

Yathu Yathu: an impact evaluation of community-based peer-led sexual and reproductive health services for adolescents and young people aged 15-24 in Lusaka, Zambia

Submission date 14/09/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/10/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/05/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Zambia has the 5th highest adolescent birth rate in sub-Saharan Africa (the region with the highest rates in the world) and 44.7% of women under 20 report an unplanned pregnancy. HIV prevalence rates in the Lusaka communities chosen for this study are 6.4% among 15-24 year old adolescent girls and women and 1.6% amongst adolescent boys and men of the same age, rising rapidly thereafter. The Zambian Adolescent Health Strategy 2017-2021 recognises sexual and reproductive health and HIV as the two leading priorities for health service planning with a mission "to ensure equity of access to appropriate, quality and cost-effective adolescent-friendly health platforms and an adolescent responsive health system as close to the people as possible." The aim of this study is to investigate whether a community-based, peer-led intervention that makes use of innovative technology, namely a prevention points "loyalty card" to incentivise service access and use, will increase knowledge of HIV status and uptake of other sexual and reproductive health services.

Who can participate?

Adolescents and young people aged 15-24 years in Lusaka, Zambia.

What does the study involve?

The study involves the delivery of comprehensive community-based, peer-led sexual and reproductive health services, including: HIV testing services, condom promotion and distribution, referral to voluntary medical male circumcision, comprehensive sexuality education, supported by the prevention points card system. The prevention points card enables service users to collect of "prevention" points, which can be exchanged for goods and services, to encourage uptake of services and measure access. The study will compare the uptake of sexual and reproductive health services by adolescents and young people living in 10 areas randomly allocated to the Yathu Yathu intervention compared to ten areas randomly allocated to have services provided via the local health facilities. To measure knowledge of HIV status, we will conduct a cross-sectional survey in all 20 areas approximately 18-months after the intervention

implementation and compare these outcomes between the intervention and control sites. To measure coverage, we will use the data routinely collected at point of service access and use by the prevention points cards system.

What are the possible benefits and risks of participating?

The direct benefit from study participation will be minor, but participants may feel good about having represented their communities and providing feedback about the uptake of health services and other related issues among young people their communities. In addition, knowledge gained from this study will help researchers understand how better to deliver sexual and reproductive health services to young people in Zambia and Southern Africa more generally. Participants will also benefit from knowing your HIV status.

Possible risks include that participants may become embarrassed, worried or anxious when answering some survey questions. To minimize any discomforts, some questions in the survey are “self-administered” and participants do not have to answer any questions that they do not want to answer.

Where is the study run from?

London School of Hygiene and Tropical Medicine (UK)

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

March 2019 to March 2022

Who is funding the study?

UK Medical Research Council (grant reference: MR/R022216/1)

Who is the main contact?

Prof Helen Ayles, helen@zambart.org.zm

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

NCT04060420

Secondary identifying numbers

MR/R022216/1

Study information

Scientific Title

Yathu Yathu: a cluster randomised trial to evaluate the impact of community-based peer-led sexual and reproductive health services on knowledge of hiv status among adolescents and young people aged 15-24 in Lusaka, Zambia

Acronym

Yathu Yathu

Study objectives

Through a cluster-randomised trial, this study will address the research question: Do community-based peer-led interventions increase knowledge of HIV status and coverage of sexual and reproductive health services among adolescents and young people in Lusaka, Zambia, compared to control? To address this question, the study aims to build a rigorous evidence-base of the effectiveness of community-based, peer-led HIV services designed with and for adolescents and young people living in Lusaka, Zambia, and evidence of the process of delivering such an intervention to support replication and scale-up if the intervention is effective. The study hypothesis is that Yathu Yathu community-based, peer-led services will increase knowledge of HIV status among adolescents and young people residing in zones randomised to Yathu Yathu when compared with knowledge of HIV status among adolescents and young people residing in control zones.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 27/06/2019, University of Zambia Biomedical Research Ethics Committee (Ridgeway Campus, P.O. Box 50110, Lusaka, Zambia; +260-1-256067; no email provided), ref 007-04-19
2. Approved 28/06/2019, Ethics Committee of the London School of Hygiene and Tropical Medicine (Keppel Street, London WC1E 7HT, UK; no telephone number provided; ethics@lshtm.ac.uk), ref 17104

Study design

Interventional cluster randomized trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Other

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

Increasing knowledge of HIV status among adolescents and young people aged 15-24, and increasing access to other sexual and reproductive health services (including family planning, STI screening, menstrual hygiene products).

Interventions

This is a cluster randomised trial, with 20 study clusters within two study communities. Randomisation was carried out during a public ceremony. During this ceremony, the 20 trial clusters were randomly allocated, in a 1:1 ratio, to one of the two trial arms (Yathu Yathu intervention or control arm). Randomisation was stratified by community (5 intervention and 5 control clusters per community) and restricted to provide balance by age (15-19 and 20-24) and sex, among other characteristics. After randomisation, blinding of study participants and staff to the allocation of the intervention was not feasible given the nature of the intervention (community-based, peer-led spaces (hubs) that provide comprehensive sexual and reproductive health services supported by a "loyalty" card system that incentivises service use). The control arm consists of the existing services in the ten control clusters and the prevention points card, which was offered to all adolescents and young people during enumeration of the two study communities.

For the intervention, the adolescents and young people (AYP) can choose whether or not to participate – we provided a service over 21 months. There is no follow-up time. The AYP randomly selected to participate in the survey are asked to complete a one-off questionnaire.

Yathu Yathu consists of hubs and a prevention points card loyalty system. The Yathu Yathu hubs are fixed spaces in the community that are physically away from the local health facility, but linked to the health facility through a referral system. All standard services available at the hubs are free of charge. The day-to-day management of the hubs is the responsibility of peer support workers (PSWs), with support from lay counsellors and nurses. Yathu Yathu hubs offer a comprehensive package of sexual and reproductive health services, key services available include: HIV testing and counselling, condom demonstrations and distribution, comprehensive sexuality education, information and referral for ART and VMMC, information and advice on contraceptives, provision of (emergency) contraceptives, including the pill, provision of menstrual hygiene products, among other services. The prevention points cards are similar to store "loyalty" cards and are intended to incentivise use of the Yathu Yathu services and to provide adolescents and young people with access to health and non-health related products through the points system. Similar to a "loyalty cards", each time an individual accesses a specific service at a hub or the local health facility, and presents their card, they accrue points dependent on the service accessed. The number of points offered was discussed with adolescents and young people during a formative research study and depends on the psychological challenge associated with accessing specific services. For example, collecting condoms accrues fewer points than having an HIV test. In addition to receiving points for accessing services, additional nudges (e.g. 'bring a friend') are implemented periodically. Once an individual has accrued sufficient points, these can be exchanged for products, such as branded condoms, soap and a wash cloth, toothbrush and paste, and branded sanitary pads.

Intervention Type

Behavioural

Primary outcome measure

Knowledge of HIV status measured in an endline cross-sectional survey, administered by an interviewer and conducted 18 months after implementation of the Yathu Yathu intervention.

Secondary outcome measures

1. The average number of services accessed at least once during a 12-month period, among 6 "key" services (including HIV testing, VMMC, long-acting contraceptives, condoms, PrEP, and ART) measured using data collected on the prevention points card and measured at the end of Yathu Yathu implementation.
2. The proportion of all adolescent boys and young men undergoing voluntary medical male circumcision in the last 12 months and since the implementation of Yathu Yathu, as measured using self-report in the endline cross sectional survey.
3. The proportion of adolescent girls and young women who do not want children or want to delay having children who report using family planning services, measured in the endline cross-sectional survey.
4. The proportion of HIV negative adolescents and young people who report use of PrEP in the past 12-months measured in the endline cross-sectional survey.
5. The proportion of HIV-positive AYP who report current use of ART in the endline cross-sectional survey.
6. The proportion of adolescent girls and young women who report a pregnancy in the last 12 months, as measured in the endline cross sectional survey.

Overall study start date

01/03/2019

Completion date

31/03/2022

Eligibility

Key inclusion criteria

1. ~16 – 26 years of age at time of the endline cross-sectional survey (15 to 24 at the time of household enumeration and prevention points card distribution)
2. Residing within the cluster during enumeration of the cluster
3. Received a prevention points card before intervention implementation (at the time of household enumeration)

Participant type(s)

All

Age group

Other

Sex

Both

Target number of participants

2400

Total final enrolment

1990

Key exclusion criteria

Anything that, in the opinion of the investigator, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.

Date of first enrolment

01/09/2019

Date of final enrolment

30/10/2021

Locations

Countries of recruitment

Zambia

Study participating centre

Zambart

Nationalist Road

Lusaka

Zambia

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Organisation

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Sponsor type

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Funder(s)

Funder type

Research council

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Primary and secondary outcomes of the trial measured in the cross sectional survey will be submitted for presentation at a relevant conference and for publication in a high impact journal. The secondary outcome measured using the prevention points card data will be submitted as a separate manuscript. Prior to submission to international conferences and journals, findings will be shared nationally. Data will be made available through LSHTM Data Compass, subject to ethical, data protection and other obligations being addressed.

Intention to publish date

31/07/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository. The data from this study will be recorded, described and made accessible in the LSHTM Data Compass. The study team will have exclusive use of the data up to 12 months after the end of the study.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Poster results			18/08/2022	No	No
Protocol article		17/09/2021	18/08/2022	Yes	No
Results article		21/04/2023	24/04/2023	Yes	No
Results article	Self-reported uptake of STI testing services	04/03/2024	07/03/2024	Yes	No
Results article		28/05/2024	29/05/2024	Yes	No