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The INSPIRING Project – building capacity to reduce child deaths in Jigawa State, Nigeria

Submission date
05/12/2019

Recruitment status
No longer recruiting

Registration date
11/12/2019

Overall study status
Completed

Last Edited
09/06/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 10/11/2020:

Background and study aims
Mortality rates in children under-five years are unacceptably high, and pneumonia is the leading cause of such deaths, with 880,000 deaths in 2016. Half of these global deaths occurred in just five countries, one of which is Nigeria. The under-5 mortality in Jigawa state (North-West Nigeria) is 192 per 1000 live births, and it is estimated that there are 14,988 cases of paediatric pneumonia in Jigawa annually. From November 2018 to June 2019 we conducted a situational analysis of paediatric pneumonia in Jigawa, to inform the design of an intervention programme aiming to reduce paediatric mortality in these settings. We found protective and preventive factors, such as vaccine coverage and clean cooking fuel use, were low. Additionally, knowledge, care-seeking and health system factors were poor. Therefore, a whole systems approach, from prevent and protect to diagnose and treat, is needed for sustainable reductions in child mortality.

Since March 2020, Nigeria reported cases of COVID-19 and instituted various control measures to try and mitigate the local epidemic. We therefore delayed the start of the trial from January 2020 to January 2021. In Kiyawa local government authority area (LGA), Jigawa State, Save the Children Nigeria implemented a radio-based participatory information campaign about COVID-19 and child health from June-December 2020. In addition, healthcare providers have been trained in infection prevention and control, and the use of pulse oximetry. This study aims to reduce the number of under-five deaths, with a specific focus on pneumonia morbidity and mortality, in Kiyawa LGA, Jigawa State.

Who can participate?
The study will include the whole population of Kiyawa LGA, excluding those in the catchment area of Kiyawa Primary Health Centre. In particular, the intervention will target caregivers of children under-five years and healthcare providers.

What does the study involve?
The intervention is a whole systems approach to building capacity, focussed on child health and paediatric pneumonia.

The trial will run from January 2021 – December 2022. The intervention will delivered and evaluated as a cluster randomised controlled trial, with 32 primary health facility catchment areas as the unit of randomisation. All primary healthcare facilities of Kiyawa LGA (and their surrounding villages) will be included in the trial, excluding Kiyawa PHC – as this facility is planned to be upgraded to a secondary referral facility during the period of the trial.
The intervention consists of two elements:
1. Community women's and men's groups
2. An adapted community-score card process which links men's and women's groups with health facility committees
All facilities in Kiyawa LGA will be supported with Integrated management of childhood illnesses (IMCI), infection prevention and control training and mentorship, and personal protective equipment. In addition, the secondary government health facilities will be supported with medical oxygen, to ensure this is always available for children who are referred throughout the whole project period. The intervention is delivered by Save the Children Nigeria, independent from the evaluation.
The main outcome is the reduction in under-five (children aged 7 days to 59 months) mortality between intervention and control clusters. A baseline (Jan 2021) and endline (June 2022) cross-sectional compound survey, will measure secondary outcomes of care-seeking behaviours, knowledge, and pneumonia prevalence. The main outcome will be measured through a prospective cohort evaluation amongst a randomly selected cohort of compounds, with vital event reporting every 4 months. The evaluation will include a random selection of 4,160 compounds, covering all villages in Kiyawa LGA. A concurrent process and economic evaluation will be conducted.

What are the potential benefits and risks to participation?
We are conscious that the nature of the group intervention could increase participants' risks of transmitting COVID-19 if there is on-going community transmission. We will therefore conduct a local risk assessment prior to commencing the trial, which deems the risk of infection to be low. The risk assessment will be based on reported local and national numbers of cases, numbers of deaths (ascertained by speaking with community and religious leaders and healthcare workers), and in accordance with local government advice. We will also engage with traditional leaders, local government and communities prior to starting to ensure there is community consent to proceed. In addition, stop and start rules will be used (based on the same criteria as above), and the COVID-19 situation will be reviewed on a monthly basis to minimise risks to both participants and project staff. Decisions to stop or re-start will be approved by both the Project Management Board (PMB) and Trial Steering Committee (TSC).
Further, all facilitators and study staff will be provided with face masks, hand sanitizer and training on physical distancing procedures and healthcare facilities will be supported with PPE. We will monitor the use and access to PPE as part of the process evaluation, and therefore the project may benefit communities and healthcare providers by improving infection prevention and control practices. Aside from possible COVID-19 risks, we do not anticipate any other serious negative impacts to participants taking part in this research, and the intervention package could provide benefits to individuals and wider communities. If there are concerns regarding the benefits of the intervention, the TSC will have the power to terminate the study.
The main ethical concern is the study team's responsibility to act if a severely sick child is identified during the compound survey. The data collector conducting these assessments will be clinically trained, and will follow World Health Organisation guidelines to classify children who have any signs and symptoms of pneumonia. If a child meets the referral criteria (i.e. has a general danger sign or is hypoxic) they will recommend the child is referred to secondary care, and support the family to find transportation.
Interviews and surveys will all take between 15 and 90 minutes, which will impose a time-burden on participants. To mitigate this as much as possible, data collection will be conducted in

locations that are convenient to the participants, or by phone, but ensuring these locations offer privacy to maintain confidentiality. In addition, participants will be reimbursed for any transport cost to attend, and given a small token of appreciation (e.g. soap or face masks). Participants will be informed of the use of their data during informed consent, and will be reminded that they do not have to participate.

Where is the study run from?
University College Hospital, Ibadan (Nigeria)

When is the study starting and how long is it expected to run for?
The trial will run from January 2021 to February 2023. Two cross-sectional surveys will be conducted (01/21-03/21, 07/22-09/22), with prospective vital sign registration in between. The intervention will be delivered over 18 months, from 01/2021 - 06/2022. October - December 2022 will be used for write-up and dissemination of the results.

Who is funding the study?
This study is funded by Save the Children UK

Who is the main contact?
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3. Prof. A. G. Falade
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Study website
https://www.ucl.ac.uk/igh

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
INtegrated and Sustainable childhood Pneumonia and Infectious disease Reduction In NiGeria – the INSPIRING Project, Jigawa

Acronym
INSPIRING Project

Study objectives
The implementation of a whole systems approach to build capacity and empowerment for improved childhood health, with a focus on paediatric pneumonia, in Kiyawa LGA, Jigawa State, Nigeria, will reduce deaths in children aged 0-59 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 27/09/2019, University College London Research Ethics Committee (Office of the Vice Provost Research, 2 Taviton Street, University College London, London, WC1H 0BT, UK; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 3433/004 (An amendment was submitted and approved

on 14/08/2020)
2. Approval 26/11/2019, Jigawa State Ministry of Health (Block B-Q2/23, New Secretariat Complex, Dutse, Jigawa State, Nigeria; no telephone number provided; smoh_jigawa@yahoo.com), ref: JPHCDA/ADM/GEN/073/V.I. (An amendment was submitted and approved on 20/07/2020)
3. Approved 10/01/2020, University of Ibadan/University College Hospital Ibadan research ethics committee (College of Medicine, University of Ibadan, Ibadan, Oyo State, Nigeria; Tel: +234 (0) 8033264593; Email: cfalade@comui.edu.ng), ref: UI/EC/19/0551

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community, Home, Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Under-five mortality, with a specific focus on the prevention of pneumonia morbidity and mortality in children under-five

Interventions
Current interventions as of 10/11/2020:

The intervention is a whole systems approach to building capacity, focussed on child health and paediatric pneumonia.
The intervention will delivered and evaluated as a cluster randomised controlled trial, with primary health facility catchment areas as the unit of randomisation. All primary healthcare facilities of Kiyawa LGA (and their surrounding villages) will be included in the trial, excluding Kiyawa PHC – as this facility is planned to be upgraded to a secondary referral facility during the period of the trial and the cluster is peri-urban, different from the others.
The intervention consists of two elements:
1. Community women’s and men’s groups
2. An adapted community-score card process which links men's and women's groups with health facility committees
All facilities in Kiyawa LGA will be supported with Integrated management of childhood illnesses (IMCI), infection prevention and control training and mentorship and supported with personal protective equipment. In addition, the secondary government health facility will be supported to ensure that medical oxygen is always available for children who are referred throughout the whole project period. The intervention will be delivered by Save the Children Nigeria, independent from the evaluation.

Previous interventions:

Cluster randomized controlled trial, that will run from January 2020 to December 2021, with a subsequent scale-up to control clusters from January 2022 to October 2022

Clusters will be populations living within 39 primary health centre catchment areas, with a 1:1 allocation into intervention and control. Clusters will be assigned using a random number sequence, and due to the nature of the intervention, participants will not be blinded to their allocation.

The intervention is a whole systems approach to capacity building and empowerment, consisting of three elements:
1. Community women's and men's groups
2. An adapted community-score card process which links men's and women's groups with health facility committees
3. Integrated management of childhood illnesses (IMCI) training and mentorship for primary healthcare providers.

In addition, one secondary government health facility, outside of the study area, will be supported to ensure that medical oxygen is always available for children who are referred there as part of improved case management. The intervention will be delivered by Save the Children Nigeria, independently of the evaluation team.

The main outcome will be the reduction in under-five mortality, between intervention and control clusters after two years of intervention delivery. This will be measured through three cross-sectional household surveys, conducted at the start of the trial, in the middle and at the end. The household surveys will be done in a random sub-set of 3900 households in each survey, covering all villages in Kiyawa LGA. A concurrent process and economic evaluation will also be conducted.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 02/03/2023:
Survival time in days for children up to five years of age compared between intervention and control clusters. This will be measured as any verified deaths of eligible children, who were residing in the compound at the time of their death. Deaths will be verified by study staff during Verbal Autopsy interviews. We will exclude deaths in the first week of life due to inaccuracies in reporting of early neonatal deaths, and we do not expect the intervention to impact on perinatal causes of death. We expect very few verbal autopsies to not record dates of birth or death. For deaths missing dates in children aged 1-59 months, the WHO VA tool records an age category, and these deaths will be included, with an assumed date of death as the midpoint between the last interview where they were alive and the one where they were reported as dead. These data will be collected from self-reporting by women aged 15-49 years old during the vital events surveillance (prospective cohort evaluation), in a random sample of compounds from all villages within study clusters. Compounds will be selected using stratified random sampling within the health facility catchment areas. Primary outcome data will be collected from January 2021 to October 2022.

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Previous primary outcome measure from 10/11/2020 to 02/03/2023:

Under-five mortality compared between intervention and control clusters. This will be calculated as the number of children aged 7 days to 59 months reported to have died over a 12-month period who resided in sampled compounds (numerator), divided by the total number of children aged 7 days to 59 months who reside in sampled compounds (denominator). We will exclude deaths in the first week of life due to inaccuracies in reporting of early neonatal deaths, and we do not expect the intervention to impact on perinatal causes of death. These data will be collected from self-reporting by women aged 15-49 years old during the vital events surveillance (prospective cohort evaluation), in a random sample of compounds from all villages within study clusters. Compounds will be selected using stratified random sampling within the health facility catchment areas. Primary outcome data will be collected from January 2021 to October 2022.

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Previous primary outcome measure:

Under-five mortality after two years of intervention implementation. This will be calculated as the number of children aged 0-59 months reported to have died in the previous 12 months who resided in sampled households (numerator), divided by the total number of children age 0-59 months who reside in sampled households (denominator). These data will be collected from women aged 15-49 years old during household surveys, in a random sample of households from all villages within study clusters. Households will be selected using stratified random sampling. Data will be collected at three timepoints, a baseline survey (January-March 2020), midline survey (January-March 2021) and endline survey (January-March 2022).

Secondary outcome measures

Current secondary outcome measures as of 10/11/2020:
1. Suspected-pneumonia under-five mortality rate, assigned using InterVA-4
2. Caregiver knowledge of pneumonia symptoms
3. Clinical pneumonia point prevalence, defined according to the World Health Organisation's Integrated Management of Childhood Illnesses guidelines
4. Care-seeking behaviours for pneumonia
5. Vaccination coverage
6. Protective/prevention measures for pneumonia including exclusive breastfeeding, handwashing with soap, no indoor smoke from cooking.

These data will be collected from women aged 15-49 years old during compound surveys and from clinical screening of children under-five by a study nurse, in a random sample of compounds from all villages within study clusters. Compounds will be selected using stratified random sampling within the health facility catchment areas. The trial will run from January 2021 to October 2022. Two cross-sectional surveys will be conducted (01/21-03/21 baseline survey, 07/22-09/22 – endline survey), and prospective recording of vital events will be done every four months in between the baseline and endline survey.

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Previous secondary outcome measures:

1. Suspected-pneumonia under-five mortality rate
2. Caregiver knowledge of pneumonia symptoms

3. Clinical pneumonia point prevalence
4. Care-seeking behaviours for pneumonia
5. Vaccination coverage

These data will be collected from women aged 15-49 years old during household surveys and from clinical screening of children under-five by a study nurse, in a random sample of households from all villages within study clusters. Households will be selected using stratified random sampling. Data will be collected at three timepoints, a baseline survey (January-March 2020), midline survey (January-March 2021) and endline survey (January-March 2022).

Overall study start date
01/11/2019

Completion date
15/02/2023

Eligibility

Key inclusion criteria
1. Resident in Kiyawa local government area, Jigawa State, Nigeria
2. A child aged 0-59 months is resident in the household

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
4,160 compounds, with a minimum target of 6,225 resident children aged 0-59 months.

Total final enrolment
12934

Key exclusion criteria
1. Caregivers aged <15 years or >49 years
2. Temporary residents in the study clusters
3. Individuals who decline to participate in the survey
4. Individuals who lack the capacity to consent to participate in the study

Date of first enrolment
06/01/2020

Date of final enrolment
25/06/2021

Locations

Countries of recruitment
Nigeria

Study participating centre
University College Hospital Ibadan
University College Hospital Department of Paediatrics
Queen Elizabeth II Road
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Sponsor information

Organisation
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Sponsor type
University/education

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Funder(s)

Funder type
Charity

Funder Name
Save the Children UK - GSK Partnership

Results and Publications

Publication and dissemination plan
Local dissemination meetings will be held with the Jigawa Ministry of Health and communities. Planned publication of study protocol, process evaluation and trial results papers, including cost-effectiveness, in peer-reviewed journals.

Intention to publish date
30/04/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon email request from Dr Carina King (carina.king@ki.se), Dr Tim Colbourn (t.colbourn@ucl.ac.uk) or Prof. Adegoke Falade (afalade33@hotmail.com). Fully anonymised data will be shared for the purposes of scientific research, subject to review by the co-investigators and approval from research ethics committees. Consent for sharing of anonymised data for research purposes is included in the informed consent process.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		31/01/2022	02/02/2022	Yes	No
Statistical Analysis Plan	version V3.1	16/01/2023	24/02/2023	No	No
Other publications	Qualitative information on factors affecting trial implementation	07/06/2023	08/06/2023	Yes	No
Other publications	Development of intervention involving community	16/11/2023	20/11/2023	Yes	No
Results article		17/10/2024	24/10/2024	Yes	No
Other publications		31/05/2025	09/06/2025	Yes	No