ISRCTN94590823 https://doi.org/10.1186/ISRCTN94590823

Intensive combination approach to rollback the HIV epidemic in Nigerian adolescents

Submission date
11/05/2021

Recruitment status
No longer recruiting

Registration date
12/05/2021

Overall study status
Completed

Last Edited
31/10/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Youth, particularly young men who have sex with men, are weak links in Nigeria's response to the HIV epidemic. While there are many complicated factors that fuel the epidemic in these groups, a void of evidence-based interventions is remediable and necessary to advance the UNAIDS 90-90-90 goals. Therefore, we will investigate a novel youth-specific approach that includes peer navigation and mHealth components and has been locally adapted using focus groups and stakeholder consultations.

The HIV testing and linkage pilot study will reach at-risk youth through social media and in-person outreach conducted by peer navigators, who will be trained to implement the manualized combination intervention, focused on promoting HIV testing and linkage to care.

Who can participate?
The study will evaluate the number and results of HIV tests of young men ages 15 - 24 years residing in Ibadan city and surrounding areas.

What does the study involve?
HIV tests taken before (24 weeks) and during the intervention period (48 weeks), will be abstracted from surveillance records for analysis.

What are the possible benefits and risks of participating?
There may be no benefit of participation in this study, however, participants may enjoy the opportunity to interact with the peer navigator. The primary risks are breach of confidentiality.

Where is the study run from?
University of Ibadan (Nigeria)

When is the study starting and how long is it expected to run for?
November 2017 to May 2020

Who is funding the study?
The study is funded by the National Institutes of Health in the United States of America.

Who is the main contact?
Dr Robert Garofalo, rgarofalo@luriechildrens.org

Contact information

Type(s)
Scientific

Contact name
Dr Robert Garofalo

ORCID ID
https://orcid.org/0000-0001-9513-9416

Contact details
225 E. Chicago Ave
Box 161
Chicago
United States of America
60611
+1 312-227-6800
rgarofalo@luriechildrens.org

Additional identifiers

Protocol serial number
STU00207490

Study information

Scientific Title
Intensive Combination Approach to Rollback the Epidemic in Nigerian adolescents: UG3 phase, HIV testing arm

Acronym
iCARE

Study objectives
1. HIV Testing Hypothesis: The number of male youths who undergo HIV testing through the study site will be greater in the 48-weeks after the introduction of the intervention (in 24-week intervals) compared to 24 weeks before initiating the intervention.
2. Seroincidence Hypothesis: The number of confirmed HIV positive cases divided by total number of tests (i.e., seroincidence) will be greater in the 48 weeks post intervention compared to post intervention (in 24-week intervals).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 10/05/2018, Northwestern University IRB (750 N. Lakeshore Drive, 7th FL, Chicago, IL 60611, USA; +1-312-503-9338; irb@northwestern.edu), ref: STU00207490

Primary study design
Interventional

Study design
Quasi-experimental pre-post design

Study type(s)
Screening

Health condition(s) or problem(s) studied
HIV screening and prevention

Interventions
We promoted HIV prevention education and community-based HIV testing through social media platforms and navigated interested young men to HIV testing in clinic or community locations. Among young men who engaged in HIV testing visits, data on their demographics, testing history, HIV test result, and satisfaction with the testing visit were collected via anonymous survey and abstracted from testing surveillance records. Individuals with a preliminary positive test result were navigated to HIV care at a clinical location of their choice. Consent for data collection was provided via a consent statement with a waiver of documentation of consent, to maintain anonymity.

Intervention Type
Behavioural

Primary outcome(s)
1. Number of male youth who undergo HIV testing through the study site (i.e. tested on site or by a peer navigator in the community) measured using completed HIV tests abstracted from HIV surveillance forms at the point of HIV testing and immediately thereafter
2. The HIV seroincidence of this group, calculated as the number of confirmed HIV cases divided by the total number of tests measured using HIV test results abstracted from HIV surveillance forms at the point of HIV testing and immediately thereafter

Key secondary outcome(s)
1. The proportion of newly diagnosed youth who are linked to care for antiretroviral therapy measured using linkage to HIV care abstracted from HIV surveillance forms at the point of HIV testing and immediately thereafter
2. Feasibility, acceptability, and satisfaction with the intervention measured using the Client Satisfaction Questionnaire (CSQ-8) at the point of HIV testing

Completion date
31/05/2020

Eligibility

Key inclusion criteria

HIV tests of young men ages 15 - 24 years residing in Ibadan city, Nigeria and surrounding areas before (24 weeks) and during the intervention period (48 weeks) will be abstract from surveillance records of the Infectious Disease Institute of the University of Ibadan, College of Medicine for analysis.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
Male

Total final enrolment
339

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/06/2019

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
Nigeria

Study participating centre
University of Ibadan
Infectious Disease Institute
College of Medicine
P.M.B 3017 G.P.O
Oyo State
Ibadan
Nigeria
P.M.B 3017 G.P.O

Sponsor information

Organisation
National Institutes of Health

ROR
https://ror.org/01cwqze88

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health

Alternative Name(s)
US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The de-identified data from the study trial are available from the study investigators by request (rgarofalo@luriechildrens.org)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/02/2022	23/02/2022	Yes	No
Other publications	Qualitative results	30/10/2023	31/10/2023	Yes	No