

Social group and health care provider interventions to increase the demand for malaria rapid diagnostic test among community members in Ebonyi state, Nigeria: study protocol for a cluster randomized controlled trial

Ugwu Innocent Omale (✉ ugwu.omale@fetha.gov.ng; omaleiu@gmail.com)

Federal Teaching Hospital, Abakaliki <https://orcid.org/0000-0001-6586-8992>

Ndubueze B. Azuogu

Federal Teaching Hospital, Abakaliki. Ebonyi state University, Abakaliki.

Chihurumnanya Alo

Federal Teaching Hospital, Abakaliki. Ebonyi state University, Abakaliki.

Ugochukwu C. Madubueze

Alex-Ekwueme Federal University, Ndufu Alike, Ebonyi state. Federal Teaching Hospital, Abakaliki.

Onyinyechukwu U. Oka

Federal Teaching Hospital, Abakaliki.

Chijioke K. Okeke

Federal Teaching Hospital, Abakaliki.

Ifeyinwa M. Okafor

Federal Teaching Hospital, Abakaliki.

Rowland Utulu

Nigerian Field Epidemiology and Laboratory Training Programme. Federal Teaching Hospital, Abakaliki.

Uduak E. Akpan

Federal Teaching Hospital, Abakaliki.

Chijioke V. Iloke

Federal Teaching Hospital, Abakaliki.

Ogechukwu A. Nnubia

Federal Teaching Hospital, Abakaliki.

Ifeyinwa I. Eze

Federal Teaching Hospital, Abakaliki.

Ogechukwu C. Anene

Federal Teaching Hospital, Abakaliki.

Chukwuka R. Nnabu

Government House Clinic, Abakaliki.

Desi O. Ibemesi

Federal Teaching Hospital, Abakaliki.

Study protocol

Keywords: MRDT, Demand, Social groups, Providers, Community members

Posted Date: July 16th, 2019

DOI: <https://doi.org/10.21203/rs.2.378/v2>

License:   This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Version of Record: A version of this preprint was published on October 10th, 2019. See the published version at <https://doi.org/10.1186/s13063-019-3620-0>.

Abstract

Background: The World Health Organization in 2010 recommended universal testing for suspected malaria cases due to some fundamental changes in malaria trend such as the declining malaria incidence in high burden countries, the emergence of parasite resistance to anti-malarial drugs especially artemisinin-based combination therapies (ACTs) and the increased availability of diagnostic testing such as malaria rapid diagnostic test (MRDT). The Nigerian government has long adopted this recommendation and has scaled up the availability of MRDT with the support of foreign partners. However, the malaria/MRDT test rate in the communities is still far short of the recommendation. This study aims to evaluate the effectiveness of social group and social group/provider interventions in increasing the demand (use and/or request) for MRDT among community members with fever or malaria-like illness in Ebonyi state, Nigeria. Methods: A three-arm, parallel, stratified cluster randomized design will be used to evaluate the effect of two interventions compared to control: control involves the usual practice of provision of MRDT services by public primary health care providers and patent medicine vendors; social group intervention involves the sensitization/education of social groups about MRDT; social group/provider intervention involves social group treatment plus the training of health care providers in health communication with clients about MRDT. The primary outcome is the proportion of under-5 children with fever/malaria-like illness in the preceding two weeks to a household survey that received MRDT. The co-primary outcome is the proportion of 5 years and above children and adults (excluding pregnant women) with fever/malaria-like illness in the preceding two weeks to a household survey that received MRDT. The primary outcome will be assessed through household surveys at baseline and end-line. Discussion: The pragmatic and behavioural nature of the interventions which are delivered to groupings of individuals and the need to minimize contamination informed the use of a cluster randomized design by this study in investigating whether the social group and social group/provider interventions will increase the demand for MRDT among community members. “Pragmatic” means the interventions would occur in natural settings or real live situations.

Background

The World Health Organization (WHO) in 2010 recommended that all patients suspected of having malaria receive prompt parasitological testing (with microscopy or malaria rapid diagnostic test – MRDT) to confirm diagnosis before treatment¹. Treatment based on presumptive diagnosis should only be considered when parasitological diagnosis is not accessible¹. However, patients suspected of having severe malaria, including children and high risk groups, should receive immediate treatment on presumptive grounds when parasitological diagnostic test result is delayed up to or more than two hours.¹ The WHO recommendation for universal testing is based on some fundamental changes in malaria trend worldwide such as the declining malaria incidence in high burden countries, the emergence of parasite resistance to anti-malarial drugs especially artemisinin-based combination therapies (ACTs) and the increased availability of diagnostic testing such as malaria rapid diagnostic test (MRDT).^{2,3} Though malaria parasite resistance to artemisinin-based combination therapy (ACTs) have been detected

in the Greater Mekong Area,⁴⁻⁷ ACTs are still effective because the parasite resistance manifested was either in the form of delayed parasite clearance or resistance to the partner drug.^{4,6,7} But widespread over-treatment of malaria with ACTs as a result of inaccurate presumptive diagnosis is likely to compound the problem.

The use of malaria rapid diagnostic test (MRDT) is a key part of the strategy for universal parasitological diagnostic testing recommended by the WHO^{1,2,8,9} and this has been demonstrated by some countries like Senegal^{10,11} and Lao People's Democratic Republic.¹⁰ Many countries have started emphasizing parasitological diagnostic testing as the basis for malaria treatment and have been scaling up the availability and use of MRDT especially in the public sector. It is worth noting that uptake and use of MRDT can only remedy over-treatment with ACTs when providers (and patients) respond appropriately to negative test results.¹² Accurate diagnosis of malaria is important in all settings^{1,13}: In malaria endemic setting highly sensitive diagnosis is essential especially in children in whom falciparum malaria can quickly become fatal; in all settings, highly specific diagnosis will minimize unnecessary anti-malarial treatment and improve the diagnosis of other causes of fever. The World Health Organization (WHO) recommended a policy of "test, treat and track" in 2012 to improve the quality of care and surveillance.³

Malaria is a disease of public health importance in Nigeria. It is endemic with varying endemicity and risk across the regions of the country.¹⁴⁻¹⁶ Nigeria also bears about 29 percent of the malaria burden in Africa,¹⁵ and more than 25 percent of global malaria cases and of global malaria mortality in 2015.⁴ Malaria Rapid Diagnostic Test (MRDT) was introduced in Nigeria during the period of the national malaria strategic plan 2009-2013 with the aim of extending MRDT to all public and private sector health facilities including the community level.^{14,17,18} Aligning with the WHO's Global Technical Strategy (GTS) for Malaria 2016-2030, the current national malaria strategic plan 2014-2020 aims for Nigeria to achieve a pre-elimination status and reduce malaria mortality to zero by 2020.¹⁴ One of the objectives of the 2014-2020 national malaria strategic plan is to test all care seeking suspected malaria patients with MRDT or microscopy by 2020 and the strategic actions include ensuring the availability of and access to MRDT (and or microscopy) at public and private health facilities; building the capacity of the health personnel; and creating demand for the utilization of parasitological diagnostic testing via actions targeted at both the health workers and the general public.¹⁴

The WHO's recommendation of universal parasitological testing has long been adopted by countries around the world, including Nigeria. The Nigerian government (with the support of foreign partners) has scaled up the availability of MRDT in recent years but significant challenges remain. The malaria/MRDT test rate in the communities is still unacceptably low. In the recent Nigeria Malaria Indicator Survey (NMIS) 2015,¹⁹ the proportion of febrile under-5 children (in the preceding two weeks) who were reported to have had blood taken from a finger or heel for testing (indicating a malaria test) was 13 percent nationally and 11 percent in the South-East, indicating a very low test rate in the South-East zone which includes Ebonyi state. Also, the world malaria report 2016²⁰ reported that among 22 nationally representative surveys in sub-Saharan Africa between 2013 and 2015, the median proportion of febrile

children who received a finger or a heel stick, indicating that a malaria diagnostic test was performed, was 51 percent in the public sector, 40 percent in the formal private sector and 9 percent in the informal private sector (which include the patent medicine vendors - PMVs).

Also, the scale-up have mainly been in the public health sector (and only to a lesser extent in the private sector) despite that in Nigeria the majority of febrile patients (adults and children), especially from the less educated lower socio-economic groups and in the rural settings, first seek care in the informal private sector (with the patent medicine vendors - PMVs)^{15,21-23} where they are more likely to receive inappropriate treatment for malaria^{15,21-25} usually based on presumptive diagnosis.²³⁻²⁵ This problem is similar across sub-Saharan African countries.^{4,20,26-28}

Moreover, following the recommendations of ACTs as the first-line anti-malarial drug in 2006²⁹, there have been progressive and widespread increase in the use of ACTs across Nigeria^{15,21,30} and sub-Saharan African countries^{4,20} that is associated with over-treatment (over-prescription). This has heightened the risk of selection pressure and drug resistance. Though there is increased rate of testing in the public facilities (which is still below recommendation), the test rate in the private sector, especially the informal private sector such as the patent medicine vendors (PMV) is at best negligible and the problem of non-adherence to negative test results is limiting the remedy to over-prescription of ACTs by MRDT.¹²

Patients'/caregivers' demand significantly influences providers' treatment decision-making generally³¹⁻³⁴ and providers' treatment decision-making following (negative) MRDT test results^{31,34} (as providers appear to be influenced by their perception of patients' expectations/want in cash and kind). Also, the scaling up of MRDT for universal parasitological testing requires behavioural change interventions targeted at both health care providers,^{9,34} patients, families and community members.⁹ However, there is paucity of literature on interventional studies to increase patients'/caregivers' demand for MRDT the world over. Most studies focused on the diagnostic accuracy of MRDT; uptake and use of MRDT among providers; appropriate response to negative test results; improvement of malaria treatment according to treatment guidelines; cost-effectiveness of MRDT compared to presumptive and/or microscopic diagnosis etc. This study aims to educate/sensitize social groups about MRDT and to train health care providers in health communication with patients/caregivers about MRDT to determine whether these can increase the demand (use and/or request) for MRDT among community members with fever or malaria-like illness in Ebonyi state, Nigeria. The findings will inform health policy decisions in Ebonyi state and in Nigeria as a whole in her strive to achieve universal access to parasitological diagnosis of malaria together with the global communities.

Methods/design

The study is a pragmatic, single-centre, three-arm, parallel, open-label, stratified cluster-randomized controlled trial with 1:1:1 allocation. "Pragmatic" means the study (interventions) would occur in natural settings or real live situations. A cluster is defined as a geographical community or

village(s)/settlement(s) (with at least 250 households or a population of 1,500 people) serving as the proximate catchment area for at least one public primary health facility and one patent medicine vendor (PMV) within the study sites/strata in Ebonyi state.

A three-arm parallel design, with equal number of clusters in each arm and equal sample size in each cluster, will be used to assess the effect of two interventions compared to control:

Control Arm: No intervention. This arm involves the usual practice of provision of MRDT services by individual health care providers (in public health facilities and PMVs) with basic training in MRDT. Patent medicine vendors that have offered the MRDT service previously but are not currently doing so will be re-supplied with MRDT kits to resume provision of MRDT services for the study period.

Social Group Arm: Social group intervention. This arm involves control treatment plus the sensitization and education of social groups about MRDT.

Social Group/Provider Arm: Social group/provider intervention. Control treatment, the sensitization and education of social groups about MRDT plus the training of health care providers in health communication with patients/caregivers (clients) about MRDT.

The trial protocol development was guided by the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 checklist (see Additional file 1).

Study area

The study is being conducted in three sites/strata in Ebonyi state, south-eastern Nigeria. Ebonyi state is located in the south-east geopolitical zone of Nigeria between latitude 5⁰ 40' and 6⁰ 54'N and longitude 7⁰ 30' and 8⁰ 30'E with land area of 5,953 sq. km.³⁵ It shares borders with Benue state to the north, Enugu state to the west, Cross River state to the east, Imo and Abia state to the south.^{35,36} The State lies in the Cross River plains with rainy/wet season from April to October and dry/harmattan season from October to March.³⁵ Floods often occur during the rainy season due to poor drainage systems, stagnant rivers and ponds which expose the State to mosquito infestations and high malaria burden.³⁵ The vegetation of the state is mostly savannah in the drier northern part and forests in the wetter southern part.³⁵

The state's projected population for 2016 was 2,897,401 (based on the 2006 national census figure and a growth rate of 2.8 percent) with male making up 48.62 percent, female is 51.38 percent and under-5 years age group is 20 percent.³⁵ The people of Ebonyi are primarily of the Igbo language and ethnic extraction with ten dialects/minor languages spoken across the state.³⁶ English, especially its local variant, the pidgin, is a widely spoken language in the state. People of other languages and ethnic groups in Nigeria also live in the state especially in the capital and urban areas. Most inhabitants practice Christianity.³⁶ The State is divided into 3 senatorial zones (Ebonyi north, Ebonyi central and Ebonyi south), with 13 Local Government Areas (LGSs) (with Abakaliki LGA as the administrative and political capital), 64

development centres, 138 autonomous communities and 215 political wards.³⁵ Each autonomous community has a traditional ruler and consists of autonomous villages each having a village head called chairman. Each autonomous village is made up of smaller villages or settlements each having a village/settlement head.

The public sector is the main driver of the State economy and agriculture is the major occupation.³⁶ The state has several solid mineral resources (including lead), crude oil and natural gas³⁶ but there are few large-scale commercial mines and industries.^{35,36} The state is called "the salt of the nation" because of huge salt deposit at the Okposi and Uburu Salt Lakes.³⁶ Traditional industries and works of art include blacksmithing, pottery works and wood works (carved doors, stools, walking sticks, traditional flutes, wooden mortars and pestles).³⁶

Health care in Ebonyi state (like other states in Nigeria) is provided by the public and private sectors under the overall guidance of the federal government through the federal ministry of health (and its agencies) and the national council on health. The federal government (through the federal ministry of health – FMoH) provides health services in the state through tertiary health facilities. The state government (through state ministry of health – SMoH) provides health care through secondary health facilities (general hospitals). The state government also supports the local governments in providing primary health care (PHC) through PHC facilities. The Ebonyi state Malaria Elimination Program (SMEP), within the department of public health in the state ministry of health, coordinates the efforts to combat malaria in the state.

Other health care service providers recognized by the National Health Act 2014 include the private healthcare providers, traditional healthcare providers and alternative health care providers.³⁷ These can be grouped as the private health sector and subdivided as: formal private sector (private hospitals and clinics) and informal private sector (pharmacies, patent medicine vendors (PMVs), traditional healers and alternative health care providers).⁴ Majority of febrile patients, especially from the lower socio-economic groups seek care primarily in the informal private sector.^{14,16,18}

The three study sites/strata consist of the three senatorial zones: Ebonyi north, Ebonyi central and Ebonyi south. Ebonyi north consists of four local government areas (LGAs) with a 2016 population of 998,473.³⁸ Two of these LGAs, Abakaliki LGA (the state capital) and Ebonyi LGA, have contiguous urban areas that jointly constitute the city/metropolis of Ebonyi state. However, Ebonyi north is a predominantly rural area. The vegetation is mostly savannah and it is drier than the other sites. Ebonyi central consists of four local government areas (LGAs) with a 2016 population of 861,554³⁸ and is a predominantly rural area. The vegetation changes from savannah towards forests and the weather become wetter as one move through this central zone southward towards the southern zone. Ebonyi south consists of five local government areas (LGAs) with a 2016 population of 1,037,376³⁸ and is also predominantly rural. The three sites are all endemic for malaria with year-round transmission and a high malaria burden.

Participants and participant timeline

Participants

Clusters

Clusters that will be included to participate in the study include villages/settlements (a community) that have at least one eligible public primary health care facility and one eligible patent medicine vendor (PMV) (see below) and are easily accessible (close to a motorable road) even in the rainy season. Clusters either participating in or that participated in any similar interventions within the preceding one year will be excluded from participating in the study. Clusters that are too close (less than 15kms apart), and not separated by a buffer area or natural barrier, and urban clusters (in cities/towns) will be excluded from participating in the study to minimize contamination between clusters within strata.^{39,40} Non-consenting clusters will also be excluded from participating in the study.

Social groups

Social groups are any set of persons within society with particular demographic, economic or social characteristics.⁴¹ Examples of social groups include women associations/meetings, village meetings, men associations, youth associations, market/trade unions, elders' fora, parent-teacher association etc. Social groups that are recognized by cluster heads/authorities will be included to participate in the study and non-consenting social groups will be excluded.

Primary health facilities and individual health care providers

Eligible public primary health facilities are those providing MRDT services, maternal and child health care services including immunisation; attending to at least an average of four fever cases (or suspected cases of malaria) per day and having at least two staff that are at least junior community health extension workers (JCHEWs). Individual public health care providers involved in the diagnosis (and treatment) of malaria in these facilities are eligible. Eligible patent medicine vendors (PMVs) are those with basic training in MRDT services and either currently offering or previously offered MRDT services. Non-consenting health facilities and individual providers will be excluded from the study.

Households and community members

Households will be eligible to participate in a population-based household survey if there is a report of any case of fever or suspected malaria among under-5 children, 5 years and above children, and adults (excluding pregnant women) in the household in the preceding two weeks to the survey. For each household, consent will be obtained from the mother of the house or the female primary care giver who will be the respondent to the survey. Non-consenting households will be excluded from the survey. After the baseline household survey, community members that have resided in the community for at least two

years will be eligible to participate in a focus group discussion (FGD). Non-consenting community members will be excluded from the FGD.

Participant timeline

Informed consent to participate in the study will be obtained from the selected eligible participants (clusters, social groups and providers) before clusters are randomly allocated into the three study arms. The main study outcomes will then be measures through a baseline household survey and an end-line household survey three months after the end of intervention. The participant timeline is depicted below in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guideline (see figure 1).

Interventions

The interventions in this study include: (1) the sensitization and education of social groups about MRDT (social group intervention) and (2) the sensitization and education of social groups plus the training of health care providers in health communication with client's about MRDT (social group/provider intervention). Participants in the control arm will not receive any of these interventions.

The sensitization and education of social groups

The social group intervention will involve the sensitization and education of social groups within each cluster in the social group arm. There will be three episodes of group discussion/interaction, one per month, with each social group during the intervention period of three months. Health education messages designed to change wrong beliefs and perceptions, promote right beliefs and perceptions, increase knowledge and promote key actions will be communicated to social group members in an interactive session/group discussion. The health education message is adopted from a national framework⁴² and modified for the study.

Each discussion will be a one-hour event. One investigator will moderate each discussion with a group discussion guide. In order to make the intervention more pragmatic and to optimize adherence to trial intervention, the discussions will take place at the usual meeting time of each social group, or at an agreed time, and at their usual meeting point/venue or at a central location as is most convenient for the participants. The intervention will be discontinued for a social group or cluster whenever such request is made by the respective social group head/leader or cluster head/authority. The first episode will be divided into seven sub-headings viz: (1) introduction (2) individual beliefs and opinions (3) key facts about malaria (4) key facts about MRDT (5) demonstration of testing with MRDT kit (6) key actions to practice and promote (7) closing remark. The moderator will explain the research problem and objectives to the participants and the broad role the participants (social group members) are expected to play in

addressing the problem. Each participant will then share his/her beliefs and opinion about malaria with respect to cause, symptoms, complications/fatalities, diagnosis, treatment, where to seek care and why, and prevention. The discussion will explore the reasons for and against these views and there will be questions and answers from participants. The moderator will then highlight the key facts about malaria. Key facts about MRDTs will also be highlighted and discussed. Demonstration of MRDT will be done on volunteer participants, the procedure will be explained, the results interpreted to them and those that test positive will be treated with an ACT.

The moderator will then highlight and discuss the key actions that the participants should exercise and promote as individuals, social group members, opinion leaders, parents, heads of households, family members, friends and relatives, neighbours etc. These actions include recognizing the symptoms of malaria especially in under-5 children; promptly seeking care with providers that carry out MRDT (preferably in the public primary health facilities) and requesting for the “simple test” for malaria (MRDT), receiving the test, asking for the result, and receiving treatment for malaria (with ACTs) only when the test is positive; making sure under-5 age children receives treatment within 24 hours of on-set of fever; acquiring and giving the right ACTs, in the right dose, for the right number of days. The moderator will then give a closing remark and thank the participants for their time.

The second and third episodes will take similar format as the first but will focus more on re-emphasizing the key facts and actions to practice and promote so as to reinforce participants’ knowledge and attitude. The participants will be encouraged to share their experiences in the preceding four weeks for discussion and clarifications. Visits to the social groups will end with the third episode of group discussion. However, the cell phones of the investigators will be open to group members who might still sought clarifications about malaria and MRDT during the subsequent months.

Other supportive interventions will include at least weekly reminder text messages to social group members that have cell phones; regular phone calls to social group heads (to urge them to remind and encourage the group members during meeting sessions) and regular visits by a provider (PMV or public) to the scheduled meetings of each social group for provision of MRDT services and ACTs for positive results.

The training of health care providers

The clusters in the social group/provider arm will also receive the social group treatment as described above and in addition, will receive provider training in health communication with clients. Health communication involves the use of communication strategies to inform and influence individual and community decisions that enhance health and it is a vital aspect of provider-patient relations.⁴³ The provider training will involve a one-day sensitisation and training workshop for the participating health care providers at the Abakaliki (the capital of Ebonyi state). The research team will administer the workshop with the aid of a power point projector, a provider training guide and a health communication guide. There will be a pre-post-test to assess the knowledge of participants with respect to malaria, MRDT

and communication. The training will be divided into two parts with four sessions in each. The first part will focus on sensitising the participants. The four sessions include (1) Pre-test (2) Background information: on the research problem and aim (objectives) and malaria (3) Demonstration of testing with MRDT kit (4) Key actions to practice and promote. The facilitators of the training will use a power point presentation to highlight the objectives of this part of the workshop and then to present an explanation of the problem he research wants to address and how, the objectives it hopes to achieve and the broad role the participants/providers are expected to play in this respect. Volunteer participants will then perform and receive MRDT, explain the procedure and interpret the results. This will be followed by a question and answer session on the sensitivity and specificity of MRDT, adherence to test results and what to do if result is negative, the benefits of universal testing and complete adherence to test results. The facilitators will then highlight the key actions that need to be practiced and promoted by providers. Questions and comments will be respectively answered and discussed.

The second Part of the training will focus on improving the health communication skills of participants with the aid of a health communication guide. The four sessions in this part include (1) Background information on health communication (2) Practical session (including simulation) on health communication with clients (3) Closing session and filling of assessment forms (4) Post-test. The facilitators will use power point presentation to highlight the objectives of this part of the workshop and to talk about communication and health communication with regards to definitions, communication components, process, channels/media, types, aids etc. This will be followed by a practical session and simulation of real life situation. The facilitators will then divide the participants into two groups – public provider group and private provider group. Each group will be sub-divided into clients and providers. Each client/patient sub-group will visit their respective providers with malaria-like illness. Their providers will then engage them in health communication about malaria and MRDT (with or without the use of a self-written/improvised guide). The strengths and weaknesses of each group's communication techniques during the simulation will be noted by the other group. These will be read out by a facilitator for discussion by all parties.

The facilitators will then introduce the participants to a health communication guide on how to effectively educate their clients during the discharge of their duties. They will be educated on how to use the guide in communicating with all categories of clients including those that requested for MRDT or freely accepted providers' suggestion of a test or initially declined from doing the test. The participants will then apply the guide in another round of simulation exercise. Participants will then fill an assessment form on which they will rate the training process and logistics, state what they believe or know previously that has now been corroborated, what they believe or know previously that has now been contradicted, what they just learnt for the first time, any additional key actions that can be taken or promoted to increase the use of MRDT and adherence to test results. The participants will be encouraged to use the health communication guide to effectively communicate with their clients (suspected malaria cases) about MRDT at the course of their regular duties. A facilitator will then give the closing remark and implore the participants to develop their communication skills by putting it to practice immediately.

The training workshop will be followed by a twice weekly reminder text messages and a monthly visit to each of the participating provider for supportive supervision (on-the-job training) and monitoring throughout the rest of the three month intervention period. Each support visit will aim at assessing providers' performance, exploring their experiences in the previous weeks and addressing their challenges in health communication with their clients. The on-the-job training will make the intervention more pragmatic and will optimise adherence to the trial intervention. The intervention will be discontinued for a health care provider whenever such request is made by the respective provider.

The trained providers will also be subjected to mystery client monitoring. The mystery client assessment of providers' performance will guide the researchers in properly identifying those that require more attention and in what specific areas during the support visits. Mystery clients will be trained on how to interact with providers and how to fill the assessment form thereafter. A mystery client will visit a participating provider/health facility and claim he has malaria based on familiar symptoms. If proposed by provider, he will freely accept MRDT otherwise, he will request for MRDT. He will all the while note whether the provider engaged him in health communication with basic standard techniques. He will then fill the assessment form after leaving the provider. Each provider/health facility will be visited by a mystery client at least twice.

Objectives

The primary objectives include:

To evaluate the effectiveness of the sensitization/education of social groups about MRDT (social group intervention) in increasing the demand (use and/or request) for MRDT compared to usual practice (control)

To evaluate the effectiveness of the sensitization/education of social groups about MRDT and training of providers in health communication with patients/caregivers about MRDT (social group/provider intervention) in increasing the demand for MRDT compared to usual practice (control)

To evaluate the effectiveness of the social group/provider intervention in increasing the demand for MRDT compared to the social group intervention

The secondary objectives include:

To evaluate the effect of the interventions on the care seeking practices and anti-malarial drug use pattern among community members

To assess the effect of the interventions on the knowledge and opinion of respondent female heads of households (female primary care givers) about malaria and malaria diagnosis

To evaluate the effect of the interventions on the number of suspected malaria cases visiting the public primary health centres

To assess the effect of the interventions on the knowledge and opinion of health care providers and their practice of health communication about malaria and malaria diagnosis

To evaluate the cost-effectiveness of the interventions

To assess the level of demand (use and/or request) for MRDT, care seeking practices and anti-malarial drug use pattern among community members with fever or malaria-like illness

To assess the knowledge and opinion level of female head of households (female primary care givers) and of health care providers about malaria and malaria diagnosis

To ascertain the factors that influence the demand for MRDT among community members

Hypotheses

The social group intervention is more effective (and more cost-effective) in increasing the demand (use and/or request) for MRDT compared to control.

The social group/provider intervention is more effective (and more cost-effective) in increasing the demand for MRDT compared to control and compared to social group intervention alone.

The social group intervention is expected to enhance the knowledge and opinion of community members about malaria and malaria diagnosis as well as their preference for MRDT. This will lead to a moderate increase in their demand for MRDT compared to community members in the control arm. The social groups/provider intervention is expected to (to a greater extent) enhance the knowledge and opinion of the community members and their preference for MRDT. This intervention will also enhance the knowledge and opinion of health care providers about malaria and malaria diagnosis as well as their preference for MRDT. These will lead to a large increase in the demand for MRDT among community members compared to community members in the control arm. The summary of the study's logical framework is shown in Figure 2.

Outcome measures

Primary outcome

The primary outcome is the proportion of under-5 children with fever or malaria-like illness in the preceding two weeks to a population-based household survey that received MRDT.

The co-primary outcome is the proportion of 5 years and above children and adults (excluding pregnant women) with fever or malaria-like illness in the preceding two weeks to a population-based household survey that received MRDT.

Secondary outcomes:

The main secondary outcomes at the community level include:

The proportion of these under-5 children, that received MRDT, whose caregivers requested for the MRDT

The proportion of these 5 years and above children and adults, that received MRDT, that requested for or whose caregivers requested for the MRDT

The proportion of under-5 children with fever or malaria-like illness in the preceding two weeks to a population-based household survey whose caregivers sought care with a provider, those that sought care the same or next day and among those for whom care was sought, type of provider with whom care was sought.

The proportion of these under-5 children that took any anti-malarial drug and those that took ACTs.

The proportion of 5 years and above children and adults (excluding pregnant women) with fever or malaria-like illness in the preceding two weeks to a population-based household survey that sought care with a provider, those that sought care the same or next day and among those that sought care, the type of provider with whom care was sought.

The proportion of these children and adults that took any anti-malarial drug and those that took ACTs.

The proportion of respondent female heads of households (female primary care givers) that have good knowledge and opinion about malaria and malaria diagnosis.

The secondary outcomes at the provider level include:

The number of suspected malaria cases visiting the public primary health facilities (monthly) measured using patients' register

The proportion of providers that have good knowledge and opinion and practice of health communication about malaria and malaria diagnosis.

Cost outcomes include:

Total cost of the social group and social group/provider interventions, average cost per provider who participated in the provider training and average cost per social group member who participated in the social group sensitization/education.

Measurement of study outcomes

Population-based household survey

Survey questionnaire adopted from the 2015 Nigeria Malaria Indicator Survey (NMIS)¹⁵ woman's questionnaire, and modified to collect data on both the primary and community level secondary outcomes will be pre-tested in non-participating clusters before the survey. Interviewers will be recruited and trained over a one-week period to administer the questionnaire. The training of the interviewers will include a detailed review and explanation of the questionnaire items, interview techniques, how to provide information to household respondents about the survey, how to obtain consent, the translation of key words in the questionnaire to local language and how to administer the questionnaire. Baseline survey will be carried out before intervention (see figure 1) to collect data for the assessment of the level of demand (use and/or request) for MRDT among community members with fever or malaria-like illness in Ebonyi state. A section of the questionnaire will collect data on the determinants of the demand for MRDT. End-line survey will be carried out three months after the end of intervention (see figure 1) to collect data for the evaluation of the effects of the interventions on the demand for MRDT among community members.

The interviewers will be accompanied by research supervisors at the start of the baseline survey for monitoring and supportive supervision. This will be followed by at least once weekly visit for monitoring and supportive supervision. The household survey questionnaire is designed to collect data about the following items from the respondent female head of household (the mother of the house or female primary care giver):

Basic socio-demographic characteristics (of the respondent and of eligible household members reported to have had fever/malaria in preceding two weeks)

Fever/malaria-like illness management including care seeking and demand for MRDT

Respondent's knowledge and opinion about malaria and malaria diagnosis

The determinants of the demand for MRDT

Focus group discussion (FGD)

Focus group discussions (FGDs) will be conducted at baseline to collect data on the factors that influence the demand (use and or request) for MRDT in the communities. Nine (9) focus group discussions (FGDs) will be carried out across the three study sites/strata. Participants will be purposively selected from among providers, male and female community members (who have resided in the community for at least two years). There will be three focus group discussions (FGDs) with providers, one

per stratum; three FGDs with male community members, one per stratum; three FGDs with female community members, one per stratum.

Investigators will administer the focus group discussions (FGDs) using a focus group discussion question guide prepared in English and pre-tested in non-participating clusters. The focus group discussion question guide will consist of both very open-ended and more targeted questions designed to explore the providers' and community members' knowledge and practice concerning MRDT and their perceptions on the determinants of the demand for MRDT in their communities/villages. The more targeted focus group questions are based on the proximal determinants in the study's logical framework. The more targeted questions are combined with the very open-ended questions to identify additional determinants. Before commencement of each focus group discussions (FGD), the investigators will collect background data of participants such as age, sex, level of education, occupation, years of experience with use of MRDT (for providers). Each FGD will consist of 8-10 participants and will last for about one hour. The FGD will be audio-recorded and later transcribed (and translated) verbatim into English before analysis.

Provider survey

Provider survey will be conducted at baseline and end-line (three months after the end of intervention) to collect data for the assessment of the effect of the interventions on the knowledge and opinion of health care providers and their practice of health communication about malaria and malaria diagnosis. The provider survey questionnaire is similar to the household questionnaire and is modified to collect data about the following items from the health care providers:

Basic socio-demographic characteristics

Knowledge and opinion about malaria and malaria diagnosis

The practice of health communication about malaria and malaria diagnosis

The determinants of the demand for MRDT

Review of patient register and personal medical records

Patient registers are routinely kept by public primary health facilities. The following relevant data are contained in the registers: patient's biodata (name, age, sex, address etc), date, symptoms, type of test done, test result, type of drug given. The participating patent medicine vendors (PMVs) will be asked to keep similar records. The registers will be used by the research team for monitoring, supportive supervision and evaluation. The investigators will review the patient registers for the nine months pre-intervention and nine months post-end-of-intervention records. The document review will provide data for

evaluating the effect of the interventions on the number of suspected malaria cases visiting the public primary health centres.

Documentations of the implementation/intervention process

The process of implementation of the study will be documented including challenges encountered and how these were addressed. The social group and provider intervention processes will be documented and/or recorded with respect to the name of the participants, participants' phone number/contact, individual contributions, participants' observations and evaluation of the intervention logistics and suggestions etc. The study personnel and the organisers of the interventions will also record their experience on challenges and possible solutions. These data will be used for monitoring and to guide the implementation of similar interventions in the future.

Costing of the intervention process

Direct and indirect costs of the intervention process will be assessed from the perspective of the implementer of intervention and that of the recipient of intervention (the societal perspective) using standard economic evaluation methods. Cost data will be estimated primarily from the documentation of the implementation/intervention process and the project financial accounts. The costing will be guided by the research budget.

Data management plan and quality assurance

During the household surveys, the research supervisors will revisit an average of thirty households in each participating cluster with a specially designed questionnaire to double check on responses and coverage. The supervisors will collect completed questionnaires from the interviewers weekly and crosscheck/review for internal consistency and completeness. Questionnaires with internal inconsistencies and or missing data will be returned to the respective field staff for correction with the respective respondent. The questionnaires will be serially (and uniquely) numbered and data will be double-entered using Microsoft Excel 2007 (Microsoft Inc., Redmond, Washington) and will be verified using Stata version 15 (Stata Corp, College Station, TX, USA). The datasets compare utility in Stata will be used to verify the datasets and any discrepancies identified will be crosschecked against the corresponding original questionnaire and corrected before analysis. The variables and data in the dataset will also be examined in details and range checks will be done to ensure the data entry was done correctly and appropriately.

The audio recordings of the focus group discussions (FGDs) will be transcribed (verbatim) within 24 hours of recording and translated into English before analysis. The questionnaires, the audio recordings

and the verbatim transcript of the focus group discussions (FGDs) will be stored in secure area while the electronic data file will have a back-up file. Access to study materials and data files by unauthorized persons will be prevented.

Sample size

After comparing the required sample size for each of the primary objectives, the largest sample size will be used. This is based on the primary objective to evaluate the effectiveness of the social group/provider intervention compared to the social group intervention in increasing the demand for MRDT in the communities. The sample size is estimated using the methods recommended for stratified cluster randomized trial^{39,40} and will be based on the primary outcome of the proportion of under-5 children with fever or malaria-like illness in the preceding two weeks to a population-based household survey that received MRDT. A plausible estimate of the primary outcome of 11% in the control arm, based on the reported value for the South-East zone (that includes Ebonyi state) in the Nigeria Malaria Indicator Survey (NMIS) 2015¹⁵, will be used.

Assuming a coefficient of variation between clusters within strata of 0.16, a sample size per cluster of 40 eligible under-5 children, 80% power at 5% probability of type I error, the trial will require 6 clusters per arm to detect a difference of 20% in the primary outcome between the control arm and the social group arm (an increase from 11% to 31%) and a difference of 20% between the social group arm and the socio group/provider arm (an increase from 31% to 51%). A sample size per cluster (cluster size) of 40 subjects with 6 clusters per arm gives a total cluster number of 18, with 240 subjects per arm and a total sample size of 720 subjects. The sample size per cluster (of 40) will be increased by 20% (to 50) to compensate for any probable invalid records and other field eventualities. This gives a final cluster size of 50 subjects with 300 subjects per arm and a total sample size of 900 subjects.

The same sample size will be used to assess the co-primary outcome of the proportion of 5 years and above children and adults (excluding pregnant women) with fever or malaria-like illness in the preceding two weeks to a population-based household survey that received MRDT. Equal number of clusters (6) will be allocated to each arm and to each stratum and, despite variations in population size of clusters, equal number of fixed sample size (of 50 for each target population) per cluster will be used to optimize statistical efficiency.^{39,40}

Sample size is estimated for the provider survey to give the expected level of precision (at 95% confidence level) for determining the proportion of providers that have good knowledge and opinion about malaria and malaria diagnosis. Based on the number of clusters (6) allocated to each arm and about 7-8 individual providers per cluster who consented to participate in the study, we expect to survey 42 providers per arm (7 per cluster). Assuming the outcome measure of 50% in each of the control and social group arms and 70% in the social group/provider arm, with an intracluster correlation coefficient

(ICC) of 0.01, we can estimate the true outcome measure with $\pm 15.6\%$ precision in each of the control and social group arms and $\pm 14.3\%$ precision in the social group/provider arm.

Sampling technique (recruitment)

Stratified multistage (cluster) sampling will be employed. Eighteen clusters will be randomly selected from a list of eligible clusters across three strata (6 in each stratum) using the “sample” command in Stata. To enhance reproducibility, random-number seed will be set using the “set seed” command before running the “sample” command. If written consent is not provided by any of the selected cluster(s) before randomization, replacement cluster(s) will be randomly selected from the remaining list of eligible clusters using same technique. The summary of the trial profile is shown in figure 3.

Within the selected clusters, an average of four eligible social groups per cluster will be purposively selected and non-consenting social group(s) prior to randomization will be replaced. All eligible and consenting health facilities and the individual providers involved in the diagnosis and treatment of suspected malaria cases will be selected across clusters before randomization. A number of eligible individual providers and community members, who have resided in the community for at least two years, will be purposively selected for the focus group discussion. All the households in the selected clusters will be enumerated and screened for inclusion during the pre- and post-intervention surveys. If the required sample size is not reached after the interviewers have reached the end of the enumerated households, non-eligible households will be revisited and re-assessed to see whether they have become eligible.

Randomization

Randomization will be done using Stata version 12 (Stata Corp, College Station, TX, USA). Stratified randomisation technique will be used to assign the 18 clusters across the three strata to the three treatment arms, after written consent is obtained from all recruited participants, by a statistician that will not otherwise take part in the study. The 6 clusters within each stratum will be randomly allocated to the three study arms in the ratio of 2:2:2 using a programme written in Stata. To ensure the desired balance in cluster number in the study arms, restricted randomization technique will be employed for the within strata allocation. The summary of the trial profile is shown in figure 3.

It will not be possible to blind the interviewers that will administer questionnaires in the household survey and the respondent female heads of households because of the pragmatic nature of the trial as they could acquire treatment knowledge from informal sources or grapevine. Some of the respondents could also be social group members or providers. It will also not be possible to blind the investigators that will administer intervention or participants that will receive intervention (social groups and providers).

Data analysis

Data will be double-entered using Microsoft Excel 2007 (Microsoft Inc., Redmond, Washington) and analyzed using Stata version 15 (Stata Corp, College Station, TX, USA). Since the number of subjects/household members about whom data will be collected is expected to vary across clusters (due to the method employed for household survey), the “sample” command will be used to randomly select equal number of subjects across clusters for the analysis. All analyses will be by intention-to-treat.

The effect of the interventions on the primary outcomes will be analyzed using cluster-level methods for stratified cluster randomized trials with small number of clusters per treatment arm.^{39,40} Point estimates of the intervention effects (risk difference) in each intervention arm compared to control and in both intervention arms compared to each other, will be computed from the unweighted mean of cluster-level summaries (proportions) of the outcome measures in each study arm. But since the cluster size (sample size across clusters) is constant, this point estimate will be identical to that obtained from the weighted average of individual values.^{39,40} Also, since the number of clusters across strata is constant, the estimated risk difference will be identical to the weighted average of stratum-specific risk difference.

An overall test of the null hypothesis of no difference between any of the study arms will be conducted in a two-way analysis of variance (2-way ANOVA) of the cluster-level proportion on stratum and treatment arm. This overall test is to guide the interpretation of any subsequent significant findings in pair-wise comparisons. If the distribution of the cluster summaries in each study arm is markedly skewed, logarithmic transformation may be considered before analysis. Before conducting pair-wise significance testing and computing a confidence interval, an estimate of the within-stratum between-cluster variance will be obtained as the residual mean square from a two-way analysis of variance of the cluster-level proportions on stratum and treatment arm, including interaction terms. The within-stratum between-cluster variance will then be used in a stratified t-test to tests the null hypotheses of no difference in the primary outcomes between each intervention arm and the control and between both intervention arms. It will also be used in computing the corresponding 95% confidence interval of each risk difference.

Adjusted analysis based on cluster summaries will be done in a two-staged procedure. In the first stage, covariate-adjusted residual will be obtained for each cluster using standard multiple linear regression analysis, incorporating the stratum (as a fixed effect) and all baseline cluster-level covariates of interest but excluding the intervention effect. The potential baseline covariates of interest will include cluster-level summaries of the primary outcome measures, mean knowledge and opinion score of respondents (about malaria and malaria diagnosis) and other baseline variables found to differ between the study arms and which can be determinants of a particular outcome. Only cluster-level summaries of baseline covariates will be used in the adjusted analysis because baseline and follow-up data will be on different individuals since the study employed a repeated cross-sectional design.^{39,40} The difference-residual for each cluster will be obtained as the difference between the observed outcome in each cluster and the predicted outcome in the absence of intervention effect. The covariate-adjusted residuals will replace the cluster-level proportions in the second stage in estimating the intervention effects which are thus adjusted for the covariates in the first stage.

The same cluster-level methods will be used to evaluate the effect of the interventions on the secondary outcomes. Comparative analysis of baseline data will be used to assess the balance between the treatment arms and potential baseline variables that will be reported include the cluster-level and individual-level summaries of the primary and secondary outcome measures, the age and sex of individual subjects, the respondent female head of household's age, educational level, occupation, knowledge and opinion level about malaria and malaria diagnosis, and average knowledge and opinion score. Summary statistics of baseline data will be used to assess the level of demand for MRDT, care seeking practices and anti-malarial drug use pattern among community members with fever or malaria-like illness; the knowledge and opinion level of female head of households about malaria and malaria diagnosis; the knowledge and opinion level of health care providers about malaria and malaria diagnosis.

To ascertain the factors that influence the demand for MRDT in the communities, a thematic analysis of the focus group discussions (FGDs) will be done using the method recommended by Braun and Clarke.⁴⁴ The audio recordings of the focus group discussions (FGDs) will be transcribed (and translated) verbatim into English and the transcript will be compared with the original recording to check for 'accuracy' before conducting the analysis. Exact and meaning-based translation will be used. QDA Miner Lite 2 (by Provalis Research) will be used to manage the coding and analysis process.

Discussion

This study, in investigating whether the social group and social group/provider interventions will increase the demand for malaria rapid diagnostic test among community members, is using a cluster randomized design due to its pragmatic nature, as it is occurring in natural settings, and to minimize contamination since the interventions are behavioural and are delivered to groupings of individuals. The research team is collaborating with the Ebonyi State Malaria Eradication Programme (SMEP) to enhance successful implementation of the study. Continuous collaboration with the Ebonyi SMEP, and by extension the National Malaria Elimination Programme (NMEP), will provide an opportunity for the study findings to contribute to both state and national policies that will enhance the realisation of universal parasitological diagnostic testing for suspected cases of malaria. A potential limitation of this study is due to the fact that the study will, in most part, involve interviewing respondents about past behaviour and will thus be subject to recall bias. However, as the time period is short (two weeks) the bias will be minimal. Any significant amendments to the trial protocol after protocol publication will be reported to the research and ethics committees and the registry body. Study results will be reported at local, national and international levels including via peer-reviewed journals, national and international conferences.

Trial status

The trial is ongoing. Recruitment of participants began on 27/08/2018 and is expected to end by 29/06/2019. Protocol version: Original. Date: 24 August, 2018.

List Of Abbreviations

MRDT: Malaria rapid diagnostic test; ACTs: Artemisinin-based combination therapies; PMVs: Patent medicine vendors; WHO: World health organization.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from Research and Ethics Committee of the Federal Teaching Hospital Abakaliki (FETHA) with REC Approval Number: 11/07/2018-23/07/2018 (see Additional file 2) and the Ethical Review Committee of the Ebonyi State Ministry of Health with Reference Number: SMOH/ERC/036/018 (see Additional file 3). Written informed consent will be obtained from selected participants prior to randomization. The investigators will obtain informed consent from cluster heads/authorities, leaders of social groups, owners/heads of health facilities (where appropriate) and individual health care providers who will each sign two consent forms (one for the investigator and one for the participant). The purpose and nature of the study/intervention including participants' right to seek clarification or withdraw from the study at any time will be effectively communicated to participants as required. Informed consent will also be obtained from respondent female heads of households (by interviewers) and focused group discussion participants (by the investigators) prior to data collection. The research records and results will be strictly protected from outsiders. Research records will be stored in secure area and access to study materials and data files by unauthorized persons will be prevented. Even though the results from the research may be published, no personal information that can be used to identify individual community members/participants will be included.

Consent for publication

Not applicable.

Availability of data and material

The datasets used and/or analysed during the current study will be available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This study is funded by the authors.

Authors' contributions

UIO conceived and designed the study, drafted the original protocol and drafted the manuscript. NBA, CA, UCM, OUO, CKO, IMO, and RU contributed to the study design and drafting of the original protocol. UEA, CVI, OAN, IIE, OCA, CRN and DOI contributed to the study design and the final version of the protocol. All authors read and approved the final manuscript.

Acknowledgements

We acknowledge the staff of the Ebonyi State Malaria Elimination Programme (SMEP) for their collaboration with the research team. We particularly acknowledge the Ebonyi State Malaria Elimination Programme manager, Mr Nwankwo L. O. for his support and assistance. We also acknowledge the malaria focal persons for the local government areas for their assistance.

References

1. World Health Organization (WHO). Guidelines for the treatment of malaria. 2nd ed. Geneva: WHO; 2010.
2. WHO. Universal access to malaria diagnostic testing: an operational manual. Malta: WHO; 2011.
3. WHO. Scaling up diagnostic testing, treatment and surveillance for malaria. Geneva: WHO; 2012.
4. WHO. World malaria report 2015. Geneva: WHO; 2015.
5. WHO. Eliminating malaria. Geneva: WHO; 2016.
6. Global Malaria Programme. Artemisinin and artemisinin-based combination therapy resistance. 2016.
7. WHO. Global plan for artemisinin resistance containment (GPARC). Geneva: WHO; 2011.
8. WHO. Malaria Rapid Diagnostic Test Performance: Result of WHO product testing of malaria RDTs: round 6 (2014-2015). Italy: WHO; 2015.
9. Bastiaens GJH, Bousema T, Leslie T. Scale-up of malaria rapid diagnostic tests and artemisinin-based combination therapy: Challenges and perspectives in sub-Saharan Africa. *PLoS Med.* 2014;11(1):e1001590.
10. WHO. World malaria report 2010. Geneva: WHO; 2010.

11. Thiam S, Thior M, Faye B, Ndiop M, Diouf ML, Birame M, et al. Major Reduction in Anti-Malarial Drug Consumption in Senegal after Nation-Wide Introduction of Malaria Rapid Diagnostic Tests. *PLoS One*. 2011;6(4):e18419.
12. Cohen J, Dupas P, Schaner S. Price Subsidies, Diagnostic Tests, and Targeting of Malaria Treatment: Evidence from a Randomized Controlled Trial. *Am Econ Rev*. 2015;105(2):609–45.
13. WHO. Guidelines for the treatment of malaria. 3rd ed. Geneva: WHO; 2015.
14. Federal Ministry of Health (FMoH) and National Malaria Control Programme (NMCP). National malaria strategic plan 2014-2020. 2015.
15. National Malaria Elimination Programme (NMEP); National Population Commission (NPC); National Bureau of Statistics (NBS) and ICF International. Nigeria malaria indicator survey (NMIS) 2015. Abuja, Nigeria, and Rockville, Maryland, USA: NMEP, NPC, and ICF International; 2016.
16. NMCP/suMAP/WHO/the INFORM Project. A description of the epidemiology of malaria to guide the planning of control in Nigeria. A report prepared for the Federal Ministry of Health, Nigeria, the Roll Back Malaria Partnership and the Department for International Development. UK. November, 2013;
17. Federal Ministry of Health (FMoH)/National Malaria Control Programme. Strategic plan 2009-2013: A road map for malaria control in Nigeria. 2008.
18. Federal Ministry of Health (FMoH) and National Malaria Elimination Programme (NMEP). Implementation guide for parasite-based diagnosis of malaria. Abuja; 2015.
19. National Malaria Elimination Programme (NMEP); National Population Commission (NPopC); National Bureau of Statistics (NBS); and ICF International. Nigeria malaria indicator survey (MIS) 2015. Abuja, Nigeria, and Rockville, Maryland, USA: NMEP, NPopC, and ICF International; 2016.
20. WHO. World malaria report 2016. Geneva; 2016.
21. National Population Commission (NPC) [Nigeria] and ICF International. Nigeria demographic and health survey 2013. Abuja, Nigeria, and Rockville, Maryland, USA; 2014.
22. National Malaria Elimination Programme (NMEP); National Population Commission (NPC) and ICF International. Nigeria malaria indicator survey (NMIS) 2010. Abuja, Nigeria: NPC, NMCP, and ICF International; 2012.
23. Isiguzo C, Anyanti J, Ujuju C, Nwokolo E, Cruz AD La, Schatzkin E, et al. Presumptive treatment of malaria from formal and informal drug vendors in Nigeria. *PLoS One*. 2014;9(10):e110361.
24. Ikwuobe JO, Faragher BE, Alawode G, Lalloo DG. The impact of rapid malaria diagnostic tests upon anti-malarial sales in community pharmacies in Gwagwalada, Nigeria. *Malar J*. 2013;12:380.

25. Liu J, Isiguzo C, Sieverding M. Differences in malaria care seeking and dispensing outcomes for adults and children attending drug vendors in Nasarawa, Nigeria. *Trop Med Int Heal*. 2015;20(8):1081–92.
26. Rutebemberwa E, Pariyo G, Peterson S, Tomson G, Kallander K. Utilization of public or private health care providers by febrile children after user fee removal in Uganda. *Malar J*. 2009;8:45.
27. Nonvignon J, Aikins MKS, Chinbuah MA, Abbey M, Gyapong M, Garshong BNA, et al. Treatment choices for fevers in children under-five years in a rural Ghanaian district. *Malar J*. 2010;9:188.
28. Littrell M, Gatakaa H, Evance I, Poyer S, Njogu J, Solomon T, et al. Monitoring fever treatment behaviour and equitable access to effective medicines in the context of initiatives to improve ACT access: baseline results and implications for programming in six African countries. *Malar J*. 2011;10:327.
29. WHO. Guidelines for the treatment of malaria. 1st ed. Geneva: WHO; 2006.
30. Ezenduka CC, Ogbonna BO, Ekwunife OI, Okonta MJ, Esimone CO. Drugs use pattern for uncomplicated malaria in medicine retail outlets in Enugu urban , south-east Nigeria: Implications for malaria treatment policy. *Malar J*. 2014;13(243):1–10.
31. Wiseman V, Ogochukwu E, Emmanuel N, J ML, Bonnie C, Jane E, et al. A cost-effectiveness analysis of provider and community interventions to improve the treatment of uncomplicated malaria in Nigeria: study protocol for a randomized controlled trial. *Trials*. 2012;13:81.
32. Mangham LJ, Cundill B, Ezeoke O, Nwala E, Uzochukwu BSC, Wiseman V, et al. Treatment of uncomplicated malaria at public health facilities and medicine retailers in south-eastern Nigeria. *Malar J*. 2011;10:155.
33. Onwujekwe O, Uzochukwu B, Dike N, Uguru N, Nwobi E, Shu E. Malaria treatment perceptions, practices and influences on provider behaviour: comparing hospitals and non-hospitals in south-east Nigeria. *Malar J*. 2009;8:246.
34. Altaras R, Nuwa A, Agaba B, Streat E, Tibenderana JK, Strachan CE. Why do health workers give anti-malarials to patients with negative rapid test results? A qualitative study at rural health facilities in western Uganda. *Malar J*. 2016;15:23.
35. Ebonyi State Ministry of Health. 2016 annual operational plan for malaria elimination programme. Abakaliki; 2016.
36. Government of Ebonyi State. Ebonyi State profile. 2015. <http://www.ebonyistate.gov.ng/profile.aspx>. Accessed 11 Feb 2017.
37. Federal Government of Nigeria (FGN). The national health Act, 2014. Lagos, Nigeria: FGN; 2014.

38. Ebonyi State Ministry of Health. Ebonyi state district health information system (DHIS): Ebonyi 2016 population. 2016.
39. Hayes RJ, Moulton LH. Cluster randomised trials. 1st ed. Boca Raton: CRC Press; 2009.
40. Hayes RJ, Moulton LH. Cluster randomised trials. 2nd ed. Boca Raton: CRC Press; 2017.
41. WHO. A glossary of terms for community health care and services for older persons. Japan: WHO; 2004.
42. Federal Ministry of Health (FMoH) and National Malaria Control Programme (NMCP). Advocacy, Communication and Social Mobilisation (ACSM) Strategic Framework and Implementation plan. Abuja, Nigeria: FMoH; 2010.
43. U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion. Healthy people 2010. 2000. Volumes 1 and 2, Chapt. 11, pp. 11-3.
44. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77–101.

Figures

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					
			Baseline survey	Intervention			Post-intervention period	End-line survey
TIMEPOINT	-3 months	0	1-2 months	2 month	3 month	4 month	5-7 months	8-9 months
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
Allocation		X						
INTERVENTIONS:								
<i>Social group intervention</i>				←————→				
<i>Social group/provider intervention</i>				←====→				
ASSESSMENTS:								
<i>Baseline survey</i>			X					
<i>End-line survey</i>								X

Figure 1

Schedule of enrolment, interventions, and assessments.

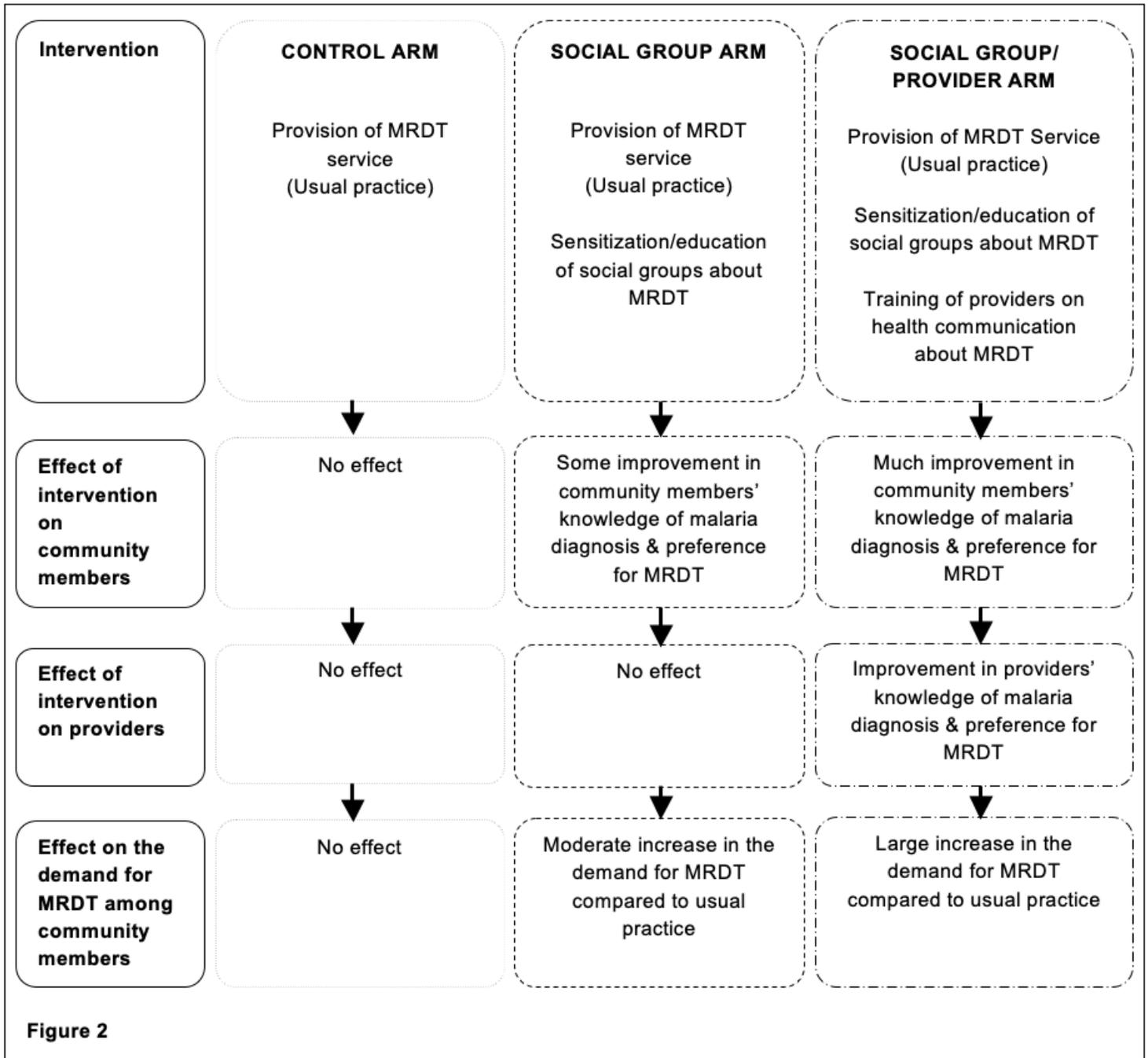


Figure 2

Summary of the study's logical framework.

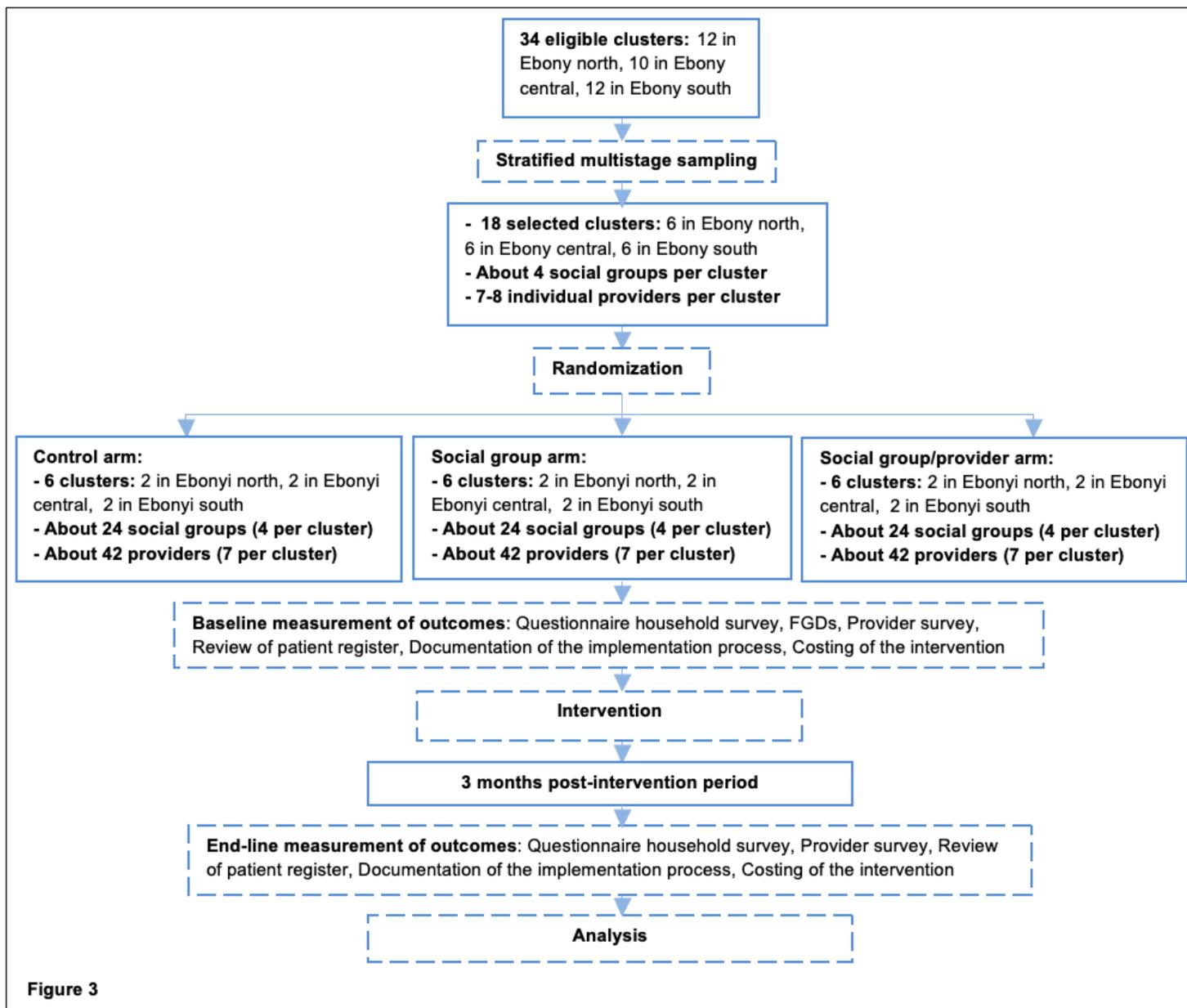


Figure 3

Summary of trial profile.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [supplement1.doc](#)