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Using parents and health workers to increase the number of children who received all the recommended childhood vaccinations without any delay in the communities of Ebonyi state, Nigeria

Submission date
24/06/2022

Recruitment status
No longer recruiting

Registration date
29/06/2022

Overall study status
Completed

Last Edited
04/04/2025

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Infectious diseases are major causes of morbidity and mortality worldwide, especially in developing countries like Nigeria. Although there are vaccines to prevent many of these infectious diseases, these diseases affected more than 90 million children younger than five years worldwide in 2015 and more than 30 million (about 33%) of these children were in Africa. Also, more than half a million (about 58%) of all the children that died from these infectious diseases were in Africa. These were due to poor access to childhood immunization in Africa. Routine immunization or vaccination of children is a very important way of preventing these infectious diseases from affecting and killing children around the world.

Routine childhood immunization services are provided in primary health care facilities in Ebonyi state (like other states in Nigeria). However, the percentage of children aged 12–23 months who received all recommended vaccinations by 12 months of age was 26.3% in 2018 in Ebonyi state, Nigeria. This was far below the 80% recommended by the 2013–2015 Nigerian National Routine Immunization Strategic Plan and the 2011–2020 Global Vaccine Action Plan. Because many children in Ebonyi state (and other states in Nigeria) do not receive their childhood vaccinations and many delay before receiving them (do not receive them on time), these infectious diseases such as pneumonia, whooping cough, measles, yellow fever, etc continue to affect and kill many children in Ebonyi state and in Nigeria.

This study aims to recruit 16 villages (communities) and discuss together with both parents of newborn babies and health care workers (in these villages) how to make children receive all the childhood vaccinations without any delay. The goal is to find out whether this approach will increase the number or percentage of children who received all the recommended childhood vaccinations without any delay. The findings from this study will help the government of Ebonyi State and Nigeria in finding ways to make sure every child receives all the recommended childhood vaccinations without any delay in order to prevent these infectious diseases from affecting and killing children in Ebonyi state and in Nigeria.

Who can participate?
Villages (communities) where the primary health care facilities have weekly routine childhood immunization clinics, parents of newborn babies, primary health care workers, and children aged between 5 and 23 months and their mothers.

What does the study involve?
The vaccination data of children aged between 5 and 23 months will be collected from their vaccination cards and by asking their mothers. 16 villages (communities) will be randomly allocated to one of two groups. In the villages in the first group, nothing will be done. In the villages in the second group, there will be several discussions with both parents of newborn babies and health care workers on how to make children receive all the childhood vaccinations without any delay. After the end of these discussions, vaccination data of children aged between 5 and 23 months will again be collected from their vaccination cards and by asking their mothers. The findings from the two groups of villages (communities) will be compared to see whether the number or percentage of children who received all the recommended childhood vaccinations without any delay has increased or not.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to participants. Potential benefits of participating in the study are improvement in health outcomes of children and improvement in health care policy on how to make sure every child receives all the recommended childhood vaccinations without any delay in order to prevent infectious diseases from affecting and killing children in Ebonyi state and in Nigeria. There are no obvious or anticipated risks in participating 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?
May 2021 to May 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ugwu I. Omale, omaleiu@gmail.com

Contact information

Type(s)
Principal Investigator

Contact name
Dr Ugwu Omale

ORCID ID
https://orcid.org/0000-0001-6586-8992

Contact details
Department of Community Medicine
Alex Ekwueme Federal University Teaching Hospital Abakaliki (AEFUTHA)

Ebonyi State
Abakaliki
Nigeria
480
+234 7035094245
omaleiu@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A cluster-randomised controlled trial of hybrid parents and health workers adaptive intervention for optimal routine childhood immunization coverage in the communities of Ebonyi state, Nigeria – The AGINTOPIC Trial

Acronym
AGINTOPIC

Study objectives
1. The hybrid parents and health workers adaptive intervention is more effective in increasing the optimal or timely (cumulative age-appropriate) routine childhood immunization coverage compared with control
2. The hybrid parents and health workers adaptive intervention is more effective in increasing timeliness (as a continuous variable) of routine childhood immunization coverage compared with control

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/06/2022, Ebonyi State Health Research and Ethics Committee (Ebonyi State Ministry of Health, Block 5, New Secretariat Complex, Centenary City, Abakaliki, Ebonyi State, Nigeria; +2349065211521; ebonyistateministryofhealth@gmail.com), ref: EBSHREC/01/06/2022–31/05/2023

Study design
Interventional pragmatic, two-arm, parallel, open label, covariate-constrained cluster-randomized controlled trial with 1:1 allocation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Vaccine-preventable infectious diseases

Interventions
Villages (communities) will be allocated into control and intervention groups in a 1:1 ratio through covariate-constrained randomisation by the principal investigator and an independent statistician. A cluster is defined as the nearest catchment area (geographical communities, villages, or settlements) for at least one public primary health care (PHC) facility with at least 500 households and a population size of 3000. In this Adaptive Group Intervention for Optimal routine childhood Immunization Coverage – AGINTOPIC Trial – there will be hybrid or combined parents and PHC workers adaptive engagement in the intervention arm to foster regular communication and working relationship between them regarding optimal routine childhood immunization uptake. The intervention is planned to take about 10 months. There will be no intervention in the control arm.
The intervention is a composite action consisting of two broad strategies: basic and adaptive intervention actions.
Basic intervention actions:
1. Formation of the Promoters of Optimal Routine Childhood Immunization Coverage (PORCHIC) group. The primary members of the PORCHIC group will include the investigators, parents, and PHC workers while others will include key community members such as the cluster heads, community resource persons (CORPs), religious leaders and traditional birth attendants (TBAs), etc as locally relevant.
2. Physical PORCHIC group discussions every alternate month within a ten-month period regarding non-receipt and untimely receipt of vaccinations to identify the determinants and proximal barriers and possible feasible solutions and strategies to addressing these barriers and to enlighten the PORCHIC group members, and by extension other community members.
3. Subsequent registration of new members (parents of newborn babies) into the PORCHIC group by PHC workers. PHC workers will facilitate enlightenment discussion with each new members, immediately after their registration, based on the PORCHIC group discussion format.
4. Weekly enlightenment discussions with parents at immunization clinics using the PORCHIC group discussion format, facilitated by the PHC workers.
Adaptive intervention actions:
Other cluster-specific intervention strategies will be informed as appropriate by any feasible proximal solutions or strategies, within the time frame and perspective of the study, identified during the PORCHIC group discussions.

Intervention Type
Behavioural

Primary outcome measure
1. The optimal or timely (cumulative age-appropriate) receipt of the recommended vaccines in the routine childhood immunization schedule by children aged 5–9 completed months and 10–11 completed months measured using population-based household surveys at baseline and 11 month follow-up
2. The age-appropriate vaccines receipt score for the recommended vaccines in the routine childhood immunization schedule by children aged 5–9 completed months and 10–11 completed months measured using population-based household surveys at baseline and 11 months

Secondary outcome measures
1. The up-to-date receipt of the recommended vaccines in the routine childhood immunization schedule by children aged 5–9 completed months and 10–11 completed months measured using population-based household surveys at baseline and 11 months
2. The dropout rate between Penta-1 and Penta-3 among children aged 5–9 completed months and 10–11 completed months measured using population-based household surveys at baseline and 11 months
3. The optimal or timely receipt of vitamin A-1, receipt of vitamin A-1, and vitamin A-1 receipt score among children aged 10–11 completed months measured using population-based household surveys at baseline and 11 months
4. The up-to-date receipt of the recommended vaccines in the routine childhood immunization schedule by children aged 12–23 completed months measured using population-based household surveys at baseline and 11 months
5. The (12 months) age-appropriate receipt of the recommended vaccines in the routine childhood immunization schedule by children aged 12–23 completed months measured using population-based household surveys at baseline and 11 months
6. The optimal or timely (cumulative age-appropriate) receipt of the recommended vaccines in the routine childhood immunization schedule by children aged 12–23 completed months measured using population-based household surveys at baseline and 11 months
7. The age-appropriate vaccines receipt score for the recommended vaccines in the routine childhood immunization schedule by children aged 12–23 completed months measured using population-based household surveys at baseline and 11 months
8. The dropout rate between Penta-1 and Penta-3 among the children aged 12–23 completed months measured using population-based household surveys at baseline and 11 months

Overall study start date
06/05/2021

Completion date
31/05/2023

Eligibility

Key inclusion criteria
Clusters:
1. Catchment PHC facilities are providing maternal and child health care services including routine childhood immunization and have weekly immunization clinics or sessions
2. Estimated average number of monthly deliveries is >20

3. Easily accessible or close to a road that is drivable even during the rainy season
4. No similar intervention is ongoing or occurred within the preceding year
5. Are at least 10 km apart or are separated by a buffer area or natural barrier
6. Cluster heads and PHC workers (the officers-in-charge) in the catchment PHC facilities give consent to participate

PHC workers:
1. Involved in the provision of routine childhood immunization services in the PHC facilities within the selected clusters
2. Provide consent to participate

Parents:
1. Parents (mothers, fathers, primary caregivers, or guardians) of infants aged between 0 and 2 months within the selected clusters
2. Permanent and regular residents of the clusters
3. Do not plan to migrate within the next year
4. Provide consent to participate

Household members:
1. Children aged between 5 and 23 months
2. Mother or primary caregivers who give provides consent to participate

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
A minumum of 45 children per cluster, with 720 children total. 16 clusters; minimum of 15 children aged 10–11 completed months per cluster; minimum of 15 children aged 5–9 completed months per cluster; minimum of 15 children aged 12–23 completed months per cluster; all eligible parents of infants aged zero to two months; and all eligible PHC workers.

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
30/06/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
Nigeria

Study participating centre
Villages (communities) in Ebonyi State
Ebonyi State
Nigeria
480

Sponsor information

Organisation
Alex Ekwueme Federal University Teaching Hospital Abakaliki (AEFUTHA)

Sponsor details
Ebonyi state
Abakaliki
Nigeria
480
+234 8037468896
drewah08@yahoo.com

Sponsor type
Hospital/treatment centre

Website
https://www.aefutha.gov.ng/

Funder(s)

Funder type
Other

Funder Name
Investigator 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 in a peer-reviewed journal before the end of the study.

Intention to publish date

31/03/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
omaleiu@gmail.com

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/07/2023	13/07/2023	Yes	No
Results article		02/04/2025	04/04/2025	Yes	No