themes identified.

Interim analyses {21b}

No interim analyses will be carried out.

Methods for additional analyses (e.g. subgroup analyses) {20b}

An analysis of the intervention effect within subgroups defined by age (under 5s, aged 5-15, and aged 16 or over), socioeconomic status, gender, among others will be carried out on malaria prevalence at both surveys using the same methods as for the primary endpoint.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Minimal protocol non-adherence is expected because of the nature of the intervention, however we will carry out an intention to treat in which households are analysed according to allocation regardless of whether the intervention was adhered to. A secondary per protocol analysis which excludes houses that removed the intervention will be carried out. At an individual level, participants who report being away from home for more than a week during the fortnight preceding testing will be excluded from the primary analysis but included in a secondary analysis. We expect there to be minimal missing data on the primary endpoint, in which case complete case analysis will be used. If there is more missing data than expected, a secondary analysis in which multiple imputation is applied under the assumption of missing at random will be carried out.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

Full protocol, statistical analysis plan, anonymized level-data and statistical code will be made available on reasonable request.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

The Ifakara Health Institute is the trial sponsor and coordinating centre. Study investigators meet weekly to review trial progress. A trial steering committee consisting of study investigators and independent experts will meet after every study survey.

Composition of the data monitoring committee, its role and reporting structure {21a}

Although we don't anticipate any safety issues in this trial since the intervention is similar to LLINs which are used extensively in malaria endemic regions a data monitoring committee has been appointed. The committee is composed of a clinician, an entomologist and a statistician, is independent of the trial sponsor and funder, and has no competing interests. The committee will meet after the data from each survey have been collected. The committee will consider safety data and data on trial endpoints and make recommendations on whether the trial should continue.

Adverse event reporting and harms {22}

The assessment of the risk to humans by the World Health Organization (WHO) (17) is that no unacceptable exposures were found in maintenance and use of insecticides incorporated or coated with deltamethrin and PBO synergist, and that washing or sleeping under them does not pose undue risk to adults. Moreover, there is reduced contact with ITENs and ITWs. Nevertheless, participants will be advised on possibilities of adverse effects. In case of serious adverse effect related to the

use of the study items, although not expected, affected participants will be provided with free medical care.

An assessment of adverse effects will be made using a questionnaire given in Appendix 1, and will be administered to carpenters and technicians as well as 50 randomly selected households in the village at four weeks post-installation of ITENs and ITWS. The households will be selected by the statistician using a simple random selection procedure blocked at sub-village level. The Principal Investigator shall inform the Bagamoyo District Medical Officer and the IHI ethical review board about possible reporting of adverse effects of use of ITENs and ITWS by the participants.

Frequency and plans for auditing trial conduct {23}

No trial audit is anticipated.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any protocol amendments and/or deviations will be fully justified and documented and agreed upon by the sponsor study investigators, and village representatives. Application for such protocol amendment will be written to the ethics committee and for clearance. If approval is attained from the ethics committee, the changes to the protocol will be communicated to the participants via village leaders and during study follow up.

Dissemination plans {31a}

Data will be disseminated by report to the sponsor, followed by peer-reviewed publication targeted towards consumers, scientists and policy-makers. We will publish the results and data sets in open-access, indexed, peer-reviewed journals, making the findings and the anonymized data publicly available to all stakeholders. Data obtained from the study will be presented at international conferences and stakeholder meetings including the National Malaria Control Program. At the end of the project a meeting will be held to update the local community and the District Medical Officer (DMO), to present findings and answer any questions arising.

Discussion

For malaria control, demonstrating the effectiveness of ITENs and ITWS would bring many benefits. ITENs and ITWS have the potential to be long lasting, cost-effective and protect everybody in the household at all times when they are indoors. The interventions can be fitted to any house style, unlike traditional house screening that is costly and better suited to improved housing designs. Unlike LLINs, they require no compliance from the user. Data from a pilot study in Kenya indicate that ITENs/ ITWS are far more cost-effective than LLINs, costing USD 1 - 1.75 less per household per year (assuming 3 nets and 6 people per household) due to lower material costs and improved longevity; and the saving is even greater compared to indoor residual spraying. In a separate study, the efficacy of ITENs and ITWS in the Semi Field System (SFS) setting against dengue vectors will be examined; and it is likely that ITENs and ITWS could work against other vector borne diseases such as filariasis. It is desirable as a means of preventing nuisance mosquito bites, which will likely improve uptake of the intervention. ITENs and ITWS are good candidates for deployment of new insecticides as they are not washed or in close contact with users and the fast knockdown characteristic of pyrethroids may not be required. This may offer great advantages

in insecticide resistance management, as different insecticides to those applied to LLINs can be used in further iterations of the tool once proof of efficacy. There may also be an economic boost to low-income countries that use ITENs and ITWS. Approximately 85% of the jobs associated with LLIN production are in cutting and sewing activities (fabric to finished LLIN). Since the material for ITENs and ITWS is sent on rolls and installation occurs at the site of implementation, there is a transfer of employment from the manufacturing site to the malaria endemic country.

A limitation of this trial is that randomization is at the household level rather than the village level. This means the trial will only capture direct effects of the intervention and not capture indirect effects so called "mass-effect". A trial in which villages are randomized would be substantially larger than the present trial and require much greater funding and resources. Nevertheless, this trial will gather valuable data on the efficacy of this promising intervention against both epidemiological and entomological endpoints.

Trial status

The trial protocol version number is 6 dated 4th November 2021. Recruitment of households was completed in July 2021. Households have been allocated to arms and installation of ITENs is completed in the treatment arm. Recruitment of individuals for the malaria prevalence survey will take place in January 2022.

Abbreviations

Alu: Artemether Lumefantrine

1	**AI:**	Active Ingredient
2	**ATP:**	According to Protocol
3	**CI:**	Confidence Interval
4	**CRF:**	Case Report Form
5	**DMO**:	District Medical Officer
6	**DSMB:**	Data Safety Monitoring Board
7	**GLP:**	Good Laboratory Practice
8	**HIN:**	Household Identification Number
9	**IHI:**	Ifakara Health Institute
10	**IRB:**	Institutional Review Board
11	**ITENs:**	Insecticide treated Eave Nets
12	**ITWS:**	Insecticide treated Window screens
13	**LLIN:**	Long lasting insecticidal net
14	**LTFU:**	Loss to Follow up
15	**PCR:**	Polymerase Chain Reaction
16	**PI:**	Principle Investigator
17	**RCT:**	Randomised controlled trial
18	**RDT:**	Rapid Diagnostic Test

SAE / AE: Serious Adverse Events / Adverse Events

SOP: Standard Operating Procedure

UIC: Unique Identifier Code

Declarations

Acknowledgements

Odhiambo Ojera, from the Centre for Global Health Research, Kenya Medical Research Institute, PO Box 1578, Kisumu, Kenya provided advice on the best practice to install the nets efficiently. Ms. Rose Philipo, Mr. Emmanuel Mbuba and Mr. Mgeni Muhammed from the Ifakara Health Institute were involved in the implementation of community sensitization. Mr. Selemani Mbaga provided guidance on using ODK to collect information to ensure quality data collection.

Authors' contributions {31b}

OGO is the trial coordinator; he was involved in the study design and protocol writing. SJM is the entomologist, she conceived the trial and contributed to the trial design and protocol writing. ZMM is the local principal investigator and social scientist; she was involved in the trial design and contributed to protocol writing. JM was involved in the study design and implementation. RB and OS were involved in the insecticide exploration and study design, JB is the epidemiologist and Chief Investigator, he conceived the trial, contributed to all sections of the trial and involved in the protocol writing. All authors read and approved final manuscript.

Funding {4}

The trial is funded by Medical Research Council, United Kingdon (MRC-UK) via the London School of Hygiene and Tropical Medicine (LSHTM), London with grant number MR/T0036771 & EPIDZR44.

Availability of data and materials {29}

The sponsor and funder will have access to the final trial dataset.

Ethics approval and consent to participate {24}

The trial already received ethical clearances from the Ifakara Health Institute – Institutional Review Board (IHI-IRB) referenced IHI/IRB/No: 19-2020, National Institute for Medical Research Tanzania (NIMR), Tanzania referenced NIMR/HQ/R.8c/Vol.I/885 and LSHTM Observational / Interventions Research Ethics Committee referenced 21639 - 1.

Consent for publication {32}

Consent is sought from the National Institute for Medical Research (NIMR), Tanzania.

Competing interests {28}

OGO and SJM test vector control tools for private and public companies.

References

1. PMI. Malaria Operational Plan (MOP) Tanzania 2019. 2019.
2. Matiya DJ, Philbert AB, Kidima W, Matowo JJ. Dynamics and monitoring of insecticide resistance in malaria vectors across mainland Tanzania from 1997 to 2017: a systematic review. Malar J. 2019;18(1):102.
3. Mboma ZM, Overgaard HJ, Moore S, Bradley J, Moore J, Massue DJ, et al. Mosquito net coverage in years between mass distributions: a case study of Tanzania, 2013. Malar J. 2018;17(1):100.
4. Gnanguenon V, Azondekon R, Oke-Agbo F, Beach R, Akogbeto M. Durability assessment results suggest a serviceable life of two, rather than three, years for the current long-lasting insecticidal (mosquito) net (LLIN) intervention in Benin. BMC Infectious Diseases. 2014.
5. Lindsay SW, Thomas MB, Kleinschmidt I. Threats to the effectiveness of insecticide-treated bednets for malaria control: thinking beyond insecticide resistance. The Lancet Global Health. 2021;9(9):e1325-e31.
6. Gleave K, Lissenden N, Richardson M, Choi L, Ranson H. Piperonyl butoxide (PBO) combined with pyrethroids in insecticide-treated nets to prevent malaria in Africa. Cochrane Database Syst Rev. 2018;11:CD012776.
7. Odhiambo TO, Vulule JM, Afrane YA, Ombok M, Bosselmann R, Skovmand O. Supplementary effect and durability of prototype insecticide-treated eave curtains on indoor resting mosquitoes in Kadibo division, Western Kenya. MalariaWorld Journal. 2016;7.

8. Schindler T, Robaina T, Sax J, Bieri JR, Mpina M, Gondwe L, et al. Molecular monitoring of the diversity of human pathogenic malaria species in blood donations on Bioko Island, Equatorial Guinea. Malar J. 2019;18(1):9.

9. Mboera L, Kihonda J, Braks M, Knols B. Short Report: Influence of Centers for Disease Control Light Trap position, relative to a Human-Baited Bed Net, on catches of anopheles Gambiae and culex Quinquefasciatus in Tanzania. The American Society of Tropical Medicine and Hygiene 1998:595-6.

10. WHOPES. Guidelines for laboratory and field-testing of long-lasting insecticidal nets. 2013.

11. Odufuwa OG, Ross A, Mlacha YP, Juma O, Mmbaga S, Msellemu D, et al. Household factors associated with access to insecticide-treated nets and house modification in Bagamoyo and Ulanga districts, Tanzania. Malar J. 2020;19(1):220.

12. Gleave K, Lissenden N, Chaplin M, Choi L, Ranson H. Piperonyl butoxide (PBO) combined with pyrethroids in insecticide-treated nets to prevent malaria in Africa. Cochrane Database Syst Rev. 2021;5:CD012776.

13. MoHSW. National Guidelines for Diagnosis and Treatment of Malaria. 2006.

14. Sulle E, Mkama W. A contextual analysis for village land use planning in Tanzania's Bagamoyo and Chalinze districts, Pwani region and Mvomero and Kilosa districts, Morogoro region. ILRI Project Report Nairobi, Kenya: ILRI. 2019.

15. Hartung C, Lerer A, Anokwa Y, Tseng C, Brunette W, Borriello G. Open Data Kit: Tools to Build Information Services for Developing Regions. 2010.

16. Sutton J, Austin Z. Qualitative Research: Data Collection, Analysis, and Management. PMC. 2015.

17. Organisation WH. Specifications and evaluations For Public Health Pesticides. 2012.

Appendix 1: Informed Consent Forms

INFORMED CONSENT FORM FOR HOUSEHOLDERS

Name of Principle Investigator: Dr. Zawadi Mageni Mboma

Name of Organization: Ifakara Health Institute, Bagamoyo, Tanzania

Name of Sponsor: London School of Hygiene and Tropical Medicine (LSHTM)

Household ID No. |__|__|__|__|

Part 1: Information sheet for households

Feasibility and community acceptability of Insecticide Treated Eave Nets and Insecticide Treated Window screens in Tanzania.

Introduction

My name is ……...<name of ICF administrator>. I am working for the Ifakara Health Institute, Tanzania. We are here to investigate the efficacy, community acceptability and the ease of installing a new product that is designed to prevent mosquitoes from entering the house. The name of the product is Insecticide Treated Eave Nets (ITENs) with Insecticide Treated Window screens (ITWS), they are basically nets treated with special insecticide in the factory that do not need retreatment throughout their functional life, the insecticide in them, kills mosquitoes. These nets are designed for installation on windows and eaves, to block all mosquito from entry.

Therefore, preventing you and your household members from malaria and other vector-borne diseases.

This study is meant to demonstrate if ITENs and ITWS are efficacious in controlling local strains of mosquitoes and to know the cost of installing them and if people will be willing to use them if provided for public use.

Your village has been selected for this study. We have informed the district and village leaders about the study and permission has been granted. ITENs with ITWS will be installed in your house to cover your eaves and windows to protect you and your house members from mosquito bites and to kill mosquitoes, and at the same time allowing airflow.

To understand how good these tools are in your community, we shall install ITENs with ITWS in your house, we will measure the time and economic cost it takes to install them, and we will also ask you about the tools, whether you think they are beneficial for malaria and other vector-borne diseases control and how they can be improved on for public use. We will also conduct a malaria test for you and members of your household.

Installation of ITENs and ITWS will begin immediately you agree to participate in the study, you shall provide information about your household, and after 6 months and one year, we will visit you again. We shall request for permission to come in your house to look at the condition of the ITENs with ITWS, we shall ask questions about the condition. Shortly before the end of each of the two rainy seasons from now (short rainy season in year 2021 and long rainy season in year 2022), we shall come to place CDC light traps in your house to capture mosquitoes. Also, after each of the two rainy seasons (short rainy season in the year 2021 and long rainy season in the year 2022), we shall come to conduct malaria test for you and the

members of your household. Two tests will be done, that include, RDT and dry blood spots. All these tests will involve pricking of a finger. The pricking for all these tests will only be done once. The blood will be stored for 10 years at IHI, Bagamoyo for malaria testing only, and will not be used for another test.

If you agree to participate, below are the research procedures:

1. Head or any adult member of your household will be interviewed and questions about your household's demographic and socioeconomic characteristics, house structures, sleeping arrangement, pattern of use of nets and perception on ITENs with ITWS will be asked.
2. We shall install ITENs with ITWS in your house to cover the windows and eaves.
3. The team shall visit again after one month of ITENs with ITWS installation, to interview you and your household members on experiences with the presence of ITENs and ITWS in your house.
4. After 6 months and one year of installation, the team shall visit again to check for the presence and condition of the ITENs with ITWS and you shall also be interviewed again. You or any other adult family member shall be quizzed on acceptance of the tool, handling, use and perception on the tool.
5. The interview may last about 30 minutes.
6. **Shortly before the end of the rainy seasons, we shall place CDC light traps in your household to collect mosquitoes.**
7. We shall also test all the house members for malaria shortly **after the end of 1) long rainy season, 2021, 2) short rainy season 2021 and 3) long rainy season 2022.**

8. In addition, you may also be selected to participate in a focus Group Discussion about your experience on the use of ITENs and ITWS, this will also last about 30 minutes.

Risks and adverse effects

Sleeping in houses with ITENs and ITWS will protect you from mosquito bites indoor and diseases such as malaria and dengue. However, it does not protect when you and your family are not inside the house, so it is possible you still get bitten by mosquitoes and eventually be infected with malaria. Thus, if you suffer from fever, you should immediately approach the health staff at the Government dispensary for treatment where adequate facilities exist for treatment of malaria. You may seek advice/assistance from the Ifakara Health Institute as per the contact details given below.

Deltamethrin and PBO, the insecticide used on the nets and screens, have been tested before on nets and have been found to be tolerant to human health. However, sneezing, runny nose, headache, numbness, itching, discharge from eyes, nausea, and unpleasant smell have been recorded in some people when new nets freshly taken from their package are used for the first time or few days of use. We will ask you for these symptoms, as well as any other adverse effects of using them. Although, most of these adverse effects will stop after a day or two. But, if symptoms persist for more than 48 hours, please consult a doctor at the local health facility or report to our staff immediately at the contact details given below and we will provide you with all the necessary medical care.

Benefits

ITENs with ITWS will protect you and everyone in your household from indoor mosquito bites and malaria. The information you will provide about the tools while using it will help the Institute,

stakeholders and government to know the best tool to control malaria and other vector-borne diseases in your community, Tanzania or globally.

Voluntary participation: right to refuse or withdraw consent

Your participation in the study and interviews is entirely voluntary. You are not under any obligation to participate. If at any time during the study or interviews, you decide not to participate further, you are free to withdraw immediately, with no further discussion. This will have no adverse consequences on you. The study ITENs with ITWS that have been installed in your house belong to you and are yours to keep.

Confidentiality

All information related to your participation will be kept confidential and will not be revealed to anyone, except if required by law, such as in a legal request for the list of beneficiaries. Your identity will not be revealed in any reports or publications resulting from the study. The results of the interview will be put into a computer with the code numbers of the household, but without the names of the people interviewed. The data, both in hard copy and digital format, collected will be analysed to prepare a report for the London School of Hygiene and Tropical Medicine (LSHTM) and will be archived at IHI for scientific reference.

Sharing of results

The main outcomes of the study will be communicated to all villagers in a community meeting upon completion of the study. Any important new information concerning the results of our study will be made known to you.

Who to contact

If you have any questions you may ask them now or later. If you wish to ask questions later, you may contact any of the following, **they will provide answers to your questions**:

Zawadi Mageni. Mobile no.: +255 757177155

Ms Rose Phillipo Mobile no.: +255 714583404.

Should you wish to contact any of the above-named officials on phone, you need not spend your money but approach our village-level health worker who will facilitate the phone call on our behalf.

This proposal has been reviewed and approved by Ifakara Health Institute (IHI) Institutional Review Board and the National Institute of Medical Research (NIMR) Institutional Review Board, which are committees whose task are to make sure that research participants are protected from harm.

However, if you are not satisfied with responses given by the study team, feel free to contact the representative of IHI institutional review board **Dr. Mwifadhi Mrisho**, (+255 0788766676), or NatHREC Secretariat (0222121400) National Institute of Medical Research.

We are leaving with you a copy of this informed consent form for your information and future reference.

PART 2. CERTIFICATE OF CONSENT

(This is an integral part of the information sheet and not a stand-alone document)

I have read the foregoing information, or it has been read to me in kiswahili. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to

my satisfaction. I consent voluntarily to participate as a householder in this study and understand that I have the right to withdraw from the study at any time without in any way affecting my medical care. I also understand that the Principal Investigator of the study can exclude my household from the study without my consent. I have been provided with a copy of this consent form.

Participant Name: _____

Participant Signature: _____Date _____DD/MM/YY

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Independent Literate Witness: _____

Signature of Witness: _____ Date _____DD/MM/YY

(if possible, this person should be selected by the participant and should have no connection to the research team)

Statement by the researcher/person taking consent

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Researcher: _____

Signature of Researcher: _____ Date _____DD/MM/YY

INFORMED CONSENT FORM FOR HOUSEHOLDERS FOR FOLLOW-UP ITENs SURVEY

Name of Principle Investigator: Dr. Zawadi Mageni Mboma

Name of Organization: Ifakara Health Institute, Bagamoyo, Tanzania

Name of Sponsor: London School of Hygiene and Tropical Medicine (LSHTM)

Household ID No. |__|__|__|__|

Part 1: Information sheet for households

Feasibility and community acceptability of Insecticide Treated Eave Nets and Insecticide Treated Window screens in Tanzania.

Introduction

My name is ……...<name of ICF administrator>. I am working for the Ifakara Health Institute, Tanzania. We are here to investigate the attrition, fabric integrity and community acceptability of the Insecticide Treated Eave Nets (ITENs) with Insecticide Treated Window

screens (ITWS) installed in your house. This study is meant to assess if ITENs and ITWS are still present and intact in your house.

If you agree to participate in the study, you shall provide information about your household and we shall request for permission to come in your house to assess the condition of the ITENs and ITWS and ask questions about the condition.

If you agree to participate, below are the research procedures:

1. Head or any adult member of your household will be interviewed and questions about your household's demographic and socioeconomic characteristics, house structures, sleeping arrangement, pattern of use of nets and perception on ITENs with ITWS will be asked.
2. The team shall interview you and your household members on experiences with the presence of ITENs and ITWS in your house since installation.
3. The team shall check for the presence and condition of the ITENs with ITWS and you shall also be interviewed on acceptance of the tool, handling, use and perception of the tool.
4. The interview may last about 30 minutes.
5. In addition, you may also be selected to participate in a Focus Group Discussion about your experience on the use of ITENs and ITWS.
6. We may also cut a piece of net (25cm by 25 cm) from your windows and eaves facing the east and west to check if the nets are still killing mosquitoes in the laboratory, this will be repaired with new net.

Benefits

The information you will provide about the ITENs and ITWS while using it will help the study investigators, stakeholders and government to know the best tool to control malaria and other vector-borne diseases in your community, Tanzania and other malaria endemic countries.

Voluntary participation: right to refuse or withdraw consent

Your participation in the study and interviews is entirely voluntary. You are not under any obligation to participate. If at any time during the study or interviews, you decide not to participate further, you are free to withdraw immediately, with no further discussion. This will have no adverse consequences on you. The study ITENs and ITWS that have been installed in your house belong to you and are yours to keep.

Confidentiality

All information related to your participation will be kept confidential and will not be revealed to anyone, except if required by law, such as in a legal request for the list of beneficiaries. Your identity will not be revealed in any reports or publications resulting from the study. The results of the interview will be put into a computer with the code numbers of the household, but without the names of the people interviewed. The data, both in hard copy and digital format, collected will be analysed to prepare a report for the London School of Hygiene and Tropical Medicine (LSHTM) and will be archived at IHI for scientific reference.

Sharing of results

The main outcomes of the study will be communicated to all villagers in a community meeting upon completion of the study. Any important new information concerning the results of our study will be made known to you.

Who to contact

If you have any questions or queries you may ask them now or later. If you wish to ask questions later, you may contact any of the following,

Zawadi Mageni Mboma: Mobile no.: +**255 787428218**

Ms Rose Phillipo Mobile no.: +255 714583404.

Should you wish to contact any of the above-named officials on phone, you need not spend your money but approach our village-level head who will facilitate the phone call on our behalf.

This proposal has been reviewed and approved by Ifakara Health Institute (IHI) Institutional Review Board and the National Institute of Medical Research (NIMR) Institutional Review Board, which are committees whose task are to make sure that research participants are protected.

However, if you are not satisfied with responses given by the study team, feel free to contact the representative of IHI institutional review board **Dr. Mwifadhi Mrisho**, (+255 0788766676), or NatHREC Secretariat (0222121400) National Institute of Medical Research.

A copy of this informed consent form will be left for your information and future reference.

PART 2. CERTIFICATE OF CONSENT

(This is an integral part of the information sheet and not a stand-alone document)

I have read the foregoing information, or it has been read to me in kiswahili. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a householder in this study and understand

that I have the right to withdraw from the study at any time without in any way affecting my medical care. I also understand that the Principal Investigator of the study can exclude my household from the study without my consent. I have been provided with a copy of this consent form.

Participant Name: _____

Participant Signature: _____Date _____DD/MM/YY

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Independent Literate Witness: _____

Signature of Witness: _____ Date _____DD/MM/YY

(This person should be selected by the participant and should have no connection to the research team)

Statement by the researcher/person taking consent

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Researcher: _____

Signature of Researcher: _____ Date _____DD/MM/YY

INFORMED CONSENT FORM FOR AN ADULT FOR MALARIA TESTING

Name of Principle Investigator: Dr. Zawadi Mageni Mboma

Name of Organization: Ifakara Health Institute, Bagamoyo, Tanzania

Name of Sponsor: London School of Hygiene and Tropical Medicine (LSHTM)

Household ID No. |__|__|__|__|

Part 1: Information sheet for households

Feasibility and community acceptability of Insecticide Treated Eave Nets and Insecticide Treated Window screens in Tanzania.

Introduction

My name is ……...<name of ICF administrator>. I am working for the Ifakara Health Institute, Tanzania. We are here to investigate the effectiveness of Insecticide Treated Eave Nets

(ITENs) with Insecticide Treated Window screens (ITWS) on malaria. This study is to check if the nets protect from malaria.

If you agree to participate in the study, we shall ask for your demographic information and the children in your household. We shall conduct malaria test and fever checks on you. We shall also request for your consent to conduct malaria tests and fever checking on the children in your household. Two tests will be done, that include, malaria Rapid Diagnostic Test (mRDT) and dry blood spots. All these tests will involve pricking of a finger. The pricking for all these tests will only be done once. The blood will be stored for 10 years at IHI, Bagamoyo for malaria testing only, and will not be used for another test.

If you agree to participate, below are the research procedures:

1. You shall provide your demographic information and that of your children.
2. We shall conduct malaria test on you by pricking your finger to take blood for mRDT and storage to check for malaria in the laboratory located in IHI, Bagamoyo.
3. We shall check you for fever using body thermometer.
4. We shall also conduct malaria and fever check on your children above 6 months old.
5. The procedure may last about 20 minutes.

Risks

There is no risk in pricking your finger because the kits are new and withdrawal of no more than 500µl of blood will be done. The only risk is a slight physical pain from pricking the finger when performing the screening test.

Benefits

If you or your children test positive for malaria, treatment will be offered.

Voluntary participation: right to refuse or withdraw consent

Your participation in the study and interviews is entirely voluntary. You are not under any obligation to participate. If at any time during the study or interviews, you decide not to participate further, you are free to withdraw immediately, with no further discussion. This will have no adverse consequences on you. The study ITENs with ITWS that have been installed in your house belong to you and are yours to keep.

Confidentiality

All information related to your participation will be kept confidential and will not be revealed to anyone, except if required by law, such as in a legal request for the list of beneficiaries. Your identity will not be revealed in any reports or publications resulting from the study. The results of the interview will be put into a computer with the code numbers of the household, but without the names of the people interviewed. The data, both in hard copy and digital format, collected will be

analysed to prepare a report for the London School of Hygiene and Tropical Medicine (LSHTM) and will be archived at IHI for scientific reference.

Sharing of results

The main outcomes of the study will be communicated to all villagers in a community meeting upon completion of the study. Any important new information concerning the results of our study will be made known to you.

Who to contact?

If you have any questions or queries you may ask them now or later. If you wish to ask questions later, you may contact any of the following,

Zawadi Mageni Mboma: Mobile no.: +**255 787428218**

Ms Rose Phillipo Mobile no.: +255 714583404.

Should you wish to contact any of the above-named officials on phone, you need not spend your money but approach our village-level health worker who will facilitate the phone call on our behalf.

This proposal has been reviewed and approved by Ifakara Health Institute (IHI) Institutional Review Board and the National Institute of Medical Research (NIMR) Institutional Review Board,

which are committees whose task are to make sure that research participants are protected from harm.

However, if you are not satisfied with responses given by the study team, feel free to contact the representative of IHI institutional review board **Dr. Mwifadhi Mrisho**, (+255 0788766676), or NatHREC Secretariat (0222121400) National Institute of Medical Research.

A copy of this informed consent form will be left for your information and future reference.

PART 2. CERTIFICATE OF CONSENT

(This is an integral part of the information sheet and not a stand-alone document)

I have read the foregoing information, or it has been read to me in kiswahili. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a householder in this study and understand that I have the right to withdraw from the study at any time without in any way affecting my medical care. I also understand that the Principal Investigator of the study can exclude my household from the study without my consent. I have been provided with a copy of this consent form.

Participant Name: _____

Participant Signature: _____Date _____DD/MM/YY

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Independent Literate Witness: _____

Signature of Witness: _____ Date _____DD/MM/YY

(if possible, this person should be selected by the participant and should have no connection to the research team)

Statement by the researcher/person taking consent

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Researcher: _____

Signature of Researcher: _____ Date _____DD/MM/YY

ADOLESCENT (Ages 13-17) ASSENT TO PARTICIPATE IN MALARIA TESTING

Name of Principle Investigator: Dr. Zawadi Mageni Mboma

Name of Organization: Ifakara Health Institute, Bagamoyo, Tanzania

Name of Sponsor: London School of Hygiene and Tropical Medicine (LSHTM)

Household ID No. |__|__|__|__|

<u>Part 1: Information sheet for households</u>

Feasibility and community acceptability of Insecticide Treated Eave Nets and Insecticide Treated Window screens in Tanzania.

Introduction

My name is ……...<name of ICF administrator>. I am working for the Ifakara Health Institute, Tanzania. We are here to investigate the effect of Insecticide Treated Eave Nets (ITENs) with Insecticide Treated Window screens (ITWS) on malaria. These nets were made basically not

to need retreatment throughout their functional life, the insecticide in them kills mosquitoes and the nets block all mosquito from entry. Therefore, we want to check if it can prevent people from malaria.

You have been selected to participate in this study. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes" you can still decide not to do this.

If you agree to be in this study, we shall conduct malaria tests on you and we will also check if you have fever using thermometer. Two tests will be done, that include, RDT and dry blood spots. All these tests will involve pricking of a finger. The pricking for all these tests will only be done once.

There are NO health risks associated with this particular study. The only risk is a slight physical pain from pricking the finger when performing the screening test. If you are found to be malaria positive, we will provide malaria medication for you.

Voluntary participation: right to refuse or withdraw consent

Your participation in the study and interviews is entirely voluntary. You are not under any obligation to participate. If at any time during the study, you decide not to participate further, you are free to withdraw immediately, with no further discussion. This will have no adverse consequences on you.

Confidentiality

All information related to your participation will be kept confidential and will not be revealed to anyone, except if required by law, such as in a legal request for the list of beneficiaries. Your identity will not be revealed in any reports or publications resulting from the study. The results of the interview will be put into a computer with the code numbers of the household, but without the names of the people interviewed. The data, both in hard copy and digital format, collected will be analysed to prepare a report for the London School of Hygiene and Tropical Medicine (LSHTM) and will be archived at IHI for scientific reference.

Sharing of results

The main outcomes of the study will be communicated to all villagers in a community meeting upon completion of the study. Any important new information concerning the results of our study will be made known to you.

Who to contact?

If you have any questions or queries you may ask them now or later. If you wish to ask questions later, you may contact any of the following,

Zawadi Mageni Mboma: Mobile no.: +**255 787428218**

Ms Rose Phillipo Mobile no.: +255 714583404.

Should you wish to contact any of the above-named officials on phone, you need not spend your money but approach our village-level health worker who will facilitate the phone call on our behalf.

This proposal has been reviewed and approved by Ifakara Health Institute (IHI) Institutional Review Board and the National Institute of Medical Research (NIMR) Institutional Review Board, which are committees whose task are to make sure that research participants are protected from harm.

However, if you are not satisfied with responses given by the study team, feel free to contact the representative of IHI institutional review board **Dr. Mwifadhi Mrisho**, (+255 0788766676), or NatHREC Secretariat (0222121400) National Institute of Medical Research.

A copy of this informed consent form will be left for your information and future reference.

SIGNATURE OF STUDY PARTICIPANT

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING ASSENT

In my judgment the participant is voluntarily and knowingly agreeing to participate in this research study.

Name of Person Obtaining Assent	Contact Number

Signature of Person Obtaining Assent	Date

ASSENT FOR CHILDREN 7-12 YEARS OLD TO PARTICIPATE IN MALARIA TESTING

Name of Principle Investigator: Dr. Zawadi Mageni Mboma

Name of Organization: Ifakara Health Institute, Bagamoyo, Tanzania

Name of Sponsor: London School of Hygiene and Tropical Medicine (LSHTM)

Household ID No. |__|__|__|__|

Feasibility and community acceptability of Insecticide Treated Eave Nets and Insecticide Treated Window screens in Tanzania.

1. My name is [……], I am working for the Ifakara Health Institute, Tanzania.

2. We are here to investigate the effectiveness of Insecticide Treated Eave Nets (ITENs) with Insecticide Treated Window screens (ITWS) installed in your house. These nets were made basically not to need retreatment throughout their functional life, the insecticide in them kills mosquitoes and the nets block all mosquito from entry. Therefore, we want to check if it can prevent people from malaria.

3. If you agree to be in this study, you will be requested to do malaria tests and test if you have fever. Two tests will be done, that include, RDT and dry blood spots. All these tests will involve pricking of a finger. The pricking for all these tests will only be done once.

4. There are **NO** health risks associated with this particular study. The only risk is a slight physical pain from pricking the finger when performing the screening test.

5. There will be no direct benefits towards you but your participation will help us determine exact incidence of malaria in your community. Through this information, we will be able to know if ITENs control malaria.

6. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes" you can still decide not to do this.

7. If you don't want to be in this study, you don't have to participate. Remember, being in this study is up to you and no one will be upset if you don't want to participate or even if you change your mind later and want to stop.

8. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call either of the two numbers below or ask me next time:

Dr Zawadi Mageni Mboma: Phone number: +255 0787428218

Ms Rose Phillipo – Phone number: +255 714583404

9. Signing your name at the bottom means that you agree to be in this study. In case you are found with malaria, you will be provided with ALU free of charge. You and your parents will be given a copy of this form after you have signed it.

_____ _____

Name of participant Date

INFORMED CONSENT FORM FOR MOSQUITO DENSITY SURVEY

Name of Principle Investigator: Dr. Zawadi Mageni Mboma

Name of Organization: Ifakara Health Institute, Bagamoyo, Tanzania

Name of Sponsor: London School of Hygiene and Tropical Medicine (LSHTM)

Household ID No. |__|__|__|__|

Part 1: Information sheet for households

Feasibility and community acceptability of Insecticide Treated Eave Nets and Insecticide Treated Window screens in Tanzania.

Introduction

My name is ……...<name of ICF administrator>. I am working for the Ifakara Health Institute, Tanzania. We are here to investigate the effect of Insecticide Treated Eave Nets (ITENs) with Insecticide Treated Window screens (ITWS) on mosquito density inside the house. This study is meant to know if the nets are truly preventing the mosquitoes from indoor entry.

If you agree to participate in the study, we shall install CDC light traps in your house from 18:00 to 6:00.

If you agree to participate, below are the research procedures:

1. Field team will seek for your permission to install Center for Disease Control (CDC) light traps in your house.
2. One CDC light trap will be placed at one of the sleeping spaces used in the household at the foot end of the bed, with the light source positioned at approximately 0.7m from the ground.
3. Field team will install the trap at 18:00 and collect the trap in the morning at 6:00.
4. This will only be done in your house once.

Risks and adverse effects

Installation of CDC light trap in your house do not have any risk except from the inconvenience of coming to your house in the evening and morning when you may be sleeping.

Benefits

CDC light traps will catch some of the mosquitoes that are supposed to bite you, thereby giving you and your family overnight protection from mosquitoes.

Voluntary participation: right to refuse or withdraw consent

Your participation in the study and interviews is entirely voluntary. You are not under any obligation to participate. If at any time during the study or interviews, you decide not to participate further, you are free to withdraw immediately, with no further discussion. This will have no adverse consequences on you. The study ITENs with ITWS that have been installed in your house belong to you and are yours to keep.

Confidentiality

All information related to your participation will be kept confidential and will not be revealed to anyone, except if required by law, such as in a legal request for the list of beneficiaries. Your identity will not be revealed in any reports or publications resulting from the study. The results of the interview will be put into a computer with the code numbers of the household, but without the names of the people interviewed. The data, both in hard copy and digital format, collected will be analysed to prepare a report for the London School of Hygiene and Tropical Medicine (LSHTM) and will be archived at IHI for scientific reference.

Sharing of results

The main outcomes of the study will be communicated to all villagers in a community meeting upon completion of the study. Any important new information concerning the results of our study will be made known to you.

Who to contact?

If you have any questions or queries you may ask them now or later. If you wish to ask questions later, you may contact any of the following,

Zawadi Mageni Mboma: Mobile no.: +**255 787428218**

Ms Rose Phillipo Mobile no.: +255 714583404.

Should you wish to contact any of the above-named officials on phone, you need not spend your money but approach our village-level health worker who will facilitate the phone call on our behalf.

This proposal has been reviewed and approved by Ifakara Health Institute (IHI) Institutional Review Board and the National Institute of Medical Research (NIMR) Institutional Review Board, which are committees whose task are to make sure that research participants are protected from harm.

However, if you are not satisfied with responses given by the study team, feel free to contact the representative of IHI institutional review board **Dr. Mwifadhi Mrisho**, (+255 0788766676), or NatHREC Secretariat (0222121400) National Institute of Medical Research.

A copy of this informed consent form will be left for your information and future reference.

PART 2. CERTIFICATE OF CONSENT

(This is an integral part of the information sheet and not a stand-alone document)

I have read the foregoing information, or it has been read to me in kiswahili. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a householder in this study and understand that I have the right to withdraw from the study at any time without in any way affecting my medical care. I also understand that the Principal Investigator of the study can exclude my household from the study without my consent. I have been provided with a copy of this consent form.

Participant Name: _____

Participant Signature: _____Date _____DD/MM/YY

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Independent Literate Witness: _____

Signature of Witness: _____ Date _____DD/MM/YY

(if possible, this person should be selected by the participant and should have no connection to the research team)

Statement by the researcher/person taking consent

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of Researcher: _____

Signature of Researcher: _____ Date _____DD/MM/YY