Yathu Yathu (“For us, by us”): design of a cluster-randomised trial of the impact of community-based, peer-led comprehensive sexual and reproductive health services for adolescents and young people aged 15 to 24 in Lusaka, Zambia

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Background

In sub-Saharan Africa, the growing population of adolescents and young people aged 15 to 21 (AYP) face a high burden of HIV, particularly adolescent girls and young women (AGYW). In 2019, AGYW in sub-Saharan Africa accounted for 24% of new HIV infections globally, despite AGYW accounting for only 10% of the global population. Although anti-retroviral therapy (ART) has dramatically improved survival for people living with HIV, and reduces the risk of onward transmission, reaching zero new infections requires increased coverage of all aspects of the HIV prevention and care continuum among AYP. AYP also experience a high burden of preventable and treatable sexually transmitted infections (STIs), and globally, an estimated 11% of births are among adolescent girls aged 15 to 19. Unplanned pregnancies and unsafe abortion result in high morbidity and mortality among AGYW, and have important social and economic implications.

Despite high burdens of HIV and a high risk of other STIs and unplanned pregnancies, AYP are the population least served by available sexual and reproductive (SRH) services. Adolescence is a period of rapid physical, social and cognitive transition, and AYP have unique sexual health needs as they progress to adulthood. Addressing these needs requires services that overcome barriers at the individual and structural levels, including limited psychosocial support, power imbalances within sexual relationships, lack of age-appropriate services, and fears of confidentiality of available services and of stigma/discrimination for accessing services. Strategies to increase coverage of SRH services, including HIV and STI testing, among AYP have largely focused on delivering youth-friendly services at health facilities, including MEMA kwa Vijana in Tanzania, which combined teacher-led, peer-assisted lessons on SRH with youth-friendly services, condom promotion and distribution, and community mobilisation; Regai Dzive Shiri Project in Zimbabwe, which combined youth-friendly services with peer education to increase knowledge and community mobilisation to change norms related to AYP’s access to SRH services, and, in Ghana, youth-friendly services delivered alongside peer outreach, school-based SRH education, and community mobilisation. Although these strategies have shown modest increases in service use, there remain barriers in consistently reaching high numbers of AYP. A gap in our knowledge is whether community-based approaches are more effective than health-facility-based services at reaching AYP.
Zambia remains one of the countries most affected by HIV despite declines in HIV prevalence and increased ART coverage. The 2018 Demographic and Health Survey estimated that HIV prevalence was 14% among women and 8% among men aged 15 to 59. To address the burden of HIV in Zambia, the HPTN-071 (PopART) trial evaluated the impact of a home-based combination HIV prevention intervention, the Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART) intervention, which included universal HIV testing and treatment, on HIV incidence. After four years of intervention, the first of the UNAIDS 90-90-90 targets (90% of people living with HIV to know their status) was met among 18-19 year olds and met among women but not men aged 20-24; while the second target (90% of those who know their HIV-positive status on ART) was not achieved among 18-24 year olds. The PopART for Youth (P-ART-Y) sub-study demonstrated that, despite improvements in knowledge of HIV status and ART coverage, maintaining high coverage among AYP is challenging.

Although PopART achieved high levels of knowledge of HIV status and ART uptake, there remained gaps in reaching AYP and sustainability was of concern. Key challenges included contacting 15-17 year olds and young men at home and slow linkage to care among young HIV-positive men. Rigorous evidence of community-based strategies that increase coverage of HIV and broader SRH services among AYP in Zambia, and other countries in sub-Saharan Africa, is critical.

In response to HPTN-071(PopART) findings, consultations were held with PopART adolescent community advisory board (aCAB) members in Lusaka to understand how we might reach AYP. During these consultations, aCAB members suggested that community-based services led by youth for youth would be more acceptable to them. In response, we co-designed “Yathu Yathu (For us, by us)”community-based, peer-led and incentivised comprehensive SRH services. We describe a cluster-randomised trial (CRT), carried out to address the research question: Does community-based, peer-led delivery of SRH services increase knowledge of HIV status and coverage of SRH services among AYP in Lusaka, Zambia, compared to facility-based service delivery? This study aims to build a rigorous evidence-base of the effectiveness of SRH services designed with and for AYP living in Lusaka, and evidence of the process of delivering such an intervention to support replication and scale-up if the strategy is effective.
Methods

Study Setting

This study is being conducted in two large, peri-urban communities in Lusaka, Zambia (Figure 1). Both communities were included in the HPTN-071 (PopART) trial and received the PopART intervention. Throughout HPTN-071 (PopART), extensive work was done with community representatives to ensure residents understand the fundamentals of research and were supportive during the trial. Yathu Yathu was built on these foundations of strong community and stakeholder relations, and has also benefitted from the epidemiological data on HIV collected by HPTN-071 (PopART).

For this study, the local health-facility catchment population of the two communities was sub-divided into 20 geographical areas of approximately similar population size. Each cluster, for the purpose of this trial, was one of these 20 geographical areas. Each area corresponds to a total population of ~2,350 individuals aged 15-24 years, corresponding to approximately: 500 adolescent boys and 600 adolescent girls aged 15-19 years, and 500 men and 700 women aged 20-24 years (based on HPTN-071 (PopART) data for 2017).

Overall design

We will measure the impact of a package of community-based and peer-led comprehensive SRH services (Yathu Yathu) on knowledge of HIV status and other SRH outcomes. The CRT has two arms (Figure 2); stratified by community, 10 clusters per community were randomly allocated, in a 1:1 allocation ratio, to receive either the Yathu Yathu (intervention arm) or control arm. The primary outcome, knowledge of HIV status, will be measured in a cross-sectional survey.

Co-development of Yathu Yathu

The strategy under evaluation in this trial was co-developed with AYP in the two study communities. In a 9-month formative research study, the study team conducted qualitative research and discrete choice experiments (DCE) with AYP. The qualitative research aimed to understand AYP’s knowledge of and access to available SRH services, how they would want to be able to access these services in their communities, and their opinions about a loyalty card scheme, intended to offer AYP the opportunity to accrue points and redeem...
rewards for accessing SRH services. DCE were used to understand AYP preferences for how to access SRH services. To finalise the design of Yathu Yathu, findings emerging from the formative study were presented to AYP at a workshop held in each community.

**Distribution of the Yathu Yathu Prevention Points Cards**

At the start of the implementation period, trained enumerators systematically visited and enumerated all households in the 20 study clusters. For household members aged 15-24 years, the enumerators offered the AYP a loyalty card, called a prevention points card (PPC). This card had a unique barcode to allow the study team to know which cluster the AYP resided in. If the household head or AYP was absent, enumerators made up to three repeat visits to enumerate the household and offer the AYP a PPC. After three visits, the enumerator listed the AYP as not recruited, and the parent/guardian was informed that the AYP could visit the Yathu Yathu hub or local health facility to arrange for distribution of a PPC.

In intervention clusters, enumerators informed AYP that their PPC could be used to accrue points every time they accessed SRH services at the Yathu Yathu hub or at the local, government-run health facility. In control clusters, enumerators informed AYP that their PPC could be used to accrue points when accessing SRH services at the health facility. AYP in control clusters could access services at Yathu Yathu hubs, but would not accrue points for services accessed.

After enumeration and PPC distribution, Yathu Yathu was established during a pilot phase between September 2019 and January 2020. During this phase, adaptations were made in response to implementation outcomes measured using the PPC data, including reach and services accessed, to increase coverage of SRH services. After February 2020, no further adaptations were made and Yathu Yathu was implemented in a phase considered the evaluation phase.

**The Yathu Yathu Package of SRH Services**

The Yathu Yathu package aims to promote and contribute to AYP’s health and well-being through the provision of comprehensive HIV and other SRH services (Figure 3). Yathu Yathu aims to increase coverage of SRH services and therefore primarily offers these services.
However, in recognising that AYP’s health and well-being extends beyond improved sexual health, Yathu Yathu offers other health-related products through the PPC system and referrals to other services as detailed below.

The Yathu Yathu strategy consists of three key components provided in addition to current standard of care:

1. Community-based, peer-led spaces, called Yathu Yathu hubs, that provide comprehensive SRH services;
2. The PPC, which are “loyalty cards” that allow AYP to accrue points for accessing SRH services and spend points on rewards, and
3. Community engagement activities to inform AYP and the broader community of the services available through Yathu Yathu.

**Yathu Yathu hubs**

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 SRH services (Figure 3), key services available include:

- HIV counselling and testing, including self-testing (HIVST) and rapid testing of a finger-prick blood sample performed by lay counsellors;
- Information and referral for ART initiation;
- Comprehensive sexuality education;
- Condom use demonstrations, provision of male and female condoms and lubricants;
- Information and advice on contraceptives, provision of (emergency) contraceptives, including the pill;
- Information and referral for VMMC services at the government health facility;
• Information, screening and referral to the local health facility for diagnosis and treatment of STIs, and
• Provision of free menstrual hygiene products.

Active linkage to health facilities is facilitated by members of the Yathu Yathu study team. In addition to SRH-specific services, the Yathu Yathu hubs offer non-SRH services such as:
• Support for substance abuse (in particular alcohol use), screening for alcohol abuse and information on the harms of alcohol.
• Edutainment, including screening of videos on SRH and general adolescent health.

As described, the day-to-day management of the hubs is the responsibility of the PSW. A team of two PSW (consisting of one male, one female) manages each of the 10 hubs (N=20 PSW). PSW were trained on how to deliver SRH services and have knowledge about what SRH and other services are available to AYP outside of the hubs. They received training on core services, such as providing HIVST information and demonstrations, information on ART, the HIV prevention services and how to refer individuals to relevant services, demonstrations of condoms, and contraceptive services. They were also trained on the availability of organisations supporting individuals reporting gender-based violence and referral to these organisations.

PSW are supported and managed by hub supervisors, who are trained HIV lay counsellors. One hub supervisor is responsible for one hub and one pair of PSW (N=10 overall). At the hubs, hub supervisors provide HIV testing services (HTS) and support linkage to and retention on ART. Hub supervisors mentor the PSW, have regular supervision meetings with the PSW and support the delivery of HTS and ART services in particular. Each hub supervisor, in addition to their role as lay counsellor, was trained on delivering a brief intervention for alcohol dependency.

Two nurses are trained in the provision of adolescent-friendly health services, in particular contraceptive services. Nurses rotate between the hubs, such that a nurse is available at each hub approximately one-day per week. In addition to dispensing contraceptives, nurses provide personalised contraceptive advice and support linkage to ART.
Two intervention coordinators, one in each study site, are responsible for ensuring the implementation of the study is conducted according to the study protocol. Their role includes, but is not limited to, ensuring commodities and rewards are available and standard operating procedures are followed, identifying and tracking weaknesses and gaps in implementation, tracking study progress and ensuring coordination with Ministry of Health and other partners in the community.

**Yathu Yathu prevention points cards**

The PPC are intended to incentivise use of SRH services and provide AYP with access to health and non-health related products through the points system. The cards are similar to store “loyalty cards”. Each time AYP access a specific service at a hub or the local health facility, and present their card, they accrue points dependant on the service accessed. The number of points offered 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 AYP have 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. As with accruing of points, the rewards “cost” differing numbers of points. The points and reward system was designed such that it incentivises service use among AYP who want and need to access services, yet isn’t coercive. The system was discussed with AYP and the broader study community during the formative phase in order to achieve this balance.

**Community Engagement**

In each study community, a community mobiliser is responsible for community engagement activities. The community mobiliser creates awareness regarding the study among AYP and other groups through community meetings, workshops with key stakeholders, and meetings with other existing groups such as health committees, development committees, and civil society. One of the main tasks of the community mobiliser is to keep dialogue open and ongoing between researchers and the community. Community engagement staff document the number of community engagement activities conducted, the number of AYP reached by each activity, and the response received from the community.
The Control Arm

The control arm consists of the existing services in the ten control clusters, including:

a) All standard health services offered at the health facility such as HTS, ART, TB screening and treatment, ANC, STI screening and treatment, VMMC, PEP, pregnancy testing, condom provision and family planning services, which are available to the general population, and

b) Services available at youth-friendly corners located within the local health facilities, such as condom provision, health talks to provide information on SRH, and support groups for youth living with HIV. All other services that may be needed will be accessed in the same way as for the general population.

In the ten control clusters, AYP are able to accrue points on their PPC by accessing services at the local health care facilities through self-referral or via youth-friendly corners. AYP can redeem rewards at the local health facility.

Randomisation

Randomisation was carried out during a public ceremony in July 2019. During this ceremony, the 20 trial clusters were randomly allocated to one of the two trial arms. 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, on: 1) participation in the PopART intervention (although both communities were allocated the PopART intervention, households and individuals could refuse to participate); 2) knowledge of HIV status during the last year (2017) of the PopART intervention; 3) Uptake of HIV testing during the last year (2017) of the PopART intervention; 4) average population of AYP aged 15-24, and 5) average distance from the centre of the zone to the local health facility. Overall, this provided 5,449 possible allocations. The list of possible allocations was generated by SF using Stata 15 prior to the public ceremony.

Evaluation of Impact

Evaluation of the impact of Yathu Yathu on the primary outcome of knowledge of HIV status will be measured among AYP randomly selected for participation in a cross-sectional survey in each study cluster. The cross-sectional survey started in 29 April 2021.
Simple random sampling, stratified by sex and age group (15-19, or 20-24 years; ~25 participants/group) at the time of population enumeration, will be used to select approximately 100 AYP per cluster (~2,000 AYP across all 20 clusters) from the list of AYP aged 15-24-years who were enumerated and given a PPC at the start of the study. Within each of the four combinations of sex and age group, individuals will be randomly ordered and approached for participation in this order until the target sample size for each group and the ~100 participants per cluster are reached. Research staff will visit the households of individuals randomly selected to participate in the survey. Up to three household visits will be conducted. If, after three household visits, the selected AYP has not been met, it will be recorded that they were not contacted and did not participate in the survey.

AYP consenting to participate will be asked to complete a questionnaire. The questionnaire includes modules on socio-demographic variables, knowledge and uptake of HIV testing, treatment and prevention services, alcohol use, history of contraceptive use and pregnancy, and the Hope scale, to measure AYP’s expectations for the future. The questionnaire will be completed on a personal digital assistant (PDA) and administered by a research assistant. For the module on sexual behaviours, individuals will be offered the option to self-complete this on the PDA.

As part of the survey, consenting AYP will be offered HIV testing services to provide an opportunity for AYP to learn their HIV status. HIV testing will be conducted using finger prick blood sample rapid HIV tests according to Zambian national guidelines. Research assistants, who will be trained as lay counsellors, will perform the rapid finger-prick HIV testing, with confirmatory testing of a positive test result conducted using a second HIV test. As HIV testing is primarily being offered as a service, an individual not consenting to HIV test can still complete the questionnaire.

**Study outcomes**

The primary outcome of the study is knowledge of HIV status, defined as self-reporting HIV-positive status or reporting HIV-testing in the previous 12-months. Secondary outcomes of the study, which will be measured using the PPC data (first secondary outcome only) or self-reported in the cross-sectional survey, include:
• The average number of services accessed at least once during a 12-month period, among 6 “key” services (including HTS, VMMC, long-acting contraceptives, condoms, PrEP, and ART; measured using PPC data);
• The percentage of young men reporting that they underwent medical male circumcision in the past 12-months;
• The percentage of young women who do not want children or want to delay having children who report using family planning services;
• The percentage of HIV negative AYP who report use of PrEP in the past 12-months;
• The percentage of HIV-positive AYP who report current use of ART; and
• The percentage of young women reporting a pregnancy within the past 12-months.

Process Evaluation

A mixed methods process evaluation is embedded within the impact evaluation (Table 1). The process evaluation aims to provide evidence of how and why the intervention did (or did not) have an impact, by focusing on three key domains: implementation, AYP’s uptake of and response to Yathu Yathu, and contextual factors affecting implementation and response to the intervention. The process evaluation will use data routinely collected via the PPC and qualitative data collected via focus group discussions, observations of service delivery, in-depth interviews (including a longitudinal cohort), and “mystery” shoppers, who will attend hubs and access services while assessing, among other factors, youth-friendliness of services.

To document implementation, the process evaluation will assess:

a) Fidelity (whether the strategy was delivered as intended), dose-delivered and received, including how many condoms were distributed, HIV tests conducted, among other services, overall and at each hub, and average number of services accessed by each AYP attending the hubs;

b) Feasibility of delivering Yathu Yathu, as determined by providers’ experiences with delivery.

To document who is reached by the intervention, we will:

c) Measure who accessed the hubs by age and sex, and the specific services accessed;
Conduct two case control studies to examine factors related to:

- men’s attendance of the Yathu Yathu hubs (case-control study 1), and
- use of points to redeem rewards among AYP attending the hubs (case-control study 2).

We will use findings emerging from the qualitative data to:

e) Assess the acceptability of the intervention among AYP, their parents/guardians and the community as a whole.

f) Evaluate AYP experiences of accessing Yathu Yathu services and any positive consequences of service access.

g) Document unintended consequences and social harms.

h) Document the influence of contextual factors on intervention implementation and AYP engagement with the intervention, including stigma, and community perceptions about delivering SRH services to AYP.

**Nested Case-control studies**

Two case-control studies will examine factors associated with uptake of the intervention components in the 10 intervention clusters.

The first case-control study will examine factors associated with non-attendance of the hubs among men aged 18-24 years, with harmful alcohol use the primary factor of interest. Cases are defined as men who do not access a Yathu Yathu hub in the first 12 months of implementation and controls defined as men who do access a Yathu Yathu hub at least once in the first 12 months of implementation. Stratified by community, 320 cases and controls will be randomly recruited, in a 1:1 ratio using data on who accepted a PPC as the sampling frame, from the ten intervention zones. Men participating in the study will complete a questionnaire, with questions on socio-demographics, harmful alcohol use measured using the Alcohol Use Disorders Identification Test (AUDIT-C), social support, and access to other health services.

The second case-control study will explore what factors, primarily household socioeconomic position, are associated with redeeming rewards and will explore AYP’s motivation for
accessing services. Cases are defined as AYP who attended the hubs at least twice and earned points but did not redeem rewards using their PPC and controls defined as AYP who attended the hubs at least twice and earned points and redeemed rewards using their PPC. The rationale for restricting recruitment to AYP for whom there is evidence (on the basis that they made at least one repeat visit after initial hub attendance) that they likely value the available services. As with the first case-control study, 320 cases and controls will be randomly recruited, stratified by community and in a 1:1 ratio, from the ten intervention zones.

**Economic evaluation**

A prospective cost analysis will be undertaken from the societal perspective to calculate costs of delivering Yathu Yathu. Costs will be collected via a bottom-up approach, coupled with field observation to account for opportunity cost and establish cost allocation factors. Cost categories will include items such as: capital costs (buildings, equipment and facilities, project set-up, and one-off trainings), recurrent costs (personnel, supplies, recurrent training, quality control, supervision and mentorship) and project coordination (project administration, building operations costs and utilities). Unit costs will be calculated as cost per AYP accessing the hubs, and per AYP HIV-tested, among other indicators. We will also conduct time observations with all PSWs and community mobilisers for two days each in the intervention arm to document daily activities and running time. For the control arm, 1-3 SRH care providers will be observed for 2 days each at each health facility to document running time for every activity. Yathu Yathu supervisors and coordinators will be given time cards to complete as they execute their daily activities for 2 weeks.

Patient costs will be collected through exit interviews. Exit interview participants will be sequentially recruited on a daily basis at all hubs (n≈100) and the two local health facilities (n≈20) until a sample of ~120 AYP are included in the study. AYP will be asked about costs incurred for accessing SRH services.

**Statistical considerations**

The trial has been powered to detect whether Yathu Yathu has an impact on the primary outcome and on the first of the secondary outcomes. Several secondary outcomes (described above) will also be compared between the two trial arms.
Power Calculations

Based on findings from HPTN-071 (PopART) and P-ART-Y, we estimated that, in control arm clusters, ~25%-50% of AYP would not know their HIV status compared with 10-20% in intervention clusters, and that the coefficient of between-cluster variation in this outcome would be in the range 0.2-0.3. For a comparison of 25% vs 10%, which we consider plausible and of difference of public health importance, study power is 99% among all individuals and 98% in sub-group analysis of those aged 15-19 and 20-24 years; for a comparison of 35% vs 20%, study power is 91% among all individuals and 85% in sub-group analysis, assuming that the coefficient of between cluster variation $k=0.3$.

The composite measure of service coverage will be measured using the PPC data. We estimated that the average number of services accessed at least once during a 12-month period, among 6 “key” services, will be in the range 0.8-1.3/individual in control arm clusters and in the range 1.2-1.8/individual in intervention clusters. If, in control clusters, 40% of AYP access none of the key services, 40% access one, 15% access two, and 5% access three, this gives an average of 0.85 services accessed per individual; if in intervention clusters, 20% access none of the key services, 40% access one, 30% access two, and 10% access three this gives an average of 1.3 services accessed per individual. We next assumed: that the standard deviation of the number of services accessed per individual is 1 in all clusters and a coefficient of variation in the range $k=0.2$ to $k=0.25$.

With these assumptions, study power is 93% for comparisons among all individuals, and in sub-group analysis, if the true value of the mean number of services accessed per individual is 0.85 in the control arm and 1.3 in the intervention arm.

Statistical Analysis

The primary analysis will be based on an intention-to-treat analysis comparing knowledge of HIV status between the Yathu Yathu intervention and control clusters. We will use cluster-level analysis as is standard for cluster-randomised trials with <15 clusters in each trial arm. We will report our findings in line with the CONSORT guidelines on reporting CRT and complete a statistical analysis plan before analysis of the endline survey.

The percentage of individuals with each outcome, and the average number of services accessed per individual (for the composite indicator), will be summarised for each of the 20
clusters. Analysis of variance will be done on these cluster-level summaries, adjusted for community, with the effect of the intervention summarised using prevalence ratios and mean differences (for the composite indicator), with corresponding 95% confidence intervals and p-values.

In adjusted analysis, we will adjust only for community, age group and sex, using the two-stage approach for analysis of CRTs. We will use logistic regression (for binary outcomes) and linear regression (for the composite indicator) applied to the individual-level data to estimate the predicted proportions and number of services for each individual, respectively, under the null hypothesis of no intervention effect. Following this, the predicted values will be summed for each cluster, and we will then calculate cluster-level residuals as (a) the ratio of the observed number of individuals with the outcome divided by the predicted number, for binary outcomes (b) as the difference between the observed total number of services accessed and the predicted total number of services accessed, divided by the number of individuals contributing to the analysis, for quantitative outcomes. Analysis of variance will then be done on these cluster-level residuals, in the same way as for the unadjusted analysis, to estimate the effect of the intervention and corresponding 95% confidence intervals. A priori sub-group analyses will be done for males and females, by age group (15-19 and 20-24 years) and for these four sex/age groups.

As there is a risk of contamination, with AYP in control zones able to access services from the hubs albeit without redeeming points, we will conduct a sensitivity analysis to explore the implications of contamination for our findings. In sensitivity analyses, we will exclude individuals in control zones from the numerator if they accessed services relevant to the outcome from the hubs. For example, for the primary outcome, if AYP in control zones accessed HIV testing services from the hubs it will be assumed that they would not have accessed these services in the absence of Yathu Yathu.

**Ethical Considerations**

The trial was approved by the University of Zambia Biomedical Research Ethics Committee (UNZA BREC) and the Ethics Committee of the London School of Hygiene and Tropical Medicine. Individual consent was sought during PPC distribution at the time of enumeration. Individuals aged 18-24 were asked for written informed consent before
distribution of the PPC. For adolescents aged 15-17, parents/guardians were asked for written informed consent for the adolescent under their care to participate, and adolescents asked for informed assent.

For research activities, written informed consent and assent (for participants aged 15-17) will be required before enrolling participants in the case-control studies and in qualitative research activities that involve collection of participant-identified responses (interviews and focus groups). For the endline survey, a waiver of parental consent was granted from UNZA BREC and LSHTM, as parents/guardians provided consent during PPC distribution and, during the P-ART-Y study conducted in the same communities, CAB and aCAB members asked for waiver of parental consent. AYP will be asked to provide informed consent for participation.

**Discussion**

We outline details of a CRT that will provide rigorous evidence of whether community-based SRH services increase uptake of SRH services when compared to facility-based SRH services.

In both arms, service access will be incentivised through the availability of the PPC system. Alongside the impact evaluation, we are conducting a mixed methods process evaluation to document implementation of Yathu Yathu and understand how and why the intervention worked, or why it didn’t work should we find no evidence for an impact. With a limited evidence-base to date about the impact of community-based services on coverage of SRH services, our study will provide evidence critical to expanding our knowledge of how to reach AYP.

Despite a rigorous design, our study has limitations. Firstly, this study is at risk of contamination. The clusters are geographical areas defined by the research team, they are relatively densely populated, but contiguous and AYP are likely to move between them. AYP in control clusters may choose to access services at the Yathu Yathu hubs. The unique barcode on the PPC distributed at the start of the implementation period will indicate the cluster in which AYP reside. We will use this information to understand the extent of any contamination. Our primary outcome is based on self-reported HIV testing behaviour, which may be subject to bias. Our process evaluation and case control study 1 aim to understand
why some AYP chose not to attend hubs. Reaching AYP who choose not to engage with Yathu Yathu may prove challenging and limit our ability to understand non-engagement.

Of note, and as mentioned, Yathu Yathu is being conducted in communities previously exposed to the PopART intervention. This exposure may affect generalisability. However, Yathu Yathu is novel to the communities in that it offers comprehensive SRH services, is led by and targeted at youth, and makes use of a novel “loyalty” card system. As such, we consider findings generalizable to similar, high HIV prevalence settings exposed to strategies to promote HIV testing at population-level.

In March 2020, in response to the COVID-19 pandemic, the Yathu Yathu hubs closed for three months. Subsequently, in July 2020, hubs were reopened with revised standard operating procedures implemented to minimise the risk of transmission, including restricting the number of AYP attending hubs at any one time. These disruptions and adaptations to implementation may affect the effectiveness of the strategy. Our process evaluation will not only document the implications of COVID-19 for implementation, it will provide evidence of whether fear of COVID-19, among other contextual factors, affected AYP’s access to services at the hubs.

Despite limitations, our study will provide rigorous evidence of whether community-based SRH services, supported by incentives, reach AYP, who these services reach and the cost of these services. The delivery of community-based services supported by incentives in the form of loyalty cards is novel, and may prove a simple strategy to improve access to SRH services. AYP remain underserved by available SRH services, and are therefore lagging behind in achievement of the UNAIDS 90-90-90 goals; there remains a critical need to identify ways to provide AYP with access to SRH services. Much of the available evidence of strategies to reach AYP focus on youth-friendly services at health facilities and/or peer-led outreach and education. Rigorous evidence of whether community-based and peer-led services, with strong links to the local health facility, increase coverage of critical SRH services would add to the evidence-base of how to reach AYP.

**Trial Status**

Cross-sectional survey expected to enrol participants on 29 April 2021. ISRCTN Registry Number NCT04060420
Study Sponsorship and Funding statement

This study is funded by the UK Medical Research Council, DFID and NIHR. The sponsors had no involvement in study design; collection, management, analysis, or interpretation of data; writing of the report; nor the decision to submit this paper for publication.

Declarations

Ethics approval and consent to participate: The trial was approved by the University of Zambia Biomedical Research Ethics Committee (UNZA BREC) and the Ethics Committee of the London School of Hygiene and Tropical Medicine. Individual written consent was sought during PPC distribution at the time of enumeration. Individuals aged 18-24 were asked for written informed consent before distribution of the PPC. For adolescents aged 15-17, parents/guardians were asked for written informed consent for the adolescent under their care to participate, and adolescents asked for informed assent.

Written informed consent was obtained for all research activities. For the endline survey, a waiver of parental consent for AYP aged under 17 was granted; written informed consent was obtained for all adolescents and young people asked to participate.

Consent for publication: Consent for publication was obtained during the consenting process.

Availability of data and materials: Not applicable

Competing interests: The authors have no conflicts of interest to declare.

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Authors' contributions: HA, RH, SFid, MSimw and KS are senior investigators on the trial. BH drafted the protocol paper based on the protocol developed BH, MP, LM (economics), MS, SB, MSimw (qualitative, community engagement), LS, AS, SF (data collection, analysis, sample size). All authors have read the final manuscript, and give approval for it to be published.

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<table>
<thead>
<tr>
<th>Page</th>
<th>List of Abbreviations</th>
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<td><strong>List of Abbreviations</strong></td>
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<tr>
<td>518</td>
<td>AIDS</td>
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<td>519</td>
<td>ANC</td>
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<td>520</td>
<td>ART</td>
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<td>HPTN</td>
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<td>HTS</td>
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<td>PopART</td>
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<td>PrEP</td>
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<td>530</td>
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<td>TB</td>
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<td>UNAIDS</td>
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<td>UNZA BREC</td>
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<tr>
<td>534</td>
<td>VMMC</td>
</tr>
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<td>535</td>
<td></td>
</tr>
</tbody>
</table>
References

1. UNAIDS. Seizing the Moment: Tackling entrenched inequalities to end epidemics. GLOBAL AIDS UPDATE. (2020).


Table 1: Description of the services accessed*, conditions attached to the service access, and the number of points that are gained from the service accessed.

<table>
<thead>
<tr>
<th>Description of service accessed and conditions</th>
<th>Points gained from service accessed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection of male condoms (max once a week)</td>
<td>65</td>
</tr>
<tr>
<td>Attend a comprehensive sexuality education (CSE) session</td>
<td>65</td>
</tr>
<tr>
<td>Attend an Edutainment session (e.g. MTV Shuga, Love Games)</td>
<td>65</td>
</tr>
<tr>
<td>Collection of self-test(s) (max. 2 tests, once in the 3 months)</td>
<td>125</td>
</tr>
<tr>
<td>Collection of female condoms (max. once a month)</td>
<td>125</td>
</tr>
<tr>
<td>Male condom use demonstration (one-off)</td>
<td>125</td>
</tr>
<tr>
<td>Screened for sexually transmitted infection (STI)</td>
<td>125</td>
</tr>
<tr>
<td>HIV-test done at the hub (max. 4 times a year)</td>
<td>250</td>
</tr>
<tr>
<td>HIV-test at the clinic (max. 4 times a year)</td>
<td>250</td>
</tr>
<tr>
<td>Start of oral or injectable contraceptives (one-off)</td>
<td>250</td>
</tr>
<tr>
<td>Collection of ART</td>
<td>250</td>
</tr>
<tr>
<td>Accepted long term contraceptive (Jadelle or IUD) (one-off)</td>
<td>500</td>
</tr>
<tr>
<td>Initiation of Antiretroviral Therapy (one-off)</td>
<td>500</td>
</tr>
<tr>
<td>Initiation of Pre-Exposure Prophylaxis (one-off)</td>
<td>500</td>
</tr>
<tr>
<td>Accept and access voluntary medical male circumcision (one-off)</td>
<td>500</td>
</tr>
</tbody>
</table>

*Not All services available are listed.
Table 2: Description of the rewards offered, the actual unit cost of the item to purchase, and the number of points required to redeem the reward item (1 point is equivalent to K0.05).

<table>
<thead>
<tr>
<th>Description of reward</th>
<th>Unit cost of item*</th>
<th>Points to redeem item**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pens</td>
<td>2.00</td>
<td>40</td>
</tr>
<tr>
<td>Tooth brush</td>
<td>4.50</td>
<td>90</td>
</tr>
<tr>
<td>Facecloths</td>
<td>6.90</td>
<td>138</td>
</tr>
<tr>
<td>Hard cover note books</td>
<td>13.55</td>
<td>271</td>
</tr>
<tr>
<td>branded male condoms (moods)</td>
<td>7.00</td>
<td>140</td>
</tr>
<tr>
<td>Bathing soap</td>
<td>7.50</td>
<td>150</td>
</tr>
<tr>
<td>Deodorant</td>
<td>15.00</td>
<td>300</td>
</tr>
<tr>
<td>Tooth paste</td>
<td>8.50</td>
<td>170</td>
</tr>
<tr>
<td>Razor</td>
<td>9.50</td>
<td>190</td>
</tr>
<tr>
<td>Toiletry bags</td>
<td>10.00</td>
<td>200</td>
</tr>
<tr>
<td>Nail polish</td>
<td>10.50</td>
<td>210</td>
</tr>
<tr>
<td>Barbershop vouchers</td>
<td>15.00</td>
<td>300</td>
</tr>
<tr>
<td>Hair saloon vouchers</td>
<td>35.00</td>
<td>700</td>
</tr>
<tr>
<td>Branded t-shirts</td>
<td>84.00</td>
<td>1680</td>
</tr>
<tr>
<td>Re-usable sanitary pads (pack of 3)</td>
<td>150.00</td>
<td>3000</td>
</tr>
</tbody>
</table>

*Cost of item in Zambian Kwacha as in August, 2019. **USD=ZMW exchange rate as in August 2019 (1USD=K13.01)
Table 3. Summary of outcomes and data collection methods for three key domains of the Yathu Yathu mixed methods process evaluation

<table>
<thead>
<tr>
<th>Objective</th>
<th>Outcomes</th>
<th>Data collection method</th>
<th>Quantitative</th>
<th>Qualitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation of the intervention</td>
<td>Measure fidelity of intervention implementation</td>
<td>Logs of training, supervision meetings; PPC</td>
<td>MS; observations</td>
<td>SSI; observations; FGD</td>
</tr>
<tr>
<td></td>
<td>Assess the feasibility of delivering the intervention and providers’ experiences with delivering the intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dose-delivered of different services</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant response to and experiences of the intervention</td>
<td>Dose of specific services received by AYP</td>
<td>PPC</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Measure (by age/sex) who is reached, and what services are accessed by the AYP reached</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Investigate what factors are associated with accessing hubs</td>
<td>CC1/PPC</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Investigate whether household socioeconomic position, among other factors, is associated with redemption of rewards</td>
<td>CC2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Assess acceptability of Yathu Yathu to AYP, their parents/guardians and the broader community.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Document AYP experiences of accessing services and any positive consequences of attending hubs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Document unintended consequences and social harms</td>
<td>IDI; QC; MS; FGD</td>
<td></td>
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</tr>
<tr>
<td>Context</td>
<td>Document the influence of context on implementation and participant engagement with the intervention</td>
<td>FGD, IDI; MS</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>FGD, IDI</td>
<td></td>
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</table>

Key: CC- case control; PPC - prevention points card; FGD – focus group discussion; IDI – in-depth intervention; QC –qualitative cohort; MS – Mystery Shopper; SSI – semi-structured interview
Figure 1. Map of Zambia, the two Yathu Yathu study communities and the 20 clusters randomised to the Yathu Yathu intervention or standard of care.
Figure 2. Schematic of the cluster randomised trial to evaluate the impact of Yathu Yathu comprehensive sexual and reproductive health services.

Random allocation of 20 clusters

Household enumeration and distribution of Prevention Points Cards

10 clusters allocated to Yathu Yathu intervention, which includes:
- Yathu Yathu community-based hubs offering SRH-related, including HIV, services
- Nurse and lay counsellor as link to health facility
- Prevention points cards to redeem points after accessing services at community space/health facility

10 clusters allocated to comparison, which includes:
- Availability of SRH, including HIV, services at local health facility (standard of care)
- Prevention points cards to redeem points after accessing services at health facility

Cross-sectional survey to measure primary and secondary outcomes

Ongoing data collection through prevention points card
Case control studies
Qualitative enquiry
Economic evaluation
Figure 3. Diagram showing the Yathu Yathu Intervention Components and Process of Accruing and Redeeming Prevention Points

Yathu Yathu Hubs in the community away from clinic with Peer Support Workers (PSWs) and Yathu Yathu Hub supervisors (YYHS) providing daily services.

- Nurse to provide services at YY Hub once a week.
- Referral for services to local health facility: ART, VMMC, LARCs, TB diagnosis and treatment, ANC.
- All participants to swipe to attend any services at YY centre OR Clinic.
- AYP to access HIV testing, STI screening and treatment, contraceptive advice and contraceptives, education, substance use support, condom distribution.
- Access to comprehensive sexuality education.
- Points redeemed for rewards of health products, and non-health products.
- Present card and earn prevention points.
Figure 3. Simplified logic model showing hypothesised pathway through which Yathu Yathu will have an impact on the primary outcome

**Yathu Yathu Hubs**
- Recruit:
  - Nurses
  - Lay health workers
  - Peer support workers (PSW)
- Resources/funds for supplies (e.g., condoms, test kits, community engagement and rewards)

**Yathu Yathu Prevention Points Cards**
- Funds for technology & cards

**Inputs**
- Service delivery SOPs developed
- Staff trained on delivering SRH services to AYP and referral to other services (by research team)

**Activities**
- YY staff delivering and promoting SRH services
- Community mobilisation ongoing
- Non-SRH services
  - Staff trained on support services for substance abuse (esp. alcohol use)
  - Entertainment available

**Outputs**
- Hubs established and redecorated
- PSW confident & competent in offering youth-friendly services
- Community mobilisation activities conducted
- AYP attending hubs
- AYP have demand for & knowledge of SRH services
- AYP redeeming points & obtaining rewards using points

**Anticipated changes**
- AYP consider the services available at Yathu Yathu to be appropriate and important to their health
- AYP have positive experiences in accessing services and rewards from the hubs
- AYP consider accessing SRH services from Yathu Yathu as acceptable
- AYP consider the rewards available at Yathu Yathu hubs to have value to them
- A high number of AYP attend hubs and accessing services

**Impact**
- Increased knowledge of HIV status

**Contextual factors affecting implementation and participant engagement**
- (including stigma, alcohol (ab)use, attitudes toward AYP access of SRH services)