

# Using social groups and health care providers to increase the use of simple malaria tests in Ebonyi State, Nigeria

<b>Submission date</b> 05/08/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/08/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/02/2021	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Malaria is a disease that affects many people, especially in developing countries like Nigeria and other sub-Saharan African countries. In Nigeria, malaria medicine can be bought from drug sellers without doctors' prescription. This means that when people have a fever or malaria-like illness, they take these medicines without first doing a malaria test. Many health workers also give their patients malaria medicines based on symptoms alone. However, most of these people do not actually have malaria, and taking malaria medicine when one does not have the disease makes it easier for the malaria parasite to become resistant to medicines.

One of the most important medicines is artemisinin-combination therapy (ACTs) has now been shown to have resistance against it in some countries. In order to prevent this, WHO have recommend that patients suspected of having malaria should be tested for malaria prior to taking medicine for it.

The Nigerian government, with the support of international organisations, have provided a simple test for malaria, that will be readily available in public health facilities, where the test is done free or at little cost. Whilst many patients attend public health facilities to take a malaria test before taking medicine, the majority of patients still go to private health facilities and drug sellers for treatment. Therefore, the number of community members that do malaria tests before taking medicine is still very low in Nigeria.

This study aims to recruit 18 villages to create awareness among social groups and train healthcare workers in these villages on how to communicate with their patients about the simple malaria test. We want to determine whether these approaches can increase the number of people who do malaria tests before taking the medicine.

### Who can participate?

1. Villages with health facilities where a simple malaria test can be done
2. Social group members (e.g. women associations/meetings, village meetings, men associations, youth associations, elders' fora, ward/community/village development committees)
3. Public health care workers
4. Private health care workers
5. Household members

What does the study involve?

18 villages (communities) will be randomly allocated to 1 of 3 groups - the control group, the social group and the social/provider group. At the start of the study, household members that have a fever or malaria-like illness in the past 2 weeks will be asked whether they tested for malaria before taking the medicine.

Villages in the control group will receive the usual, standard treatment.

Amongst the social group, awareness will be created about the simple malaria test over a 3 month period, in addition to the same treatment as the control group.

In the social/provider group, participants will receive the same treatment as the social and control groups, along with training for public and private healthcare workers about how to communicate with patients about the simple malaria test.

3 months after the end of the awareness creation and training, household members that have a fever or malaria-like illness in the past 2 weeks will again be asked if they tested for malaria before taking medicine, to determine whether malaria testing before treatment increased from the start to the end of the study.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to participants. The potential benefits of participating in the study are improvement in health outcomes of community/village members with malaria, improvement in the health communication skills of health providers in the community and improvement in health care policy on how to make every malaria patient complete a malaria test before treatment, so that medicine-resistant malaria will not become a major problem in Nigeria. There are no known risks to participants taking part in this study.

Where is the study run from?

Villages (communities) in Ebonyi State, South-Eastern Nigeria

When is the study starting and how long is it expected to run for?

September 2016 to July 2019

Who is funding the study?

This study is self-funded

Who is the main contact?

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## **Study information**

### **Scientific Title**

Social Group and Health Care Provider Interventions to Increase the Demand for Malaria Rapid Diagnostic Test Among Community Members in Ebonyi State, Nigeria: A Cluster Randomised Controlled Trial.

### **Study objectives**

1. The social group intervention is more effective (and more cost-effective) in increasing the demand (use and/or request) for malaria rapid diagnostic test in the communities compared to usual practice.
2. The social group/provider intervention is more effective (and more cost-effective) in increasing the demand for malaria rapid diagnostic test in the communities compared to usual practice and compared to social group intervention.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Research and Ethics Committee of the Federal Teaching Hospital Abakaliki (FETHA), 23/07/2018, 11/07/2018-23/07/2018

Ethical Review Committee of the Ebonyi State Ministry of Health, 02/08/2018, SMOH/ERC/036/018

### **Study design**

Interventional pragmatic single-centre three-arm parallel open-label stratified cluster-randomised controlled trial with a 1:1:1 allocation

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

**Study setting(s)**

Community

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Malaria

**Interventions**

Interventions as of 26/11/2018:

Participants will be randomised into 3 groups in a 1:1:1 ratio through cluster randomisation by an independent statistician - the social group, social group/provider group and the control group. A cluster is defined as a geographical community or group of neighbouring villages/settlements serving as the proximate catchment area for at least 1 public primary health facility and 1 patent medicine vendor (PMV). Each group will have an equal number of clusters and each cluster will have an equal sample size.

All groups will receive usual treatment, which involves provision of malaria rapid diagnostic test (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 kits for the study period.

The control group will receive usual treatment only.

Participants in the social group will receive the social group intervention, which involves the control group treatment (usual treatment), along with the sensitisation and education of social groups about MRDT. Social groups are defined as women associations/meetings, village meetings, men associations, youth associations, elders' fora, ward/community/village development committees etc. Sensitisation and education will occur at the usual meeting point /venue of each social group or at a central location. There will be 3 episodes of group discussion /interaction (1 per month). Each group discussion will be moderated by the investigators with the aid of a group discussion guide. The first episode of group discussion will involve a health education message, designed to challenge and change incorrect and promote correct beliefs and perceptions and increase knowledge and promote key actions (including testing before treatment). Volunteer participants will also receive MRDT. The second and third episodes will take a similar format to the first, but will focus more on re-emphasising key facts and actions to practice and promote participants knowledge and attitude. Participants will be encouraged to share their experiences in the preceding weeks for discussion and clarifications. Social group members that have phone numbers will also receive at least weekly reminder text messages and regular visits by a health care provider to the scheduled meetings of each social group for the provision of MRDT services.

Participants in the social group/provider group will receive the same treatment as the control group and social group (usual treatment and sensitisation/education), along with the training of healthcare providers in health communication with patients/caregivers (clients) about MRDT. The provider training will involve a one day sensitisation and training workshop for health care providers, administered by the research team with a provider training guide and health communication guide. The training will be divided into 2 parts, with 4 sessions in each. Part one will focus on sensitising the participants, with the 4 sessions involving:

1. Pre-testing
  2. Background information on the research problems and objectives, and malaria
  3. Demonstration of testing with the MRDT kit
  4. Key actions to practice and promote, including testing before treatment
- Part two will focus on improving the health communication skills of participants with the aid of a health communication guide. The 4 sessions in this part involve:

1. Background information on health communication
2. A practical session, including simulation, on health communication with clients
3. Closing session and completing assessment forms
4. Post-testing

The participants will then be encouraged to use the health communication guide to effectively communicate with their clients (suspected malaria cases) about MRDT during their regular duties.

The training workshop will be followed by twice-weekly reminder text messages and a monthly visit to each of the participating providers for supportive supervision (on-the-job training) and monitoring throughout the rest of the implementation period. 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.

#### Interventions as of 01/10/2018:

Participants will be randomised into 3 groups in a 1:1:1 ratio through cluster randomisation by an independent statistician - the social group, social group/provider group and the control group. A cluster is defined as a geographical community or group of neighbouring villages/settlements serving as the proximate catchment area for at least 1 public primary health facility and 1 patent medicine vendor (PMV). Each group will have an equal number of clusters and each cluster will have an equal sample size.

All groups will receive usual treatment, which involves provision of malaria rapid diagnostic test (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 kits for the study period.

The control group will receive usual treatment only.

Participants in the social group will receive the social group intervention, which involves the control group treatment (usual treatment), along with the sensitisation and education of social groups about MRDT. Social groups are defined as women associations/meetings, village meetings, men associations, youth associations, elders' fora, ward/community/village development committees etc. Sensitisation and education will occur at the usual meeting point /venue of the social group members. There will be 3 episodes of group discussion/interaction (1 per month). Each group discussion will be moderated by the investigators with the aid of a group discussion guide. The first episode of group discussion will involve a health education message, designed to challenge and change incorrect and promote correct beliefs and perceptions and increase knowledge and promote key actions (including testing before treatment). Volunteer participants will also receive MRDT. The second and third episodes will take a similar format to the first, but will focus more on re-emphasising key facts and actions to practice and promote participants knowledge and attitude. Participants will be encouraged to share their experiences in the preceding weeks for discussion and clarifications. Social group members will also receive twice-weekly reminder text messages and regular visits by a health care provider to the scheduled meetings of each social group for the provision of MRDT services.

Participants in the social group/provider group will receive the same treatment as the control group and social group (usual treatment and sensitisation/education), along with the training of healthcare providers in health communication with patients/caregivers (clients) about MRDT.

The provider training will involve a one day sensitisation and training workshop for health care providers, administered by the research team and staff of the Ebonyi State Malaria Elimination Programme (SMEP) with a provider training guide and health communication guide. The training will be divided into 2 parts, with 4 sessions in each. Part one will focus on sensitising the participants, with the 4 sessions involving:

1. Pre-testing
  2. Background information on the research problems and objectives, and malaria
  3. Demonstration of testing with the MRDT kit
  4. Key actions to practice and promote, including testing before treatment
- Part two will focus on improving the health communication skills of participants with the aid of a health communication guide. The 4 sessions in this part involve:

1. Background information on health communication
2. A practical session, including simulation, on health communication with clients
3. Closing session and completing assessment forms
4. Post-testing

The participants will then be encouraged to use the health communication guide to effectively communicate with their clients (suspected malaria cases) about MRDT during their regular duties.

The training workshop will be followed by twice-weekly reminder text messages and a monthly visit to each of the participating providers for supportive supervision (on-the-job training) and monitoring throughout the rest of the implementation period. 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.

Previous interventions as of 24/08/2018:

Participants will be randomised into 3 groups in a 1:1:1 ratio through cluster randomisation by an independent statistician - the social group, social group/provider group and the control group. A cluster is defined as a geographical community or group of neighbouring villages/settlements serving as the proximate catchment area for at least 1 public primary health facility and 1 patent medicine vendor (PMV). Each group will have an equal number of clusters and each cluster will have an equal sample size.

All groups will receive usual treatment, which involves provision of malaria rapid diagnostic test (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 kits for the study period.

The control group will receive usual treatment only.

Participants in the social group will receive the social group intervention, which involves the control group treatment (usual treatment), along with the sensitisation and education of social groups about MRDT. Social groups are defined as women associations/meetings, village meetings, men associations, youth associations, elders' fora, ward/community/village development committees etc. Sensitisation and education will occur at the usual meeting point /venue of the social group members. There will be 3 episodes of group discussion/interaction (1 per month). Each group discussion will be moderated by the investigators with the aid of a group discussion guide. The first episode of group discussion will involve a health education message, designed to challenge and change incorrect and promote correct beliefs and perceptions and increase knowledge and promote key actions (including testing before treatment). Volunteer participants will also receive MRDT. The second and third episodes will take a similar format to the first, but will focus more on re-emphasising key facts and actions to practice and promote participants knowledge and attitude. Participants will be encouraged to share their experiences in the preceding weeks for discussion and clarifications. Social group members will also receive

twice-weekly reminder text messages and regular visits by a health care provider to the scheduled meetings of each social group for the provision of MRDT services.

Participants in the social group/provider group will receive the same treatment as the control group and social group (usual treatment and sensitisation/education), along with the training of healthcare providers in health communication with patients/caregivers (clients) about MRDT. The provider training will involve a 2 day sensitisation and training workshop for health care providers, administered by the research team and staff of the Ebonyi State Malaria Elimination Programme (SMEP) with a provider training guide and health communication guide. The training will be divided into 2 parts, with 4 sessions in each. Part one will take place on the first day of the workshop and will focus on sensitising the participants, with the 4 sessions involving:

1. Pre-testing
2. Background information on the research problems and objectives, and malaria
3. Demonstration of testing with the MRDT kit
4. Key actions to practice and promote, including testing before treatment

Part two will be held on the second day of the workshop and will focus on improving the health communication skills of participants with the aid of a health communication guide. The 4 sessions in this part involve:

1. Background information on health communication
2. A practical session, including simulation, on health communication with clients
3. Closing session and completing assessment forms
4. Post-testing

The participants will then be encouraged to use the health communication guide to effectively communicate with their clients (suspected malaria cases) about MRDT during their regular duties.

The training workshop will be followed by twice-weekly reminder text messages and a monthly visit to each of the participating providers for supportive supervision (on-the-job training) and monitoring throughout the rest of the implementation period. 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.

#### Previous interventions:

Participants will be randomised into 3 groups in a 1:1:1 ratio through cluster randomisation by an independent statistician - the social group, social group/provider group and the control group. A cluster is defined as a geographical community or group of neighbouring villages/settlements serving as the proximate catchment area for at least 1 public health facility and 1 private health facility. Each group will have an equal number of clusters and each cluster will have an equal sample size.

All groups will receive usual treatment, which involves provision of malaria rapid diagnostic test (MRDT) services by individual health care providers (public and private) with basic training in MRDT. Private providers 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 kits for the study period.

The control group will receive usual treatment only.

Participants in the social group will receive the social group intervention, which involves the control group treatment (usual treatment), along with the sensitisation and education of social groups about MRDT. Social groups are defined as women associations/meetings, village meetings, men associations, youth associations, elders' fora, ward/community/village development committees etc. Sensitisation and education will occur at the usual meeting point /venue of the social group members. There will be 3 episodes of group discussion/interaction (1 per month). Each group discussion will be moderated by the investigators with the aid of a group discussion guide. The first episode of group discussion will involve a health education message,

designed to challenge and change incorrect and promote correct beliefs and perceptions and increase knowledge and promote key actions (including testing before treatment). Volunteer participants will also receive MRDT. The second and third episodes will take a similar format to the first, but will focus more on re-emphasising key facts and actions to practice and promote participants knowledge and attitude. Participants will be encouraged to share their experiences in the preceding weeks for discussion and clarifications. Social group members will also receive twice-weekly reminder text messages and regular visits by a health care provider to the scheduled meetings of each social group for the provision of MRDT services.

Participants in the social group/provider group will receive the same treatment as the control group and social group (usual treatment and sensitisation/education), along with the training of healthcare providers in health communication with patients/caregivers (clients) about MRDT. The provider training will involve a 2 day sensitisation and training workshop for health care providers, administered by the research team and staff of the Ebonyi State Malaria Elimination Programme (SMEP) with a provider training guide and health communication guide. The training will be divided into 2 parts, with 4 sessions in each. Part one will take place on the first day of the workshop and will focus on sensitising the participants, with the 4 sessions involving:

1. Pre-testing
2. Background information on the research problems and objectives, and malaria
3. Demonstration of testing with the MRDT kit
4. Key actions to practice and promote, including testing before treatment

Part two will be held on the second day of the workshop and will focus on improving the health communication skills of participants with the aid of a health communication guide. The 4 sessions in this part involve:

1. Background information on health communication
2. A practical session, including simulation, on health communication with clients
3. Closing session and completing assessment forms
4. Post-testing

The participants will then be encouraged to use the health communication guide to effectively communicate with their clients (suspected malaria cases) about MRDT during their regular duties.

The training workshop will be followed by twice-weekly reminder text messages and a monthly visit to each of the participating providers for supportive supervision (on-the-job training) and monitoring throughout the rest of the implementation period. 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.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Current primary outcome measures as of 29/09/2020:

The following will be assessed through a population-based household questionnaire at the baseline and 3 months after the end of the intervention:

- 1.1. The proportion of children under 5 years of age with fever or malaria-like illness, in the 2 weeks preceding a population-based household survey, who received MRDT
- 1.2. The proportion of children ages 5 years and above and adults (excluding pregnant women) with fever or malaria-like illness, in the 2 weeks preceding a population-based household survey, who received MRDT



Previous primary outcome measures:

The following will be assessed through a population-based household questionnaire at the baseline and 3 months after the end of the intervention:

1. The proportion of children under 5 years old with a fever or malaria-like illness in the preceding 2 weeks that received MRDT
  - 1.1. The proportion of these children for whom their caregivers requested MRDT
2. The proportion of children aged 5 years and above and adults (excluding pregnant women) with a fever or malaria-like illness in the preceding 2 weeks that received MRDT
  - 2.1. The proportion of these subjects that requested or whose caregivers requested MRDT

## **Secondary outcome measures**

Current secondary outcome measures as of 29/09/2020:

The following will be assessed through a population-based Household Member's Questionnaire at the baseline and 3 months after the end of the intervention:

1. The proportion of these children under 5 years of age, who received MRDT, whose caregivers requested the MRDT
2. The proportion of these children ages 5 years and above and adults, who received MRDT, who requested or whose caregivers requested the MRDT
3. The proportion of children under 5 years old with a fever or malaria-like illness in the preceding 2 weeks:
  - 3.1. Whose caregivers sought care with a provider
  - 3.2. Those that sought care the same or next day
  - 3.3. For those for whom care was sought, the type of provider with whom care was sought
  - 3.4. The proportion of these children that took any anti-malarial drug
  - 3.5. The proportion of these children that took ACTs
4. The proportion of children aged 5 years and above and adults (excluding pregnant women) with a fever or malaria-like illness in the preceding 2 weeks:
  - 4.1. That sought care with a provider
  - 4.2. That sought care the same or next day
  - 4.3. Amongst those that sought care, the type of provider with whom care was sought
  - 4.4. The proportion of these children and adults that took any anti-malarial drug
  - 4.5. The proportion of these children and adults that took ACTs
5. The proportion of respondent female heads of households (female primary caregivers) that have good knowledge and opinion about malaria and malaria diagnosis
6. The number of suspected malaria cases visiting the public primary health centres measured using patients' register
7. The proportion of providers that have good knowledge and opinion and practice of health communication about malaria and malaria diagnosis
8. Total cost of the social group and social group/provider interventions, average cost per provider and average cost per social group member

Previous secondary outcome measures from 26/11/2018 to 29/09/2020:

The following will be assessed through a population-based Household Member's Questionnaire at the baseline and 3 months after the end of the intervention:

1. The proportion of children under 5 years old with a fever or malaria-like illness in the preceding 2 weeks:
  - 1.1. Whose caregivers sought care with a provider
  - 1.2. Those that sought care the same or next day
  - 1.3. For those for whom care was sought, the type of provider with whom care was sought
  - 1.4. The proportion of these children that took any anti-malarial drug
  - 1.5. The proportion of these children that took ACTs

2. The proportion of children aged 5 years and above and adults (excluding pregnant women) with a fever or malaria-like illness in the preceding 2 weeks:
  - 2.1. That sought care with a provider
  - 2.2. That sought care the same or next day
  - 2.3. Amongst those that sought care, the type of provider with whom care was sought
  - 2.4. The proportion of these children and adults that took any anti-malarial drug
  - 2.5. The proportion of these children and adults that took ACTs
3. The proportion of respondent female heads of households (female primary care givers) that have good knowledge and opinion about malaria and malaria diagnosis
4. The number of suspected malaria cases visiting the public primary health centres measured using patients' register
5. The proportion of providers that have good knowledge and opinion and practice of health communication about malaria and malaria diagnosis
6. Total cost of the social group and social group/provider interventions, average cost per provider and average cost per social group member

Previous secondary outcome measures:

The following will be assessed through a population-based Household Member's Questionnaire at the baseline and 3 months after the end of the intervention:

1. The proportion of children under 5 years old with a fever or malaria-like illness in the preceding 2 weeks:
  - 1.1. Whose caregivers sought care with a provider
  - 1.2. Those that sought care the same or next day
  - 1.3. For those for whom care was sought, the type of provider with whom care was sought
  - 1.4. The proportion of these children that took any anti-malarial drug
  - 1.5. The proportion of these children that took ACTs
2. The proportion of children aged 5 years and above and adults (excluding pregnant women) with a fever or malaria-like illness in the preceding 2 weeks:
  - 2.1. That sought care with a provider
  - 2.2. That sought care the same or next day
  - 2.3. Amongst those that sought care, the type of provider with whom care was sought
  - 2.4. The proportion of these children and adults that took any anti-malarial drug
  - 2.5. The proportion of these children and adults that took ACTs

**Overall study start date**

01/09/2016

**Completion date**

13/07/2019

## Eligibility

### Key inclusion criteria

Current participant inclusion criteria as of 24/08/2018:

Clusters:

1. Availability of eligible health care facilities:
  - 1.1. At least one eligible public primary health care facility
  - 1.2. At least one eligible patient medicine vendor (PMV)
2. Ease of access - closeness to a motorable road that is usable even in the rainy season

Public primary health facilities:

1. Functionality

- 1.1. Provision of MRDT services
- 1.2. Provision of maternal and child health care services including immunisation
2. Attending to at least an average of four fever cases (or suspected cases of malaria) per day
3. Having at least 2 staff that are at least junior community health extension workers (JCHEWs)

Patent medicine vendors (PMVs):

1. Have basic training in MRDT services
2. Either currently offering or previously offered MRDT services

Individual public health care providers must have involvement in the diagnosis (and treatment) of malaria

Social groups (women associations/meetings, village meetings, men associations, youth associations, elders' fora, ward/community/village development committees etc) must be recognised by cluster heads/authorities.

Households must have 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 a population-based household survey.

Previous participant inclusion criteria:

Clusters:

1. Availability of eligible health care facilities:
  - 1.1. At least one eligible public primary health care facility
  - 1.2. At least one eligible private health facility or PMV (patient medicine vendor)
2. Ease of access - closeness to a motorable road that is usable even in the rainy season

Public primary health facilities:

1. Functionality
  - 1.1. Provision of MRDT services
  - 1.2. Provision of maternal and child health care services including immunisation
2. Attending to at least an average of four fever cases (or suspected cases of malaria) per day
3. Having at least 3 staff that are at least junior community health extension workers (JCHEWs)

Individual private health care providers and patent medicine vendors (PMVs):

1. Have basic training in MRDT services
2. Either currently offering or previously offered MRDT services

Individual public health care providers must have involvement in the diagnosis (and treatment) of malaria

Social groups (women associations/meetings, village meetings, men associations, youth associations, elders' fora, ward/community/village development committees etc) must be recognised by cluster heads/authorities.

Households must have 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 a population-based household survey.

**Participant type(s)**

Other

**Age group**

Other

## **Sex**

Not Specified

## **Target number of participants**

18 clusters, average of 4 social groups/cluster, all eligible primary health care facilities, all eligible individual health care providers, 50 eligible under-5 children/cluster, 50 eligible 5 years and above children and adults (excluding pregnant women)/cluster.

## **Total final enrolment**

18

## **Key exclusion criteria**

For clusters:

1. Participation in similar interventions within the preceding year
2. Clusters that are too close (less than 15 km apart) and not separated by a buffer area or natural barrier
3. Urban clusters (in cities/towns)
4. No consent provided

For all other participant groups, non-consenting participants will be excluded from the study.

## **Date of first enrolment**

27/08/2018

## **Date of final enrolment**

29/06/2019

# **Locations**

## **Countries of recruitment**

Nigeria

## **Study participating centre**

**Ebonyi State.**

South-Eastern Nigeria.

N/A

Nigeria

480

# **Sponsor information**

## **Organisation**

Department of Community Medicine, Ebonyi State University

## Sponsor details

Department of Community Medicine, Federal Teaching Hospital Abakaliki. Ebonyi State.  
Abakaliki  
Nigeria  
480

## Sponsor type

Other

## ROR

<https://ror.org/01jhpwy79>

# Funder(s)

## Funder type

Not defined

## Funder Name

Investigators initiated and funded

# Results and Publications

## Publication and dissemination plan

Study results will be reported at local, national and international levels. We are planning to publish the study protocol before the end of the study.

## Intention to publish date

31/03/2021

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Omale Ugwu Innocent ([omaleiu@gmail.com](mailto:omaleiu@gmail.com)).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	10/10/2019	14/10/2019	Yes	No
<a href="#">Results article</a>	results	01/03/2021	18/02/2021	Yes	No