

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

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19 **Background**

20 In sub-Saharan Africa, the growing population of adolescents and young people aged 15 to
21 24 (AYP) face a high burden of HIV, particularly adolescent girls and young women (AGYW).
22 In 2019, AGYW in sub-Saharan Africa accounted for 24% of new HIV infections globally,
23 despite AGYW accounting for only 10% of the global population.¹ Although anti-retroviral
24 therapy (ART) has dramatically improved survival for people living with HIV,² and reduces
25 the risk of onward transmission,³ reaching zero new infections requires increased coverage
26 of all aspects of the HIV prevention and care continuum among AYP.^{4,5} AYP also experience
27 a high burden of preventable and treatable sexually transmitted infections (STIs),⁶ and
28 globally, an estimated 11% of births are among adolescent girls aged 15 to 19.⁷ Unplanned
29 pregnancies and unsafe abortion result in high morbidity and mortality among AGYW, and
30 have important social and economic implications.⁸

31 Despite high burdens of HIV and a high risk of other STIs and unplanned pregnancies, AYP
32 are the population least served by available sexual and reproductive (SRH) services.^{9,10}
33 Adolescence is a period of rapid physical, social and cognitive transition, and AYP have
34 unique sexual health needs as they progress to adulthood.¹¹ Addressing these needs
35 requires services that overcome barriers at the individual and structural levels, including
36 limited psychosocial support, power imbalances within sexual relationships, lack of age-
37 appropriate services, and fears of confidentiality of available services and of
38 stigma/discrimination for accessing services.^{12,13} Strategies to increase coverage of SRH
39 services, including HIV and STI testing, among AYP have largely focused on delivering youth-
40 friendly services at health facilities, including MEMA kwa Vijana in Tanzania, which
41 combined teacher-led, peer-assisted lessons on SRH with youth-friendly services, condom
42 promotion and distribution, and community mobilisation;¹⁴ Regai Dzive Shiri Project in
43 Zimbabwe, which combined youth-friendly services with peer education to increase
44 knowledge and community mobilisation to change norms related to AYP's access to SRH
45 services,¹⁵ and, in Ghana, youth-friendly services delivered alongside peer outreach, school-
46 based SRH education, and community mobilisation.¹⁶ Although these strategies have shown
47 modest increases in service use, there remain barriers in consistently reaching high numbers
48 of AYP. A gap in our knowledge is whether community-based approaches are more effective
49 than health-facility-based services at reaching AYP.

50 Zambia remains one of the countries most affected by HIV despite declines in HIV
51 prevalence and increased ART coverage.^{5,17} The 2018 Demographic and Health Survey
52 estimated that HIV prevalence was 14% among women and 8% among men aged 15 to 59.¹⁸
53 To address the burden of HIV in Zambia, the HPTN-071 (PopART) trial evaluated the impact
54 of a home-based combination HIV prevention intervention, the Population Effects of
55 Antiretroviral Therapy to Reduce HIV Transmission (PopART) intervention, which included
56 universal HIV testing and treatment, on HIV incidence.¹⁹ After four years of intervention, the
57 first of the UNAIDS 90-90-90 targets (90% of people living with HIV to know their status) was
58 met among 18-19 year olds and met among women but not men aged 20-24; while the
59 second target (90% of those who know their HIV-positive status on ART) was not achieved
60 among 18-24 year olds.²⁰ The PopART for Youth (P-ART-Y) sub-study demonstrated that,
61 despite improvements in knowledge of HIV status and ART coverage, maintaining high
62 coverage among AYP is challenging.²⁰⁻²⁴

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

69 In response to HPTN-071(PopART) findings, consultations were held with PopART
70 adolescent community advisory board (aCAB) members in Lusaka to understand how we
71 might reach AYP. During these consultations, aCAB members suggested that community-
72 based services led by youth for youth would be more acceptable to them.²⁵ In response, we
73 co-designed “Yathu Yathu (For us, by us)” community-based, peer-led and incentivised
74 comprehensive SRH services. We describe a cluster-randomised trial (CRT), , carried out to
75 address the research question: Does community-based, peer-led delivery of SRH services
76 increase knowledge of HIV status and coverage of SRH services among AYP in Lusaka,
77 Zambia, compared to facility-based service delivery? This study aims to build a rigorous
78 evidence-base of the effectiveness of SRH services designed with and for AYP living in
79 Lusaka, and evidence of the process of delivering such an intervention to support replication
80 and scale-up if the strategy is effective.

81 **Methods**

82 **Study Setting**

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

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

96 **Overall design**

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

103 **Co-development of Yathu Yathu**

104 The strategy under evaluation in this trial was co-developed with AYP in the two study
105 communities. In a 9-month formative research study, the study team conducted qualitative
106 research and discrete choice experiments (DCE) with AYP.²⁵ The qualitative research aimed
107 to understand AYP's knowledge of and access to available SRH services, how they would
108 want to be able to access these services in their communities, and their opinions about a
109 loyalty card scheme, intended to offer AYP the opportunity to accrue points and redeem

110 rewards for accessing SRH services. DCE were used to understand AYP preferences for how
111 to access SRH services. To finalise the design of Yathu Yathu, findings emerging from the
112 formative study were presented to AYP at a workshop held in each community.

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

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

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

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

135 **The Yathu Yathu Package of SRH Services**

136 The Yathu Yathu package aims to promote and contribute to AYP's health and well-being
137 through the provision of comprehensive HIV and other SRH services (Figure 3). Yathu Yathu
138 aims to increase coverage of SRH services and therefore primarily offers these services.

139 However, in recognising that AYP’s health and well-being extends beyond improved sexual
140 health, Yathu Yathu offers other health-related products through the PPC system and
141 referrals to other services as detailed below.

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

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

150 **Yathu Yathu hubs**

151 The Yathu Yathu hubs are fixed spaces in the community that are physically away from the
152 local health facility, but linked to the health facility through a referral system. All standard
153 services available at the hubs are free of charge. The day-to-day management of the hubs is
154 the responsibility of peer support workers (PSWs), with support from lay counsellors and
155 nurses. Yathu Yathu hubs offer a comprehensive package of SRH services (Figure 3), key
156 services available include:

- 157 • HIV counselling and testing, including self-testing (HIVST) and rapid testing of a
158 finger-prick blood sample performed by lay counsellors;
- 159 • Information and referral for ART initiation;
- 160 • Comprehensive sexuality education;
- 161 • Condom use demonstrations, provision of male and female condoms and lubricants;
- 162 • Information and advice on contraceptives, provision of (emergency) contraceptives,
163 including the pill;
- 164 • Information and referral for VMMC services at the government health facility;

- 165 • Information, screening and referral to the local health facility for diagnosis and
166 treatment of STIs, and
- 167 • Provision of free menstrual hygiene products.

168 Active linkage to health facilities is facilitated by members of the Yathu Yathu study team. In
169 addition to SRH-specific services, the Yathu Yathu hubs offer non-SRH services such as:

- 170 • Support for substance abuse (in particular alcohol use), screening for alcohol abuse
171 and information on the harms of alcohol.
- 172 • Edutainment, including screening of videos on SRH and general adolescent health.

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

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

189 Two nurses are trained in the provision of adolescent-friendly health services, in particular
190 contraceptive services. Nurses rotate between the hubs, such that a nurse is available at
191 each hub approximately one-day per week. In addition to dispensing contraceptives, nurses
192 provide personalised contraceptive advice and support linkage to ART.

193 Two intervention coordinators, one in each study site, are responsible for ensuring the
194 implementation of the study is conducted according to the study protocol. Their role
195 includes, but is not limited to, ensuring commodities and rewards are available and standard
196 operating procedures are followed, identifying and tracking weaknesses and gaps in
197 implementation, tracking study progress and ensuring coordination with Ministry of Health
198 and other partners in the community.

199 **Yathu Yathu prevention points cards**

200 The PPC are intended to incentivise use of SRH services and provide AYP with access to
201 health and non-health related products through the points system. The cards are similar to
202 store “loyalty cards”. Each time AYP access a specific service at a hub or the local health
203 facility, and present their card, they accrue points dependant on the service accessed. The
204 number of points offered depends on the psychological challenge associated with accessing
205 specific services. For example, collecting condoms accrues fewer points than having an HIV
206 test. In addition to receiving points for accessing services, additional nudges (e.g. ‘bring a
207 friend’) are implemented periodically.

208 Once AYP have accrued sufficient points, these can be exchanged for products, such as
209 branded condoms, soap and a wash cloth, toothbrush and paste, and branded sanitary
210 pads. As with accruing of points, the rewards “cost” differing numbers of points. The points
211 and reward system was designed such that it incentivises service use among AYP who want
212 and need to access services, yet isn’t coercive. The system was discussed with AYP and the
213 broader study community during the formative phase in order to achieve this balance.

214 **Community Engagement**

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

223 **The Control Arm**

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

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

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

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

236 **Randomisation**

237 Randomisation was carried out during a public ceremony in July 2019. During this ceremony,
238 the 20 trial clusters were randomly allocated to one of the two trial arms. Randomisation
239 was stratified by community (5 intervention and 5 control clusters per community) and
240 restricted to provide balance, by age (15-19 and 20-24) and sex, on: 1) participation in the
241 PopART intervention (although both communities were allocated the PopART intervention,
242 households and individuals could refuse to participate); 2) knowledge of HIV status during
243 the last year (2017) of the PopART intervention; 3) Uptake of HIV testing during the last year
244 (2017) of the PopART intervention; 4) average population of AYP aged 15-24, and 5) average
245 distance from the centre of the zone to the local health facility. Overall, this provided 5,449
246 possible allocations. The list of possible allocations was generated by SF using Stata 15 prior
247 to the public ceremony.

248 **Evaluation of Impact**

249 Evaluation of the impact of Yathu Yathu on the primary outcome of knowledge of HIV status
250 will be measured among AYP randomly selected for participation in a cross-sectional survey
251 in each study cluster. The cross-sectional survey started in 29 April 2021.

252 Simple random sampling, stratified by sex and age group (15-19, or 20-24 years; ~25
253 participants/group) at the time of population enumeration, will be used to select
254 approximately 100 AYP per cluster (~2,000 AYP across all 20 clusters) from the list of AYP
255 aged 15-24-years who were enumerated and given a PPC at the start of the study.

256 Within each of the four combinations of sex and age group, individuals will be randomly
257 ordered and approached for participation in this order until the target sample size for each
258 group and the ~100 participants per cluster are reached. Research staff will visit the
259 households of individuals randomly selected to participate in the survey. Up to three
260 household visits will be conducted. If, after three household visits, the selected AYP has not
261 been met, it will be recorded that they were not contacted and did not participate in the
262 survey.

263 AYP consenting to participate will be asked to complete a questionnaire. The questionnaire
264 includes modules on socio-demographic variables, knowledge and uptake of HIV testing,
265 treatment and prevention services, alcohol use, history of contraceptive use and pregnancy,
266 and the Hope scale, to measure AYP's expectations for the future.²⁶ The questionnaire will
267 be completed on a personal digital assistant (PDA) and administered by a research assistant.
268 For the module on sexual behaviours, individuals will be offered the option to self-complete
269 this on the PDA.

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

277 **Study outcomes**

278 The primary outcome of the study is knowledge of HIV status, defined as self-reporting HIV-
279 positive status or reporting HIV-testing in the previous 12-months. Secondary outcomes of
280 the study, which will be measured using the PPC data (first secondary outcome only) or self-
281 reported in the cross-sectional survey, include:

- 282 • The average number of services accessed at least once during a 12-month period,
283 among 6 “key” services (including HTS, VMMC, long-acting contraceptives, condoms,
284 PrEP, and ART; measured using PPC data);
- 285 • The percentage of young men reporting that they underwent medical male
286 circumcision in the past 12-months;
- 287 • The percentage of young women who do not want children or want to delay having
288 children who report using family planning services;
- 289 • The percentage of HIV negative AYP who report use of PrEP in the past 12-months;
- 290 • The percentage of HIV-positive AYP who report current use of ART, and
- 291 • The percentage of young women reporting a pregnancy within the past 12-months.

292 **Process Evaluation**

293 A mixed methods process evaluation is embedded within the impact evaluation (Table 1).
294 The process evaluation aims to provide evidence of how and why the intervention did (or
295 did not) have an impact, by focusing on three key domains: implementation, AYP’s uptake of
296 and response to Yathu Yathu, and contextual factors affecting implementation and response
297 to the intervention.²⁷ The process evaluation will use data routinely collected via the PPC
298 and qualitative data collected via focus group discussions, observations of service delivery,
299 in-depth interviews (including a longitudinal cohort), and “mystery” shoppers, who will
300 attend hubs and access services while assessing, among other factors, youth-friendliness of
301 services.

302 To document implementation, the process evaluation will assess:

- 303 a) Fidelity (whether the strategy was delivered as intended), dose-delivered and -
304 received, including how many condoms were distributed, HIV tests conducted,
305 among other services, overall and at each hub, and average number of services
306 accessed by each AYP attending the hubs;
- 307 b) Feasibility of delivering Yathu Yathu, as determined by providers’ experiences with
308 delivery.

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

- 310 c) Measure who accessed the hubs by age and sex, and the specific services accessed;

- 311 d) Conduct two case control studies to examine factors related to:
- 312 ○ men’s attendance of the Yathu Yathu hubs (case-control study 1), and
 - 313 ○ use of points to redeem rewards among AYP attending the hubs (case-
 - 314 control study 2).

315 We will use findings emerging from the qualitative data to:

- 316 e) Assess the acceptability of the intervention among AYP, their parents/guardians and
- 317 the community as a whole.
- 318 f) Evaluate AYP experiences of accessing Yathu Yathu services and any positive
- 319 consequences of service access.
- 320 g) Document unintended consequences and social harms.
- 321 h) Document the influence of contextual factors on intervention implementation and
- 322 AYP engagement with the intervention, including stigma, and community
- 323 perceptions about delivering SRH services to AYP.

324 **Nested Case-control studies**

325 Two case-control studies will examine factors associated with uptake of the intervention

326 components in the 10 intervention clusters.

327 The first case-control study will examine factors associated with non-attendance of the hubs

328 among men aged 18-24 years, with harmful alcohol use the primary factor of interest. Cases

329 are defined as men who *do not* access a Yathu Yathu hub in the first 12 months of

330 implementation and controls defined as men who *do* access a Yathu Yathu hub at least once

331 in the first 12 months of implementation. Stratified by community, 320 cases and controls

332 will be randomly recruited, in a 1:1 ratio using data on who accepted a PPC as the sampling

333 frame, from the ten intervention zones. Men participating in the study will complete a

334 questionnaire, with questions on socio-demographics, harmful alcohol use measured using

335 the Alcohol Use Disorders Identification Test (AUDIT-C), social support, and access to other

336 health services.

337 The second case-control study will explore what factors, primarily household socioeconomic

338 position, are associated with redeeming rewards and will explore AYP’s motivation for

339 accessing services. Cases are defined as AYP who attended the hubs at least twice and
340 earned points but *did not* redeem rewards using their PPC and controls defined as AYP who
341 attended the hubs at least twice and earned points and redeemed rewards using their PPC.
342 The rationale for restricting recruitment to AYP for whom there is evidence (on the basis
343 that they made at least one repeat visit after initial hub attendance) that they likely value
344 the available services. As with the first case-control study, 320 cases and controls will be
345 randomly recruited, stratified by community and in a 1:1 ratio, from the ten intervention
346 zones.

347 **Economic evaluation**

348 A prospective cost analysis will be undertaken from the societal perspective to calculate
349 costs of delivering Yathu Yathu. Costs will be collected via a bottom-up approach, coupled
350 with field observation to account for opportunity cost and establish cost allocation factors.
351 Cost categories will include items such as to: capital costs (buildings, equipment and
352 facilities, project set-up, and one-off trainings), recurrent costs (personnel, supplies,
353 recurrent training, quality control, supervision and mentorship) and project coordination
354 (project administration, building operations costs and utilities). Unit costs will be calculated
355 as cost per AYP accessing the hubs, and per AYP HIV-tested, among other indicators. We will
356 also conduct time observations with all PSWs and community mobilisers for two days each
357 in the intervention arm to document daily activities and running time. For the control arm,
358 1-3 SRH care providers will be observed for 2 days each at each health facility to document
359 running time for every activity. Yathu Yathu supervisors and coordinators will be given time
360 cards to complete as they execute their daily activities for 2 weeks.

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

365 **Statistical considerations**

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

369 **Power Calculations**

370 Based on findings from HPTN-071 (PopART) and P-ART-Y,²⁴ we estimated that, in control
371 arm clusters, ~25%-50% of AYP would *not* know their HIV status compared with 10-20% in
372 intervention clusters, and that the coefficient of between-cluster variation in this outcome
373 would be in the range 0.2-0.3. For a comparison of 25% vs 10%, which we consider plausible
374 and of difference of public health importance, study power is 99% among all individuals and
375 98% in sub-group analysis of those aged 15-19 and 20-24 years; for a comparison of 35% vs
376 20%, study power is 91% among all individuals and 85% in sub-group analysis, assuming that
377 the coefficient of between cluster variation $k=0.3$.

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

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

391 **Statistical Analysis**

392 The primary analysis will be based on an intention-to-treat analysis comparing knowledge of
393 HIV status between the Yathu Yathu intervention and control clusters. We will use cluster-
394 level analysis as is standard for cluster-randomised trials with <15 clusters in each trial
395 arm.²⁸ We will report our findings in line with the CONSORT guidelines on reporting CRT²⁹
396 and complete a statistical analysis plan before analysis of the endline survey.

397 The percentage of individuals with each outcome, and the average number of services
398 accessed per individual (for the composite indicator), will be summarised for each of the 20

399 clusters. Analysis of variance will be done on these cluster-level summaries, adjusted for
400 community, with the effect of the intervention summarised using prevalence ratios and
401 mean differences (for the composite indicator), with corresponding 95% confidence
402 intervals and p-values.

403 In adjusted analysis, we will adjust only for community, age group and sex, using the two-
404 stage approach for analysis of CRTs.²⁸ We will use logistic regression (for binary outcomes)
405 and linear regression (for the composite indicator) applied to the individual-level data to
406 estimate the predicted proportions and number of services for each individual, respectively,
407 under the null hypothesis of no intervention effect. Following this, the predicted values will
408 be summed for each cluster, and we will then calculate cluster-level residuals as (a) the ratio
409 of the observed number of individuals with the outcome divided by the predicted number,
410 for binary outcomes (b) as the difference between the observed total number of services
411 accessed and the predicted total number of services accessed, divided by the number of
412 individuals contributing to the analysis, for quantitative outcomes. Analysis of variance will
413 then be done on these cluster-level residuals, in the same way as for the unadjusted
414 analysis, to estimate the effect of the intervention and corresponding 95% confidence
415 intervals. A priori sub-group analyses will be done for males and females, by age group (15-
416 19 and 20-24 years) and for these four sex/age groups.

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

424 **Ethical Considerations**

425 The trial was approved by the University of Zambia Biomedical Research Ethics Committee
426 (UNZA BREC) and the Ethics Committee of the London School of Hygiene and Tropical
427 Medicine. Individual consent was sought during PPC distribution at the time of
428 enumeration. Individuals aged 18-24 were asked for written informed consent before

429 distribution of the PPC. For adolescents aged 15-17, parents/guardians were asked for
430 written informed consent for the adolescent under their care to participate, and
431 adolescents asked for informed assent.

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

440 **Discussion**

441 We outline details of a CRT that will provide rigorous evidence of whether community-based
442 SRH services increase uptake of SRH services when compared to facility-based SRH services.
443 In both arms, service access will be incentivised through the availability of the PPC system.
444 Alongside the impact evaluation, we are conducting a mixed methods process evaluation to
445 document implementation of Yathu Yathu and understand how and why the intervention
446 worked, or why it didn't work should we find no evidence for an impact. With a limited
447 evidence-base to date about the impact of community-based services on coverage of SRH
448 services, our study will provide evidence critical to expanding our knowledge of how to
449 reach AYP.

450 Despite a rigorous design, our study has limitations. Firstly, this study is at risk of
451 contamination. The clusters are geographical areas defined by the research team, they are
452 relatively densely populated, but contiguous and AYP are likely to move between them. AYP
453 in control clusters may choose to access services at the Yathu Yathu hubs. The unique
454 barcode on the PPC distributed at the start of the implementation period will indicate the
455 cluster in which AYP reside. We will use this information to understand the extent of any
456 contamination. Our primary outcome is based on self-reported HIV testing behaviour, which
457 may be subject to bias. Our process evaluation and case control study 1 aim to understand

458 why some AYP chose not to attend hubs. Reaching AYP who choose not to engage with
459 Yathu Yathu may prove challenging and limit our ability to understand non-engagement.

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

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

474 Despite limitations, our study will provide rigorous evidence of whether community-based
475 SRH services, supported by incentives, reach AYP, who these services reach and the cost of
476 these services. The delivery of community-based services supported by incentives in the
477 form of loyalty cards is novel, and may prove a simple strategy to improve access to SRH
478 services. AYP remain underserved by available SRH services, and are therefore lagging
479 behind in achievement of the UNAIDS 90-90-90 goals; there remains a critical need to
480 identify ways to provide AYP with access to SRH services. Much of the available evidence of
481 strategies to reach AYP focus on youth-friendly services at health facilities and/or peer-led
482 outreach and education.³⁰ Rigorous evidence of whether community-based and peer-led
483 services, with strong links to the local health facility, increase coverage of critical SRH
484 services would add to the evidence-base of how to reach AYP.

485 **Trial Status**

486 Cross-sectional survey expected to enrol participants on 29 April 2021. ISRCTN Registry
487 Number NCT04060420

488 **Study Sponsorship and Funding statement**

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

492 **Declarations**

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

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

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

504 **Availability of data and materials:** Not applicable

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

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

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515 in the study.

516

517 **List of Abbreviations**

518	AIDS	Acquired Immunodeficiency Syndrome
519	ANC	Antenatal Clinic
520	ART	Anti-Retroviral Therapy
521	AYP	Adolescents and young people
522	HIV	Human Immunodeficiency Virus
523	HPTN	HIV Prevention Trials Network
524	HTS	HIV Testing Services
525	PPC	Prevention points card
526	PopART	Population Effects of Antiretroviral Therapy to Reduce HIV Transmission
527	PEP	Post-exposure prophylaxis
528	PrEP	Pre-Exposure Prophylaxis
529	SRH	Sexual and Reproductive Health
530	STI	Sexually Transmitted Infection
531	TB	Tuberculosis
532	UNAIDS	United Nations Programme on HIV/AIDS
533	UNZA BREC	University of Zambia Biomedical Research Ethics Committee
534	VMMC	Voluntary medical male circumcision
535		

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605

606

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.

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

*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).

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

*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

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

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

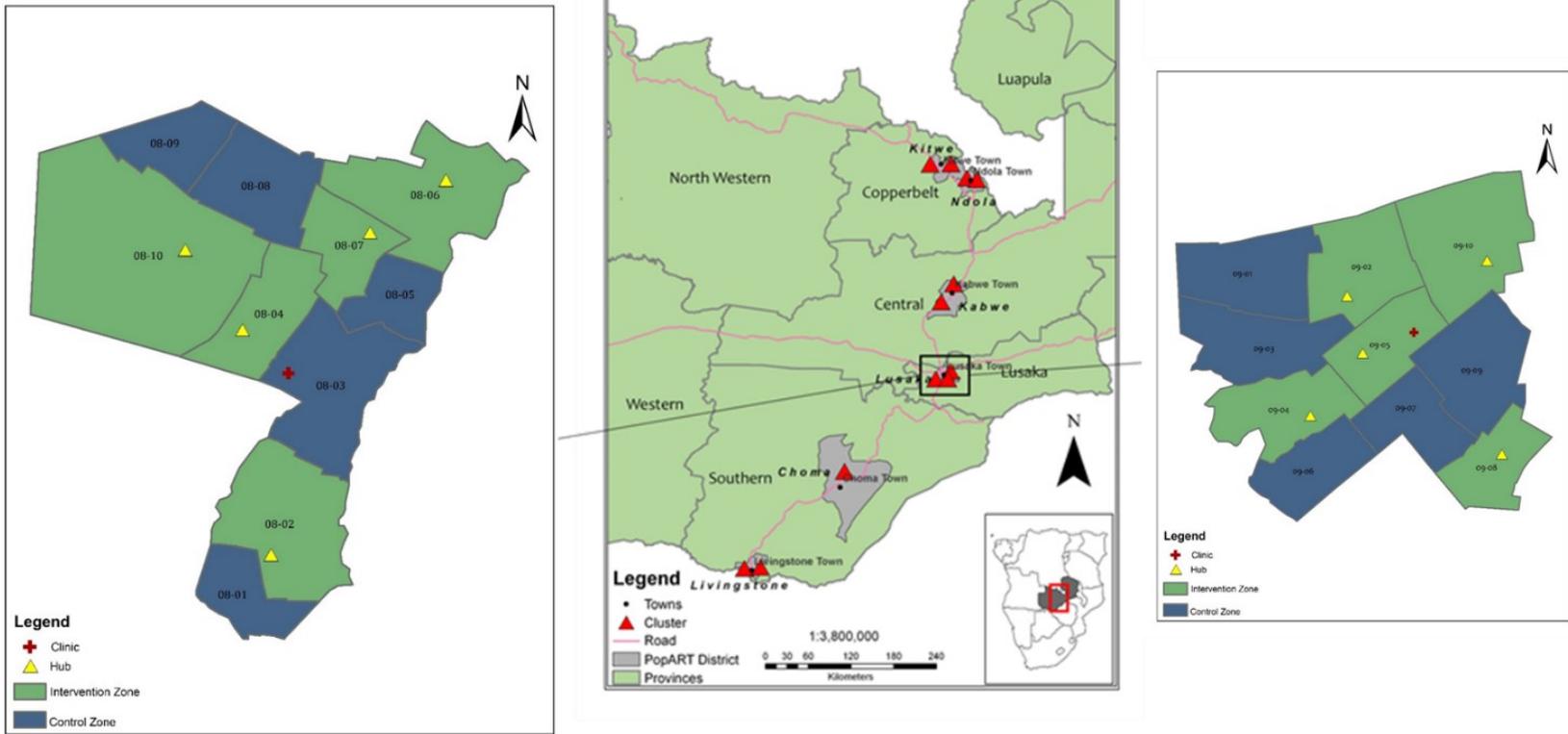


Figure 2. Schematic of the cluster randomised trial to evaluate the impact of Yathu Yathu comprehensive sexual and reproductive health services.

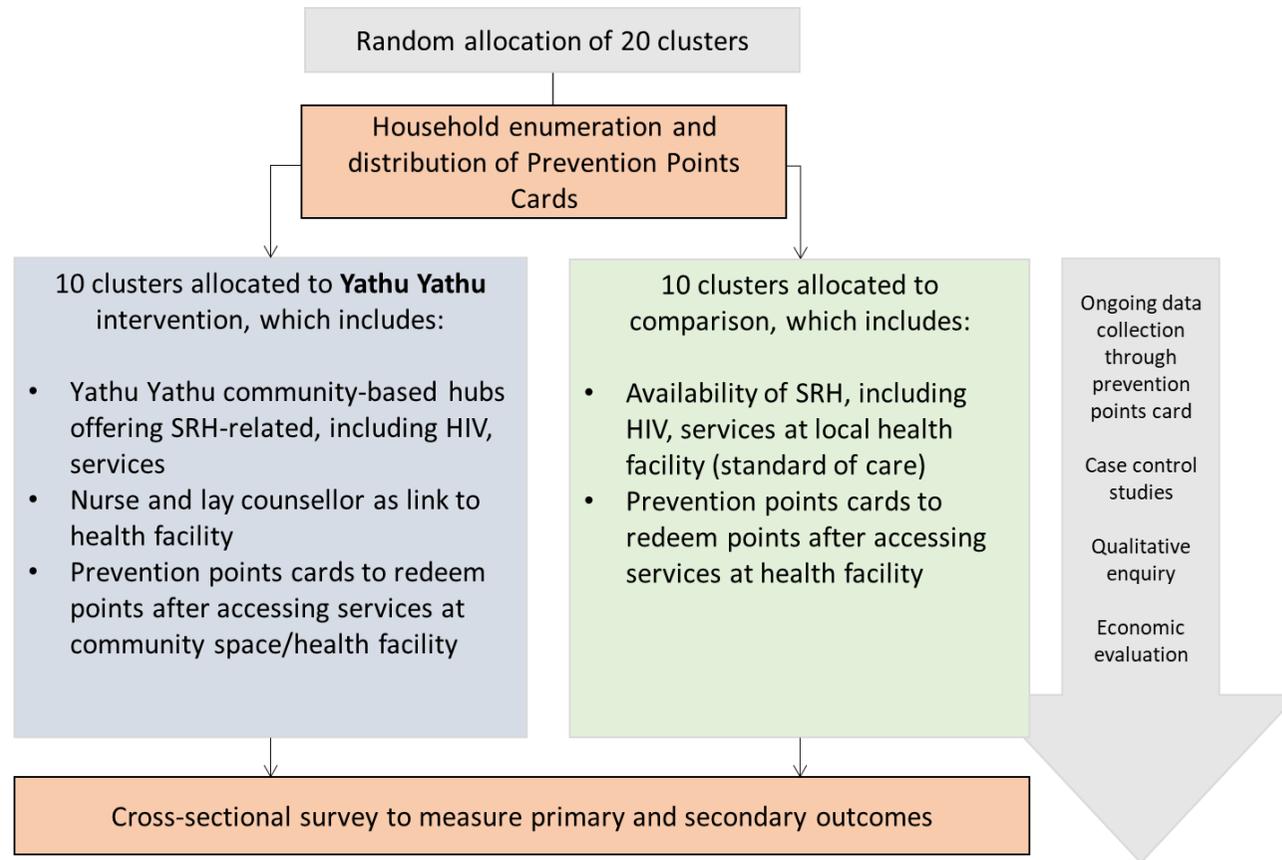


Figure 3. Diagram showing the Yathu Yathu Intervention Components and Process of Accruing and Redeeming Prevention Points

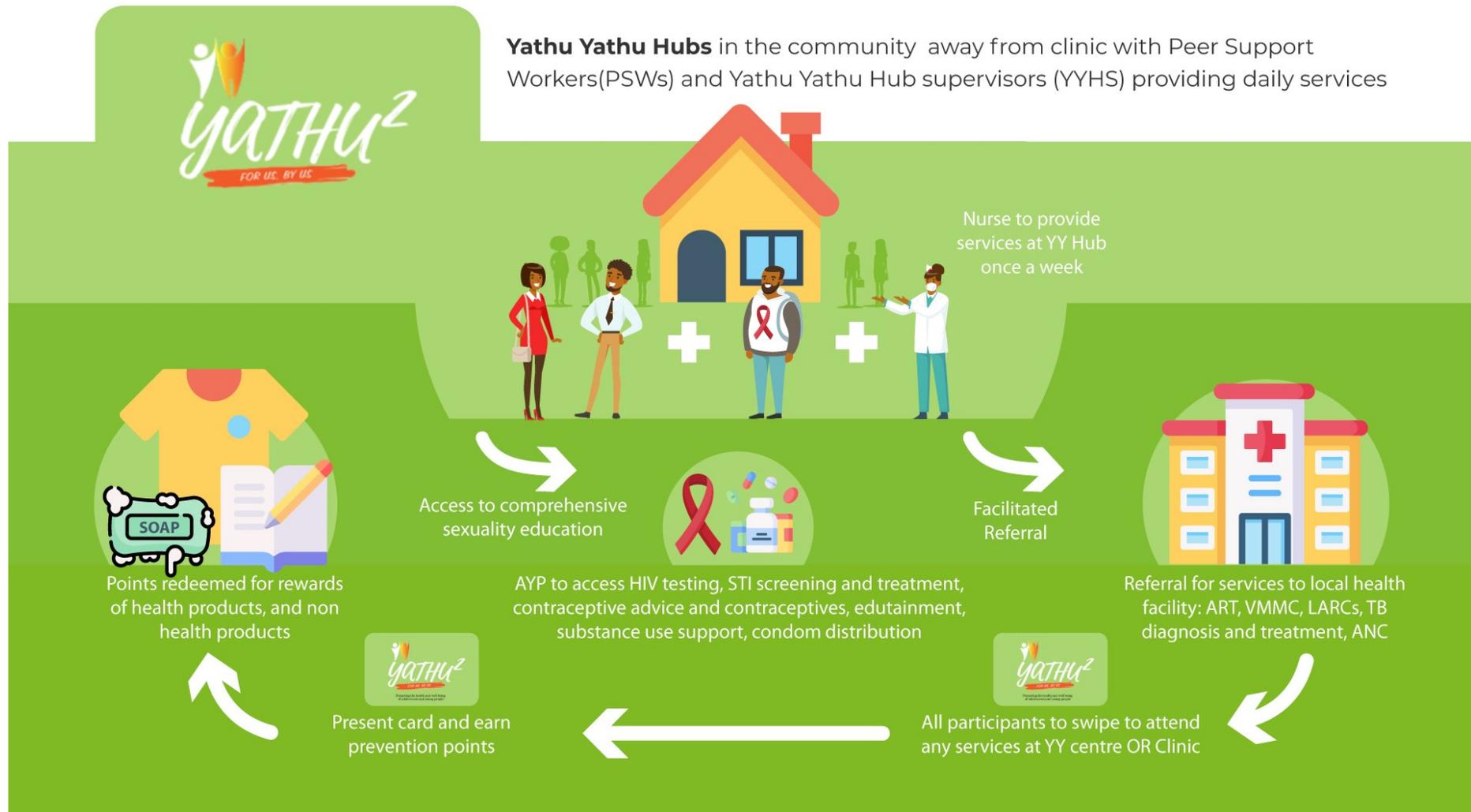


Figure 3. Simplified logic model showing hypothesised pathway through which Yathu Yathu will have an impact on the primary outcome

