Adolescent sexual and reproductive health project

Submission date	Recruitment status No longer recruiting	Prospectively registered		
17/03/2024		[X] Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
20/03/2024		Results		
Last Edited		[X] Individual participant data		
20/03/2024	Other	[] Record updated in last year		

Plain English summary of protocol

Background and study aims

It is estimated that about 2 in 10 young women will become pregnant before 18 years of age worldwide. West Africa has the highest proportion of adolescent pregnancies (28%). These pregnancies are often unintended and impact negatively on the well-being of mother and child. The gap between sexual intentions and contraceptive behaviour (unmet need for contraceptives) is high among adolescents in Nigeria. There has been heightened awareness and action towards adolescent reproductive health in Nigeria. Nevertheless, the need to close the widening gap between sexual behaviour and contraceptive intentions still persist. This calls for well-designed interventions that draws from participation of all stakeholders to ensure ownership and sustainability, as well as set the pace for adolescent health action at subnational levels in Nigeria. The general aim of this study is to adapt, implement and evaluate an inclusive community-embedded intervention program to address unmet contraceptive need of adolescents in Ebonyi state.

Who can participate?

The study population are adolescents (males and females) ages 13-18 years in and out of secondary schools in rural and urban areas of Ebonyi state, Nigeria; parents and guardians of adolescents; and health professionals.

What does the study involve?

The study involved a situation analysis will be conducted to assess the SRH needs of adolescents. A comprehensive mapping of health determinants during the situation analysis and consultation with stakeholders resulted to the design and implementation of a multi-component intervention comprising, (i) Training of primary health care workers, community health workers and patent medicine providers to ensure that adolescents have access to quality SRH services; (ii) School-based interventions - peer education and school health club - to ensure that adolescents have access to and receive accurate information on SRH; and (iii) community sensitization campaigns - including media campaigns - to ensure community support for adolescent SRH, and promote parent-child communication of SRH matters.

What are the possible benefits and risks of participating?
The risk to human subjects from participating in the interviews was minimal. Participants that

were concerned about the confidentiality of the information they provide, or those who experienced discomfort when responding to sensitive questions about sexual behaviour were managed well. Interviewers reminded participants that they could skip questions that cause discomfort and terminate the interview at any stage. Participants benefitted directly or indirectly from the interventions that were designed and implemented in their communities.

Where is the study run from? The study was run from Health Policy Research Group in Ebonyi State, Nigeria.

When is the study starting and how long is it expected to run for? March 2018 to March 2022

Who is funding the study? International Development Research Centre, Canada

Who is the main contact?
Dr Chinyere Mbachu, chinyere.mbachu@unn.edu.ng

Contact information

Type(s)

Public

Contact name

Ms Nkechi Onwuameze

Contact details

13/15 Leach Road Abakaliki Nigeria 480101 +234 8033127633 onwuamezenkechi@yahoo.com

Type(s)

Principal Investigator

Contact name

Dr Chinyere Mbachu

ORCID ID

http://orcid.org/0000-0003-3936-6184

Contact details

13/15 Leach Road Abakaliki Nigeria 480101 +234 8033401942 chinyere.mbachu@unn.edu.ng

Type(s)

Scientific

Contact name

Ms Ifunanya Agu

Contact details

13/15 Leach Road Abakaliki Nigeria 480101 +234 9069798391 ifreda198@gmail.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

108677-001

Study information

Scientific Title

Addressing unmet need for contraceptives among adolescents using a community-embedded intervention in Ebonyi state, Nigeria

Acronym

ASRH

Study objectives

Multicomponent community-embedded interventions improve access to sexual and reproductive health information and health services for adolescents.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 13/03/2018, Health Research Ethics Committee, University of Nigeria Teaching Hospital (Enugu Port-Harcourt Expressway, Ituku-Ozalla, Enugu, 400001, Nigeria; +234 (042) 252022; cmdunth2011@yahoo.com), ref: UNTH/CSA/329/OL..5

Study design

Non-randomized before and after intervention study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community, School

Study type(s)

Prevention

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Sexual and Reproductive Health

Interventions

- 1. Community-based interventions (i) Training of formal and informal healthcare providers on the provision of adolescent-friendly sexual and reproductive health services; (ii) Community sensitization on the SRH needs and rights of adolescents involving community leaders, parents and caregivers of adolescents
- 2. School-based interventions (i) Establishment of school health clubs in public secondary schools; (ii) Training of peer health educators and teachers on the SRH needs and rights of adolescents; (iii) Distribution of IEC materials to secondary school students through the school health clubs.

Intervention Type

Behavioural

Primary outcome measure

Unplanned pregnancies among adolescents measured using a questionnaire at baseline and endline

Secondary outcome measures

- 1. Contraceptive prevalence rate among adolescents measured using a questionnaire at baseline and endline
- 2. Availability and provision of contraceptives and other SRH services for adolescents in primary health centers measured using data collected in patient notes at the end of the study
- 3. Availability and provision of contraceptives and other SRH services for adolescents in patent medicine stores measured using data collected in patient notes at the end of the study

Overall study start date

13/03/2018

Completion date

31/03/2022

Eligibility

Key inclusion criteria

- 1. Health professional primary care providers of SRH services including frontline providers in primary health centers (formal providers), community health workers and patent medicine vendors (informal providers)
- 2. Learner/students secondary school students in public/government-owned secondary schools
- 3. Population community leaders and representatives, parents and guardian of adolescents aged 10-18, adolescents in communities
- 4. Service user adolescents aged 13-18 years accessing SRH services from primary health centers, community health workers, and patent medicine vendors

Participant type(s)

Health professional, Learner/student, Population, Service user

Age group

Mixed

Lower age limit

13 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

1775

Total final enrolment

1763

Key exclusion criteria

- 1. Adults and adolescents who had cognitive disabilities that preclude them from consenting or giving assent. Cognitive and other disabilities were assessed on a case-by-case basis.
- 2. Adolescents aged 13-14 years who were no longer under the care of a parent/guardian

Date of first enrolment

01/08/2018

Date of final enrolment

14/06/2021

Locations

Countries of recruitment

Nigeria

Study participating centre Health Policy Research Group

13/15 Leach Road Abakaliki Nigeria 480101

Sponsor information

Organisation

University of Nigeria

Sponsor details

Health Policy Research Group, No 1 Old UNTH Site Enugu Nigeria 400001 +234 803700771 hprg@unn.edu.ng

Sponsor type

Research organisation

Website

https://www.unn.edu.ng/the-health-policy-research-group-hprg/

ROR

https://ror.org/01sn1yx84

Funder(s)

Funder type

Government

Funder Name

International Development Research Centre

Alternative Name(s)

Centre de recherches pour le développement international, IDRC, CRDI

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Canada

Results and Publications

Publication and dissemination plan

Planned publication in high-impact peer-reviewed journal.

Intention to publish date

01/06/2024

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study have been stored in a publicly available repository (UK Data Service https://doi.org/10.5255/UKDA-SN-854374)

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Dataset</u>			18/03/2024	No	No
Participant information sheet			20/03/2024	No	Yes
<u>Protocol file</u>			20/03/2024	No	No