# Intensive combination approach to rollback the HIV epidemic in Nigerian adolescents

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
11/05/2021		☐ Protocol		
Registration date 12/05/2021	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 31/10/2023	Condition category Infections and Infestations	Individual participant data		
31/10/2023	inrections and infestations			

#### 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 inperson 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

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# Additional identifiers

#### **EudraCT/CTIS** number

Nil known

#### **IRAS** number

#### ClinicalTrials.gov number

Nil known

#### Secondary identifying numbers

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

#### Study design

Quasi-experimental pre-post design

#### Primary study design

Interventional

#### Secondary study design

Non randomised study

#### Study setting(s)

Other

#### Study type(s)

Screening

#### Participant information sheet

Not applicable (retrospective study)

#### 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 measure

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

#### Secondary outcome measures

- 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

#### Overall study start date

01/11/2017

#### 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

#### Age group

Mixed

#### Sex

Male

### Target number of participants

339

#### 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

#### Sponsor details

9000 Rockville Pike Bethesda United States of America 20892 +1 301-496-4000 nichdpress@mail.nih.gov

#### Sponsor type

Government

#### Website

http://www.nih.gov/

#### **ROR**

https://ror.org/01cwqze88

# Funder(s)

#### Funder type

Government

#### **Funder Name**

#### National Institutes of Health

#### Alternative Name(s)

Institutos Nacionales de la Salud, US National Institutes of Health, NIH

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

United States of America

# **Results and Publications**

#### Publication and dissemination plan

The results of this study will be published in peer reviewed manuscripts.

#### Intention to publish date

01/03/2022

#### 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	Qualitative results	01/02/2022	23/02/2022	Yes	No
Other publications		30/10/2023	31/10/2023	Yes	No