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Community discussions of local evidence leading to local culturally appropriate actions to improve adolescent sexual and reproductive health in Bauchi State, Nigeria

Submission date	**Recruitment status**	[X] Prospectively registered
19/10/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/10/2021	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/11/2024	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims:
Adolescents (10-19 years) are a big segment of the Nigerian population, and they face serious risks to their health and well-being. Adolescent sexual and reproductive health (ASRH) indicators are worse in the north of the country, including in Bauchi State, where the conservative Muslim cultural context limits open discussion of the issues. Over the last five years, a partnership of CIET/PRAM from McGill University, a Nigerian NGO (Federation of Muslim Women Association of Nigeria) in Bauchi State, and the Bauchi State Primary Health Care Development Agency implemented and demonstrated the impact of a program of universal home visits for improving the health of mothers and children. The partnership also explored the sensitive issue of child-spacing and co-designed with stakeholders culturally safe interventions to support child-spacing. This work has built trust between researchers and local leadership and communities.
Many studies have described the problems faced by adolescents. This participatory research study goes further and tests the effect of a community-based intervention to improve the health and well-being of adolescents in communities in Bauchi State in northern Nigeria.

Who can participate?
In this study, whole communities will participate. Sixty communities in six wards (administrative units) of Toro Local Government Area in Bauchi State will take part in the trial, with half of them having the intervention and half not. All adolescents, and other community members, living in the 30 intervention communities can participate in the intervention activities.

What does the study involve?
Before the trial begins, we will undertake focus group discussions with adolescents and others (parents, community leaders, and service providers) in Toro LGA communities to hear their views about the most important ASRH problems. Groups of adolescents and others will then map out their knowledge of the causes of these problems. A household survey of adolescents and their parents will measure the extent of the ASRH problems. It will include about 6,000 female adolescents, 4,000 male adolescents, 4,000 mothers of adolescents and 2,500 fathers of

adolescents. Working with adolescents, the research team will create materials such as video dramas to share findings with stakeholders in intervention communities. Male and female adolescents and other community stakeholders will discuss the evidence and plan and implement local culturally acceptable actions to improve ASRH. These groups will work within their communities to implement their plans over about 18 months. A repeat household survey will test whether the intervention has improved the priority ASRH outcomes, as well as knowledge and attitudes about these issues.

What are the possible benefits and risks of participating?
The participating communities and adolescents within these communities can benefit if the intervention helps to reduce the sexual and reproductive health problems of adolescents. Discussing topics such as violence or sexual abuse could potentially be distressing and bring back painful memories. Community support groups will help anyone affected in this way.

Where is the study run from?
The study will be run by Participatory Research at McGill (PRAM) in the department of Family Medicine at McGill University, Montreal, Canada, in collaboration with the Bauchi Chapter of the Federation of Muslim Women's Associations of Nigeria (FOMWAN) and the Bauchi State Primary Health Care Development Agency.

When is the study starting and how long is it expected to run for?
January 2021 to September 2026

Who is funding the study?
The study is funded by the Canadian Institutes for Health Research (CIHR).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PJT 178066

Study information

Scientific Title
Impact oriented dialogue for culturally safe adolescent sexual and reproductive health in Bauchi State, Nigeria. A trial among adolescents and other stakeholders in Toro LGA of evidence-based community dialogues and local actions as an intervention to improve key adolescent sexual and reproductive health outcomes, comparing 30 intervention communities with 30 control communities

Study objectives
Dialogues between adolescents and other stakeholders, based on qualitative and quantitative local evidence about adolescent sexual and reproductive health, can lead to community actions that improve adolescent sexual and reproductive health outcomes.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 01/03/2021, Bauchi State Health Research Committee (Bauchi State Ministry of Health, Bello Kirfi Road, Off Murtala Mohammed Way, Bauchi, PMB 065, Nigeria; -; bauchismoh@gmail.com), ref: NREC/03/11//19B/2021/03

2. Approved 13/09/2021, McGill University Faculty of Medicine and Health Sciences (3655 Sir William Osler #633, Montreal, Quebec , H3G 1Y6, Canada; +1 (514) 398 3124; irbsec.med@mcgill.ca), ref: A09-B51-21B

Study design
Interventional cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Adolescent sexual and reproductive health

Interventions
In the 30 intervention communities, groups of male and female adolescents and of other stakeholders will meet to consider and discuss evidence about issues of adolescent sexual and reproductive health and related factors coming from initial qualitative (focus groups and fuzzy cognitive mapping) and quantitative (household survey of adolescents and their parents) data collection in the 60 communities in the trial. Meeting first separately and later together, the groups will plan and implement actions based on this evidence. In the control communities there will be no dialogue groups. The intervention period will be approximately 18 months.

Intervention Type
Behavioural

Primary outcome measure
Adolescent sexual and reproductive health outcomes (priority outcomes will be determined from the focus groups and fuzzy cognitive mapping in the pre-trial period). The outcomes are likely to include: sexually transmitted diseases, experience and perpetration of physical or sexual violence, emotional distress, use of health services. The outcomes will be measured through a questionnaire to adolescents in households at baseline and 18-24 months later.

Secondary outcome measures
1. Knowledge and attitudes of adolescents about sexual and reproductive health outcomes measured by questionnaire survey at baseline and 18-24 months later in intervention and control communities
2. Knowledge and attitudes of parents, community leaders and service providers measured by questionnaire survey at baseline and 18-24 months later in intervention and control communities

3. Experience of participating in the intervention assessed by narratives of change from a range of participants in intervention communities after 18-24 months

Overall study start date
01/01/2021

Completion date
30/09/2026

Eligibility

Key inclusion criteria
Adolescents living in the trial communities and other stakeholders living in and serving these communities, including parents of adolescents, community traditional and religious leaders, and service providers

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
60 clusters (communities) in six wards. In the baseline and follow up surveys, 100 female adolescents, 67 male adolescents, 67 female parents and 25 male parents per cluster

Total final enrolment
60

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/07/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
Nigeria

Study participating centre

Federation of Muslim Women's Associations of Nigeria (FOMWAN)
Attahiru Bafarawa Street
Club Close GRA
Bauchi
Nigeria
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Sponsor information

Organisation
McGill University

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Sponsor type
University/education

Website
http://www.mcgill.ca/

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Planned publication in reputable peer-reviewed journals

Intention to publish date
01/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/03/2022	29/09/2022	Yes	No