ISRCTN13151175 https://doi.org/10.1186/ISRCTN13151175

Mobilizing voices for science to promote trust in vaccination: the health ambassadors multi-site randomized controlled trial

Submission date
16/02/2024

Recruitment status
No longer recruiting

Registration date
16/02/2024

Overall study status
Completed

Last Edited
16/07/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims

This study is motivated by the challenges in achieving high rates of adult vaccination during the COVID pandemic observed in low-income countries. The current scope extends beyond COVID-19 and considers other types of adult and adolescent vaccination (e.g., cholera, typhoid, HPV, and Hepatitis B). The COVID crisis revealed how “infodemics” can exacerbate health emergencies. Misinformation and disinformation spread through various media or word of mouth can drown out information from health authorities and conflate health recommendations with politics. As a consequence efforts by health authorities to promote scientifically recommended courses of action to contain emergencies are hampered. This is undermining current regular vaccination campaigns. Most interventions addressing vaccine hesitancy are based on unilateral transmission of information (whether through social media or traditional media) and have had very limited impacts.

This context motivates the design of the Health Ambassadors study:

1. “Voice for Science”: Rather than relying on non-expert intermediaries for vaccine-related and other health information, evidence shows that individuals want a trustworthy point of reference who can speak with expertise on the science.
2. Safe space for discussing concerns: Evidence shows that simple unilateral messaging may not work and that behavioral change requires opportunities to privately discuss concerns so that they see clearly that their concerns are heard and addressed.
3. Building trust: Evidence suggests that vaccine hesitancy among the public is not a lack of information from health authorities; health authorities have ensured that information is ubiquitous. Rather members of the public lack trust in the sources, suggesting the need to build new bridges of trust between health authorities and the public.
4. Replicable: To ensure that the research directly informs policy options, rather than being a merely academic exercise, we want to test interventions that are integrated into health systems.

The study involves an intervention that recruits “Health Ambassadors” with relevant expertise to be deployed to build trust by initiating private and non-confrontational conversations with the vaccine-hesitant. The study is implemented in four countries across the African continent. The countries were selected to represent contexts in which the burden of COVID-19 was pronounced in terms of infection and death rates, but where COVID-19 vaccine coverage was moderate or

low. Across sites the study follows the same protocol with small site-specific adjustments. In Malawi and Zimbabwe, the ambassadors are recruited from among the community nurses and health workers currently deployed by the public health system. In Cote d'Ivoire and Senegal, ambassadors are recruited among recent graduates from graduate programs in the biomedical sciences. To create a safe space for discussing concerns ambassadors will be trained on a protocol based on the AIMS ("Announce, Inquire, Mirror, Secure") method. Ambassadors use active listening to discuss subjects' reasons for hesitancy, seek ways to build trust, and identify ways to overcome hesitancy without countering subjects' concerns in a confrontational manner. To maximize replicability and scalability, the studies in each country are being designed in collaboration with partners from the relevant health ministries and municipal health departments.

Who can participate?
Adults residing in catchment areas (clusters) of selected urban health facilities in Côte d'Ivoire, Malawi, Senegal, and Zimbabwe where vaccines, including those for COVID-19, Typhoid, HPV and Hepatitis B are available. Eligible participants are adults (at least 18 years old) who live in households located within the catchment areas of health facilities where the Health Ambassadors will be based (the catchment area is a 1 km circular buffer surrounding the health facility). At least one adult member of the household has not been vaccinated against COVID-19 at the baseline survey.

What does the study involve?
Households are randomly allocated to the treatment group or the control group. The control group receives no intervention. Households in the treatment group receive visits by Health Ambassadors to discuss vaccine-related concerns. Health Ambassadors are trained in the AIMS approach ("Assume Inquire Mirror Secure"). 16 Health Ambassadors will be mobilized per country, with each Health Ambassador covering one treated cluster. They will have 6 weeks to work with the 24 households in their cluster. Over the course of a 6-week implementation period, the Health Ambassador will be required to have one initial engagement and then at least one follow-up engagement with each of the 24 households (although additional engagements are encouraged). Individual engagements should consist of a conversation with the head of household and another adult, on a one-on-one basis and in private. Each conversation is expected to last 30 minutes. However, in some cases, the conversation may extend beyond the designated 30-minute timeframe if all parties have an interest in doing so. For all participating households, a survey interviewer will contact the head of household or another adult who represents the household to conduct a brief (20-40 minute) intake interview during the household selection process and a 30-60-minute interview in the month that follows the end of the 6-week implementation period.

What are the possible benefits and risks of participating?
Participants can gain access to health information that conforms with health authority guidance and convey health-related concerns to the Health Ambassadors or survey interviewers, and such information conveyed to the Health Ambassadors or survey interviewers can be used in the study to develop guidance to improve general health policies. The study will maintain the confidentiality of any information provided by participants. There are no anticipated risks beyond the ordinary for participants in this study.

Where is the study run from?
This study is running in 128 clusters (catchment areas around selected health facilities) across 12 cities in four countries, namely Côte d'Ivoire (Abidjan and Bouaké), Senegal (Dakar, Kaolack, Mbacke, Pikine/keur Massar, Saint-Louis and Thies), Malawi (Blantyre and Lilongwe), and Zimbabwe (Bulawayo and Harare). The project is implemented by research centers and

universities located in the countries targeted by the study, notably the Centre de Recherche et d'Action pour la Paix (Côte d'Ivoire), the Université Gaston-Berger (Senegal), the Kamuzu University of Health Sciences (Malawi), and the Centre for Sexual Health and HIV/AIDS Research (Zimbabwe), in collaboration with the respective Ministries of Health of these countries. Evidence in Governance and Politics (EGAP), the EGAP regional hub at the Centre de Recherche et d'Action pour la Paix (Côte d'Ivoire), and the Partnership for African Social and Governance Research (PASGR) provide scientific coordination for the project.

When is the study starting and how long is it expected to run for?
November 2022 to December 2024

Who is funding the study?
The study is funded by the Social Science Research Council's Mercury Project, which received funds from the Rockefeller Foundation and the Bill & Melinda Gates Foundation

Who is the main contact?
Cyrus Samii, cds2083@nyu.edu

Study website
https://egap.org/healthambassadors/

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Cyrus Samii

ORCID ID
http://orcid.org/0000-0002-0823-1319

Contact details
19 W 4th St
New York
United States of America
10012
+1 (0)9173016421
cds2083@nyu.edu

Type(s)
Scientific

Contact name
Dr Fortunate Machingura

ORCID ID
http://orcid.org/0000-0003-4623-8180

Contact details

4 Bath Road, Belgravia
Harare
Zimbabwe
0002
+263 (0)772 971481
fmachingura@ceshhar.co.zw

Type(s)
Scientific

Contact name
Dr Paul Kawale

ORCID ID
http://orcid.org/0000-0001-8739-859X

Contact details
52X8+782, Mahatma Gandhi Rd
Blantyre
Malawi
52X8+782
+265 (0)999081857
pkawale@kuhes.ac.mw

Type(s)
Scientific

Contact name
Dr Arsene Brice Bado

ORCID ID
http://orcid.org/0000-0003-2398-8800

Contact details
15 Avenue Jean Mermoz, 08 BP 2088
Abidjan
Côte d'Ivoire
08 BP 2088
+225 (0)555978045
arsenebrice.bado@cerap-inades.org

Type(s)
Scientific

Contact name
Dr Mame Mor Anta Syll

ORCID ID
http://orcid.org/0000-0001-7639-5780

Contact details

BP: 234 - Saint-Louis,
Nationale 2, route de Ngallèle
Saint-Louis
Senegal
BP: 234
+221 (0)773679434
syll.mame-mor-anta1@ugb.edu.sn

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A multi-site randomized controlled trial of a health ambassadors intervention to promote trust in vaccination among adults in four sub-Saharan African countries

Acronym
HAMRCT

Study objectives
Primary Hypothesis:
H1: The Health Ambassador intervention increases vaccine trust.

Secondary Hypotheses:
H2: The Health Ambassador intervention increases vaccine uptake.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 06/12/2023, Direction de la Formation et de la Recherche en Santé de Côte d'Ivoire (Health Training and Research Department) (Immeuble SOGEFIHA Boulevard Carde 1er étage / BPV 4 Abidjan, Abidjan, BPV 4, Côte d'Ivoire; +225 (0)27 20 21 88 31; dfrsante1@yahoo.fr), ref: 02335/MSHPCMU/DGS/DFRS/DKL

2. Approved 23/01/2024, Kamuzu University of Health Sciences COMREC (College of Medicine Research & Ethics Committee, Private Bag 360, Chichiri, Blantyre, Private Bag 360, Chichiri, Malawi; +265 (0)1 810 911; comrec@medcol.mw), ref: P.10/23-0324

3. Approved 05/02/2024, Comité National d'Ethique pour la Recherche en Santé (CNERS) (Rue Aimé Césaire-Fann Résidence-DAKAR-SENEGAL, Dakar, BP 4024, Senegal; +221 (0)773614212; cnrs2008@live.fr), ref: SEN2023/95

4. Approved 16/12/2023, Medical Research Council of Zimbabwe (Medical Research Council of Zimbabwe, 20 Cambridge Road, Avondale, Harare, 0002, Zimbabwe; +263 (0)8644073772; mrcz@mrcz.org.zw), ref: MRCZ/A/3110

Study design
Blocked-cluster interventional unblinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community, Home

Study type(s)
Other

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Trust in vaccination among adults eligible for vaccination but who were not vaccinated for COVID-19

Interventions
This study targets adults residing in catchment areas (clusters) of selected urban health facilities in Côte d'Ivoire, Malawi, Senegal, and Zimbabwe where vaccines, including those for COVID-19, Typhoid, HPV and Hepatitis B are available. In each of the four countries - Côte d'Ivoire, Malawi, Senegal, and Zimbabwe - the researchers selected 32 health centers in densely populated urban areas based on (1) the availability of the priority vaccines for each country and (2) making sure that the health facilities are at least 4 km apart to avoid spillovers. In each cluster, the researchers obtained approval from the relevant health authorities to proceed with field activities. Field enumeration staff (separate from the Health Ambassadors) operate under the research team's supervision to select 24 households to be surveyed within each cluster. The household selection process is as follows:
1. Using Google Maps, the researchers plot the GPS coordinates of the focal health facility in the cluster and then create a circular buffer of 1 km around that coordinate point.
2. They stratify the circular area into six evenly spaced concentric bands of increasing distance to the health facility.
3. They randomly sample a geolocated point within each band.
4. Using Google Maps, the researchers identify the residential structure (house, flat, etc) nearest to each of those sampled points. Enumerators are instructed to select one household from within this structure.
5. Proceeding 50 m along the same side of the street in either direction from the initial residential structure (turning the corner if necessary), select six additional residential structures

that are spread evenly between the first selected residential structure and the ends of the 50 m segment. (The 50 m distance will be adjusted if needed to account for low-density areas)
6. Enumerators randomly order these six additional structures and select the first three. The three additional households will be selected from these chosen structures.
7. If a structure includes more than one household, enumerators number them and then draw one number at random from a hat.
8. If a household either does not consent to participation or is ineligible on the basis of intake information (see below), enumerators move to the next structures in the list of six. If one exhausts this list, then perform the same enumeration strategy on the other side of the street.
Upon being selected, an enumerator will approach the household head or an adult representing the household for their consent to a brief intake survey to determine the household's eligibility. If consent is granted, the intake survey will determine whether the household is eligible on the basis of whether it contains at least one adult member who was eligible for COVID-19 vaccination but has never been vaccinated against COVID-19.
If eligible, the household head or adult representing the household will be asked for their consent to participate in the full study, which involves being approached at a future date for in-person "discussions of health-related issues, including adult vaccination." This consent process will be done for households in both treated and control clusters. For those in treated clusters, such "discussion" would include the visit from the health ambassador and then the endline survey. In control clusters, such "discussion" would include only the endline survey.

In each country, 16 clusters are block-randomized to the treatment group and 16 clusters to the control group using complete randomization within blocks defined by city (at least 2 cities per country). In total, the treatment group consists of 64 clusters and the control group consists of 64 clusters, across four countries.

The control group receives no intervention.

Households in treatment group clusters receive visits by Health Ambassadors to discuss vaccine-related concerns. Health Ambassadors are trained in the AIMS approach ("Assume Inquire Mirror Secure"). 16 Health Ambassadors will be mobilized per country, with each Health Ambassador covering one treated cluster. They will have 6 weeks to work with the 24 households in their cluster. Over the course of a 6-week implementation period, the Health Ambassador will be required to have one initial engagement and then at least one follow-up engagement with each of the 24 households (although additional engagements are encouraged). Individual engagements should consist of a conversation with the head of the household and another adult on a one-on-one basis and in private. Each conversation is expected to last 30 minutes. However, in some cases, the conversation may extend beyond the designated 30-minute timeframe if all parties have an interest in doing so.

The Health Ambassadors are trained by experts on the AIMS methodology and are provided with a handbook that includes the following:
1. Guidance material on the strategy for engaging in conversations with households. The engagement strategy is based on the AIMS (Announce, Inquire, Mirror, Secure) methodology. The Health Ambassadors are trained to avoid confrontation or disparagement of household members' points of view, as this can undermine the goal of building trust.
2. Relevant scientific information on vaccine safety, the scientifically understood protective benefits of vaccines, and the scientifically understood risks of vaccinations, along with a brief country-specific "factsheet" to use as a tool when engaging households. Health Ambassadors are provided a list of households that they are assigned to proactively contact and engage in conversation. The criteria for selection will be that the household contains adult members who are not vaccinated for COVID-19.

Intervention Type
Behavioural

Primary outcome measure
Vaccine trust measured using the Vaccine Trust Index (VTI) for COVID-19 and other targeted vaccines at baseline prior to any intervention and then at endline, which will occur within 1 month after the end of the six-week intervention implementation period.

Secondary outcome measures
Vaccine uptake measured for each vaccine and each household member using:
1. Household member's verbal affirmation of receiving the vaccination (yes or no)
2. Whether the household member provided documentation of vaccination (e.g. their vaccination card) (yes or no)
Measured at baseline prior to any intervention and then at endline, which will occur within 1 month after the end of the 6-week intervention implementation period.

Overall study start date
21/11/2022

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Eligible participants are adults (at least 18 years old) who live in households located within the catchment areas of health facilities where the Health Ambassadors will be based (the catchment area is a 1km circular buffer surrounding the health facility) and who meet all the following three conditions:
1. At least one adult member of the household has not been vaccinated against COVID-19 at the baseline survey.
2. The head of the household or their representative consents to carry out the survey at the baseline and endline survey.
3. The head of the household or their representative consents to be contacted again by the research team.

Participant type(s)
Resident

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex

Both

Target number of participants
768 households sampled per country, with an overall sample size of 3,072 households over 128 clusters across all four countries

Total final enrolment
3773

Key exclusion criteria
1. Below 18 or above 80 years of age
2. Resides in a household in which all adults over 18 were vaccinated for COVID-19
3. Head of household or adult representing the household does not consent to interview or future visits from the research team

Date of first enrolment
25/02/2024

Date of final enrolment
01/07/2024

Locations

Countries of recruitment
Côte d'Ivoire

Malawi

Senegal

Zimbabwe

Study participating centre
Centre de Recherche et d'Action pour la Paix/Université Jésuite
15 Avenue Jean Mermoz, 08 BP 2088
Abidjan
Côte d'Ivoire
BP 2088

Study participating centre
Kamuzu University of Health Sciences
52X8+782, Mahatma Gandhi Rd
Blantyre
Malawi
52X8+782

Study participating centre
Université Gaston-Berger
BP: 234 - Saint-Louis,
Nationale 2, route de Ngallèle
Saint-Louis
Senegal
BP: 234 - Saint-Louis

Study participating centre
Centre for Sexual Health and HIV/AIDS Research
4 Bath Road, Belgravia
Harare
Zimbabwe
0002

Sponsor information

Organisation
Evidence in Governance and Politics at the University of California, Berkeley

Sponsor details
113 Philosophy Hall
Berkeley
United States of America
94720
+1 (0)6467090264
admin@egap.org

Sponsor type
Research organisation

Website
https://egap.org/

Funder(s)

Funder type
Research council

Funder Name
Social Science Research Council

Alternative Name(s)
U.S. Social Science Research Council, Social Science Research Council (U.S.), The Social Science Research Council, SSRC

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The datasets produced and/or analyzed in the present study will be published as a supplement to the results publication. De-identified data will be uploaded to a publicly available repository (Harvard Dataverse: https://dataverse.harvard.edu/).
The type of data stored: De-identified household-level data with roster data on household members, stored in CSV or tabular format.
The process for requesting access (if non-publicly available): Access will be public on the host archive (Harvard Dataverse).
Dates of availability: Upon publication of journal article.
Whether consent from participants was required and obtained: Verbal assent is required to be obtained.
Comments on data anonymization: The publicly available data will be stripped of any household or individual identifying information, including any names, telephone numbers, street addresses, or precise geographic location information.

IPD sharing plan summary
Stored in publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		15/07/2024	16/07/2024	No	No
Statistical Analysis Plan		15/07/2024	16/07/2024	No	No