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Understanding How Youth-Centered Interventions Influence Adolescent Sexual and
Reproductive Health in East and Southern Africa

by

Lila Aziz Sheira

A dissertation submitted in partial satisfaction of the

requirements for the degree of

Doctor of Philosophy

in

Epidemiology

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Graduate Division

of the

University of California, Berkeley

Committee in charge:

Professor Sandra McCoy, Chair

Professor Julianna Deardorff

Professor Jenny Liu

Professor Will Dow

Spring 2024

Understanding How Youth-Centered Interventions Influence Adolescent Sexual and
Reproductive Health in East and Southern Africa

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Lila Aziz Sheira

Abstract

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Doctor of Philosophy in Epidemiology

University of California, Berkeley

Professor Sandra McCoy, Chair

Despite global advances in the treatment and prevention of HIV, adolescent girls and young women (AGYW, aged 15-24) remain vulnerable to HIV acquisition in sub-Saharan Africa (SSA). There, AGYW outnumber their male peers in terms of HIV incidence three to one, and account for nearly two-thirds of all incident HIV infections. Pre-exposure prophylaxis (PrEP), which is 99% effective at preventing HIV, could contribute to reducing the burden of HIV among AGYW if used at scale and effectively. Nevertheless, awareness of PrEP in high HIV burden settings—especially among populations most vulnerable to HIV acquisition such as AGYW—remains unacceptably low and presents a primary barrier for effective PrEP coverage. Compounding this low awareness of PrEP are three interrelated drivers of behaviors that put AGYW at risk of adverse sexual and reproductive health (SRH) outcomes: 1) inequitable gender views, 2) poor sexual and reproductive empowerment, and 3) low reproductive autonomy. These three drivers collectively form a set of documented upstream determinants to poor sexual health outcomes, including reduced engagement in preventive health care, such as condom, contraceptive, and/or PrEP use. This dissertation is thus motivated by the overarching question: “How might AGYW-centered interventions improve the realization of SRH intentions and subsequent SRH outcomes among AGYW in east and southern Africa?”. To address this question, I use data from studies conducted in three countries and designed in collaboration with AGYW and with the purpose of understanding how to reduce inequitable gender views, improve sexual and reproductive empowerment, and increase reproductive autonomy as intermediaries to larger, downstream health behaviors (Chapters 1 and 3). For Chapter 2, I conduct primary data collection for a discrete choice experiment to understand AGYW’s preferences for potential HIV prevention implementation models, specifically for PrEP.

In Chapter 1, I leverage data from a Type 2 Effectiveness-Implementation cluster randomized controlled trial (CRCT) of CyberRwanda, a digital SRH intervention for Rwandan youth,

to examine the intervention’s impact on: 1) inequitable equitable views, and 2) reproductive autonomy. Both inequitable gender views and reproductive autonomy are upstream determinants of a host of SRH outcomes, including contraceptive uptake, experiencing intimate partner violence, and unintended pregnancy, highlighting the potential impact that improving these domains may have on long-term AGYW health and wellbeing. To evaluate the intervention’s impact on these two outcomes, sixty secondary schools in eight districts in Rwanda were randomized 1:1:1 across three arms: two CyberRwanda implementation models (self-service, with unstructured tablet access to the digital platform; or facilitated, which included both unstructured and structured tablet access plus CyberRwanda clubs led by peer facilitators), and a comparison arm. Leveraging data from 2,955 AGYW at 12-months post intervention start and compared to AGYW at comparison schools, AGYW from schools assigned to the CyberRwanda facilitated model experienced small improvements in inequitable gender views and reproductive autonomy; no effect was observed among AGYW at self-service schools. These findings suggest that facilitated digital health interventions among school-age AGYW may be a promising strategy for improving inequitable gender views and reproductive autonomy.

In Chapter 2, I report the results of a forced choice discrete choice experiment (DCE) that I designed and conducted with local partners to evaluate preferences for different PrEP modalities and delivery models for AGYW at risk for HIV in Lake Zone, Tanzania. There exist numerous barriers to uptake and retention in PrEP, compounded by low awareness, resulting in preventable HIV cases. With newer PrEP modalities (i.e. injectable, vaginal ring) under regulatory review, we are at an opportune juncture where an understanding of AGYW preferences could ensure that implementation of future PrEP modalities could be grounded in users’ preferences. We enrolled 696 AGYW who met the criteria of being recently ($n=138$) or currently ($n=558$) PrEP eligible, and evaluated five attributes: (i) PrEP modality, (ii) screening location, (iii) refill location, (iv) provider identity, and (v) cost per refill. Results show that prior to the educational module explaining PrEP (which preceded the DCE), knowledge of PrEP was low—less than 1 in 5 respondents had ever heard of PrEP. Modality of PrEP, specifically injectable PrEP, was the most preferred and influential component driving AGYW preferences. Respondents reported high levels of interest in taking up PrEP across various implementation scenarios, demonstrating that newer modalities of PrEP, such as long-acting injectables, may help close the gap between unmet need for PrEP and barriers to uptake of current PrEP modalities.

In Chapter 3, I leverage data from the ‘SKILLZ’ study, a Type 1 hybrid effectiveness-implementation CRCT evaluating the impact of SKILLZ, a peer-led, sports-based program intended to empower adolescent girls implemented by Grassroot Soccer (GRS) in Zambia. Sports-based programming is associated with delayed sexual debut and higher empowerment among AGYW, yet these relationships have not been rigorously evaluated via a CRCT. The study enrolled 2,153 AGYW across 46 secondary schools in and surrounding Lusaka, Zambia; my dissertation evaluates the impact of the intervention on sexual and reproductive

empowerment, measured via the Sexual and Reproductive Empowerment (SRE) for Adolescents and Young People scale. Results show small to moderate impacts of the intervention on SRE, with these impacts magnified for those who were sexually active and those who attended more than eight of twelve sessions.

The central hypothesis linking the three chapters is that interventions developed by and for youth that reduce barriers to engaging in sexual health care will result in reduced inequitable gender views and improved sexual and reproductive empowerment and reproductive autonomy, all of which are key determinants of subsequent uptake and engagement with SRH and HIV prevention. The development of each of the interventions evaluated herein is consistent with several internationally recognized frameworks guiding AGYW-focused SRH research and intervention design, such as those developed by the Human-centered Design (HCD) Exchange and the World Health Organization. Further, the focus on upstream determinants of SRH health, such as gender views and reproductive autonomy and empowerment, aligns with World Health Organization priorities to ensure universal access to SRH to improve quality of life and reduce health inequalities. Taken together, the knowledge generated from this research may lead to a better understanding of how to address upstream determinants of poor HIV and SRH care among AGYW, as well as provide timely information to influence policy on the roll-out of novel PrEP products. Further, they may provide insight on effective programs and policies related to HIV and SRH care among AGYW among other southern- and eastern- African countries.

I dedicate this dissertation to my sweet and wonderful children, Aziz and Dalia. I love you more than words can describe, and am so thankful that I had you in my life during these challenging four years to remind me that there are much more important things in life than research. I will always strive to be the best mother first and foremost, and hope that in addition, I can make you proud in my career as an epidemiologist.

I also dedicate this to all the adolescent girls and young women globally who face barriers in their sexual and reproductive health and overall well-being. May these barriers decrease with time and your full potential be realized, unburdened and unimpeded.

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Introduction

Adverse sexual and reproductive health (SRH) outcomes, such as unplanned pregnancy and HIV infection, disproportionately affect AGYW in sub-Saharan Africa (SSA).[1, 2, 3] These adverse outcomes are compounded by a related web of low condom negotiating power, intergenerational sex (defined as sex with someone 10 years older or greater),[4] and harmful sexual relationship power dynamics.[5] Impoverished AGYW are more likely to engage in intergenerational and transactional sexual activities to meet basic needs, even while cognizant of the potential health risks.[6] Indeed, the average age at sexual debut is 15 for AGYW in east Africa,[7] and 44% of unplanned pregnancies globally occur among AGYW in SSA.[1, 8] AGYW accounted for ~25% of incident HIV cases in 2022 in SSA,[9] despite comprising just 10% of the populace.[10] Furthermore, AGYW make up 80% of all adolescent HIV cases in SSA.[11] These risks are heightened in east and southern Africa, where the largest number and greatest incidence of HIV occurs.[12, 13] Often, the acquisition of HIV or an unplanned pregnancy results in being falling behind or in legally being prohibited from completing schooling, thus creating a vicious intergenerational cycle of poverty, HIV risk, and unplanned pregnancy.[14]

The dissertation research presented herein took place across three countries: Rwanda (Chapter 1), Tanzania (Chapter 2), and Zambia (Chapter 3). There are numerous parallels in the risk profiles for adverse SRH outcomes and HIV risk among AGYW across these settings. For example, unmet need for contraception is prevalent, ranging from 23% in Tanzania to nearly 80% in Rwanda;[15, 16] in turn, unintended pregnancies among AGYW account for 30-50% of all pregnancies across these settings.[17, 18, 19, 20, 21] In terms of HIV prevalence, the countries differ. Rwanda has the lowest prevalence of HIV in the general population (3%) compared to Tanzania (4.4%) and Zambia (11%); there also exist significant regional differences in the distribution of HIV prevalence within each country.[22, 23, 24] For example, in both Lake Zone Tanzania and Lusaka, the research sites for Chapters 2 and 3, respectively, the HIV burden is more pronounced and the HIV epidemic is generalized (i.e. prevalence $\geq 5\%$), with an HIV prevalence of 15% in Lusaka and 5.5% and 6.5% in Shinyanga and Mwanza, Tanzania, respectively.[22, 23, 16] Further, significant gender gaps in HIV exist in all three countries, whereby women and AGYW in particular are more likely to acquire HIV than their male counterparts.[23, 25, 26] This is particularly heightened in Tanzania, where AGYW account for 80% of all incident HIV cases.[24] These risk profiles necessitate pub-

lic health action, and highlight the potential impact that addressing some of the upstream drivers of unintended pregnancy and HIV, such as gender views, reproductive empowerment, and centering choice and preferences for care, might have on downstream health behaviors.

The role of reproductive empowerment, autonomy, and inequitable gender views on sexual health behaviors of AGYW

Low reproductive empowerment and autonomy, intensified by inequitable gender views as a result of cultural programming (i.e., the acquirement of socio-culturally normative values), is a significant predictor of sexual health behaviors,[27] which in turn impact SRH outcomes. Sexual and reproductive empowerment (SRE), defined as “the capacity of individuals to achieve their sexual and reproductive goals”[28] is an umbrella term with numerous dimensions to conceptualize the overlapping phenomena of empowerment, or “the expansion of people’s ability to make strategic life choices in a context where this ability was previously denied to them,”[29] with SRH matters. Reproductive autonomy, defined as “having the power to decide about and control matters associated with contraceptive use, pregnancy, and childbearing”[30] is an important dimension of the overarching domain of reproductive empowerment and women’s reproductive health. Furthermore, adolescence is a particularly important period to successfully intervene on domains related to gender equity and reproductive autonomy. The Gender Intensification Hypothesis posits that adolescence presents the most intensive period for socialization of culturally normative gender roles, especially for girls.[31] These interconnected domains may be compounded by inequitable views on gender,[32] and collectively form a set of documented upstream determinants to sexual health behaviors that can lead to adverse SRH outcomes, and which may serve as a focus for the development of AGYW SRH-focused behavior change interventions.

There is a well-documented relationship between poor sexual empowerment and inequitable gender views and a host of SRH and HIV risk related behaviors. A multi-country analysis from 32 countries in sub-Saharan Africa found that various measures of women’s empowerment were positively and significantly associated with contraceptive use.[27] Conversely, other studies have shown how inequitable gender views, gender norms, and low autonomy are associated with unintended pregnancy,[33] intimate partner violence,[34] and low condom negotiating power.[35, 36, 37, 38] Low relationship power, a domain of sexual empowerment, has been linked with condomless sex and multiple partners among AGYW,[38, 5] two dominant risk factors for HIV acquisition. Beyond SRH, inequitable gender views at the individual level are also associated with poor mental and physical health outcomes, highlighting how poor SRH can impact other health domains and overall well being.[39]

The measurement of the interconnected domains of reproductive autonomy and sexual and reproductive empowerment is in its nascency;[30] primary limitations include a lack of re-

search among AGYW as a specific subpopulation and a lack of validation in global settings. Conversely, the measure of both equitable and inequitable gender views has more standardized measures and has been internationally validated.[37, 40] The most recent measure for reproductive autonomy has notable limitations,[30] namely that the scale was validated among American women seeking family planning and abortion care in the United States, with limited external validity to adolescent populations whose sexual health needs, and in turn, their ability to practice them autonomously and in an empowered fashion, differ. Nevertheless, the scale has been implemented widely within the United States and other countries, including Vietnam,[41] Ghana,[42] and Brazil, the latter location where a cultural adaption was undertaken.[43] In recognition of these limitations, Upadhyay et al. developed and validated the Sexual and Reproductive Empowerment Scale for Adolescents and Young Adults (SRE for AYA; herein "SRE") in 2021 via a rigorous process of qualitative interviews, cognitive testing, literature review, and a psychometric analysis.[44] This scale was developed among adolescent populations throughout the United States, and the multidimensional scale captures the unique experiences and needs of adolescents in their unique life and developmental stage of life, with ongoing uses in global settings, including adaptation studies in Lebanon and Kenya, which occurred after data for this dissertation was collected.[45, 46] Taken together, the SRE and gender equity views are important predictors of sexual health outcomes, and a growing evidence base that reproductive autonomy is also an important dimension of understanding sexual health behaviors. Nevertheless, many of these studies focused on the downstream consequences of these interrelated dimensions; to the best of my knowledge, no studies have rigorously evaluated interventions to improve SRE, reproductive autonomy, and views on gender equity among AGYW in SSA.

Possible approaches to improve reproductive empowerment, autonomy, and inequitable gender views

School-based interventions are a common and successful implementation strategy for SRH interventions given access to youth, the efficiency of the group format, and evidence that schools offering SRH programs may serve as the first point of contact with SRH services.[47, 48] The interventions described in Chapters 1 and 3 are both school-based SRH interventions with specific components meant to improve reproductive autonomy, inequitable gender views, and SRE; while similar in implementation location, the two were implemented via unique and innovative approaches. Chapter 1 describes a three-arm intervention evaluating two different implementation models of a digital SRH intervention (compared to the control arm) implemented in Rwanda. The two implementation models for the tablet-based digital content included a "facilitated" arm, with structured and unstructured tablet access as well as a peer-led, group component, and a "self-service" arm which offered unstructured tablet access. Using digital technology to promote SRH is highly feasible, acceptable, protects confidentiality, and can improve uptake of SRH services.[49, 50] Previous "mHealth"

interventions focused on phone-based apps. However, AGYW without consistent internet access and/or without access to a personal phone or tablet may be excluded from the potential reach of these programs.[51] Moreover, a 2022 systematic review of digital health interventions focused on improving AGYW SRH reported that nine out of ten studies were SMS based; just one of the included studies used a web-based platform.[50] Promoting a digital SRH intervention whereby the technology and internet is provided free of cost to the potential user is a promising means to address technology related barriers to access and engagement. Linking the digital with peer-led group components, which is regarded as a participatory method which can encourage youth engagement,[52] can address sociocultural barriers that AGYW and youth in general may experience when engaging in SRH-related activities. Despite broad evidence showing the impact of digital health outcomes on other SRH outcomes, such as HIV knowledge and testing,[53, 54, 55] a gap remains in rigorously evaluating the potential impact of digital health interventions on reproductive autonomy and inequitable gender views.

Chapter 3 evaluates the impact of a school-based sports-based and SRE empowerment curriculum on SRE among in-school Zambian AGYW. While there exists a smaller evidence base regarding engagement in sports and SRH outcomes among AGYW compared to that of digital interventions, observational studies have documented how engagement in sports may be protective against sexual behaviors that increase risk for pregnancy, HIV, and/or other sexually transmitted infections (STIs) among AGYW.[56, 57, 58] However, these studies were predominantly conducted in low-HIV burdened Western settings; studies outside of Western settings demonstrate that sports based-interventions, often with other sexual health components, are associated with increased HIV knowledge and testing.[59, 60, 61, 62] Prior qualitative and observational studies have also elucidated a path between participation in sports-based programming and SRE,[59, 63] a hypothesized mediator on the path to SRH behaviors. However, there is less rigorous evidence quantifying the impact of sport-based programming on upstream drivers of sexual behaviors, such as SRE.

Prevention of HIV acquisition among AGYW

AGYW face unique challenges in accessing HIV preventative care, including low awareness of HIV prevention options,[64] low HIV risk perception,[65] inability to pay for transportation or other related costs, concerns about privacy and stigma,[66] and limited access to AGYW-centered care, which undermine efforts to obtain products for preventing unplanned pregnancy and HIV.[67, 68] Mystery visits to public health facilities by school-age and/or unmarried AGYW seeking contraception in Tanzania reported misinformation by healthcare providers, questioning of desired services, and judgement of sexual activity.[69] Despite the high efficacy of pre-exposure prophylaxis (PrEP) for HIV prevention, AGYW may be deterred from seeking it out for fear of being seen as promiscuous or already living with HIV.[70] Not surprisingly, perceived and internalized stigma for seeking HIV care result in the under-

utilization of crucial HIV preventative and SRH promoting services among AGYW.[71, 72, 73, 74] Combined with providers' poor understanding of AGYW SRH needs[74] and shortages of trained workers and supplies,[75] AGYW's vulnerability to HIV is exacerbated.

Increasing access to confidential and youth-centered HIV testing and PrEP for AGYW is one piece of a larger multi-pronged approach to lowering HIV incidence.[76] Compounding their HIV acquisition vulnerability, AGYW are less aware of their HIV status compared to adults[77] and have low self-perceived risk of HIV.[78] Indeed, while PrEP is highly effective at preventing HIV,[79] uptake and continuation of PrEP among AGYW and other key vulnerable populations continues to be a challenge in HIV prevention research.[80] The most common PrEP regimen offered globally is once daily oral PrEP, with effectiveness ranging between 30-100% depending on adherence.[81] In Tanzania, PrEP is often distributed in the same location as HIV medication at health clinics, requires screening and blood tests, and is given in similar packaging as antiretroviral therapy (ART). Numerous studies have documented how these characteristics present barriers for uptake and adherence to AGYW, primarily as users do not want to be perceived as having HIV by virtue of being seen at the clinic where HIV care is given.[82, 83, 84] Moreover, AGYW experience heightened challenges with seeking clinic-based care, including transportation and time for the frequent visits.[85] Compounding these barriers, a recent study in Tanzania reported low provider willingness to prescribe PrEP to AGYW, underscoring that fact that even once AGYW overcome barriers to get to the health facility, barriers remain within.[86] Interestingly, the same study found that providers felt PrEP care for AGYW should be separated from HIV services, highlighting these providers' awareness of potential gaps in the HIV prevention care service provision for AGYW. Taken together, these studies illustrate the numerous barriers AGYW face in seeking out and adhering to PrEP, and outline potential areas for intervention to address the disproportionate burden of HIV they face.

There are several new PrEP modalities in various stages of regulatory approval by on a country-by-country basis which may address some of the known barriers AGYW face when seeking HIV care. The dapivirine ring is worn vaginally and slowly releases dapivirine for 28 days[87] and can reduce HIV acquisition by 27-62%.[88, 89] Another modality is a long-term (two months) gluteal injectable known as long-acting cabotegravir (herein referred to as CAB-LA), which had an 89% reduction in HIV among ciswomen in SSA (i.e., as or more effective than daily oral PrEP).[90, 91] At the time of this writing, these modalities were not yet approved in Tanzania but are under consideration; both Zambia and Rwanda have approved the vaginal ring. Indeed, just four African countries have authorized the use of CAB-LA to date (Zimbabwe, Zambia, South Africa, and Uganda), although it is not yet widely available.[92] Nevertheless, these new modalities show promise in addressing some of the documented barriers to PrEP uptake and adherence among AGYW, mainly having an identifiable medicine on one's person and frequent clinic visits. However, if required to be acquired in the same way as oral PrEP, i.e., at HIV clinics, one of the primary barriers remains a concern. Thus, understanding how to address remaining barriers not addressed

by a given PrEP product is a crucial to reaching populations vulnerable to HIV, such as AGYW for whom clinic-based access is out of reach.

While public health facilities fill an important role in SRH care in lower income countries, interventions that serve AGYW with HIV preventive care, namely PrEP, may consider exploring other avenues for healthcare provision to address perceived stigma and confidentiality concerns as well as address barriers to access to care. This may include working with peer-led programs, which have been successful in engaging AGYW in other SRH care activities, such as knowing HIV status, HIV testing, and PrEP initiation,[93] as well as psycho-social outcomes such as self-efficacy and self-esteem.[94] Another potential avenue involves engaging with the private sector, such as local pharmacies, who have both interest and potential for supporting the public health infrastructure given their ubiquity in communities relative to health facilities.[95] Kenya’s 5-year plan for scaling PrEP delivery includes enabling pharmacy provision,[96] while Tanzania’s National HIV Strategy aims to increase community-based care though, to date, PrEP is only offered through public healthcare facilities and research studies;[97] comprehensive data demonstrating feasibility of alternative service delivery models may position and accelerate future HIV prevention programming efforts. Initial feasibility and acceptability studies of differentiated care models have demonstrated interest and high fidelity,[98, 99, 100] with more ongoing.[101] Indeed, differentiated care models for adolescents living with HIV is a priority given they may meet the unique needs of adolescents in ways that the current standard of care cannot.[3] Nevertheless, there is a paucity of research investigating the preferences among potential users of these differentiated care delivery models, including AGYW, who remain a target population for HIV prevention outreach and care.

Dissertation objectives

The objective of my dissertation was to evaluate whether two interventions developed with input from and for the benefit of AGYW improved reproductive autonomy and empowerment and reduced inequitable gender views in Rwanda (Chapter 1) and Zambia (Chapter 3). In Chapter 2, I also sought to understand preferences for potential implementation models for HIV prevention services among AGYW in Tanzania via a discrete choice experiment developed with youth and local stakeholder input.

My dissertation leveraged data from three sources: two cluster-randomized controlled trials (CRCTs) of interventions in Rwanda and Zambia, as well as a discrete choice experiment in Tanzania (Table 0.1). These objectives were achieved through the following specific aims which correspond to each chapter:

Aim 1: Determine whether access to a digital, sexual health and livelihood/economic, direct-to-consumer digital intervention in Rwanda (“CyberRwanda”) can result in improved reproductive autonomy and reduced inequitable gender views among adolescent girls.

Table 0.1: Overview of each chapter and analytic sample by country

Aim	Country, Study	Study Design	Analytic Sample	Outcome Measure
1	Rwanda, CyberRwanda Study	Type 2 Hybrid Effectiveness-Implementation CRCT	AGYW 12-19 across 60 schools (sexually active & all)	The inequitable gender views of the Gender Equitable Men Scale; the decision-making subscale of the Reproductive Autonomy Scale
2	Tanzania, primary data collection for DCE	Discrete choice experiment	AGYW 15-24	Formative research, Preferences for potential PrEP implementation models
3	Zambia, SKILLZ	Type 1 Hybrid Effectiveness-Implementation C-RCT	AGYW in 10 th grade across 46 schools	Sexual and Reproductive Empowerment for Adolescents and Young People Score

Hypothesis: Attending a CyberRwanda intervention-arm school will be associated with increased reproductive autonomy among AGYW in both intervention arms compared to the control arm.

Aim 2: Understand preferred implementation models for PrEP among currently and recently PrEP-eligible AGYW via a discrete choice experiment (DCE) in Tanzania.

Hypothesis: AGYW will prefer longer-acting PrEP methods and may trade off convenience in the screening location and refills to have such longer-acting methods.

Aim 3: Evaluate whether a peer-led, sports-based program ('SKILLZ') for empowering in-school adolescent girls in Zambia can increase sexual and reproductive empowerment.

Hypothesis: Attending a school offering SKILLZ will be associated with increase sexual and reproductive empowerment measured via the SRE compared to being in a control school.

The proposed Aims 1 and 3 have the potential to further the literature on how youth-developed behavioral interventions may improve reproductive autonomy, empowerment, and inequitable gender views, all of which are important predictors of general and sexual health and well-being. Furthermore, Aim 2 has the potential to inform policy-makers on the desires of AGYW, a generally disenfranchised from HIV preventative services yet vulnerable population to HIV acquisition in east Africa.

Chapter 1

The Impact of a Digital Sexual and Reproductive Health Intervention on Reproductive Autonomy and Inequitable Gender Views Among AGYW: Midline Results of the CyberRwanda Effectiveness-Implementation Trial

1.1 Abstract

Background: Adolescence is a formative time to deliver gendered programming to positively influence the trajectory of sexual health outcomes, especially among adolescent girls and young women (AGYW). Inequitable gender views and diminished reproductive autonomy are associated with intimate partner violence, low contraceptive uptake, unplanned pregnancy, and HIV transmission globally.

Methods: We leverage midline (i.e., at 12 months post intervention launch) data from a Type 2 Hybrid Effectiveness-Implementation trial of CyberRwanda, a digital, sexual and reproductive health (SRH) intervention which includes a direct-to-consumer shop for SRH products linked to youth-friendly pharmacies and health posts. Sixty secondary schools in eight districts in Rwanda were randomized 1:1:1 across three arms: two CyberRwanda implementation models (self-service with unstructured tablet access to CyberRwanda; or facilitated which included unstructured tablet access plus scheduled CyberRwanda clubs led by peer facilitators) and a comparison arm. The outcomes were 1) inequitable gender views,

measured via the gender inequity subscale of the Gender Equitable Men Scale (GEMS; range 17-51; higher = less inequitable gender views), and 2) decision-making related to reproductive autonomy measured via the Reproductive Autonomy Scale (RAS; range 0-3; lower to higher autonomy). An intent-to-treat analysis was conducted using generalized linear models and controlling for district strata were estimated to assess the relationship between study arm and the two outcomes measured at 12 months/midline.

Results: All AGYW (n=2,955) CyberRwanda participants were analyzed; they were on average age 15 years old (range 12 to 22) of whom 20.6% (609) reported being sexually active at midline. Being in schools assigned to the facilitated and self-service arms of CyberRwanda were associated with 1.61 (standard error [SE] = 0.37; $p < 0.001$) and 0.52 (SE = 0.38, $p = 0.17$) points higher GEMS score compared to the control arm, respectively. Being in the facilitated and self-service arms of the CyberRwanda intervention were associated with 0.090 (SE: 0.047, $p = 0.059$) and -0.030 (SE: 0.048, $p = 0.53$) points higher and lower on the RAS, respectively. Results from sensitivity analyses restricted to AGYW aged 15-22 demonstrated similar magnitudes and directions of effect.

Conclusions: Compared to AGYW at control schools, AGYW enrolled in schools assigned to the CyberRwanda facilitated arm experienced small improvements in gender views and reproductive autonomy; no effect was observed among AGYW at self-service schools. We identified opportunities for improving the measurement of reproductive autonomy among Rwandan AGYW to better reflect potential scenarios of beneficial shared decision-making. Future research may benefit from a more comprehensive understanding of how reproductive autonomy may be experienced within this context.

1.2 Introduction

Reproductive autonomy, defined as “having the power to decide about and control matters associated with contraceptive use, pregnancy, and childbearing” [30] is a central dimension of women’s reproductive health and an important predictor of sexual health behaviors globally, [102, 103] which in turn impact sexual and reproductive health (SRH) outcomes. Gender and gendered power, [104] which are independently strong determinants of health, [105] are inextricably tied to reproductive autonomy. [37] For example, gender power differentials limit women’s access to [106] and negotiation around [35] contraceptives, as well as place women at risk for sexual violence, [107] both of which contribute to forced pregnancy and childbearing. [108] Cultural and structural factors, including harmful views on gender roles, [37] poverty, [109] and poor treatment of adolescent girls and young women (AGYW, aged 15-24) in SRH care settings [110] further undermine efforts to achieve reproductive health equity globally. [111] These barriers in turn may manifest in HIV incidence and other adverse SRH outcomes. [112, 113] This impact is magnified among AGYW, who may have to overcome greater barriers than their older female peers to access SRH services and achieve reproductive autonomy and sexual health well-being due to negative social norms/views related to youth sexuality. [114]

Restrictive parental and societal views on adolescent engagement in sexual activity has in turn resulted in a less frequent focus of the study of upstream factors relating to reproductive autonomy. [115, 116] Further, the appropriate definition and measurement of reproductive autonomy among adolescents may differ from other age groups, given different sexual health needs and subsequent autonomous exercise of them. [117] This measurement is further complicated due to the multidimensional nature and socio-cultural specificities of reproductive autonomy. [30] Previous research on reproductive autonomy in the general population has focused on defining this concept within individual sub-domains, such as contraceptive decision-making. [118] Reproductive autonomy has also been explained and studied within the context of reproductive coercion, whereby one’s reproductive autonomy is infringed upon, [119] as well as covert contraceptive use, whereby a woman may not feel she can freely utilize a contraceptive method. [120] These related domains of reproductive decision-making and sexual relationship communication are associated with views on gender equity, contraceptive uptake, [103, 120] intimate partner violence, [35] and unintended pregnancy. [121] While important, these individual domains provide insight on the different components but cannot address the multidimensionality of reproductive autonomy.

Comprehensive and validated scales to measure reproductive autonomy among AGYW emerged fairly recently [30] and are not widely used among AGYW, as evidenced by the low number of published studies using these measures among AGYW. [103, 116] This is especially important in the African context, where women bear the highest burden of unmet need for contraception globally, [122] one-third of pregnancies are unintended, [1, 123] and the average adolescent pregnancy rate (in sub-Saharan Africa [SSA]) is nearly twice that of their global

peers.[124] In Ghana, a cross-sectional study of 1,080 AGYW found that high reproductive autonomy was associated with contraceptive[103] and family planning service use.[102] Another study among the female partners (who were not explicitly AGYW) of men enrolled in a masculinity focused family planning intervention in Kenya found that female partners with more reproductive autonomy reported increased odds of modern contraceptive use.[125] Addressing these health disparities among AGYW is of critical importance; in addition to being a population experiencing substantial inequities on SRH care and outcomes, improving gender equity and reproductive autonomy decision-making in adolescence has the potential to have long-lasting impacts on the life trajectories of AGYW.[126] This idea is supported by the Gender Intensification Hypothesis,[31] whereby socialization of culturally normative gender roles and pressure for conformity is most intense during adolescence compared to other developmental periods, especially for girls, highlighting the importance of this formative time for action and intervention.

While reproductive autonomy is less studied, gender equity is well-studied,[37, 40] with strong evidence demonstrating how restrictive views on gender equity in particular are associated with poor mental, physical,[39] and sexual health outcomes.[37] Indeed, a recent systematic review of programs focused on reducing gender inequality for children, adolescents, and young adults found that nearly half (48%) of the 59 evaluated programs focused on reproductive health outcomes.[127] Among AGYW in SSA in particular, gender inequities are associated with intimate partner violence,[128] unintended pregnancy,[129] and HIV risk,[130] demonstrating that adolescence is a particularly vulnerable time in the lifespan of women in terms of sexual health outcomes which may be worsened by gender inequity. Taken together, there is a small yet growing evidence base that reproductive autonomy, and a robust evidence base that gender equity, are important predictors of sexual health outcomes among AGYW. Nevertheless, the majority of these studies have focused on the downstream consequences of low reproductive autonomy and gender inequities, such as their impacts on intimate partner violence, pregnancy, and contraceptive need and uptake.

While understanding downstream impacts of inequitable gender views and low reproductive autonomy is of public health relevance, understanding how to sustainably and meaningfully influence these factors “upstream” has the potential to impact multiple downstream outcomes and promote overall improved SRH among AGYW. To date and to the best of our knowledge, no intervention studies have evaluated upstream drivers of poor reproductive autonomy and views on gender inequity among AGYW in SSA. Given concerns for privacy by AGYW in learning and engaging in sexual health knowledge acquisition and care,³⁸ digital interventions, which have been employed to influence other adolescent SRH outcomes such as knowledge, attitudes, and behaviors,[131] hold particular potential for influencing upstream drivers of reproductive autonomy and gender equity. Systematic reviews of digital interventions delivered to adolescents with a focus on sexual health outcomes were reported in 2012 detailing ten[131] and 2019[132] detailing twenty-five studies of various types (i.e. randomized, observational); each review reported just one intervention on the African conti-

nent each,[53, 54] neither of which measured reproductive autonomy nor inequitable gender views. Similar media-based interventions focusing on adolescent SRH exist, such as MTV Shuga in South Africa, which focused on improving adolescent sexual health and HIV knowledge via a TV series,[133] and the Well-Told Story project, which targeted married AGYW for contraceptives via an interactive radio program,[55] improved knowledge of HIV status and HIV testing and uptake of modern contraceptives, respectively. However, a gap remains in quantifying the potential impact of digital health interventions on reproductive autonomy and inequitable gender views. To address this gap, we evaluate whether CyberRwanda, a digital, sexual health and livelihood direct-to-consumer digital intervention in Rwanda, results in improved reproductive autonomy and reduced inequitable gender views among secondary school-age AGYW.

1.3 Methods

Study Setting

This study took place in eight districts across Rwanda, where 37% of all pregnancies nationally are unplanned[17] and the proportion of all pregnancies that are among AGYW increased from 2010 to 2015.[18, 19] Overall, 12% of unmarried, sexually-active AGYW aged 15-19 in Rwanda use a contraceptive method.[15]

Study Design

This is a secondary analysis of data from the CyberRwanda Type 2 Effectiveness-Implementation trial (referred to as the parent study). The study began enrollment in February 2021 and continued through May 2021; midline data was collected February through August 2022 and is analyzed for this sub-study. The evaluation was conducted among 60 day schools (no boarding or mixed) across six districts involving over 6,000 students.

Trial Design

There are three arms of the Hybrid Trial Type 2 Effectiveness-Implementation study (randomized 1:1:1), further detailed below and in Figure 1.1: a control arm (20 schools), a “facilitated” arm (20 schools) where schools receive the CyberRwanda web-based platform via tablets during structured and unstructured access periods, and a “self-service” arm (20 schools) in which students have access to the CyberRwanda platform without guidance (i.e., “lighter-touch”). Student in the control arm received standard SRH curriculum per Ministry of Health and Ministry of Education guidelines,[134] as well as any other services publicly or privately available in each community.

Intervention

The protocol has been described in detail elsewhere;[135] in brief, the intervention leverages a digital platform designed with human-centered design (HCD), an approach which aims to center human preferences and needs to develop innovative solutions via an iterative process of idea generation, prototyping, and iterative testing of potential solutions.[136] This included the input of over 1000 adolescents and other stakeholders and was subsequently piloted to assess feasibility and acceptability.[137] The final product was the CyberRwanda digital platform and network of youth-friendly providers. Available at the CyberRwanda website[138] for public access, there are three sections: 1) “stories”, 2) “shop”, and 3) “ask”, which focus on educational content in the form of comics following characters across seasons of content, acquisition of SRH products such as sanitary pads, condoms, and contraceptives through a direct-to-consumer shop linked to youth-friendly pharmacies and government-run health posts, and a frequently asked questions forum, respectively.

The “facilitated arm” offers a more interactive and intensive experience of the CyberRwanda digital platform, whereby, in addition to the web-based platform via tablets, some students in these schools are exposed to the intervention via school clubs led by trained peer facilitators (who are also students) using a weekly curriculum complementary to the digital content. This was developed from feedback in the HCD process that peer supported learning is desired for some youth.[138] The “self-service” arm is a less resource-intensive implementation model which offers the CyberRwanda platform in schools without peer facilitation nor guidance; the facilitated arm provides more emphasis on themes of reproductive autonomy, gender equity, and related themes such as discussing contraception with partners and sexual coercion during the weekly sessions. Thus, it is reasonable to hypothesize that while exposure to the CyberRwanda platform may impact equitable views on gender and reproductive autonomy decision-making, this impact may be higher among those students enrolled from schools randomized to the facilitated arm.

Students enrolled in schools in either of the two intervention arms were introduced to the CyberRwanda digital platform during a launch event; tablet access therein was available on a voluntary basis during free time; Wi-Fi was provided to ensure internet connectivity was not a barrier to access. It was suggested for both intervention arms that access to the tablets be at a minimum of five hours per week. Further, any and all students could access the tablets, not just those who agreed to participate in the study (described below). In both intervention arms, students could order sexual health products through the app at market price and pick them up discreetly. It is important to note that the CyberRwanda platform is available on devices outside of school-based tablets, so many students, including those in the control arm, could theoretically be exposed to the platform; however, in practice and per administrative records, few did.

Theory of Change

Changing subjective norms and normative beliefs, such as those around gender and reproductive autonomy, is one of the first phases of the Theory of Planned Behavior, where, in parallel with attitudes and perceived behavioral control, subjective norms and normative beliefs work synergistically to shape behavioral intentions.[139] The CyberRwanda Hybrid Effectiveness-Implementation study was designed by first mapping the path from the intervention to the desired outcomes using an intervention mapping protocol,[140] whereby subjective norms such as inequitable views on gender, as well as perceived control, such as decision-making and reproductive autonomy, are intermediaries on the path to the primary CyberRwanda outcomes of uptake of a modern contraceptive and HIV testing.[135] Understanding how CyberRwanda may impact views on gender equity and reproductive autonomy decision-making requires an understanding of the content with which the participants interact. There are several aspects within the stories and ask sections of the platform that are related to and could influence both inequitable gender views and reproductive autonomy. For example, there are stories told in comic book form from the perspective of an AGYW that touch on topics of relationships, planning to have sex, and negotiation with partners. In the ask section, there are multiple sections related to reproductive autonomy, including discussing consent, how to know when one is ready to be in an intimate relationship, how to deal with pressure to engage in activities that one may not wish to engage in, good communication in relationships, and questions related to gender equality and gender-based violence. After exposure to these sections, more autonomous AGYW may seek to procure their own sexual health products via the shop section, such as condoms or contraceptives, or may be influenced to think about previous views on relationships and sexual relationships through a new, and more equitable, gender lens.

Participant recruitment and inclusion criteria

For the parent study, eligible secondary schools included: 1) those that were located ≤ 4.5 kilometers of a participating pharmacy; 2) were located ≥ 1.5 km from another secondary school to reduce spillover; 3) had ≥ 150 students; 4) were a day school (not mixed or boarding); and 5) were willing to participate (determined by school leadership). This resulted in 62 eligible schools across eight districts, of which 60 were randomly selected. Students who were unable to provide consent (I.e., < 18 years of age) were invited to participate in evaluation activities and those who were interested received parental consent forms to take home; students aged 18 or older were able to consent for themselves. A sampling frame was created among students aged 12-19 in secondary school grades 1 or 2 who assented and had parental consent (if < 18) and those who self-consented (≥ 18). The study team randomly sampled approximately fifty students of each sex per school, resulting in 6,082 students (3,130 or 51.5% female) enrolled at study baseline (Feb-May 2021).

Data Collection

Data were collected via Qualtrics-enabled tablet computers in “offline” mode from February-May 2021 for baseline and February-May 2022 for midline (endline occurred during the same timeframe of 2023, although not used in this analysis) at the schools. At baseline, 6,082 students (of whom 6,079 were eligible) completed the survey and 5,087 of the original sample completed the midline survey (84%). Data were collected on the weekends to reduce disruption to regular school activities; participant identity was ensured via confirmation of multiple identifiers (name, address, etc.) during the study interview. For participants who moved schools or were no longer in school, data collection also occurred on weekends at local youth centers. All survey instruments were administered in Kinyarwanda, the average duration for the entire survey was one hour, and participants were reimbursed for their time (3,000 RWF or ~3 USD). The survey included modules on the following areas: sociodemographic characteristics, knowledge about family planning and reproductive health, social norms related to sexual health, gender roles including inequitable views on gender, norms related to gender-based violence, intentions related to having a family, use of contraceptives, reproductive autonomy, communication with partners, sexual behavior, childbearing, future aspirations and goal setting, and attitudes and intentions toward school and employment. Surveys were administered by trained interviewers who entered the participants’ responses, except in the case of sensitive sexual data, at which point the participants were given the tablet to confidentially enter their own responses.

Independent Variable

The independent variable was a three-category variable indicating the study arm of the school from which the AGYW was recruited. In secondary analyses, I collapsed the two CyberRwanda arms into one category to evaluate “any possible exposure to CyberRwanda” versus the control arm.

Outcomes

The two outcomes of interest were: 1) inequitable gender views and 2) decision-making related to reproductive autonomy (Table 1.1). The former is measured using the inequitable gender norms subscale of the validated Gender Equitable Men’s Scale (GEMS);[141] the latter is measured using the decision-making subscale of the validated Reproductive Autonomy Scale.[30] The GEMS was collected among all CyberRwanda participants (male and female) at the midline wave only; the decision-making subscale of the Reproductive Autonomy Scale (RAS) was collected among sexually active AGYW at both baseline and midline. Sexual activity was determined via an affirmative response to one of multiple questions asking about age at first vaginal sex or ever engagement in vaginal sex.

GEMS: While originally validated among men in Brazil by Pulerwitz et al,[141] the GEMS has since been translated to many languages and validated globally among other populations; among those most relevant for this work include among Ugandan youth (females and males)[142] led by Pulerwitz et al, as well as among adolescents in Uganda.[143] The original scale is 24 items across two subscales which each measure inequitable (n=17 items) and equitable gender views (7 items), respectively; for the inequitable gender views score, validated versions of the scale range from 11-15 items, as they have been adapted in different contexts, and have demonstrated reliability.[144] Scores for the subscales can be calculated and analyzed individually or combined into a composite scale. Due to concerns about survey length and participant burden, CyberRwanda collected 16 of the 17 items of the inequitable gender views subscale (missing item: “It is alright for a man to beat his wife if she is unfaithful”) given there was a comprehensive section on intimate partner violence separate from this survey. Response options were “agree,” “partially agree,” “do not agree,” and “refuse to answer”; items in the analysis were reverse coded so that the direction of all items reflect a higher score indicating higher support for gender equity. All items for the subscale are provided in Supplementary Materials, Table 1.6. The subscale had good internal consistency (reliability; Cronbach’s Alpha = 0.72).

Reproductive Autonomy Scale: The RAS was developed and validated among thirteen urban and suburban American family planning and abortion clinics.[30] It has since been translated and validated among married women in Nepal[145] and in Brazil,[43] and utilized (but not validated) among AGYW in Ghana.[103] The RAS is comprised of 14-items which are divided into three subscales: freedom from coercion (n=5 items), communication (n=5), and decision-making (n=4). Each subscale is scored by a row average where higher scores indicate more freedom from coercion, more communication about sex, and more decision-making autonomy. Subscales can be analyzed individually and/or combined to one overall scale; however, due to concerns about participant burden and survey length, the study only collected (and thus our analysis is restricted to) the decision-making subscale, which was collected at baseline and midline and only among those AGYW who reported ever being sexually active. The subscale items are provided in Supplementary Materials, Table 1.7; response options to the decision-making subscale were “me [3],” “my partner and me [2],” “someone else and me[2],” “my partner [1],” and “someone else [1].” The scores are averaged, with a range of 1-3 and higher scores indicating higher decision-making autonomy. This coding, which is per the standard algorithm of the reproductive autonomy scale, inherently ranks individual decision-making above co-decision making with a partner or someone else. The decision-making subscale had low internal reliability (Cronbach’s Alpha = 0.56) in our sample similar to the original validation study[30]; as such, we opted to evaluate the items individually in addition to the full subscale.

For these analyses, female students aged 12-19 at study baseline who were enrolled at schools participating in the Effectiveness-Implementation study were eligible for inclusion. At baseline, 51.5% (3,130) of the CyberRwanda participants were female of whom 20.2% (633) were

sexually active; at midline 51.4% (2,964) of participants were female of whom 608 (20.5%) were sexually active; thus, the analytic sample for the GEMS included all 2,964 female participants who completed the form at midline, whereas the RAS analysis will include sexually active AGYW at midline who completed the midline assessment (n=608) (Figure 1.2; full CONSORT available in Supplementary Materials, Figure 1.4).

Statistical Analysis

Following the analytic approach for the primary outcomes of the main trial,[135] we conducted an intent-to-treat analysis using midline data only including all schools which were randomized to one of the three arms in the CyberRwanda Effectiveness-Implementation study and including all AGYW enrolled at baseline. We constructed a generalized linear mixed model where the outcomes—inequitable gender views subscale of the GEMS and the decision-making subscale of the RAS—were operationalized as continuous variables. Further, additional models treating each of the five items of the RAS as individual outcomes were constructed. A random intercept for each school (n=60) where students were enrolled at baseline was modelled to account for school-level clustering of participants. The model was defined as Equation 1.1:

$$[Y_{ij}] = \beta_0 + \beta_1 x_{1j} + \beta_2 x_2 + \zeta_j + \epsilon_{ij} \quad (1.1)$$

where Y_{ij} was one of the two continuous outcomes of interest (each subscale) within individuals i within schools j , β_0 was the constant, x_{1j} was a three-category study arm (with the control arm as the reference), x_2 was a six-category variable for district, the stratification variable, ζ_j was the cluster level error term, and the error term for students i within schools was ϵ_{ij} . The interpretation of β_1 is the difference in the outcome scores among AGYW in the facilitated and self-service arms, respectively, compared to the control arm controlling for the stratification factor. To aid the interpretation of effect sizes between groups, a Cohen's D was calculated, which provided the magnitude of the effect size (negligible, small, medium, or large, per standard scoring) between two groups.[146] Given baseline data is available for the RAS, a difference-in-difference analysis was conducted and results are included in Supplementary Table 1.8.

As a sensitivity analysis, we combined the intervention arms and ran additional models with a two-category predictor variable (enrolled at a CyberRwanda school at baseline vs. control arm) to assess whether *any* potential CyberRwanda exposure, versus none, impacts the outcomes. Further, given the age of sexual debut in east Africa is approximately age 16,[34, 147] I conducted a secondary sensitivity analysis restricting the sample to those AGYW who were aged 15-22 at midline, as these older AGYW may be more impacted by gender

and reproductive health programming. To test the difference in effect between the two intervention arms, we changed the reference group to assess the impact of the intervention arms compared to each other. As a final sensitivity analysis and to take into account the potential bias presented by those cases where the entire scale is missing, i.e., those baseline participants who were not re-contacted at midline, we conducted an inverse probability of censoring weighted (IPCW) analysis.[148] The model to generate the weights was fit using baseline sociodemographics (age, parental education, religion, sexual activity, school level, and in the case of the Reproductive Autonomy Scale, baseline Reproductive Autonomy Scale scores) to generate the predicted probability of being observed, of which the weight was the inverse. This IPCW analysis was conducted with the two primary outcomes using the intent-to-treat sample and the generalized mixed linear models.

1.4 Results

Overall 3,130 AGYW enrolled into the study. At baseline, the median age of AGYW was 15 (inter-quartile range [IQR] 14, 16), the majority reported not being partnered (79%), and one-fifth (633; 20.6%) reported being sexually active (Table 1.2). The majority (2,955, 94.4%) completed the midline assessment. Overall, there was balance in baseline demographic characteristics by arm (Supplementary Materials, Table 1.9).

GEMS

Nearly all ($N = 2897$, 97.7%) eligible AGYW completed the inequitable gender views subscale of the GEMS; median subscale score was 34 (IQR: 30, 39); median scores for the facilitated, self-service, and control arms were 35 (IQR: 31, 40), 34 (IQR: 29, 39), and 34 (IQR: 29, 38), respectively (Figure 1.3). AGYW attending a school assigned to the facilitated or self-service CyberRwanda intervention was associated with a 1.61 (standard error [SE]=0.37; $p<0.001$) and 0.52 (SE=0.38, $p=0.17$) higher subscale score compared to AGYW enrolled in the control arm, respectively (Table 1.3). This translates to 5.4% and 1.7% higher scores in the facilitated and self-service arms, respectively, compared to the control arm. Finally, the facilitated arm had a 0.85 point higher score (SE: 0.41, $p=0.037$) compared to the self-service arm in the secondary analysis changing the reference group; the control arm was not significantly different in score compared to the self-service arm. In analyses among male participants, median scores were similar at baseline (37, 35, and 35 for facilitated, self-service, and control arms, respectively), with similar direction and magnitude of effect of the facilitated arm compared to the control arm (Supplementary Materials, Table 1.11).

In sensitivity analyses restricted to AGYW aged 15-22, the facilitated and self-service arms of the CyberRwanda intervention were associated with 1.52 (SE: 0.40, $p<0.001$) and 0.55 (SE: 0.40, $p=0.17$) higher subscale scores compared to the control arm, respectively (Table 1.3). Finally, AGYW in either CyberRwanda arm was associated with 1.11 (SE: 0.35, $p=0.0013$) higher subscale points compared to the control arm (Table 3). The Cohen's D

comparing the facilitated to the control arm was 0.21, indicating a small magnitude of effect. Finally, the facilitated arm had a 0.12 point higher score (SE: 0.046, $p=0.011$) compared to the self-service arm in a secondary model changing the reference group; control arm was not significantly different in score compared to the self-service arm.

Reproductive Autonomy Scale

The reproductive autonomy scale was completed by nearly all (599; 98.5%) eligible ($n=608$), sexually active AGYW. The overall median RAS score was 2.00 (IQR: 2.0, 2.5); median scores for the facilitated, self-service, and control arms were 2.25 (IQR: 2, 2.5), 2.00 (IQR: 2.0, 2.5), and 2.00 (IQR: 2.0, 2.5), respectively. Compared to AGYW enrolled at control schools, AGYW attending a school assigned to the facilitated and self-service arms of the CyberRwanda intervention were associated with 0.090 (SE: 0.047, $p=0.059$) and -0.030 (SE: 0.048, $p=0.53$) point higher and lower scores on the RAS, respectively (Table 1.4). This translates to a 3% and 1% difference in the RAS in the facilitated self-service arm compared to the control arm, respectively.

In sensitivity analyses restricted to AGYW aged 15-22, the facilitated and self-service arms of the CyberRwanda intervention were associated with 0.084 (SE = 0.049, $p = 0.088$) and -0.034 (SE = 0.051, $p = 0.50$) points higher subscale score compared to the control arm, respectively. Being in either intervention arm was associated with 0.033 (SE= 0.044, $p = 0.46$) higher subscale points compared to the control arm (Table 1.4). Among individual items, only Item 1 (decision-making around method to prevent pregnancy) and Item 4 (decision-making around an unplanned pregnancy) were significantly impacted by the intervention, specifically in the facilitated arm, with total scores 6.3% and 6.2% higher in the facilitated arm compared to the control arm for each item, respectively (Table 1.5). The Cohen's D comparing the facilitated arm to the control arm was 0.16, indicating a negligible magnitude of effect. In analyses among male participants, median scores were similar at baseline (2.00), however there were negative coefficients for the facilitated arm, demonstrating a decrease in the RAS compared to the control arm (Supplementary Materials, Table 1.12).

Inverse Probability of Censoring Weights

There was high retention at study midline (95%) among AGYW that was non-differential by arm; nevertheless, AGYW who were not retained at midline were more likely to self-report being sexually active at baseline. In the IPCW analysis for the GEMS, the magnitude of the impact in the self-service arm was larger and statistically significant compared to the primary intent-to-treat analysis; the effect was similar in both models for the facilitated arm. In the IPCW analysis for the Reproductive Autonomy Scale, the effect detected in the facilitated arm was attenuated compared to the primary analysis in the intent-to-treat sample, whereas the effect in the self-service arm was stronger in magnitude and in the same direction as the primary intent to treat analysis. Results of the IPCW are shown in Supplementary Materials, Table 1.10.

1.5 Discussion

This study presented a midline evaluation of the CyberRwanda intervention on inequitable gender views and reproductive autonomy among school-age Rwandan AGYW. Our study demonstrated that, compared to the control group, the facilitated, but not self-service, arm and implementation model of CyberRwanda positively impacted views on gender equity although the magnitude of effect was small. Our study did not detect a statistically significant impact on the overall measure of reproductive autonomy, although small impacts on individual items were detected. To our knowledge, this is the first rigorous trial evaluating a digital health intervention’s impact on these two measures among AGYW and indicates that digital health interventions hold some promise for influencing gender equity and some domains of reproductive autonomy.

Our detection of small impacts of some of the individual items of the reproductive autonomy scale and on the overall inequitable gender views scales in the facilitated arm solely is an informative finding which helps elucidate the potential mechanism(s) underlying intervention impact. The primary difference between the two implementation models practiced between the two arms is 1) the facilitated (rather than self-service) exposure to CyberRwanda which could impact the breadth and depth of CyberRwanda exposure and 2) the use of peer facilitators, who provide weekly activities using a standard activity guide and curriculum which emphasize and complement the CyberRwanda platform via voluntary, school-based clubs.[135] In the former difference, program data indicate that while knowledge of CyberRwanda was equal between the two intervention arms, engagement in CyberRwanda was higher in the facilitated arm. In regards to the second difference, incorporating peer facilitators is regarded as an inclusive, participatory method which fosters engagement among youth in particular.[52] In regards to the impact of peer approaches on adolescent SRH outcomes, a 2019 systematic review of 20 studies from low- and middle-income countries reported mixed results in regards to the impact of peer facilitators on SRH outcomes[149] such as HIV and STI incidence and condom use. While these outcomes parallel the primary trial outcomes,[135] there is less quantitative evidence available to demonstrate the impact of peer navigators on changes inequitable gender views and reproductive autonomy among in-school adolescents, which are intermediate outcomes on the hypothesized impact path of CyberRwanda. Nevertheless, a qualitative study of a peer-facilitated based SRH intervention found that among AGYW specifically, participation was associated with increased self-esteem, gender empowerment, and positive role modelling.[94] Taken together, it is plausible that a higher and more interactive “dose” of CyberRwanda and/or peer facilitator support was instrumental for impacting inequitable gender views and some, but potentially not all, domains of reproductive autonomy in this context.

The fact that CyberRwanda impacted some—but not all—of the measured domains of reproductive autonomy decision-making is also informative in understanding the mechanisms and potential reach of CyberRwanda. Given the scoring algorithm for the decision-making sub-

scale, whereby individual decision-making has the highest possible score, individual decision-making is inherently *always* seen as exhibiting higher reproductive autonomy than shared decision making. However, within the context of unmet need for contraception in lower-resourced settings, reproductive health decision-making is, per Kabagenyi et al., a “joint responsibility” [150] between partners, and there is a growing evidence base that including men in decision-making has, in certain instances of interventions focused on improving male knowledge of and communication around, actually *increased* uptake of contraceptives.[151, 152] Nevertheless, this evidence is outnumbered by studies of men being obstructive to modern contraceptive use[153, 154] and subsequent covert contraceptive use globally,[155] and is often within the context of spousal relationships, which is less relevant to CyberRwanda participants, who are overwhelmingly (99.98%) unmarried. Indeed, there is some evidence for differential impacts of the intervention by individual items,[138] whereby the platform components focuses on *joint* decision-making and partner involvement rather than the individual. For example, in Season 3, Chapter 3 of the comic series (from the “Stories” component of CyberRwanda), one of the female characters, Happy, has a conversation with her partner and communicates her discomfort with initiating a sexual relationship; the storyline continues in Chapter 4 where Happy reflects on her relationship improving once she communicated her discomfort and her partner made changes accordingly. Further, the “ask” section has questions related to how to talk to your partner about sex and condom use, how to navigate differences in sexual desires (such as engaging in sex or using contraceptives). Finally, the peer facilitator guidebook has a session specifically about gender and sex where they focus on ideal communication within a relationship, as well as condom negotiation within partnerships, among other topics.

The impact of the focus on these partner-centered approaches is mirrored in the scores for the reproductive autonomy decision-making scale which hover around a mean of 2, consistent with the average response being “me and my partner/someone else.” Further, while we are not sure who the “someone else” may be (which is coded with the same weight as “me and my partner”), there is some evidence from the United States that AGYW often rely on a parent to help them make reproductive decisions, which, like shared decision-making in partnerships, may be just as if not more empowering of an experience, especially for AGYW.[156] While we did not detect effects on the overall scale, we did detect intervention effects on two of the individual items: the first item, which asks about decision-making around the use of any method to prevent pregnancy, and the fourth item, which asks about decision-making in the case of an unplanned pregnancy. In both these cases, there are enough CyberRwanda content components that focus on the individual—such as stories and peer facilitated workshops about contraceptive methods other than condoms, as well as a discussion of emergency contraception—that may influence female participants to believe these are individual decisions, rather than those which might be made by AGYW *and* their male partners (such as condom negotiation). For these reasons the use of the individual items rather than the entire scale may be more relevant for understanding the most salient domains of reproductive autonomy decision-making that can be affected by CyberRwanda, and may be a consider-

ation for future research among AGYW who have yet to exercise all potential domains of reproductive autonomy.

The findings of this midline analysis are strengthened by a number of factors. First, CyberRwanda has a large sample of over 6,000 students across sixty schools within eight districts, and this analysis included nearly 3,000 AGYW of whom approximately 600 were sexually active. Second, the CyberRwanda study team has extensive participant retention techniques which contributed to a high 12-month retention of 95%. Third, all content offered across the various domains of CyberRwanda were designed using Human Centered Design, with the Implementation-Effectiveness using the Theory of Planned Behavior[139] to understand the impact pathway and subsequent measurable outcomes[135]; the intentionality of these components and measurement of outcomes across these hypothesized pathways, facilitates its rigorous evaluation. However, these findings must be interpreted within the context of its limitations. We did not collect baseline data on views on gender inequity to assess baseline equivalence by arm, however, given the baseline balance in other factors, we have no reason to suspect that there is an unmeasured imbalance that could impact our estimation at the midline assessment. A limitation related to internal validity is whether the reproductive autonomy decision-making subscale is the most appropriate tool for measuring reproductive autonomy in this specific population of school-age, Rwandan AGYW, especially since it has only been validated in Nepal[145] and in Brazil[43]. While the examination of the individual items in addition to the entire scale was informative in understanding how the content may impact different domains of reproductive autonomy, the larger question remains of whether AGYW who are just experiencing sexual debut and/or have little sexual experience are having grounded conversations around family size and choosing contraceptive methods and are able to answer these questions in a meaningful way. Likewise, there is evidence that shared decision-making may be equally as autonomous as individual decision-making[156] future research using questions that disentangle empowering from unempowering shared decision-making, perhaps with indicators of satisfaction or concurrence with the final decision, would further improve our measurement of reproductive autonomy. Last, the reproductive autonomy scale has not been validated outside of the United States context; a recent use of the reproductive autonomy scale in Vietnam among a sample of women largely in their thirties and married also reported low internal reliability and hypothesized poor cross-cultural relevance.[41] This highlights a fundamental question of cross-cultural validity and the need for a deeper understanding of what reproductive autonomy is and how it is operationalized for AGYW, especially within the east African and Rwandan milieu.

In conclusion, our study demonstrated that CyberRwanda was an effective intervention for modestly improving views on gender equity, as well as some components of reproductive autonomy, among school-age AGYW in Rwanda. CyberRwanda's approach and platform is aligned with multiple guidelines from the World Health Organization for the promotion of adolescent sexual and reproductive health and rights.[157] These results are generalizable to other districts in Rwanda and may be generalizable to the east African setting where there

are shared socio-cultural drivers of gender and reproductive health among AGYW. Thus, the replication of the CyberRwanda model may hold promise outside of Rwanda.

1.6 Tables and Figures

Table 1.1: Overview of study outcome scales

	Inequitable Gender Views subscale of the GEM Scale	Decision-Making subscale of Reproductive Autonomy Scale
Analytic sample	AGYW	Sexually active AGYW
N Items	17 (16 in CyberRwanda)	4
Cronbach's Alpha	0.72	0.55
Response options ¹	3	3
Score Range	16-49 (Simple sum)	1-3 (Row average)
Interpretation	Higher score = higher gender equity views	Higher score = higher reproductive autonomy
Countries where validated	Brazil, Uganda, South Africa, Kenya, Mexico, India, USA	USA, Nepal, Brazil
Source	Pulerwitz, J, Barker J. 2008. "Measuring attitudes toward gender norms among young men in Brazil: Development and psychometric evaluation of the GEM Scale," <i>Men and Masculinities</i> 10: 322–338.	Upadhyay UD, Dworkin SL, Weitz TA, Foster DG. Development and validation of a reproductive autonomy scale. <i>Studies in family planning</i> 2014;45(1):19-41.

¹ Excluding NA

Table 1.2: Characteristics of enrolled AGYW in CyberRwanda at study baseline, 2021

	All AGYW (n=3,130)	Sexually Active AGYW (n=633)
Age (median, IQR)	15 (14, 16)	15 (14, 17)
Marital Status		
Married	1 (0.0%)	0 (0.0%)
No partner	2,461 (78.6%)	402 (63.5%)
Partnered/boyfriend	665 (21.2%)	228 (36.0%)
Other	3 (0.1%)	3 (0.5%)
Religion		
Christian	1,853 (59.2%)	356 (56.2%)
Catholic	1,097 (35.1%)	245 (38.7%)
Muslim	63 (2.0%)	12 (1.9%)
Other	114 (3.6%)	19 (3.0%)
Refuse to answer	2 (0.1%)	1 (0.2%)
Wealth quartile		
First	835 (26.7%)	192 (30.3%)
Second	795 (25.4%)	158 (25.0%)
Third	775 (24.8%)	152 (24.0%)
Fourth	724 (23.1%)	131 (20.7%)
Parent's highest education		
Unknown	415 (13.3%)	78 (12.3%)
None	266 (8.5%)	54 (8.5%)
Some primary	634 (20.3%)	130 (20.5%)
Completed primary	1,518 (48.5%)	321 (50.7%)
Completed secondary	228 (7.3%)	42 (6.6%)
Completed university	53 (1.7%)	5 (0.8%)
Vocational training	16 (0.5%)	3 (0.5%)
Food security status		
Little to no hunger	2,227 (71.3%)	436 (68.9%)
Moderate hunger	822 (26.3%)	179 (28.3%)
Severe hunger	76 (2.4%)	18 (2.8%)

Table 1.3: CyberRwanda’s impact on GEMS score among enrolled AGYW at midline, 2021^{1,2}

	Full intent-to-treat sample of AGYW (n=2,897)			AGYW aged 15-22 (n=2,486)		
	Mean	Beta (SD)	p-value	Mean	Beta (SD)	p-value
Primary model						
Control arm	33.73	Reference		33.63	Reference	
CyberRwanda facilitated arm	35.16	1.61 (0.37)	<0.001	35.00	1.52 (0.40)	<0.001
CyberRwanda self-service arm	34.38	0.52 (0.38)	0.17	34.38	0.55 (0.40)	0.17
Secondary model combining arms						
Control arm	33.73	Reference		33.63	Reference	
Either CyberRwanda arm	34.76	1.11 (0.35)	0.0013	34.68	1.06 (0.58)	0.003

¹ Participant scores ranged from 16-49; higher scores indicate more equitable gender views

² Models control for district and account for school level clustering

Table 1.4: CyberRwanda’s impact on the Decision-Making subscale of the Reproductive Autonomy Scale scores among enrolled and sexually active AGYW at midline, 2021^{1,2}

		Full sample (n=2,897)			AGYW aged 15-22 (n=551)		
		Mean	Beta (SD)	p-value	Mean	Beta (SD)	p-value
Primary model							
Control arm		2.16	Reference		2.15	Reference	
CyberRwanda facilitated arm		2.23	0.090 (0.047)	0.059	2.21	0.084 (0.049)	0.088
CyberRwanda self-service arm		2.13	-0.030 (0.048)	0.53	2.11	-0.034 (0.051)	0.50
Secondary model combining arms							
Control Arm		2.16	Reference		2.15	Reference	
Either CyberRwanda arm		2.18	0.033 (0.044)	0.46	2.17	0.028 (0.045)	0.53

¹ Scores range from 1-3; higher scores indicate more individual decision-making

² Models control for district and account for school level clustering

Table 1.5: CyberRwanda’s impact on individual items of the Decision-Making subscale of the Reproductive Autonomy Scale among enrolled and sexually Active AGYW at midline, 2021 (n=599)¹

	Item 1 ²		Item 2 ³		Item 3 ⁴		Item 4 ⁵	
	Beta (SD)	p-value	Beta (SD)	p-value	Beta (SD)	p-value	Beta (SD)	p-value
Control arm	Reference	–	Reference	–	Reference	–	Reference	–
Facilitated arm	0.19 (0.076)	0.021	-0.066 (0.073)	0.37	0.076 (0.069)	0.27	0.18 (0.072)	0.013
Self-service arm	0.043 (0.078)	0.078	-0.098 (0.074)	0.19	-0.021 (0.070)	0.76	-0.021 (0.073)	0.78

¹Models included a random intercept for school and controlled for the district (stratification factor)

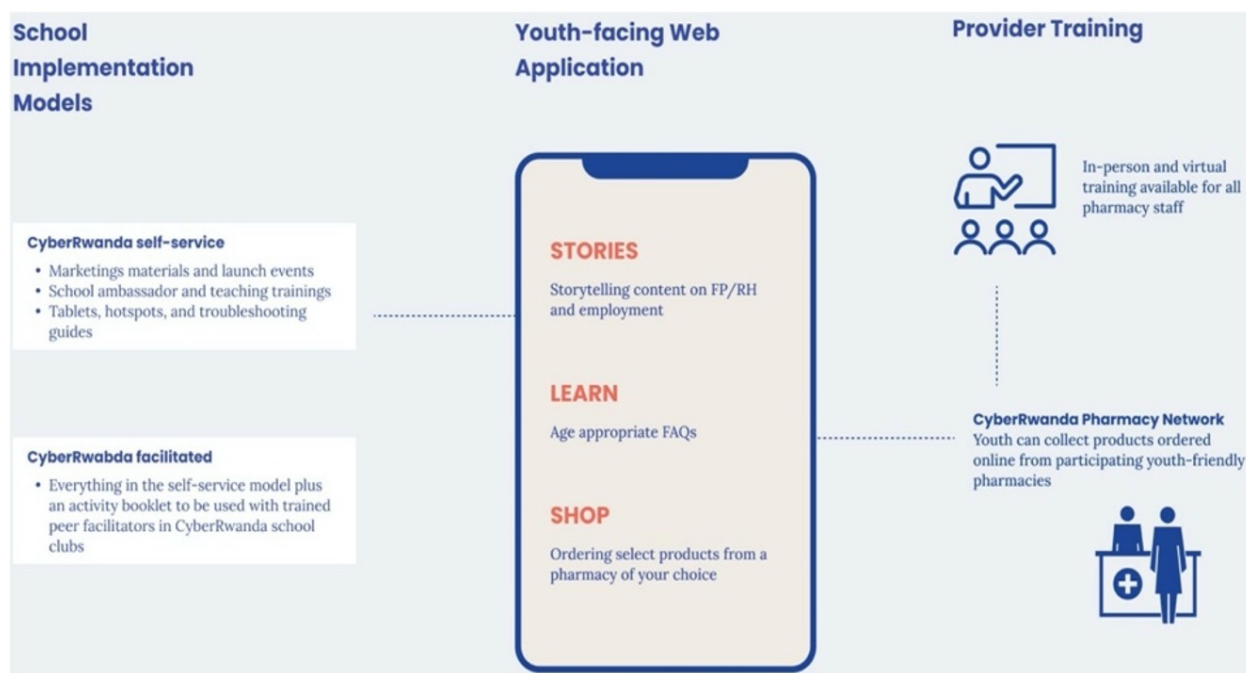
² Who has the MOST say about whether you use a method to prevent pregnancy?

³ Who has the MOST say about which method you would use to prevent pregnancy?

⁴ Who has the MOST say about when you should have a baby in your life?

⁵ If you or your partner became pregnant but it was unplanned, who would have the MOST say about whether you would raise the child, seek adoptive parents, or have an abortion?

Figure 1.1: CyberRwanda platform features and implementation models¹



¹ Source: Hémeno et. al; *Sexual and Reproductive Health Matters*, 2022

Figure 1.2: Recruitment flow of CyberRwanda participants

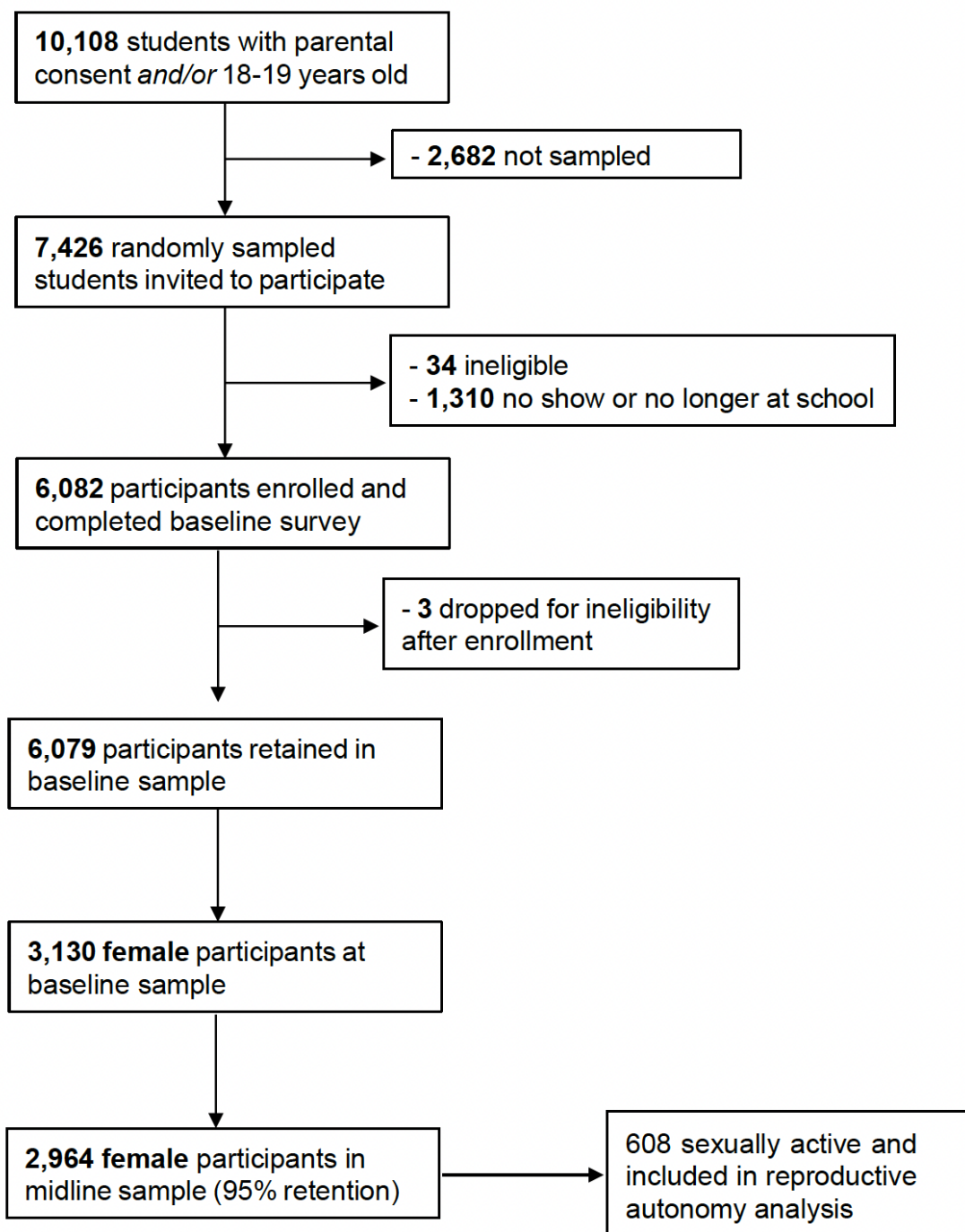
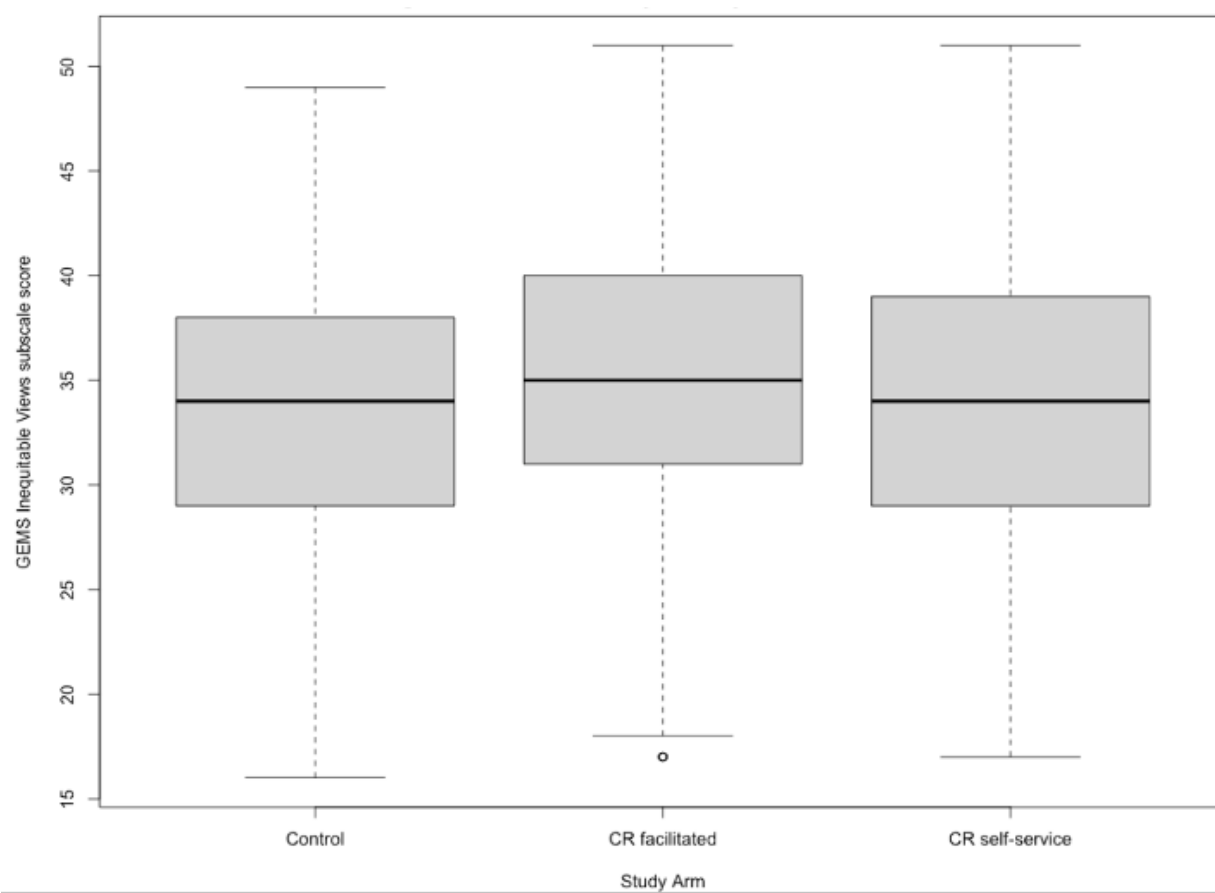


Figure 1.3: GEMS Score by arm among enrolled AGYW at midline, Cyber-Rwanda, 2021 (n=2,897)



1.7 Supplementary Materials

CyberRwanda Survey Questions

Table 1.6: **Inequitable Gender Views subscale of the GEMS**

Domain	Question ¹
Violence	1. There are times when a woman deserves to be beaten 2. A woman should tolerate violence in order to keep her family together 3. It is alright for a man to beat his wife if she is unfaithful. 4. It is okay for a man to hit his wife if she won't have sex with him 5. If someone insults a man, he should defend his reputation with force if he has to.
Sexual relationships	6. It is the man who decides what type of sex to have. 7. Men are always ready to have sex. 8. Men need sex more than women do. 9. A man needs other women even if things with his wife are fine. 10. You don't talk about sex, you just do it
Reproductive health and disease prevention	11. Women who carry condoms on them are easy. 12. Men should be outraged if their wives ask them to use a condom. 13. It is a woman's responsibility to avoid getting pregnant.
Domestic chores and daily life	14. Changing diapers, giving a bath, and feeding kids is the mother's responsibility 15. A woman's role is taking care of her home and family.
Other	16. I would never have a gay friend

¹ Response options: agree, partially agree, do not agree, and refuse to answer

Table 1.7: **Decision-making subscale of the Reproductive Autonomy Scale**

Question
1. Who has the most say about whether you use a method to prevent pregnancy?
2. Who has the most say about which method you would use to prevent pregnancy?
3. Who has the most say about when you have a baby in your life?
4. If you became pregnant but it was unplanned, who would have the most say about whether you would raise the child, seek adoptive parents, or have an abortion?

¹ Response options: Me, my partner, someone else, my partner and me, someone else and me, refuse to answer.

Table 1.8: **Difference in difference results using baseline and midline data for the Decision-Making subscale of the Reproductive Autonomy Score (RAS)¹ among sexually active AGYW enrolled in CyberRwanda, 2021 (n=599)**

	Mean Baseline RAS	Mean Endline RAS	Difference by arm	D-i-D Estimate ² (SE, p-value)
Control Arm	2.206	2.161	-0.045	Ref.
Facilitated Arm	2.153	2.239	0.076	0.11 (0.068; 0.10)
Self-Service Arm	2.238	2.129	-0.10	-0.070 (0.07; 0.32)

¹ Scores range from 1-3; higher scores indicate more individual decision-making

² Models control for district and account for school level clustering

Table 1.9: Characteristics of enrolled AGYW in CyberRwanda at study baseline stratified by arm, 2021

	All AGYW (n=3,130)		
	Facilitated (n=1,050)	Self-Service (n=1,031)	Control (n=1,049)
Age (median, IQR)	15 (14, 16)	15 (14, 16)	15 (14, 16)
Marital Status			
Married	0 (0.0%)	1 (0.1%)	0 (0.0%)
No partner	810 (77.1%)	831 (79.2%)	810 (77.1%)
Partnered/boyfriend	2 (0.2%)	1 (0.1%)	2 (0.2%)
Other	238 (22.7%)	216 (20.6%)	238 (22.7%)
Religion			
Christian	586 (55.8%)	608 (59.0%)	660 (62.9)
Catholic	386 (37.4%)	378 (36.0%)	333 (31.7%)
Muslim	17 (1.6%)	23 (2.2%)	23 (2.2%)
Other	42 (4.0%)	38 (3.7%)	33 (3.1%)
Refuse to answer	0 (0.0%)	1 (0.1%)	1 (0.1%)
Wealth quartile			
First	291 (27.7%)	297 (28.8%)	247 (23.6%)
Second	267 (25.4%)	258 (25.0%)	269 (25.7%)
Third	260 (24.8%)	262 (25.4%)	253 (24.1%)
Fourth	232 (22.1%)	214 (20.8%)	279 (26.6%)
Parent's highest education			
Unknown	132 (12.8%)	157 (15.0%)	126 (12.0%)
None	69 (6.7%)	96 (9.2%)	101 (9.6%)
Some primary	225 (21.8%)	198 (18.9%)	211 (20.1%)
Completed primary	517 (50.1%)	488 (46.5%)	513 (48.9%)
Completed secondary	64 (6.2%)	78 (7.4%)	86 (8.2%)
Completed university	20 (1.9%)	23 (2.2%)	10 (1.0%)
Vocational training	4 (0.4%)	9 (0.9%)	3 (0.3%)
Food security status			
Little to no hunger	749 (72.6%)	751 (71.6%)	728 (69.3%)
Moderate hunger	256 (24.8%)	268 (25.5%)	297 (28.3%)
Severe hunger	26 (2.5%)	28 (2.7%)	22 (2.1%)
Sexually active			
Yes	226 (21.9%)	197 (18.8%)	210 (20.0%)
No	7 (0.7%)	2 (0.2%)	5 (0.5%)
Refused	798 (77.4%)	850 (81.0%)	835 (79.5%)

Table 1.10: **CyberRwanda’s impact on the Reproductive Autonomy Scale and GEMS among enrolled AGYW at midline, inverse probability of censoring weighted (IPCW) analysis, 2021¹**

	RAS ² (n=599)		GEMS ³ (n=2,897)	
	Beta (SE)	p-value	Beta (SE)	p-value
Control Arm	Reference		Reference	
CyberRwanda Facilitated arm	0.049 (0.068)	0.35	1.32 (0.34)	<0.001
CyberRwanda Self-Service arm	-0.073 (0.072)	0.55	0.71 (0.33)	0.033

¹Models control for district and account for school level clustering

²Scores range from 1-3; higher scores indicate more individual decision-making

³ Scores range from 16-49; higher scores indicate more equitable gender views

Appendix 3: Adolescent boys and young men (ABYM) analysis

Rationale

While my dissertation focuses on understanding how to impact drivers of and engagement in behaviors which will reduce the disproportionate burden of adverse SRH outcomes among AGYW, ABYM face their own unique set of socio-cultural challenges and impact their health outcomes. Much like AGYW, adolescence is a period of time whereby males experience gender socialization.[31] These gender norms, often shaped by family and peers,[158] are manifest in gender attitudes, which are put into practice during adolescence,[159] making this formative phase an ideal time for gender-focused intervention. The paths by which CyberRwanda may have impacted the primary outcomes (reproductive autonomy and gender inequitable views) differs between males and females. For example and as described previously, whereas AGYW and their views on gender may be served by messages around empowerment and agency in decision-making, ABYM may be served by messages focused on consent, shared decision-making, and equitable treatment of their female sexual partners, themes of which CyberRwanda focused. The impact on inequitable gender views and reproductive autonomy vary by gender as well: while women are often victims of intimate partner violence, have interrupted schooling, and are biologically vulnerable to HIV and other sexually transmitted infections, males are often the perpetrators. Nevertheless, males are adversely impacted by gender inequities,[160] despite the social standing and power it offers to men, with poor mental health being associated with inequitable gender views.[160] Further consequences of inequitable gender views among men include behaviors that put men at risk for HIV and STIs, include low condom-use and HIV testing[161] and poor engagement in HIV care.[162]

While the paths to impact may differ between males and females, AGYW beliefs, norms, and behavior may be greatly impacted by ABYM peers,[159] and their male partners in particular.[163] Thus changes in gendered views and reproductive autonomy among the adolescent males, may, in addition to independent intervention effects, impact the outcomes of interest of this study.

Results

A total of 2,949 ABYM were enrolled at CyberRwanda baseline. Median age was 16 (IQR: 14, 17), the majority reported not being partnered (82%), and over one-third (1090; 37%) reported being sexually active at baseline. The majority (2,804, 95.1%) completed the mid-line assessment.

GEMS The overall median GEMS score among ABYM was 35, similar to the arm-specific male scores of 37, 35, and 35 for the facilitated, self-service, and control arms, respectively. Compared to ABYM enrolled at control schools, ABYM attending a school assigned to the facilitated and self-service arms of the CyberRwanda intervention were associated with

1.38 (SE: 0.41, $p \leq 0.001$) and -0.12 (SE: 0.43, $p = 0.78$) points higher and lower scores on the GEMS, respectively (Supplementary Materials, Table 1.11). In sensitivity analyses restricted to ABYM aged 15-22, the facilitated and self-service arms of the CyberRwanda intervention were associated with 1.21 (SE = 0.41, $p = 0.003$) and -0.22 (SE = 0.43, $p = 0.62$) points higher lower subscale score compared to the control arm, respectively. Results showing the binarized intervention arm are also shown in Supplementary Materials, Table 1.11.

Reproductive Autonomy The overall median male RAS scores were 2.00 across all three arms. Compared to ABYM enrolled at control schools, ABYM attending a school assigned to the facilitated and self-service arms of the CyberRwanda intervention were associated with -0.075 (SE: 0.03, $p = 0.024$) and -0.015 (SE: 0.034, $p = 0.65$) points lower scores on the RAS, respectively (Supplementary Materials, Table 1.12). In sensitivity analyses restricted to ABYM aged 15-22, the facilitated and self-service arms of the CyberRwanda intervention were associated with -0.068 (SE = 0.035, $p = 0.050$) and -0.0036 (SE = 0.035, $p = 0.92$) points lower subscale score compared to the control arm, respectively. Results showing the binarized intervention arm are shown in Supplementary Materials, Table 1.12.

Discussion

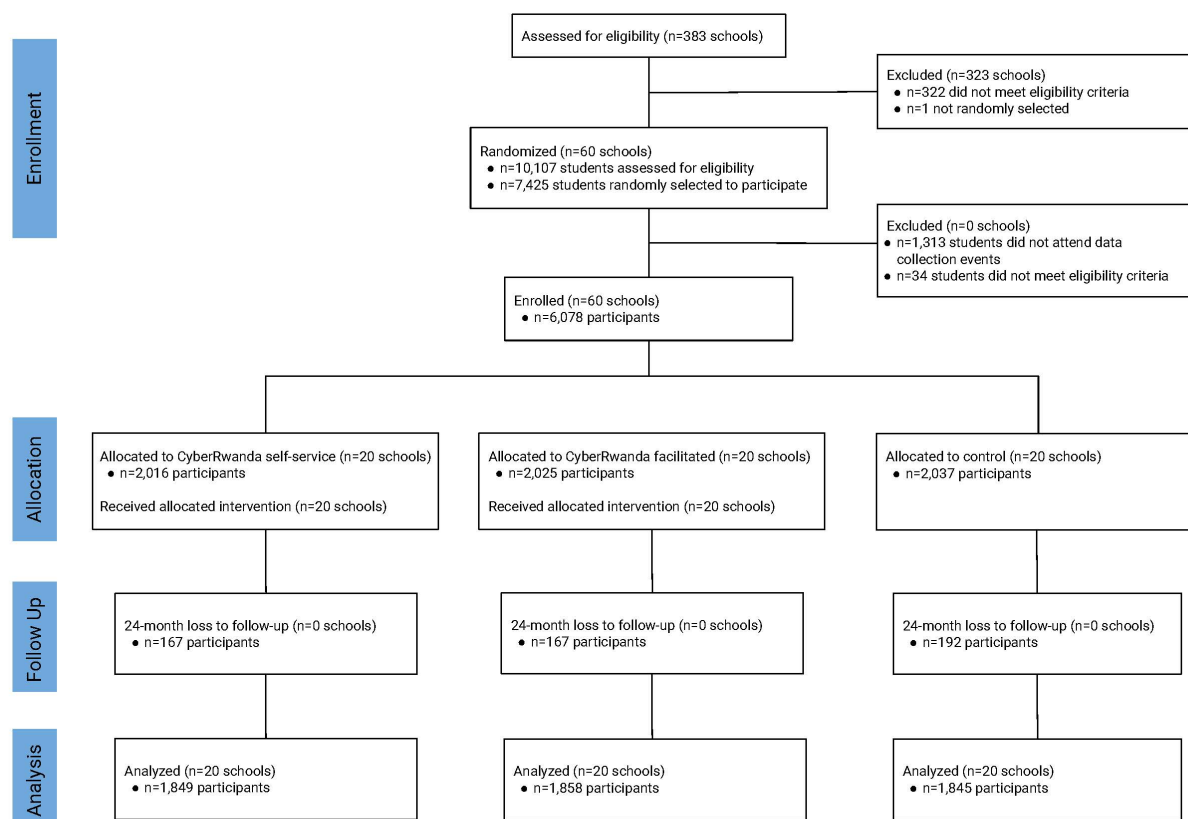
Among ABYM, there is evidence that the CyberRwanda intervention resulted in higher inequitable gender views scores and lower reproductive autonomy scores. While negative coefficients on the RAS may appear counter-intuitive to a hypothesized impact on improved reproductive autonomy and decision-making, further research is needed to understand how this scale has been used among other males, and if this corresponds to a shift from baseline in more shared—rather than individual—decision-making, which may be a signal of improved reproductive autonomy decision-making. Further, the RAS was validated among women and, to the best of my knowledge, has only been used among women since; unlike GEMS, the relevance and validity of the RAS scale among men is yet to be determined. The similarity of the median scores at baseline between ABYM and AGYW may signal a generational shift away from traditional sex-biased gender beliefs; alternatively, it could signal a neutrality preceding a more substantial gender programming to come in later adolescence which may or may not cause a divergence in these views and attitudes by sex. Further, there was similarity in the effect sizes as the magnitudes of impact were negligible to small with both ABYM and the AGYW. The small effect sizes, as well as negative direction of effect for the RAS in particular, may be a reflection of the limitations of the RAS as described in the primary discussion section. Nevertheless, these results demonstrate that the intervention—primarily the facilitated arm—was associated with reduced inequitable gender views among ABYM, which warrants further investigation to understand which components specifically may have driven this shift in gender views and how this may be applied in other settings of ABYM.

Table 1.11: **CyberRwanda’s Impact on GEMS among enrolled and sexually active adolescent boys and young men at midline, 2021**

	Full sample (n=1,106)			Aged 15-22 (n=1,052)		
	Mean	Beta (SD)	p-value	Mean	Beta (SD)	p-value
Control arm	35.01	Reference		35.02	Reference	
Facilitated arm	36.11	1.38 (0.41)	<0.001	36.03	1.21 (0.41)	0.003
Self-service arm	35.11	-0.12 (0.43)	0.78	35.06	-0.22 (0.43)	0.62
Control arm	35.01	Reference		35.02	Reference	
Combined intervention arms	35.61	0.72 (0.38)	0.060	35.55	0.58 (0.38)	0.13

Table 1.12: **CyberRwanda’s impact on the Decision-Making subscale of the Reproductive Autonomy Scale among enrolled adolescent boys and young men at midline, 2021**

	Full sample (n=1,106)			Aged 15-22 (n=1,052)		
	Mean	Beta (SD)	p-value	Mean	Beta (SD)	p-value
Control arm	2.23	Reference		2.22	Reference	
Facilitated arm	2.17	-0.075 (0.03)	0.024	2.16	-0.068 (0.035)	0.050
Self-Service arm	2.21	-0.015 (0.034)	0.65	2.22	-0.0036 (0.035)	0.92
Control arm	2.23	Reference		2.22	Reference	
Combined intervention arms	2.19	-0.047 (0.030)	0.12	2.19	-0.037 (0.031)	0.23

Figure 1.4: Study CONSORT diagram¹¹ Credit to Rebecca Hémeno and Lauren Hunter for developing the CONSORT

Chapter 2

Understanding Preferences for PrEP Modalities and Implementation among Adolescent Girls and Young Women at Risk for HIV acquisition in Tanzania

2.1 Abstract

Background: Despite high efficacy, the uptake and effective use of oral pre-exposure prophylaxis (PrEP) among young people can be stymied by low awareness, cultural and social barriers, stigma, and user dissatisfaction. We sought to understand preferences for potential PrEP products and implementation models, which may address these barriers for adolescent girls and young women (AGYW) aged 15-24.

Methods: We used a forced choice discrete choice experiment (DCE) to evaluate different PrEP modalities and components of potential implementation models for AGYW in Lake Zone, Tanzania. We enrolled AGYW recently or currently vulnerable to HIV acquisition per Tanzanian PrEP eligibility guidelines. Our DCE included an educational model to ensure understanding of DCE components and PrEP, and evaluated five attributes with varying levels: (i) PrEP modality [daily oral, vaginal ring, long-acting injection]; (ii) screening location [HIV clinic, mobile clinic, pharmacy]; (iii) refill location [pharmacy, mobile clinic, community health worker]; (iv) provider identity [anyone, old/young female, old/young male]; and (v) cost per refill [free, 1000-5000 Tanzanian shillings [TSh]]; participants were offered 10 task sets each with two alternatives between which to choose. I estimated effects-coded preference weights for each level and calculated the predicted probability of choosing an alternative via mixed logit regression models. I also estimated overall attribute importance using standard

scoring.

Findings: We enrolled 696 AGYW who met the criteria of being recently (n=138) or currently (n=558) PrEP eligible. Median age was 20, the majority (87%) were Christian, 18.5% were ever married, and 62% were nulliparous. Prior to the educational module, 77% of participants had never heard of PrEP. The vaginal ring (preference weight [PW]: -0.88, 95% confidence interval [CI]: -0.97, -0.79, $p < 0.001$) was less preferred than the mean response while daily oral PrEP (PW: 0.25, 95% CI: 0.18, 0.32, $p < 0.001$) and long-acting injectable PrEP (0.63, 95% CI: 0.55, 0.71; $p < 0.001$) were significantly more preferred. We did not detect significant positive preferences for any screening or refill locations, although screening via mobile clinics was significantly less preferred (PW: -0.081, 95% CI: -0.13, -0.032, $p = 0.001$). Respondents preferred younger female providers (PW: 0.14, 95% CI: 0.070, 0.22, $p < 0.001$) while both older provider identities were less preferred. Effects-coded preference weights for potential price points were negative when at or greater than 4,000 TSh and positive for <2,000 TSh or free. In terms of attribute importance, modality had the greatest relative influence overall (54.2%), followed by cost (30.8%). Nearly all (89%) reporting that they would take up the choices they selected if available to them.

Interpretation: PrEP awareness was low in this population. Product type, specifically injectable PrEP, was the most influential attribute on AGYW's choices. There were no dominating preferences in the screening or refill attributes. AGYW demonstrated high levels of interest in taking up PrEP across various implementation scenarios.

Funding: The research was supported by the UCSF Center for AIDS Research BOOST Award and the National Institutes of Health (R01MH124516).

2.2 Introduction

Sub-Saharan Africa's [SSA] 400 million adolescents have disproportionately high risk of HIV transmission, subsequent morbidity and mortality, and myriad threats to their health and wellbeing.[2, 3] In 2021, adolescent girls and young women (AGYW) accounted for 63% of all new HIV infections in SSA[164] despite comprising approximately 10% of the population,[10, 76] translating to 600-800 infections per day. Consequently, UNAIDS' 2025 target of no more than 50,000 annual incident HIV cases among AGYW worldwide is currently unachievable.[165] Risks for HIV acquisition are heightened in east and southern Africa where the largest number and greatest incidence of HIV cases occur.[12, 13] Often, HIV seropositivity or being affected by HIV is associated with poor educational outcomes,[166] thus creating a vicious intergenerational cycle of poverty and HIV risk.[14]

Pre-exposure prophylaxis (PrEP), which is up to 99% effective at preventing HIV when consistently and effectively used,[167] could significantly reduce incident HIV cases if used at scale effectively and among key populations, such as AGYW. The current PrEP regimen (once daily combined tenofovir disoproxil fumarate [TDF, 300 mg] and emtricitabine [200 mg]) is a large blue pill taken orally (similar to some HIV antiretroviral therapy [ART]) with effectiveness varying based on adherence but ranging between 30-99%.[81] In Tanzania, oral PrEP is distributed in the same hospital and clinic-based pharmacies as ART for HIV treatment, requires at initiation blood tests to assess kidney function (measured via eGFR and creatinine) as well as confirm HIV seronegativity, and is given in similar packaging as ART. While the World Health Organization has recently relaxed the creatinine screening for individuals under age 30,[168] it is still part of the standard screening protocol in Tanzania.[169] Numerous studies have documented how these characteristics present barriers for uptake and adherence to AGYW, primarily as users do not want to be perceived as living with HIV.[82, 83, 84]

Vulnerability to HIV is compounded by a complex intersection of socio-cultural factors, including low awareness, concerns about privacy while seeking care, perceived and enacted stigma, gender dynamics, and limited ability to access AGYW friendly care.[67, 68] Among Ugandan AGYW eligible for PrEP and at risk for HIV acquisition, less than one in four had ever heard of PrEP;[170] among AGYW with PrEP awareness, they reported being often deterred from seeking it for fear of being seen as promiscuous or living with HIV.[70] Further, perceived and internalized stigma results in the underutilization of crucial HIV and sexual and reproductive health (SRH) services among this demographic.[71, 72, 73] Combined with provider's poor understanding of AGYW SRH needs[74, 86] and shortages of trained workers and supplies,[75] AGYW's vulnerability to HIV transmission is exacerbated given the multidimensional barriers they face accessing PrEP. Consequently, PrEP uptake remains low. A recent study among Kenyan AGYW engaging in family planning care at a public clinic found that while 76% met national eligibility guidelines for PrEP, just 4% initiated PrEP care; low perceived risk for HIV acquisition and the perceived burden of taking a daily pill

were the primary reasons for refusal.[171] In Kenya, missed opportunities for PrEP screening occurred among 78% of HIV-negative AGYW engaging in healthcare at public facilities,[172] and in Tanzania, HIV-incidence among AGYW outnumbers PrEP initiations by a magnitude of three.[173] Thus, despite its high effectiveness,[79] uptake and continuation of PrEP continues to be a challenge in HIV prevention programming and research among AGYW.[80]

Several new PrEP modalities are in various stages of approval by individual countries which, compared to oral PrEP, hold promise for enabling higher uptake and retention on PrEP. Dapivirine, an antiretroviral agent (non-nucleoside reverse transcriptase inhibitor [NNRTI]), has been added to a silicone vaginal ring (25 mg)[174] which can be worn vaginally for 28 days[87] and reduces HIV acquisition by 27-62%.[88, 89] Long-acting injectable Cabotegravir, an extended-release integrase inhibitor (herein referred to as CAB-LA), is delivered as a two-month gluteal injectable and reduced HIV by 89% in a research study among ciswomen in sub-Saharan Africa, making it as or more effective than daily oral PrEP.[90, 91] While the dapivirine ring is widely available, only four African countries to date have approved the use of CAB-LA (Zimbabwe, Zambia, South Africa, and Uganda); Nevertheless, these new modalities show promise in addressing some of the documented barriers to PrEP uptake and adherence given that they offer a concealable prophylactic drug, the potential for less frequent visits to HIV clinics, and the lack of need for daily adherence. However, if these new PrEP modalities are required to be initiated and acquired in the same way as oral PrEP – that is, at HIV clinics – one of the most salient barriers remains a concern.

Given the robust PrEP development pipeline, now is an optimal time to understand and build safeguards preventing potential barriers to uptake of these newer PrEP modalities, which may ensure that key populations vulnerable to HIV, such as AGYW, will be better served. To help achieve this, I conducted a discrete choice experiment (DCE), a quantitative technique which aims to elicit user preferences about a set of choices and is a technique often employed in the health policy and planning arena.[175] Asking users their preferences via more traditional avenues, such as ranking or rating, often fails to accurately predict ‘revealed’ (i.e., true) preferences respondents have when selecting from many choices, which then limits researchers’ ability to draw meaningful and clear conclusions about consumer demand from surveys.[175] DCE overcomes this limitation by offering a number of hypothetical scenarios (presented as a series of paired options), and through the selected responses allows the researcher to understand which specific components of presented scenarios are valued more or less compared to others. This elicitation method is preferred when there are multiple components of said scenarios (e.g., different prices, different healthcare locations, different provider characteristics) which must be evaluated together. DCEs have been used in the HIV literature extensively, especially to understand user preferences around potential formulations of HIV and PrEP pharmaceuticals;[176, 177] however, there is less research among AGYW and specifically, research examining actual PrEP offerings (as opposed to hypothetical formulations), as well as specifically for implementation and/or service delivery planning purposes.

2.3 Methods

This study reports formative research and findings from a forced choice discrete choice experiment designed and conducted among AGYW aged 15-24 who currently or recently were at risk for HIV acquisition in the Shinyanga and Mwanza regions of western Tanzania. Specifically, the research sought to answer the question: what are the preferred implementation models for PrEP modalities among AGYW in Tanzania, which might in turn facilitate future uptake of PrEP.

Study Setting

In the two regions where the study took place, Shinyanga and Mwanza, the prevalence of HIV is 5.6% and 4.7% respectively, above the national prevalence of 4.4%. [178] Risk for HIV transmission is high: a recent study of approximately 400 pregnant AGYW seeking care at antenatal care (ANC) clinics in Mwanza found that nearly half tested positive for at least one of six common STIs, [179] the most common one being herpes simplex virus, a documented predictor of subsequent HIV acquisition risk. [180]

Formative Research

A crucial component of designing a robust and valid DCE is thoughtful and intentional consideration and decision making about the components that will be evaluated, [181] known as attributes, and their corresponding levels. Attributes are the larger discrete categories (e.g., product type, cost) within which levels (e.g. vaginal ring or pill, low cost vs. free, etc.) are randomized. Prior to conducting this formative research and given documented barriers to PrEP uptake, such as the location of PrEP dispensing and screening, provider attitudes, and concerns about PrEP as a daily pill, [82, 83, 84] the study team hypothesized a number of potential attributes and attribute levels (Table 2.1). These included PrEP distribution sites disaggregated as: 1) screening sites where initial PrEP conversations might occur and PrEP is initiated (i.e., HIV clinic [standard of care], pharmacy, mobile clinic), and 2) refill sites (small drug shops [known as Accredited Drug Dispensing outlets, ‘ADDOS’], mobile clinic, pharmacy), as well as, 3) channels for AGYW to receive support for PrEP-related questions (i.e. youth friendly counselor, a hotline, peer navigators). Together, these hypothesized attributes served as the initial draft of the DCE, which was iteratively refined in meetings with stakeholders through brainstorming and discussion. This participatory process included meetings with members of the Youth Advisory Boards (YAB), Ministry of Health (MOH) collaborators, PrEP prescribers and dispensers, and the research staff from Tanzania-based implementing partners, Health for a Prosperous Nation (HPON).

The agenda for meetings with key stakeholders included describing the aims of the DCE, understanding knowledge of PrEP (among YAB members) and experiences screening/dispensing PrEP (health facility staff), providing education about PrEP (among YAB members), under-

standing perceived and actual barriers and facilitators to PrEP for AGYW, hypothesizing ways to address these barriers, and then brainstorming attributes and attribute levels. I presented the hypothesized attributes and levels to begin the discussions, and from there, we built upon and refined the ideas via interactive discussions. All conversations with the YAB members took place in Kiswahili led by a bilingual (Kiswahili/English) regional team lead and discussion notes were taken, transcribed, translated to English, and shared with the wider study team. Each YAB meeting was followed by a team debrief to discuss YAB proceedings; the majority of stakeholder meetings were conducted in English. Final questionnaires were piloted iteratively with YAB members to ensure appropriateness, length, and comprehension.

Inclusion Criteria and Recruitment

To ensure the results of the DCE were policy-relevant and context specific, we used the Tanzanian Ministry of Health’s National AIDS Control Programme PrEP screener (Supplementary Materials, Appendix 1) as inclusion criteria to screen AGYW aged 15-24 for the survey. This screener assesses risk for HIV transmission over the most recent 3-6 months based on self-reported behavior. In recognition of “seasonality of risk” whereby risk for HIV acquisition varies over time,[85] we assessed a second category of eligibility for AGYW who were ever but not currently at risk, whereby reference periods in the screener are extended to ask for recent ever engagement in the referenced behaviors. This screener was administered on a tablet computer and was designed to be self-administered unless the AGYW demonstrated discomfort with handling the technology or not understanding the questions; the rest of the survey was interviewer-administered by staff of Health for a Prosperous Nation (HPON, the local research team).

Identification of potential study participants and recruitment took place at small drug shops and public health facilities participating in a larger cluster randomized controlled trial (cRCT; NCT: NCT04045912) being implemented by HPON. During regularly scheduled biweekly visits by a female HPON staff member to a cRCT participating drug-shop and using convenience sampling, if an AGYW-appearing individual visited the drug-shop and interacted with the drug-shop, the shop owner or staff member invited the AGYW to learn about the study with the nearby HPON staff member. Simultaneously, HPON staff worked with our partnering cRCT referral health facilities whereby health facility staff invited AGYW to approach the HPON team members on days when they are present to screen for and potentially take part in the study. Subsequently, the HPON staff member briefly explained the aims of the study, the time commitment required, and gauged interest. If the participant agreed to learn more, the HPON staff member escorted the AGYW to a private area to determine eligibility and if eligible, review the consent form and complete the survey, which included the DCE. In both scenarios, no HPON staff member directly approached potential participants and the AGYW always maintained the right to decline to speak with the

HPON staff member. AGYW deemed ineligible were thanked for their time; those deemed eligible and who agreed to participate continued to complete the study survey and DCE.

Data collection

The questionnaire included sections on sociodemographic characteristics, PrEP knowledge, sexual behavior history, sexual empowerment, as well as an educational component which directly preceded the DCE module. The survey was programmed using Sawtooth, a software that permits random configurations of the attribute levels and can also be programmed to limit the number of paired scenarios offered to a participant (known as choice task). This also enabled us to ensure that all attributes had an equal likelihood of being presented across all participants.

The DCE module began with a two-way educational module, whereby the HPON staff member explained the DCE format through a simple practice DCE where participants chose a restaurant by evaluating different and locally relevant meal offerings as a means to explain how to weigh options. Then the staff member proceeded to explain, in-depth, the different PrEP attribute and attribute levels one by one to ensure comprehension of the different options the participants will weigh and consider. This included a laminated reference sheet available throughout the DCE administration which described the fixed characteristics of each PrEP modality (e.g., effectiveness, dosing frequency) with pictures of each of the modality types (i.e. picture of the PrEP pill, vaginal ring, and an injection) and scripted pauses for questions after each attribute description. The purpose of the educational module was to ensure that participants had a sufficient understanding of the options between which they would be evaluating and choosing.

The DCE then evaluated five attributes with 3-5 levels each (Figure 1): (i) PrEP modality [daily oral, vaginal ring, CAB-LA described simply as “injection”]; (ii) screening location [HIV clinic, mobile clinic, pharmacy]; (iii) refill location [pharmacy, mobile clinic, community health worker]; (iv) health provider identity [anyone, old/young female, old/young male]; and (v) cost per refill [free, 1000, 2000, 4000, or 5000 Tanzanian shillings [TSh]. Participants were shown a “choice task” which consisted of two alternatives, each of which had a randomly assigned attribute level for each attribute. This design allowed the DCE to assess preferences related to both the product itself as well as the implementation model, which are both potentially important influences on AGYW uptake of a new product. The DCE was designed so that only two alternatives were shown at a time at a time from which participants were asked to select their preference. While the recommended range of choice tasks is 8-16, with increasing precision yet cognitive demand as the number increases,[182] based on feedback from key stakeholders, the lower range was programmed (10) to reduce potential cognitive burden. Finally, the DCE was “forced choice” in that respondents were required to choose one of two alternatives (rather than a none or opt-out option).

The DCE included three internal validity checks. The first was a choice task that was fixed (i.e. not randomized) for all participants which included a “clear winner” [183] (i.e., an excessively high price point of 10,000 TSh for oral PrEP compared to injectable PrEP for free with other levels varying); evaluating assessment of comprehension of the task. The second was to detect “speedsters” who may not have engaged in the choice tasks by reviewing responses quickly completed or being “straight-liners,” i.e., always selecting option. Third, a brief “post-test” asked very basic questions about PrEP (i.e., “can you take PrEP if you already have HIV?”) to ensure basic comprehension.

Power

Sample size was calculated based on the formula $n \geq 500c/ta$, [184] where n is the number of respondents, t is the number of tasks (options given), a is the levels of the attributes (excluding “none”), and c is the largest number of attributes*tasks. For the purposes of sample size estimation, we assumed eight tasks/participant with five attributes of three to four levels each (3.5 was used for the power calculation), resulting in a minimum sample size of at least 286 participants. We planned a priori for sub-group analyses by current vs. ever PrEP eligible, so the target sample size was doubled. Finally, we increased the sample size to account for attrition due to missingness, non-response, failing the internal validity check (previously described) and for potential additional subgroup analyses by sociodemographic factors (such as age, education), for a total of 350 AGYW per subsample, or 700 total.

Statistical Analysis

DCE responses were reviewed prior to analysis for two primary threats to validity: incomplete results and those who failed all the internal validity checks; in these cases responses were removed. [183] Summary statistics of the sociodemographic characteristics of study sample are presented, stratified by sub-group (current or ever at risk), and by total to evaluate any potential systematic sub-group differences.

Participant responses were analyzed via mixed multinomial logit models, using random coefficients and standard errors clustered within person to model the correlation of choices across choice tasks ($n=9$) within participants. In these models, the outcome is the selected choice of the participant, and includes the variables which explain that choice, namely the attributes and their levels. [185] We used effects coding to estimate what is known as a preference weights or part-worth utilities, [185] which compares the “weight” of a chosen level to the mean effect of the overall attribute level, which is standardized at zero. [186] The multinomial model with effects coding yields a clear ordering of preference weights and allows for the error term to adjust for individual specific variations in preferences as desired (versus

the assumption of no heterogeneity in conditional logit models.[182]

Secondly, we calculated “importance scores”, ranging from 0-100%, which allows one to rank the overall attributes (but not the specific levels within each attribute, which are evaluated via their preference weights) in terms of their relative influence on whether the choice set was preferred; higher scores indicate higher importance/influence, allowing for a comparison across attributes. These scores are calculated by taking the sum of the difference in the highest and lowest preference weights per attribute as the denominator (total range), then calculating the relative proportion as the range per attribute over the total range (i.e., preference weight of highest level minus preference weight of lowest level (within an attribute) / total range (across all attributes)).[187] The relative importance is thus conditional on the total range of all attributes.

Postestimation predictive models were used to estimate marginal probabilities of selection of the specific PrEP modalities using the margins command in Stata,[182, 185, 188] as well as the marginal effect relative to a base level (i.e., difference in marginal probabilities) using the dydx option with the margins command. These estimations build upon the base multinomial model and are accompanied with standard errors and corresponding confidence intervals using the delta method.[182]

Upon completing each choice set, participants were asked if, in the case that the selected option was truly available, if they would take up PrEP under those conditions (response options: 'Yes', 'No'). This option intends to replicate real world stakes, whereby participants are not forced to select a product or program that does not satisfy them, as opposed to the primary DCE question which asks them to choose which alternative is better, which may serve to improve external validity.[189] This model is estimated using a conditional logistic regression, whereby the outcome is reporting that they would take up PrEP under the given conditions, and the explanatory variables are the attribute levels. We report the proportion of participants who responded yes, preference weights for the sample of task-sets estimated in the conditional logistic regression among participants who selected 'Yes', as well as the marginal probabilities.

Data analysis took place in Stata (Version 14; College Station, Tx) and visualizations were created in R Studio (2022.12.0+353).

Study activities were approved by the University of California, San Francisco Institutional Review Board as well as the Tanzanian National Institute for Medical Research.

2.4 Results

A total of 855 AGYW were recruited across 41 geographic political units known as wards; 696 (81.5%) AGYW were determined to be eligible for the study, and 100% of those eligible for the study consented to participate; four participants left the study after consenting and prior to conducting the DCE due to competing priorities unrelated to study participation. In total, 692 participants completed the DCE module (Figure 2.1). Among those who were ineligible to participate in the study, nearly half did not meet any of the PrEP screening criteria and approximately 18% declined to confirm their HIV status (Figure 2.1). Among those who were eligible for the study, 558 (80%) were currently eligible for PrEP (Table 2.2). Median age was 20 (interquartile range [IQR]: 18, 22), 29% were currently or ever married, and 38% had at least one child. Few (10%) were still in school, with the proportion in school higher among the ever (15%) but not currently (9%) at risk for HIV acquisition sub-group. PrEP knowledge and use was low; prior to completing the DCE module and the educational component, 535 (77%) of the participants had never heard of PrEP, and among those who had heard of PrEP, 49 (31%) had previously inquired about taking PrEP, 8 (5%) had ever taken it and among those, 4 (2.5%) were currently taking PrEP.

Injectable PrEP was the most preferred PrEP modality (preference weight [PW]: 0.63, 95% confidence interval [CI]: 0.55, 0.71; $p \leq 0.001$; Figure 2.2), followed by the daily oral pill (PW: 0.25, 95% CI: 0.18, 0.32, $p \leq 0.001$). The vaginal ring had a large negative preference weight compared to the mean effect of all levels of the modality attribute (PW: -0.88, 95% CI: -0.97, -0.80, $p \leq 0.001$). PrEP screening at HIV clinics (PW: 0.044, 95% CI: -0.0044, 0.093, $p = 0.075$) and pharmacies (PW: 0.036, 95% CI: -0.013, 0.086, $p = 0.15$) had modestly positive preference weights compared to the mean for the attribute; this contrasts with the negative preference weight for PrEP screening at mobile clinics (PW: -0.080, 95% CI: -0.13, -0.031, $p = 0.51$). There were no detectable significant positive or negative preference weights for the levels of PrEP refill locations: pharmacies had a small positive preference weight (PW: 0.014, 95% CI: -0.034, 0.062, $p = 0.57$) compared to the mean for the attribute, and was not statistically different from preferences for PrEP refills at mobile clinics (PW: -0.016, 95% CI: -0.064, 0.032, $p = 0.51$) or by community health workers (PW: 0.0018, 95% CI: -0.046, 0.050, $p = 0.94$). In terms of cost, there was a monotonic relationship between cost and preference, such that free PrEP had a significant positive preference weight (PW: 0.35, 95% CI: 0.26, 0.43, $p \leq 0.001$) and the 5,000 Tanzanian Shillings (TSh) price point had a significant and large negative preference weight (PW: -0.51; 95% CI: -0.60, -0.43, $p \leq 0.001$). Finally, for provider identity, there was a positive preference for younger female providers (PW: 0.15, 95% CI: 0.073, 0.22, $p \leq 0.001$) and a negative preference for older males (PW: -0.12, 95% CI: -0.19, -0.046, $p = 0.001$) compared to the mean for that attribute; other identities were not significantly different from the mean. Results were similar when stratified by risk level (Appendix, Figures 2.4 and 2.5) and full regression coefficients using effects coding are available in Appendix, Table 2.5.

In terms of attribute importance, modality had the greatest relative influence overall (54.2%), followed by cost (30.8%). Dispenser identity contributed to 9% of the overall utility, followed by screening location (4.5%) and refill location (1.1%) (Table 2.3).

The predicted probability of selecting either alternative in each DCE was 50% by design of being a forced choice DCE. The predicted probability of selecting injectable PrEP was 63.3% (95% CI 61.4%, 65.2%), representing the estimated probability of selecting injectable PrEP whenever it was offered in the choice set (vs. not selecting, Table 2.2). The estimated probability of selecting daily oral PrEP and the vaginal ring when offered were lower at 55.2% (95% CI: 53.3%, 57.2%) and 31.7 (95% CI: 29.9%, 33.4%), respectively. There was a significant difference in selecting injectable PrEP (31.6%, 95% CI: 29.2%, 34.1%, $p < 0.001$) and daily oral PrEP (23.6%, 95% CI: 21.2%, 25.9%, $p < 0.001$) compared to the vaginal ring (Table 2.3). The estimated probability of selecting PrEP when offered for free was 57.0% (95% CI: 55.1%, 59.0%); this decreased monotonically with the lowest probability of selection being 39.9% when PrEP was offered at the 5000 TSh price point (95% CI: 37.9%, 41.9%), translating to a significant -16.7 percentage point difference in estimated probability of selection of PrEP at 5,000 TSh compared to free PrEP (95% CI: -19.2%, -14.0%).

Of all the offered choice-tasks, 89% of the time (comprising 690 unique individuals) the participant responded that they would actually take up the DCE choice that they selected if offered to them in reality. In this conditional logistic regression, whereby the outcome was reporting that they would take up PrEP under the offered scenario, only modality remained statistically significant and with the same magnitude and direction of effect as the primary models; the preference weights for cost and identity were attenuated compared to the main analysis (Figure 2.3, Table 2.4).

Finally, survey responses were evaluated in terms of internal validity. Choosing the high price point was prevalent (18.4%) among participants, while only four participants were “straight-liners” (i.e. selecting the same response across all options), none of whom failed the previous high-price point check. The overwhelming majority of participants passed the post-test (median score 100%; mean 94%). No participants were thus excluded due to failing the internal validity checks.

2.5 Discussion

Pre-exposure prophylaxis (PrEP), which is 99% effective at preventing HIV, could contribute to ending the HIV epidemic if used at scale effectively and among key populations such as AGYW. Yet, myriad structural and social barriers prevent uptake and continued use.[67, 68, 70, 71, 72, 73] Our study explored the relative importance of PrEP modality and implementation features on preferences for PrEP among nearly 700 AGYW currently or ever at

risk for HIV acquisition in two high HIV prevalence regions of Tanzania. Our DCE methodology revealed strong, positive preferences for injectable PrEP (CAB-LA) and low-cost or free PrEP, and positive preferences for PrEP distributed by younger caregivers outside of traditional health care facilities. The study also found high interest in taking up PrEP, demonstrated by the 89% of AGYW who were “would take up” the scenario offered. This is among the first of DCEs conducted among AGYW at risk for HIV acquisition in SSA[190] with the ultimate goal of designing and implementing better PrEP programs. This study adds to a growing literature seeking to understand preferences for PrEP that has focused on other key populations such as sex workers[191] and men who have sex with men.[192, 193] The findings could pave the way toward the development of implementation models for newer PrEP modalities in the development and regulatory approval pipeline.

Modality was the most influential attribute among the five attributes evaluated, and within that attribute, injectable PrEP was most preferred; the vaginal ring, in turn, was largely unpreferred. The strong and positive preference for injectable PrEP aligns with a previous DCE conducted among 536 women aged 18-30 in South Africa that found strong preferences for injectable PrEP and a lower frequency of refill/dosing (i.e. longer duration of prophylactic effect in case of injectables).[194] Other researchers have hypothesized that a strong preference for injectable PrEP mirrors the widespread acceptance and use of injectable contraceptives across SSA.[195, 196] Suboptimal adherence to oral daily PrEP diminishes its effectiveness; long-acting, injectable PrEP obviates the need for daily adherence and outside of the infrequent clinic visits, usage lacks physical evidence, underpinning its appeal. Indeed, whenever injectable PrEP was offered in a choice set, it was selected by the AGYW nearly two out of three times; ongoing rollout of injectable PrEP will reveal whether these preferences are borne out when faced with the actual choice. Further, positive and significant preferences for PrEP provided by young female providers potentially signal an innate desire for youth friendliness by healthcare providers.[197] In other settings, other provider attributes, such as racial concordance between patient and care-provider, have been demonstrated to improve patient communication and outcomes:[198] in the context of AGYW in Tanzania, it is plausible that sex and perceived age concordance may have a similar effect.

Our study corroborates previous research demonstrating that price sensitivity is a potential barrier to PrEP uptake among AGYW.[199] Cost was included as an attribute given the necessity to balance supply- and demand-side considerations when evaluating private-sector implementation of PrEP. As demonstrated by the attribute importance scores, cost was the second most important factor in task-set selection. While we are not able to interpret the magnitude of price-sensitivity based on the preference weights, for some AGYW, it may have potentially dominated decision-making, impacting choices for other attributes related to PrEP implementation, such as screening and refill location. Previous DCEs that evaluated hypothetical PrEP products (i.e. injectables with different dosing patterns, implants with different side effects, etc.) have reported similar price sensitivities, whereby participants have selected less effective hypothetical products for lower costs:[190] many, but not all of

these evaluated the location of PrEP dispensation, and none included AGYW and actual (i.e. not hypothetical) PrEP formulations. Future studies evaluating preferences may benefit from separating willingness-to-pay from choice selection and/or offering blocks with just one modality (i.e. just injectable PrEP) with varying attributes within that modality to reduce potential dominance of one attribute over another. Further, the reduction and/or elimination of user cost for PrEP through government subsidies and/or global aid can contribute to mitigating one of the more salient barriers for PrEP uptake and retention, contributing to the World Health Organization’s call for “differentiated, simplified, demedicalized, and comprehensive PrEP services,[168] specifically in terms of comprehensive services which are offered without cost.

Awareness of PrEP in high HIV burden settings—especially among populations most vulnerable to HIV acquisition such as AGYW—remains unacceptably low and presents a primary barrier for effective PrEP coverage.[85, 170] Despite current or previous PrEP eligibility, four out of five of our study participants had no knowledge of PrEP and >99% were PrEP-naïve. In Kenya, a recent text-based survey of PrEP awareness demonstrated high PrEP awareness among adults aged 18-24, with nearly half of adults in that age group having some PrEP awareness.[200] Another study in Kenya among AGYW seeking family planning services at public clinics reported 89% were PrEP aware.[171] The disparity in PrEP awareness between Kenya and Tanzania may be policy related: Kenya is more advanced in PrEP rollout than Tanzania, having approved oral PrEP in 2015 (compared to 2020 in Tanzania); this is further evidenced by higher cumulative numbers of PrEP initiations despite a lower population and HIV burden compared to Tanzania.[201, 202] Nevertheless, services in public health facilities are often under-utilized by AGYW even when widely implemented due to perceived and internalized stigma of care-seeking there and this sample may not have been representative of the general AGYW population. Given that public health facilities are often the primary location of PrEP care, the awareness gap of crucial HIV preventative services is further compounded,[71, 72, 73, 203] undermining PrEP’s potential population-level impact among AGYW disenfranchised from care at public health facilities.

Despite substantial evidence of barriers to and low desire for health facility based PrEP care, which often occurs within a specific HIV treatment area of the health facility,[82, 83, 84] we did not detect significant positive or negative preferences for PrEP screening to occur outside of the HIV clinic. Given how salient modality and cost was as an attribute, we hypothesize—and the attribute importance results support—that when weighing the options presented in each task, screening and refill locations were less influential in the overall decision-making. We detected negative preference weights for community health worker or mobile clinic-based refills, signaling that despite the potential convenience offered by these options, engaging in HIV care in these community-based models implies some level of disclosure, be it HIV seropositivity or a need for HIV prevention care. We hypothesized that public-private sector partnerships promoting pharmacy-based PrEP may further increase access and reduce barriers to PrEP via a private healthcare location not exclusively ded-

icated to HIV care, promoting national HIV program goals regionally; nevertheless, while pharmacy-based PrEP had positive preference weights, they did not reach statistical significance. We still theorize that this model may hold promise; in rural areas of SSA with decreased access to public health facilities,[204] small retail providers of health care products such as pharmacies serve underserved areas, providing over half of all care and are often the only access point to care.[205, 206, 207] Further, studies evaluating the feasibility of pharmacy-based PrEP have reported demonstrated interest and high fidelity,[98, 99, 100] with more studies ongoing.[101] A DCE with fixed PrEP modality (i.e. just oral PrEP), reflecting the current PrEP landscape, may detect different preferences for screening and refill location. Given our results suggesting that the screening and delivery location isn't greatly influential in AGYW's choices in the DCE, the impact of these pharmacy-based PrEP delivery programs, as well as the rollout of newer PrEP, will allow researchers to further the preference findings with actual data on PrEP uptake and continuation.

Defining risk for HIV acquisition and eligibility for PrEP remains a challenge in PrEP implementation research. Numerous HIV risk assessment tools have been developed for research with AGYW,[208] Tanzanian AGYW,[209] and others.[210] These scales focus on common behaviors associated with HIV risk, such as engaging in transactional sex, intergenerational sex, or having concurrent sexual partners. While highly predictive, they are often developed ad-hoc from individual studies, with over 30 tools in use,[211] undermining comparability. For that reason, we decided to mirror the Tanzanian screening criteria for AGYW for this study's eligibility criteria, a strength of our study which ensures the results reflect the most salient risk behaviors and facilitates local policy relevance. Nevertheless, HIV risk in a setting of sexual transmission is a combination of risk behaviors of an individual, their partner(s), and while most screeners focus on individual behavior, a more comprehensive screener that accounts for relationship factors (i.e., suspected or known sexual concurrency on part of sexual partner, age of partner(s), engagement in transactional sex), or recognizes a desire for PrEP alone as sufficient for prescription, may be more sensitive statistically in identifying those who could benefit from PrEP. Given HIV risk perception is often underestimated,[212] a shift towards provider-facilitated PrEP across any healthcare encounter by AGYW (and other groups vulnerable to HIV acquisition), whereby a (trained and unbiased) healthcare provider introduces PrEP and discusses its benefits in a proactive fashion, may be an important tool to help close the gap between low awareness, low risk perception, and HIV incidence,[213] as well as serving to normalize and de-stigmatize PrEP.

The results of this study must be understood within the context of the limitations. Nearly one in five (18.5%) AGYW who completed the survey were currently married, whereby one primary risk behavior for HIV transmission—condomless sex—may not have been a true indicator for risk for HIV acquisition within a monogamous relationship. Nevertheless, 70% of these AGYW reported at least one other risk factor, and studies have documented that up to 80% of new infections in Africa occur among women in long-term or married relationships.[214, 215, 216] This highlights an inherent shortcoming of the PrEP screener, which

focuses on individual behavior rather than perception or knowledge of partner(s) behavior. Our study did not recruit many younger AGYW in the 15-19 age range. The primary reasons for their lower numbers may be related to the AGYW being in school and/or not being regular patrons of the drug-shops or health facilities where we recruited the sample. Our study was among AGYW who were overwhelmingly PrEP-naïve; despite standardized, easy to understand, and illustration-heavy procedures and documents used to educate about PrEP, the specific modalities it can be offered in, and the attributes/attribute levels, stated preferences were hypothetical and may have been answered differently among those with experience seeking out or taking PrEP (n=8). Nevertheless, an additional analysis (data not shown) among the 23% of AGYW who had ever heard of PrEP found similar results in terms of direction and magnitude of preference weights for all attributes, with slight attenuations largely due to the substantial reduction in statistical power. Further, while we intended to include the excessive price point as an internal validity check, there were AGYW who were injection averse and reported to study staff that they would never select injectable PrEP; this form of validity check has documented limitations[217] and ultimately proved less informative than the other forms of internal validity checks for our study. Finally, while 89% of the time AGYW reported they would-have taken up the particular alternative they selected, the AGYW may have been overestimating their take-up behavior; further studies among non-PrEP naïve AGYW could help us quantify whether this is, and the degree to which it may be, an overestimation. This study had substantial strengths. This was a large sample of AGYW across 41 wards (geographic political units) within two high HIV burdened provinces of Tanzania. The utilization of the national PrEP screener, despite inherent limitations of all screeners, increases policy relevance. The study also integrated the voices of AGYW throughout design and conceptualization, and focused entirely on centering their preferences and promoting choice. Finally, the DCE included two PrEP modalities that are not yet approved in Tanzania (vaginal ring, CAB-LA); the results offer critical data which may advance the implementation of PrEP for AGYW at a critical juncture in time when new modalities are being prepared for market introduction.

Conclusion

In this study of nearly 700 PrEP-eligible AGYW in Tanzania, less than one in four had ever heard of PrEP and less than one in 90 had ever used PrEP. The DCE results found strong preferences for long-acting, injectable PrEP provided at low or no cost by AGYW-friendly providers, and high interest in taking up the various models shown, largely driven by PrEP product type. As country-wide PrEP implementation plans are being updated as new PrEP modalities are improved, an opportunity juncture exists to improve upon the learning of oral PrEP and modify implementation models to meet the needs of AGYW.

2.6 Tables and Figures

Table 2.1: Attributes and levels hypothesized, brainstormed, and evaluated in the final DCE among adolescent girls and young women ever and currently at risk for HIV, Tanzania, 2023

	Pill
Modality*	Ring
	Injectable
	HF – Standard of Care
	HF- all in one place at HIV clinic
Screening location*	HF- all in one place not at HIV clinic
	Mobile clinic
	Online
	Pharmacy
	Mobile clinic
Refill location*	Community health worker
	Pharmacy
	Health facility
	Referral counselor
Support person*	Chat bot
	Dispenser
	Free
	1,000 Tanzanian Shillings
Cost	2,000 Tanzanian Shillings
	4,000 Tanzanian Shillings
	5,000 Tanzanian Shillings
	Anyone
	Young woman
Provider identity	Older woman
	Older man
	Younger man
	3-month supply (only pill and ring)
Supply given	6-month supply (only pill and ring)
	2-month supply (fixed level for injection)

*Indicates hypothesized attributes *a priori* to the formative research phase; no asterisk indicates it came about in the formative research phase

Highlight indicates those attributes and attribute levels in the final DCE

Table 2.2: Sociodemographic characteristics by risk level among enrolled adolescent girls and young women, Tanzania, 2023

	Ever risk (n=138)	Current risk (n=558)	Total (n=696)	p-value
Age (Median, IQR)	20.0 (18.0, 22.0)	20.0 (18.0, 22.0)	20.0 (18.0, 22.0)	0.14
Religion				0.45
Christian	121 (87.7%)	485 (86.9%)	606 (87.1%)	
Muslim	14 (10.1%)	67 (12.0%)	81 (11.6%)	
African traditional	1 (0.7%)	4 (0.7%)	5 (0.7%)	
Other	2 (1.4%)	2 (0.4%)	4 (0.6%)	
Relationship Status				<0.001
Single	40 (29.0%)	79 (14.2%)	119 (17.1%)	
Steady partnership	85 (61.6%)	333 (59.7%)	418 (60.1%)	
Engaged	4 (2.9%)	26 (4.7%)	30 (4.3%)	
Married	9 (6.5%)	120 (21.5%)	129 (18.5%)	
Ever married¹	10 (7.8%)	63 (14.4%)	73 (12.9%)	0.048
Any live children	40 (29.0%)	223 (40.0%)	263 (37.8%)	0.017
Ever attended school				0.037
Yes, currently	21 (15.2%)	52 (9.3%)	73 (10.5%)	
Yes, but not currently	117 (84.8%)	495 (88.7%)	612 (87.9%)	
Never attended	0 (0.0%)	11 (2.0%)	11 (1.6%)	
Recruitment region				0.055
Shinyanga	32 (23.2%)	101 (18.1%)	133 (19.1%)	
Mwanza	75 (54.3%)	275 (49.3%)	350 (50.3%)	
Kahama	31 (22.5%)	182 (32.6%)	213 (30.6%)	
Recruitment site				0.876
ADDO/drug-shop	106 (76.8%)	430 (77.2%)	536 (77.1%)	
Health facility	32 (23.2%)	126 (22.6%)	158 (22.7%)	

¹ Asked among those not currently married

Table 2.3: **Estimated probabilities of selecting each attribute level when included in the choice set, n=692¹**

Attribute	Attribute importance	Attribute level	Predicted value of selection ² (95% CI)	Difference ³ (95% CI)
Modality	54.2%	Vaginal ring	0.32 (0.30,0.33)	Ref (0)
		Injection	0.63 (0.61,0.65)	0.32*** (0.29, 0.34)
		Daily pill	0.55 (0.53,0.57)	0.24*** (0.21, 0.26)
Screening	4.5%	HIV clinic	0.51 (0.50, 0.53)	Ref (0)
		Mobile clinic	0.49 (0.47, 0.50)	-0.024** (-0.041, -0.0081)
		Pharmacy	0.51 (0.49, 0.52)	0.002 (-0.18, 0.014)
Refill	1.1%	Pharmacy	0.51 (0.49, 0.52)	Ref (0)
		Mobile clinic	0.50 (0.48, 0.51)	-0.0058 (-0.022, 0.010)
		Community health worker	0.50 (0.49, 0.52)	0.0024 (-0.014, 0.018)
Identity	9.4%	Anyone	0.50 (0.48, 0.52)	Ref (0)
		Young female	0.53 (0.51, 0.55)	0.034** (0.012, 0.056)
		Older woman	0.50 (0.49, 0.52)	0.069 (-0.015, 0.029)
		Older man	0.48 (0.46, 0.50)	-0.016 (-0.039, 0.0067)
		Younger man	0.50 (0.49, 0.52)	0.0084 (-0.014, 0.031)
Cost	30.8%	Free	0.57 (0.55, 0.59)	Ref (0)
		1,000 TSh	0.55 (0.53, 0.57)	-0.022 (-0.045, 0.00063)
		2,000 TSh	0.53 (0.51, 0.55)	-0.040** (-0.062, -0.017)
		4,000 TSh	0.46 (0.44, 0.48)	-0.11*** (-0.13, -0.08)
		5,000 TSh	0.40 (0.38, 0.42)	-0.17*** (-0.19, -0.14)

¹ 12,474 alternatives within 6,237 choice tasks

² Marginal probabilities of selection using margins postestimation command in Stata

³ Difference in marginal probabilities of selection using dydx option in margins

***p<0.001, **p<0.01, *p<0.05

Table 2.4: **Estimated probabilities of selecting each attribute level when included in the choice set among “would take up” of the offered DCE choice set, n=293¹**

Attribute	Attribute Importance	Attribute Level	Predicted Value of selection ² (95% CI)	Difference ³ (95% CI)
Modality	73.1%	Vaginal ring	0.53 (0.45, 0.62)	Ref (0)
		Injection	0.92 (0.88, 0.95)	0.38*** (0.32, 0.44)
		Daily pill	0.89 (0.85, 0.93)	0.36*** (0.30, 0.41)
Screening	4.9%	HIV clinic	0.83 (0.79, 0.87)	Ref (0)
		Mobile clinic	0.85 (0.80, 0.89)	0.018 (-0.010, 0.045)
		Pharmacy	0.83 (0.78, 0.88)	0.00063 (-0.029, 0.029)
Refill	2.3%	Pharmacy	0.84 (0.80, 0.88)	Ref (0)
		Mobile clinic	0.83 (0.78, 0.88)	-0.0071 (-0.037, 0.023)
		Community	0.84 (0.79, 0.89)	0.0013 (-0.027, 0.029)
		Health Worker		
Identity	10.8%	Anyone	0.81 (0.77, 0.85)	Ref (0)
		Young female	0.84 (0.80, 0.89)	0.031 (-0.0042, 0.067)
		Older woman	0.85 (0.80, 0.90)	0.033 (-0.002, 0.068)
		Older man	0.83 (0.78, 0.89)	0.019 (-0.020, 0.057)
		Younger man	0.83 (0.78, 0.88)	0.020 (-0.018, 0.058)
Cost	8.9%	Free	0.84 (0.81, 0.88)	Ref (0)
		1000 TSh	0.84 (0.79, 0.89)	-0.0044 (-0.038, 0.029)
		2000 TSh	0.83 (0.78, 0.88)	-0.013 (-0.048, 0.023)
		4000 TSh	0.85 (0.79, 0.90)	0.0014 (-0.036, 0.038)
		5000 TSh	0.80 (0.74, 0.86)	-0.039 (-0.083, 0.0045)

¹ 6,237 choice tasks were evaluated among 693 individuals; 399 were excluded for non-variance (always selecting they would uptake or would not uptake). Final sample included 2,646 scenarios from 293 unique individuals

² Marginal probabilities of selection using margins postestimation command in Stata

³ Difference in marginal probabilities of selection using dydx option in margins

***p<0.001, **p<0.01, *p<0.05

Figure 2.1: Recruitment and enrollment flow of adolescent girls and young women screened and enrolled in the study, Tanzania, 2023

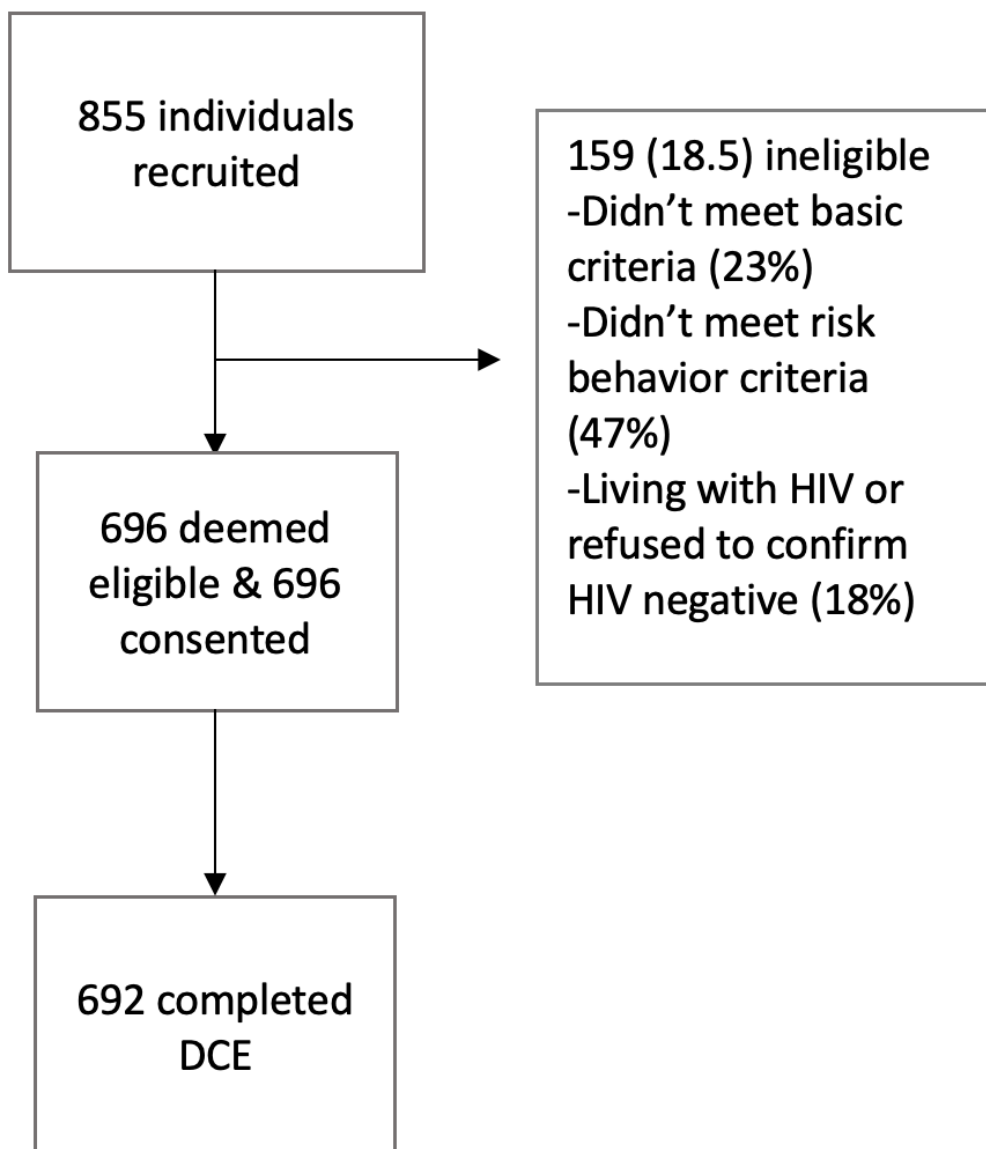


Figure 2.2: **PrEP modality and implementation preferences among AGYW currently or ever at risk for HIV acquisition in Tanzania, n=692**

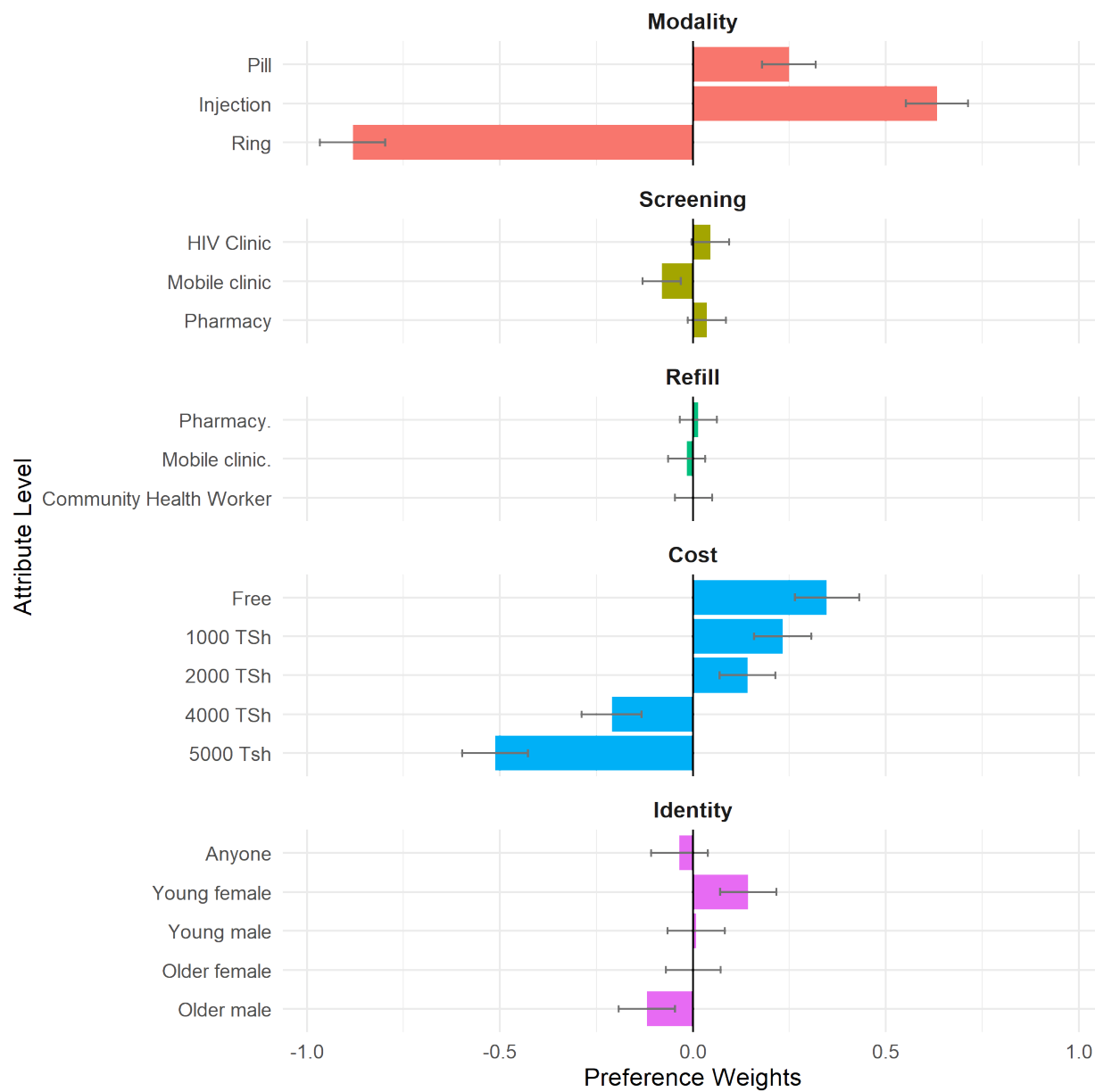
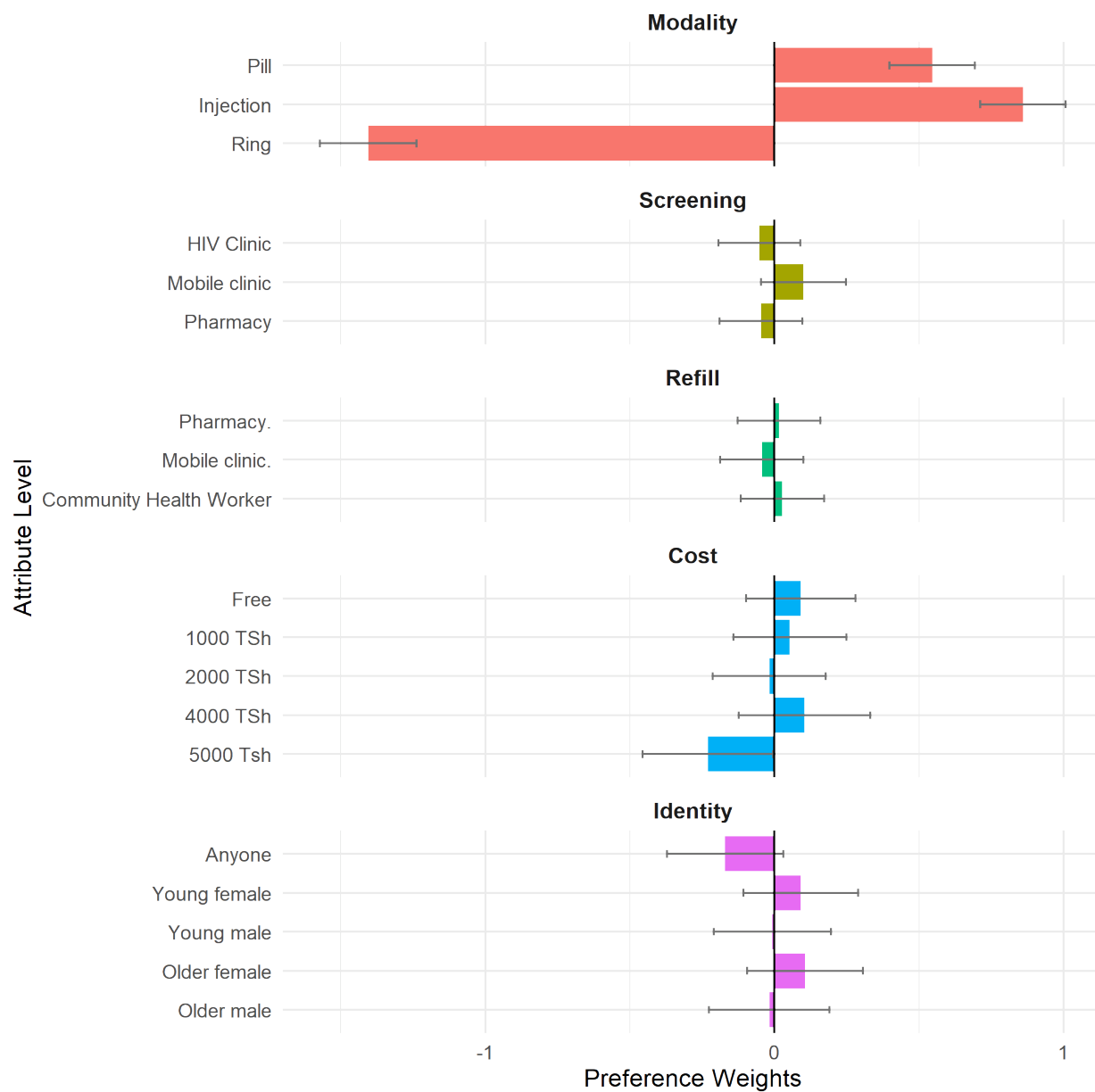


Figure 2.3: **PrEP modality and implementation preferences among AGYW currently or ever at risk for HIV acquisition who were 'would-be uptakers' of the offered DCE choice set in Tanzania, n=690**



2.7 Supplementary Materials

Appendix 1: Tanzanian PrEP Screener from the National AIDS Control Programme of the Ministry of Health, Community Development, Gender, Elderly and Children

Essential Criteria (must meet all):

1. Adults/mature minors under 18 years who are at substantial risk for HIV acquisition
2. HIV negative using a rapid antibody test
3. Hepatitis B negative
4. Normal renal function
5. Willing to consent for and use PrEP as prescribed
6. No suspicion of acute HIV infection
7. Willing to provide detailed contact information for tracing
8. Any ONE of the following substantial risks in the past six months:
 - a) *Vaginal or anal sex without a condom with more than one partner*
 - b) *History of a new sexually transmitted infection, or*
 - c) *Use of post exposure prophylaxis for sexual exposure*

Additionally, there are AGYW specific criteria (AGYW must meet 1 minimum)

1. Not used condom consistently with the latest partner in the last 3 months **OR**
2. Current or STI in the last 3 months **OR**
3. Receive cash/item for sex in the last 6 months **OR**
4. Victim of sexual violence in ongoing risk of repeated incidence **OR**
5. In sexual relationship with PWID

Figure 2.4: **PrEP modality and implementation preferences among AGYW currently at risk for HIV acquisition in Tanzania (n=554)**

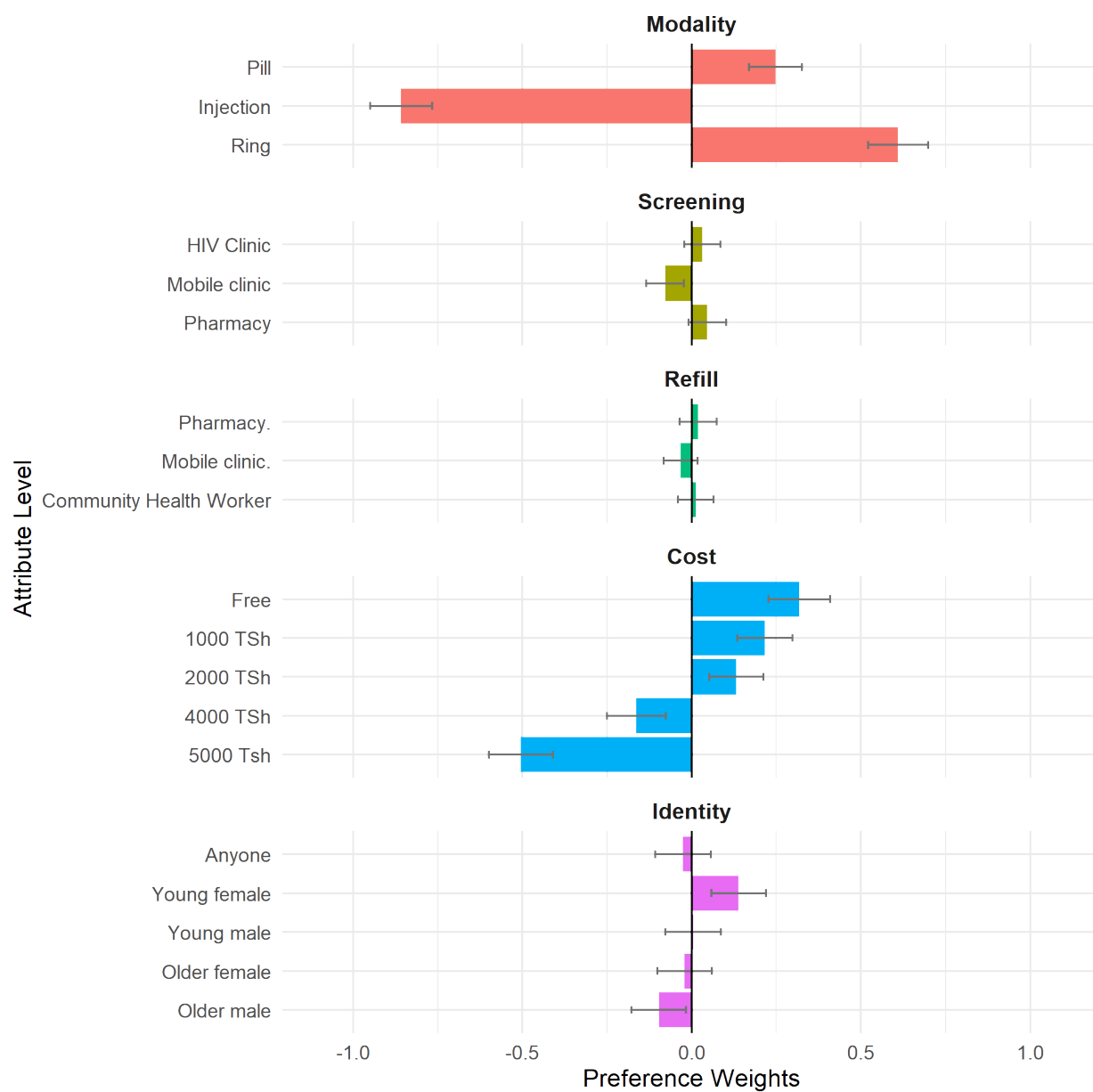


Figure 2.5: **PrEP** modality and implementation preferences among AGYW ever at risk for HIV acquisition in Tanzania (n=138)

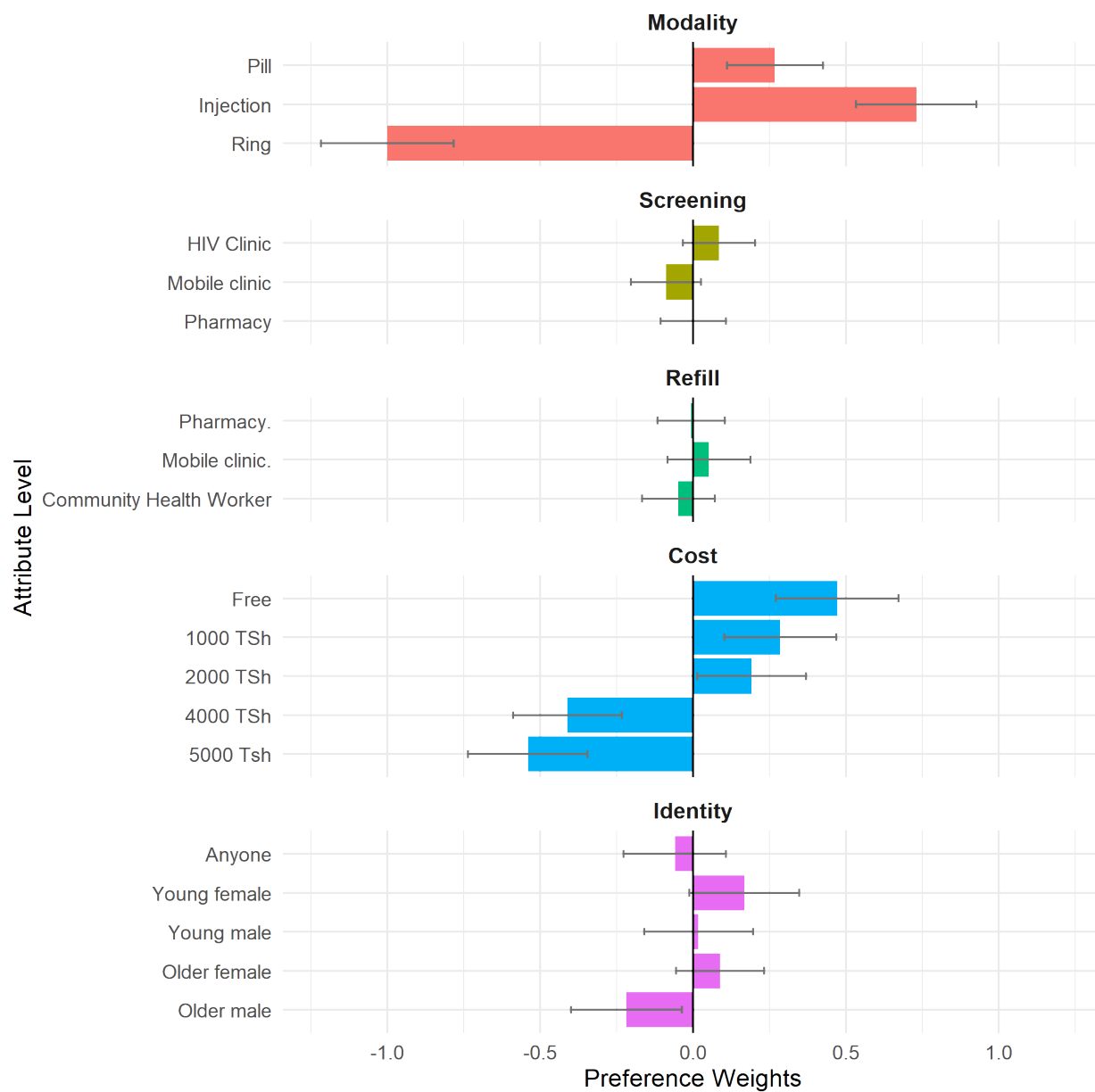


Table 2.5: **Regression output from the effects-coded multinomial regression model among AGYW enrolled in a discrete choice experiment study for PrEP product and implementation modalities in Tanzania, 2023 (n=692)**

Attribute	Attribute Level	Coefficient	95% CI lower limit	95% CI upper limit
PrEP Modality	Pill	0.25	0.18	0.32
	Injection	0.63	0.55	0.71
	Ring	-0.88	-0.97	-0.80
Screening Location	CTC	0.044	-0.0044	0.093
	Mobile clinic	-0.080	-0.13	-0.031
	Pharmacy	0.036	-0.013	0.086
Refill Location	Pharmacy	0.014	-0.034	0.062
	Mobile clinic	-0.016	-0.064	0.032
	Community health worker	0.0018	-0.046	0.050
Cost	Free	0.35	0.26	0.43
	1000 TSh	0.23	0.16	0.31
	2000 TSh	0.14	0.069	0.21
	4000 TSh	-0.21	-0.29	-0.13
	5000 Tsh	-0.51	-0.60	-0.43
Provider Identity	Anyone	-0.035	-0.11	0.039
	Young female	0.15	0.073	0.22
	Young male	0.0064	-0.068	0.081
	Older female	0.00060	-0.071	0.070
	Older male	-0.12	-0.19	-0.046

Chapter 3

The Impact of the SKILLZ Intervention on Sexual and Reproductive Health Empowerment among Zambian Adolescent Girls and Young Women

3.1 Abstract

Background: Adolescent girls and young women (AGYW, aged 15-24) experience a disproportionate burden of HIV and unplanned pregnancy in Zambia. There is growing evidence that sports-based interventions, which theoretically affect sexual health behaviors via improving sexual and reproductive empowerment (SRE), may be an innovative and effective approach for closing this gap. We sought to evaluate the impact of a school- and sports-based intervention on SRE among in-school Zambian AGYW.

Methods: Data come from the ‘SKILLZ’ study, a Type 1 Hybrid Effectiveness-Implementation cluster randomized controlled trial (CRCT) evaluating the impact of a peer-led, sports-based program intended to empower AGYW implemented by Grassroot Soccer (GRS) in Zambia. The study randomly selected from school rosters and enrolled 2,153 AGYW (1134 intervention, 1019 control) across 46 secondary schools (1:1 intervention, control) in Lusaka, Zambia across two enrollment periods, and followed the AGYW for 12 months; intervention schools received the primary intervention components during the first six months. SRE, a secondary outcome of SKILLZ, was measured via the 23-item SRE for adolescents and young adults scale (range 0-92, higher scores= more SRE) across three survey waves; multiple imputation was used to impute missing individual items for those with $\leq 25\%$ missingness. We conducted a difference-in-differences analysis using a linear model

looking at the difference in SRE scores (continuous) by arm at each survey round compared to baseline (i.e. baseline vs. midline, baseline vs. endline), controlling for stratification factors from the randomization.

Results: The median age of AGYW at the first survey round was 17; they were largely unmarried (96%), with 20% reporting being ever sexually active and 31% experiencing food insecurity; by endline nearly 40% reported being ever sexually active. Baseline SRE scores were similar between the intervention (59.7) and control (59.4) arms. Between baseline and midline, being in an intervention school was associated with a 6.21-point increase in the SRE overall score calculated using the imputed sample (SE: 0.75, $p < 0.001$) compared to being in a control school. At endline, being in an intervention school was associated with a 5.12-point increase in the SRE overall score (SE: 0.71, $p < 0.001$). Among sexually active AGYW, being in an intervention school was associated with a 7.78-point (SE: 1.17, $p < 0.001$) and 4.64-point increase (SE: 0.93, $p < 0.001$) from the baseline to the midline and endline rounds, respectively.

Conclusion: The intervention had moderate impacts on SRE which were magnified for those AGYW who reported ever being sexually active. The targeting of AGYW for this intervention, given adolescence is a critical period for gender programming, as well as a period of sexual debut, may support downstream engagement in protective sexual health behaviors that will, in turn, impact the life-course of AGYW.

3.2 Introduction

Adolescent girls and young women (AGYW, aged 15-24) living in sub-Saharan Africa [SSA] experience pronounced unmet need for contraception,[218] directly contributing to high rates of unintended pregnancy,[1] unsafe abortions,[219] and subsequent poor maternal and pediatric health outcomes.[220] Through similar transmission paths, AGYW in SSA are also vulnerable to HIV acquisition,[2, 3] with AGYW accounting for nearly 61% of incident HIV cases in 2022.[221] Low sexual empowerment[5] and condom negotiating power,[222] experiencing barriers in accessing health services,[82, 83, 84] and living in poverty[223] contribute to AGYWs' risk of unintended pregnancy and HIV acquisition, which have subsequent effects on educational attainment,[224, 225] long-term economic well-being,[226] morbidity, and mortality.[227, 228, 229, 13, 230]

Numerous studies have documented how, in predominantly western settings, AGYW participation in sports may be protective against sexual behaviors that increase risk for pregnancy, HIV, and/or other sexually transmitted infections [STIs].[56, 57, 58] For example, AGYW who engage in sports report higher condom and contraception use as well as reduced or lack of engagement in sexual risk-taking behaviors.[63] Further, studies among AGYW globally have demonstrated how engagement in sports programs is associated with increased HIV knowledge and testing.[59, 60, 61, 62] Some theorize that the association between participation in sports and sexual behavior may be facilitated through empowerment and self-efficacy;[57, 63, 59] in a study of a sports- and empowerment-based program for AGYW at risk of HIV acquisition in South Africa, both empowerment and self-efficacy improved after engagement in sports.[59] Predominantly conducted in sex-segregated settings, this program fostered “safe spaces” to discuss gender-specific issues and in an environment where AGYW could safely and comfortably engage in an activity traditionally dominated by or reserved for men (sports).[231]

The connection between engagement in sports and improved sexual and reproductive empowerment was empirically tested among 176 women aged 18-19 in the United States, where researchers evaluated whether self-reliance and general self-efficacy mediated the relationship between engaging in sports and behaviors that put them at risk for pregnancy or STIs.[63] The authors found that, in addition to sports being protective for sexual health, self-reliance and efficacy mediated both risk behaviors as well as engaging in health-seeking behaviors, such as seeking contraceptives.[63] The authors and others have posited that this interrelationship was best explained by cultural resource theory,[58, 63] whereby “cultural scripts” dictating more traditional female behavior are rewritten by engaging in sports, a traditionally male dominated activity. This engagement in sports programs may allow the skills gained in sports, including learning how to be assertive and proactive, to translate to other domains, such as interpersonal relationships. These sports sessions provide AGYW with a testing ground to practice these skills where they might, subsequently, reevaluate gendered norms around sexual empowerment using the same assertive and proactive skills gained.[59]

The impact of AGYW-centered sports programming on AGYW sexual and reproductive health empowerment has yet to be rigorously evaluated,[61] with prior evidence relying on observational data lacking a control group,[63] focus group discussions, and other qualitative data.[59] An evaluation of a recent randomized controlled trial evaluating the impact of a sports-based program implemented at schools in South Africa on AGYW pregnancy was undermined in large part due to poor attendance in program sessions, precluding meaningful evaluation of its potential.[232] Nevertheless, sexual and reproductive empowerment plays a critical role in the life course of women, including being associated with sexual violence,[5, 233] condom[5, 234] and contraceptive use,[235] and HIV and STI risk.[233] In turn, interventions which seek to improve sexual and reproductive empowerment during adolescence, a period of significant gender programming,[31] may be particularly effective at improving health across women's life course. To address this research need, this study leverages data from a cluster randomized controlled trial to evaluate the effect of a peer-led, sports-based program on the secondary outcomes of sexual and reproductive health empowerment among school-age Zambian AGYW.

3.3 Methods

Study setting

This study was conducted in four urban districts in and surrounding Lusaka, Zambia: Chitungo, Chongwe, Kafue, and Lusaka. The prevalence of HIV is 11% in Zambia, with differences between men (8%) and women (13%), as well as regionally, with the population living with HIV in the capital (Lusaka) comprising approximately 14%.[22] While the prevalence of HIV is markedly lower among Zambian adolescents (2% among those aged 15-19) compared to the general population, there exists a sex disparity whereby Zambian AGYW aged 20-24 have three times the prevalence of HIV (5.9% vs 1.8%) as their male peers, often acquired from older sexual partners.[25] Further, pregnancy among AGYW is highly prevalent in Zambia, with estimates ranging from 29-48% of Zambian women experiencing pregnancy prior to age 20.[20]

Study design

The 'SKILLZ' study ('parent trial') is a Type 1 Hybrid Effectiveness-Implementation cluster randomized controlled trial (CRCT)[236] evaluating the impact of SKILLZ, a previously piloted,[59] peer-led, sports-based program for empowering AGYW implemented by Grassroot Soccer (GRS) in Zambia. The primary outcomes of the parent trial were HIV testing and contraception use. The effectiveness of this peer-led, sport-based empowerment model on AGYW sexual and reproductive health empowerment has not been rigorously evaluated and

is a secondary outcome of the trial and focus of this study. Study activities took place in 46 schools from March 2021 to January 2023.

Participant recruitment and inclusion criteria

Schools in the four selected districts were contacted for screening to determine if they met the eligibility criteria of ≥ 40 AGYW in grade 11 and school officials who agreed to participate in the study. Of 68 schools assessed, 22 were excluded due to not having sufficient eligible AGYW in grade 11; the 46 other schools were recruited and agreed to participate. Schools were stratified by district, location (urban vs. rural), remoteness (quartiles of distance from local District Education Board), size of student body (in quartiles), and school type (co-ed or single sex) and randomized 1:1 to intervention and control arms within strata using guidance from the World Bank's Development Impact (DIME) guidance on stratification.[237]

At each school, 30 eligible AGYW students were randomly pre-selected from school rosters prior to any intervention activities began for the effectiveness study. Eligible AGYW were those who were current students, at least age 16, in grade 11 at one of the 46 participating schools, and able to provide parental consent (if under age 18; above 18 consented for themselves). The study assessed 3,208 AGYW for eligibility of whom 1,917 were recruited in the first Phase (59.8%); of those not recruited ($n=1,291$), 94% ($n=1210$) were transferred out and/or not found to be enrolled at the school during the enrollment period.

Interventions

All AGYW within schools randomized to the SKILLZ intervention were offered four intervention components: 1) twelve after-school sessions commencing after the evaluation baseline survey and which were mostly completed within six-months of the baseline assessment (see SARS-CoV-2 delays below), delivered at a frequency of approximately every one to two weeks by trained, young female adult mentors ("Coaches" aged 20-30) and lasting 90-120 minutes, which focused on comprehensive sexual and reproductive health education as well soccer classes; 2) A community "graduation" event within a month (with some variations due to SARS-CoV-2 delays, see Timeline in Supplementary Materials, Figure 3.2) of completing all 12 sessions where HIV testing and contraception were available at a mobile clinic staffed by trained nurses/midwives in AGYW-friendly care; 3) Ten follow-on and optional "Teen Club" meetings offered approximately every one to two weeks and led by peers which provided continued opportunities for guided learning about sexual health, goal-planning, empowerment, and well-being, commencing after the graduation (i.e., took place between midline and endline) and did not include sports programming; and 4) Community-based distribution of HIV self-tests kits and contraceptives from Coaches during the after-school sessions, who received training to be community-based distributors, in addition to referrals

to youth-friendly clinic services made on an as-needed basis upon request. The first, second, and fourth components were offered prior to the midline survey wave (with some adjustments due to SARS-CoV-2 related delays, described below); the third component was offered upon conclusion of the after-school sessions and graduation.

Control arm schools implemented the standard of care, which was defined as school-led comprehensive sexual education following national curriculum.[238] The trial is registered at ClinicalTrials.gov (NCT04429061) and results have been presented at the International AIDS Society showing increase in both uptake of HIV testing (up 27%) and contraception (up 12%) at six months in the intervention arm compared to the control arm.[239]

Impact path from intervention exposure to change in sexual and reproductive health (SRH) empowerment

The twelve after-school sessions included a curriculum focused on empowerment, self-efficacy, SRH rights, life-skills, body image, and decision-making in relationships, all peer-led and in addition to the sports component. Informed by Social Cognitive Theory,[240] this specific sports and empowerment curriculum model has been previously piloted, with initial evidence for improvements in self-efficacy around sexual behavior and more equitable gender views using single item indicators of these domains (e.g., “a girl’s opinion is as important as a guy’s”), as well as qualitative attestations to feelings of empowerment.[59] Those who participated in at least eight of the twelve sessions were invited to a graduation ceremony, which we hypothesize served as an empowering event given the community celebration of achieving an outcome (completion of SKILLZ) in the same school setting where it took place. In regard to the other intervention components’ place on the impact path, we hypothesize that engagement in the community distribution of HIVST and SRH products component is an outcome of increased sexual and reproductive empowerment. Further, the teen club sessions theoretically could impact sexual empowerment at endline, however, they were optional and administrative records from the peers were incomplete, precluding our ability to measure their impact. Nevertheless, given they were poorly attended, we do not hypothesize that they impacted our study outcomes.

Data collection

Self-administered surveys were given to all participants at baseline and six (midline) and twelve (endline) months post baseline (with the window for survey rounds extended at the school-level due to SARS-CoV-2 related closures); due to SARS-CoV-2 delays, we refer to encounters with study staff as survey rounds rather than in terms of month. Data were collected via audio-assisted, self-administered surveys conducted at school and on computer tablets with audio narration through headphones in English and two local languages (Bemba

and Nyanja). Research staff were nearby to support as needed for clarifications or technical issues. Survey topics included questions on sociodemographic characteristics, sexual history, HIV testing, contraceptive uptake, as well as the complete Sexual and Reproductive Empowerment for Adolescents and Young Adults (SRE for AYA; herein referred to as SRE) scale.

SARS-CoV-2 impacts

The study occurred during the global SARS-CoV-2 pandemic in which school closures occurred at different times in Zambia in response to pandemic safety measures. Out of concern for potential increased attrition, recruitment targets were increased halfway through recruitment and enrollment, with IRB approval, from 30 to up to 50 AGYW per school. Thus, a second phase of recruiting AGYW occurred, which differentially affected schools given the rolling recruitment across the 46 schools. A timeline showing school by school activities per quarter is available in Supplementary Materials, Figure 3.2. In some cases, participants may have received exposure to the intervention prior to receiving an initial assessment; in other words, some AGYW were recruited after the baseline survey wave concluded, and thus were given a first assessment as part of the midline (i.e., twelve months month) survey wave. Further, study procedures were paused twice for a three- and one-month period (June 16-August 25, 2021 and January 10-February 4, 2022), respectively, during which all intervention and data collection activities ceased in response to Zambia's larger outbreak containment measures. As such, 90% of surveys that were scheduled to occur within six months of baseline actually occurred within nine months, introducing variability in the time of completion of the intervention and data collection among participants in both arms. Despite pandemic-related obstacles, the majority of AGYW who were recruited were subsequently enrolled. Only 3.3% (n=43) of the 1,291 who were not enrolled were due to refusals; the majority (94%) were not enrolled due to the student either not being found in the school records or having transferred out of the school (see Figure 3.1, CONSORT).

Independent variable

The independent variable is study arm of the school, with the control group operationalized as the referent group and the intervention arm as the comparator.

Outcome

Current measures of sexual health empowerment build upon foundational work measuring reproductive coercion, the umbrella term “women’s empowerment,” and decision-making power. The more commonly applied and validated scales were developed in 2014 by Upadhyay et al. via the Reproductive Autonomy Scale (RAS),[30] as well as the Sexual Rela-

tionship Power Scale (SRPS), which focused on sexual relationship power among women specifically with regards to HIV risk and condom use, but not other contraceptives.[44] The RAS was validated among women seeking family planning and abortion care in the United States. The SRPS was validated among Latinas at risk of HIV acquisition in the United States and has since been used globally; it has, however, limited external validity to adolescent populations whose sexual health needs and ability to practice them autonomously and in an empowered fashion differ. In recognition of the limitations of RAS, Upadhyay et al. developed and validated the Sexual and Reproductive Empowerment Scale for Adolescents and Young Adults in 2021. The SRE was developed through with the continuous input of adolescents and young people via a rigorous process of qualitative interviews, cognitive testing, literature review, and psychometric analysis.[44] This scale was developed among adolescent populations throughout the United States and captures the diverse experiences and needs of adolescents in their unique life and developmental stage of life, with growing applications in other settings.[46, 45] At the time of study roll-out, the SRE was not validated in sub-Saharan Africa; it has since been validated in Kenya and used in other countries.[46, 45]

We measure sexual and reproductive empowerment via the SRE. The SRE scale has 23 items within seven subscales (Supplementary Materials, Table 3.10): 1) comfort talking with partner, 2) choices of partners, marriage, and children, 3) parental, 4) sexual safety, 5) self-love, 6) sense of future, and 7) sexual pleasure. Response options include “not at all true” (0), a little true (1), moderately true (2), very true (3), and extremely true (4), summing to a total score range of 0-92 where higher scores are indicative of more sexual and reproductive empowerment. The SRE was administered at each survey round among all participants regardless of engagement in sexual activity as questions are not explicitly related to being ever or currently sexually active (Supplementary Materials, Table 3.10); overall scale and subscales showed high internal consistency among the SKILLZ study participants (Table 3.1).

Statistical analysis

Summary statistics of the sociodemographic characteristics of participants at their baseline survey are presented, stratified by arm, as well as baseline self-reported proportions of AGYW who have engaged in sexual relations and SRE overall and subscale scores. By arm and visit summary statistics of the SRE are presented for the complete case, <25% missingness, and imputed (described in further detail below in Missing data) samples as well, which are analyzed in sensitivity analyses.

To examine the association between exposure to SKILLZ and SRE, we conducted an intent-to-treat analysis and include all participants who were randomly selected from each school, enrolled in the evaluation study, and completed surveys. We conducted a difference-in-difference analysis using a linear model looking at the difference in SRE scores (continuous)

by arm at each survey round compared to baseline (i.e. baseline vs. midline, baseline vs. endline). The primary model examined intervention impact from the midline survey round given this is the first follow-up upon completion of the primary components (twelve workshops, graduation, and community based distribution of SRH products) of the intervention. The second model examined sustained intervention impact at twelve months using the same difference-in-difference specifications. Standard errors were clustered within schools, the unit of randomization, and the models controlled for five stratification factors. The model will take the following form (Equation 3.1):

$$[Y_{ijt}] = \beta_0 + \beta_1 x_{1j} + \beta_2 x_{2t} + \beta_3 x_{1jt} * x_{2t} + \beta_4 x_{3j} + \zeta_j + \epsilon_{ijt} \quad (3.1)$$

where Y_{ijt} is the outcome of interest (SRE score, continuous) for AGYW i within school j over the survey waves t , β_0 is the constant, x_{1j} represents treatment assignment (0=control, 1= intervention), x_{2t} is the survey round variable (0=baseline, 1=midline or endline survey round), $x_{1jt} * x_{2t}$ is the interaction between arm and survey round, x_{3j} is a vector of indicators for the five stratification factors (district, location remoteness, size of student body, and school type; ζ_j is the school cluster random effects and ϵ_{ijt} is the error term. The error term will be calculated using standard errors clustered at the school level. The estimand is β_3 , which is the difference in mean SRE score among AGYW in the intervention arm between baseline and midline survey round less the difference in the control arm between baseline and midline; this was repeated for examining the difference between baseline and the endline survey rounds. To facilitate interpretation of effect sizes by arm, the percent change $[(\text{score}_{\text{time2}} - \text{score}_{\text{time1}} / \text{total score range [93]}) * 100]$ is presented for comparability of intervention impact across subscales.

Secondary analyses examined the impact of SKILLZ on the seven sub-domains of the SRE scale using the ITT analysis and an analysis restricted to those who self-reported being ever sexually active at any of the study survey rounds, using the same model specifications in terms of clustering and controlling for district. We theorize that the intervention would not affect an AGYW's decision to engage in sexual behavior, but rather *how* they may engage in sexual relationships, hence this secondary analysis; nevertheless, we also include an analysis among just those AGYW who report being sexually active at baseline (Supplementary Materials, Table 3.16). For all models, reported p-values adjust for multiple comparisons using a Bonferroni correction, whereby the p-value is divided by the number of comparisons (here, 8).[241] Further and following the main trial analyses, I conducted a per-protocol analysis, including those in the intervention arm who attended at least eight of twelve sessions as defined in the parent study's assessment of adherence. Given limitations of the per-protocol analysis, primarily that the randomization is not maintained,[242] I additionally conducted

an two-staged least squares instrumental variable analysis, where study arm was the instrument, a binary variable indicating whether the participant attended at least eight of the twelve sessions was the instrumented variable which was interacted with survey round, and the outcome remained the SRE score. Attendance of the eight sessions is the most salient intervention component leading to the outcome and is, by definition of the graduation, tied to the graduation component, meeting the relevance and exclusion assumptions necessary for an instrumental variable analysis; the other intervention components are either downstream outcomes of SRE (engagement in distribution of SRH and HIV prevention products) or were not able to have a causal effect on SRE (the teen clubs), and are thus not included in the instrumental variable analysis. Both the per-protocol and instrumental variable analyses control for the five stratification factors. The results of the instrumental variable analysis thus provide the effect of the “treatment on the treated”. [243]

Given extended timelines for the second phase of enrollment to meet increased enrollment targets, sociodemographic characteristics of those who were intervention-naïve at baseline (i.e., “original recruits”) are included in Supplementary Materials, Table 3.14, and a sensitivity analysis among these participants is in Supplementary Materials, Table 3.15. Similarly, an additional sensitivity analysis controlling for month of recruitment as a fixed effect given variations and delays in calendar months of enrollment was conducted. Finally, a fully-adjusted model controlling for month of enrollment, variables where baseline imbalance was observed (employment), as well as factors related to the outcome (age and ever sexually active) was conducted.

Missing data

Among participants with $\leq 25\%$ missingness in the SRE items (i.e. ≤ 6 items), individual items were imputed using multiple imputation and using the responses from the non-missing SRE items in the imputation model as well as the (unimputed) overall score, age, ever being sexually active, mother’s education, and food security status; any missingness in those predictor variables were mean imputed in order to maximize the imputation model. The 25% threshold was chosen as it is more stringent than the “half-rule” which uses a 50% threshold, [244] and excessive missingness can lead to imprecise estimation. The imputation was conducted in Stata 16 using chained equations which iteratively imputes, allowing items imputed to inform the imputation of other imputed values; the `truncreg` option was used to truncate values to limit the imputation values to between zero and four, the limits of each item’s response; imputation was conducted by study treatment assignment and survey round. Tables summarizing characteristics of those missing SRE scores and missing survey rounds were compared within arm to the entire sample to assess differential missingness by arm as well as systematic differences in the characteristics of participants with missingness; missingness was at random and non-differential by arm. We report results for those who completed 100% of the SRE items (referred to as “complete case” analysis) and those who

had $\leq 25\%$ missingness in the SRE items and for whom multiple imputation was used to address missing survey items (referred to as the “imputed sample”). At each survey wave, any participant with $>25\%$ missingness of SRE items were excluded from the analysis.

3.4 Results

The study enrolled 2,153 AGYW (1,019 control, 1,134 intervention) from 46 schools across two enrollment periods; in the first phase of enrollment, 1,917 participants (984 control, 933 intervention) were enrolled, and the remaining 236 (35 control, 201 intervention) were enrolled after the baseline survey round was completed (Table 3.2). The median age of all participants at their first survey round was 17 (interquartile range [IQR]: 16, 18). Participants were largely unmarried (95.7%), with nearly one in three (30.6%) experiencing food insecurity in the last 30 days and one in five (19.9%) ever sexually active. Baseline SRE scores among those with $\leq 25\%$ missingness were 59.0 and 57.0 in the intervention and control arms, respectively, with similar scores by arm for the subscales (Table 3.2; scores shown among complete case, $\leq 25\%$ missing, and imputed by visit are in Supplementary Materials, Table 3.12). The study also experienced high but differential retention, with a combined 87% ($n=1,873$) and 93% retention ($n=1,997$) at midline and endline survey rounds (Figure 1). Engagement in intervention components among participants in the intervention arm was high, with 71% of participating AGYW attending at least eight of twelve sessions.

Missing data

Participant non-response to SRE items was prevalent; 65% of all participant-waves had complete responses to all 23 items of the SRE score, with 92% of all participant-waves responding to at least 75% of all SRE items. At baseline, midline, and endline survey rounds, 9.3%, 8.2%, and 7.5% of participants had $>25\%$ missingness in the SRE items and were excluded from the analyses; items were imputed among those with $\leq 25\%$ and $>0\%$ missingness in items. Participants with $>25\%$ missingness in the SRE items at baseline were more likely to have access to a mobile phone, less likely to be sexually active, and were more likely to be from intervention schools compared to the original recruits with $\leq 25\%$ missingness at baseline (Supplementary Materials, 3.11). Further, at the midline survey round, 13% ($n=280$) of participants recruited in combined Phase 1 ($n=1,917$) and Phase 2 ($n=236$) were not followed up; by endline this was just 7.3% ($n=156$). Of those with missing visits, they were older, more likely to be food insecure (among those missing the midline survey round), more likely to be sexually active, more likely to be from an intervention school, and had lower overall SRE scores (among those missing the endline survey round) compared to the overall sociodemographic characteristics of those of the original recruits at baseline (Supplementary Materials, Table 3.13).

Complete case sample

Among participants with 100% complete SRE items, baseline median SRE scores were similar between participants in the intervention (60; IQR: 51, 67) and control (60.5, IQR: 51, 68) schools. Between the baseline and the midline survey rounds, being in an intervention school was associated with a 5.62-point increase in the 92-point SRE overall scale score (standard error [SE]: 1.03, $p < 0.001$). At the midline survey round (compared to baseline), being in an intervention school was associated with a 4.73-point increase (SE: 0.96; $p < 0.001$) in the SRE overall scale score compared to being in a control school. Being in an intervention school was associated with consistently higher subscale scores at both midline and endline (Table 3.3). This corresponds to a 6.11% and 5.14% change in overall score from baseline to midline and endline, respectively.

Imputed sample

Between the baseline and midline survey rounds, being in an intervention school was associated with a 6.21-point increase in the SRE overall score calculated using the imputed sample (SE: 0.75, $p < 0.001$) compared to being in a control school (Table 3.4). At endline, being in an intervention school was associated with a 5.12-point increase in the SRE overall score (SE: 0.71, $p < 0.001$) calculated using the imputed items. This corresponds to a 6.75% and 5.57% change in score from baseline to midline and endline, respectively. Enrollment at an intervention school was consistently associated with significantly higher subscale scores compared to the control between the baseline survey round and both midline and endline survey rounds (Table 3.4).

Ever sexually active subset of the imputed sample

At the baseline survey round, approximately one in five participants had ever had sex (192 [18%] intervention AGYW; 217 [21.8%] control participants). By the end of the study, two in five participants reported ever being sexually active (475 [42.1%] in intervention and 389 [38.4%] in control arm). Between the baseline and midline survey rounds, being in an intervention school was associated with a 7.78-point increase (SE: 1.17, $p < 0.001$) in the SRE overall score calculated using the imputed sample, a 25% higher effect compared to the effect with the imputed sample which included both ever sexually active AGYW and those who have never been sexually active. Between baseline and endline, this increase was 4.64 (SE: 0.93, $p < 0.001$). This corresponds to an 8.46% and 5.04% change in score from baseline to midline and endline, respectively. With the exception of the Choice of Partners, Marriage, and Children subscale, difference-in-difference estimates across all other subscales were larger in magnitude compared to the ITT analysis including both ever sexually active and never sexually active AGYW (Table 3.5) at the midline survey round; at the endline survey round,

estimates were consistently lower compared to the ITT analysis, although still statistically significant. Models examining just the subset of AGYW sexually active at baseline (i.e. not those who sexually debuted during the intervention) are reported in Supplementary Materials, Table 3.16.

Per protocol analysis

Nearly three out of four (808, 71.3%) intervention participants attended at least eight out of twelve sessions; very few (3, 0.33%) attended none. Over one in four (243; 26.9%) intervention participants attended all twelve. The median number of sessions attended was 11 (IQR: 9, 12). The per-protocol analytic sample restricted the analysis to those participants in the intervention schools who received a sufficient theoretical exposure (i.e., attended at least eight out of twelve sessions) for measurable impact and maintaining all control arm participants. Between the baseline and midline survey rounds, being in an intervention school and receiving sufficient intervention exposure was associated with a 7.56-point increase in the SRE overall score calculated using the imputed items (SE: 0.76, $p < 0.001$) compared to being in a control school (Table 3.6). Between baseline and endline, the impact was a 6.64-point increase (SE: 0.72, $p < 0.001$). This corresponds to an 8.22% and 7.22% change in score from baseline to midline and endline, respectively.

Instrumental variable analysis

In the first stage of the instrumental variable analysis, the instrument (treatment assignment) was highly associated with intervention exposure (F-statistic test of the excluded instruments: 2253.4; $p < 0.001$). Further and a result of the second stage, receiving sufficient exposure to the intervention (at least eight of twelve sessions) was consistently associated with higher SRE scores in the intervention arm compared to baseline and control arms at the midline (6.01 points; SE: 0.81, $p < 0.001$) and endline (5.08 points; SE: 0.84, $p < 0.001$) survey rounds (Table 3.7). This corresponds to a 6.53% and 5.52% change in score from baseline to midline and endline, respectively. Across subscales (Table 3.7), scores among those receiving sufficient exposure were in the same direction as the ITT and per-protocol analyses, although slightly attenuated. There were some exceptions, particularly for the Comfort talking with a partner subscale, where no significant effect was detected at midline (0.29 points, SE: 0.25, $p = 0.25$) nor endline (0.46 points, SE: 0.25, $p = 0.067$).

Sensitivity analyses

In models controlling for the month of enrollment and comparing the baseline and midline survey rounds, being in an intervention school was associated with a 6.31-point increase in

the SRE overall score calculated using the imputed sample (SE: 0.76, $p < 0.001$) compared to being in a control school (Table 3.8). At endline, being in an intervention school was associated with a 5.20-point increase in the SRE overall score (SE: 0.71, $p < 0.001$) calculated using the imputed items. This corresponds to a 6.86% and 5.59% change in score from baseline to midline and endline, respectively. In the fully adjusted model, controlling for month of enrollment, age, employment, and ever being sexually active, in addition to the stratification factors, being in an intervention school was associated with a 6.36-point increase in the SRE overall score calculated using the imputed sample (SE: 0.78, $p < 0.001$) compared to being in a control school (Table 3.9). At endline, being in an intervention school was associated with a 5.19-point increase in the SRE overall score (SE: 0.73, $p < 0.001$) calculated using the imputed items. This corresponds to a 6.91% and 5.64% change in score from baseline to midline and endline, respectively. When assessing intervention impacts in the sample restricted to just those original recruits, i.e., those who were surveyed prior to intervention start, results were similar in terms of magnitude and direction of effect (Supplementary Materials 3.15).

3.5 Discussion

This study showed that a peer-led, sports-based program among in-school Zambian AGYW modestly improved sexual and reproductive empowerment, an intermediate outcome on the path from the intervention to behavior change in terms of increased HIV testing and contraceptive uptake (the primary study outcomes). We found statistically significant changes between baseline and midline in the overall score, as well as on all seven subscales, with sustained impacts at endline, which occurred six months after the primary intervention exposure. The intervention effects were larger in magnitude among ever sexually active participants, and a series of robustness checks accounting for potential threats to internal validity demonstrated consistency in the direction and magnitude of the study's impact on SRE. This study builds upon observational literature demonstrating the impact of sports programming and engagement in sports on improved sexual health outcomes,[56, 57, 58] as well as a study which empirically tested whether sexual empowerment mediates that relationship.[63] Our study is the first, to our knowledge, to rigorously evaluate via a cRCT the association of sports programming with sexual empowerment, and the first to do so in an African setting.

In terms of size of impact relative to the overall scale range (percent change), the intervention had the greatest measurable effect when using the entire scale and within the subscale domains of comfort talking with a partner, sexual safety, and sexual pleasure. This is likely a direct result of the curriculum (see Supplementary Materials, Appendix 1 for an overview of the weekly session topics), which had explicit sessions focused on health communications, healthy relationships, and how to advocate for oneself, in addition to these themes being consistently referred to throughout other sessions. The intervention did not impact the parental support nor choice of partners, marriage, and children subscale in terms of percent

change compared to other scales; parental involvement in decision-making is mentioned just once in the curriculum in regard to choice of partner (Session 5). The lack of intervention focus on the sub-domains of parental support stems from parents being seen as an obstacle to promoting sexual well-being and empowerment among AGYW;[245, 246] it is unclear if a focus on these intervention components would have resulted in measurable impacts of greater magnitude than what we observed. Nevertheless, intervention impacts were within a small to medium effect size. While it is unclear what effect size might manifest in behavior change, the intervention did have a measurable impact on the primary outcomes, improving the relative risk (RR) of HIV testing (RR: 1.84, 95% CI: 1.53, 2.15) and contraception use (RR: 1.62, 95% CI: 1.24, 2.00) in the intervention compared to the control arm.[239]

Among the subsample of AGYW who reported ever being sexually active, the percent change in score was larger for the overall scale and all subscales except the choice of partners, marriage, and children subscale. Regarding sexual safety and pleasure, the intervention impacts were much larger in terms of magnitude of effect (11% and 14% change in score, respectively) among those ever sexually active participants. Against a backdrop of sexual violence and poverty, where 28% of sexually active participants reported ever experiencing rape and 75% reported ever engaging in transactional sex at baseline, there is more potential for these messages to be impactful. Further, the intervention took place during a period of sexual debut; compared to one in five AGYW ever being sexually active at baseline, by endline, over one in three (36.6%, non-differential by arm) reported ever being sexually active. This is consistent with multiple studies reporting the average age of sexual debut in SSA to be around age 16[247] and with most AGYW being sexually active by age 18.[111] In Zambia, the Violence against Children and Youth Surveys (VACS) found 27.6% of AGYW had first sex ≤ 15 years of age.[248] There have been conflicting effects of school-based interventions on delaying sexual debut in low- and middle-income countries, with both null and significant effects reported.[249, 250] The SKILLZ intervention did not explicitly promote abstinence in line with global calls for girl-friendly, comprehensive sexual education.[251] While control schools offered comprehensive sexual education per Zambian guidelines, this may be subject to teacher discretion and limited prioritization among those tasked with leading the curriculum.[252, 253] Given early sexual debut is a significant risk factor for HIV acquisition,[254] the timing of the intervention to overlap during a period of adolescence when AGYW are becoming sexually active is a promising approach, evidenced by the heightened impacts among sexually active girls, lending evidence for intervening during this critical period of adolescence.

Non-sports behavioral interventions which seek to address sexual empowerment have focused on parallel domains of gender and power relations. A 2020 systematic review of SRH interventions for young people in lower- and middle-income countries reported that of the 55 studies included, 17 had significant effects on the various SRH outcomes, including STI knowledge, HIV testing, attitudes around contraceptives, and condom negotiation self-efficacy.[47] The review revealed characteristics of these effective intervention designs in-

cluding SRH, HIV, STI, gender equity, and contraceptive and condom education, in addition to psychosocial components such as problem-solving, communication, and assertiveness, all components interwoven into the SKILLZ curriculum. Nevertheless, a similar evaluation of SKILLZ in 38 South African schools recently reported that, despite parallel curricula, the intervention reported null results on the primary outcomes of HIV, pregnancy, and HIV testing, and that the intervention was also not associated with improved gender roles and self-efficacy and agency, with some indication of impact among those who attended at least seven sessions (i.e., eligible to graduate).[62, 232] The authors further reported that safety concerns for getting home after the sessions, as well as competing demands on time during the after school period, may have contributed to the poor attendance, with 27.8% graduating from the program;[62] in Zambia, 89.6% graduated from the program. Similarly, a recent CRCT evaluating the impact of a two-year, AGYW-focused empowerment program (with no sports components) with weekly, peer-led “meetings” in the community reported null effects on gender equity and IPV acceptability. Similar to the SKILLZ intervention in South Africa, the authors reported low participant engagement, with only 30% of the study participants participated in at least half of sessions, with participants reporting similar demands on time.[255] The juxtaposition of these studies highlight that the success of SKILLZ in Zambia is likely attributable to high participant engagement which was further enabled by fewer competing demands outside of school, the intervention taking place at school, and a curriculum in concordance with numerous evidence-based SRH themes.

This study had substantial strengths. It boasted a large sample size of over 2,000 AGYW across 46 schools and three time points. Further, despite roll-out occurring at the same time as repeated global shutdowns related to SARS-CoV-2, there was 94% retention of participants over the study period, a high retention rate even in the absence of a global pandemic. The CRCT design makes this study among the first to evaluate a sports-based SRH program with a control group, facilitating a more rigorous evaluation of sports SRH programming compared to prior observational studies, as well as the sustained impact of the intervention at approximately one year post baseline, approximately six months after most intervention activities had concluded. Nevertheless, the findings must be interpreted within the context of their limitations. This study took place during the global SARS-CoV-2 pandemic, during which recruitment and the implementation of the intervention components experienced delays, ultimately resulting in extended timelines as well as some participants having intervention exposure prior to completing a baseline survey. Sensitivity analyses which evaluated the potential bias of this limitation support the hypothesis that this had minimal impact on the measure of the intervention’s impact. There are also limitations relation to our measure of SRE. The SRE utilized in this study was not validated in SSA at the time of the study roll out. A recent psychometric analysis of the SRE among Arabic speaking refugee and non-refugee women in Lebanon reported sub-optimal model fit with the exception of the self-efficacy subscale; this setting has limited generalizability to Zambia.[46] Since the study ended, the SRE was adapted in Kenya via a rigorous process of cognitive interviews and in-depth interviews, with attention to new item creation for the specific east African

context, item revision, and linguistic concerns for use in the east African context.[45] Future applications of the SRE in SSA may use the additional items from Kenya, as well as the original SRE items, to conduct psychometric evaluation and determine scale fit. Nevertheless, better than single item proxies, the SRE showed high internal validity on the overall and subscales, comparable to original validation study.[44] Our study data had prevalent missingness, whereby nearly one in three SRE for AYA scales had some degree of missingness, and with the missingness being more prevalent among sexually inactive AGYW, those without access to a phone, and those in intervention schools. These patterns in missingness have potential implications for statistical power, biased estimates, and invalid conclusions. To address this potential threat to validity, we utilized multiple imputation, as well as a series of robustness checks, to conduct our analysis. This missingness was not restricted to the SRE for AYA scale and may be due in some part to the self-administered nature of the survey. The choice to use a self-administered survey was made due in response to the well-documented impact of social desirability bias on reporting of sexual behavior;[256] nevertheless, future studies which aim to use self-administered surveys may avoid missing data by integrating periodic completeness checks during data collection to reconcile confidentiality with data completeness.

In conclusion, our study demonstrated that the SKILLZ intervention was effective at improving sexual and reproductive empowerment among in-school Zambian AGYW across four districts of Lusaka. The intervention's success was likely bolstered by its high attendance, whereby 90% of AGYW randomly selected for follow up participated in at least eight of twelve offered sessions. Given the null findings of the intervention on the primary sexual health outcomes in South Africa, the generalizability of these results in other settings may be bound by acceptability, ability to participate, and actual participation. Nevertheless, this model may be generalizable to AGYW coming to the age of sexual debut in high HIV burdened settings in other parts of Zambia and outside, and in turn, may promote early sexual empowerment and subsequent increases in sexual healthcare seeking behaviors.

3.6 Tables and Figures

Table 3.1: Psychometric properties of the SRE scale¹⁻³ at baseline among participants missing $\leq 25\%$ of scale items (n= 1,739), SKILLZ Study, Zambia, 2022

	N Items	Range	Cronbach's alpha
Overall SRE score	23	0-92	0.836
Subscales			
Parental support	4	0-16	0.804
Comfort talking with partner	3	0-12	0.696
Choice of partners, marriage, and children	3	0-12	0.657
Sexual safety	4	0-16	0.532
Self-love	4	0-16	0.702
Sense of future	2	0-8	0.590
Sexual pleasure	3	0-12	0.628

¹ Response Options: Not at all true (0), A little true (1), Moderately true (2), Very true (3), Extremely true (4)

² Each subscale and overall scored by summing each item

³ Uses imputed items

Table 3.2: Sociodemographic characteristics of study participants at first survey round,¹ SKILLZ Study in Zambia (n=2,153), 2022

	Control (n=1,019)	Intervention (n=1,134)	Total (n=2,153)
Age, median (IQR)			
Marital status			
Unmarried	897 (95.7%)	818 (95.7%)	1715 (95.7%)
Married or divorced	40 (4.3%)	37 (4.3%)	77 (4.3%)
Currently does any job or tasks to earn money	288 (29.3%)	198 (21.3%)	486 (25.4%)
Mother's educational attainment			
N/A	15 (1.7%)	21 (2.6%)	36 (2.1%)
Primary or less	407 (45.8%)	368 (45.2%)	775 (45.5%)
Some or complete secondary	287 (32.3%)	265 (32.6%)	552 (32.4%)
Post-secondary	179 (20.2%)	160 (19.7%)	339 (19.9%)
Access to a functional mobile phone	567 (57.9%)	483 (52.4%)	1050 (55.2%)
Food insecure	327 (33.5%)	252 (27.5%)	579 (30.6%)
Ever had sexual intercourse	217 (21.8%)	192 (18.0%)	409 (19.9%)
Overall SRE score², median (IQR)	59.0 (50.0, 67.0)	57.0 (48.0, 66.0)	58.0 (49.0, 66.0)
SRE subscales³			
Parental support, median (IQR)	12.0 (10.0, 13.0)	12.0 (10.0, 13.0)	12.0 (10.0, 13.0)
Comfort talking with partner, median (IQR)	6.0 (3.0, 9.0)	6.0 (3.0, 9.0)	6.0 (3.0, 9.0)
Choice of partners, marriage, and children, median (IQR)	9.0 (8.0, 11.0)	9.0 (8.0, 10.0)	9.0 (8.0, 11.0)
Sexual safety, median (IQR)	7.0 (4.0, 10.0)	7.0 (4.0, 10.0)	7.0 (4.0, 10.0)
Self-love, median (IQR)	12.0 (12.0, 16.0)	12.0 (12.0, 15.0)	12.0 (12.0, 15.0)
Sense of future, median (IQR)	6.0 (6.0, 8.0)	6.0 (6.0, 8.0)	6.0 (6.0, 8.0)
Sexual pleasure, median (IQR)	5.0 (2.0, 8.0)	4.5 (2.0, 8.0)	5.0 (2.0, 8.0)
School type			
Co-ed	869 (85.3%)	1083 (95.5%)	1952 (90.7%)
Girls-only	150 (14.7%)	51 (4.5%)	201 (9.3%)
District			
Chilanga	192 (18.8%)	206 (18.2%)	398 (18.5%)
Chongwe	70 (6.9%)	235 (20.7%)	305 (14.2%)
Kafue	260 (25.5%)	94 (8.3%)	354 (16.4%)
Lusaka	497 (48.8%)	599 (52.8%)	1096 (50.9%)
Phase			
Phase A	984 (96.6%)	933 (82.3%)	1917 (89.0%)
Phase B	35 (3.4%)	201 (17.7%)	236 (11.0%)
N Sessions attended median (IQR)	—	11 (9, 12)	11 (9, 12)
School in urban area (out of 46)	10 (43.5%)	12 (52.2%)	22 (47.8%)
Median N grade 10 students	139 (88, 298)	250 (107, 364)	116 (62, 297)
Median distance from dist. board	9.5 (6, 30.5)	8 (5, 32)	16 (6, 41)

¹ Responses here include those from original cohort as well as sociodemographic responses from those recruited in the second phase; ² Range 0-92; higher scores = more sexual and reproductive empowerment;

³ Scores using non-imputed items among those with $\leq 25\%$ missingness

Table 3.3: Difference-in-difference effects of the SKILLZ intervention on SRE overall score and subscales among AGYW with 100% completeness of SRE items, SKILLZ Study in Zambia, 2022

	Midline ¹				Endline ²			
	D-i-D β	SE	p-value ³	% change	D-i-D β	SE	p-value ³	% change
Overall SRE score (Range: 0-92)⁴	5.62	(1.03)	<0.001	6.11%	4.73	(0.96)	<0.001	5.14%
Subscales⁴								
Parental support (0-16)	0.69	(0.27)	0.011	4.06%	0.37	(0.25)	0.13	2.18%
Comfort talking with partner (0-12)	0.88	(0.28)	0.002	6.77%	0.80	(0.21)	<0.001	6.15%
Choice of partners, marriage, and children (0-12)	0.33	(0.16)	0.043	2.54%	0.5	(0.17)	0.004	3.85%
Sexual safety (0-16)	1.11	(0.30)	<0.001	6.53%	1.05	(0.36)	0.003	6.18%
Self-love (0-16)	0.71	(0.16)	<0.001	4.18%	0.84	(0.18)	<0.001	4.94%
Sense of future (0-8)	0.44	(0.09)	<0.001	4.89%	0.45	(0.09)	<0.001	5.00%
Sexual pleasure (0-12)	1.40	(0.28)	<0.001	10.77%	0.73	(0.23)	0.002	5.62%

¹ 1,611 unique participants comprising 2,379 participant-waves

² 1,699 unique participants comprising 2,587 participant-waves

³ Bonferroni adjusted alpha critical value cut off: $p < 0.00625$

⁴ Each line a separate regression model; each model adjusted for district, location, remoteness, school type, and number of students

Table 3.4: Difference-in-difference effects of the SKILLZ intervention on SRE overall score and subscales with imputed items among AGYW, SKILLZ Study in Zambia, 2022

	Midline ¹				Endline ²			
	D-i-D β	SE	p-value ³	% change	D-i-D β	SE	p-value ³	% change
Overall SRE score (Range: 0-92)⁴	6.21	0.75	<0.001	6.75%	5.12	0.71	<0.001	5.57%
Subscales⁴								
Parental support (0-16)	0.63	0.22	0.004	3.71%	0.43	0.2	0.027	2.53%
Comfort talking with partner (0-12)	0.86	0.22	<0.001	6.62%	0.66	0.17	<0.001	5.08%
Choice of partners, marriage, and children (0-12)	0.64	0.14	<0.001	4.92%	0.74	0.16	<0.001	5.69%
Sexual safety (0-16)	1.33	0.23	<0.001	7.82%	1.21	0.27	<0.001	7.12%
Self-love (0-16)	0.82	0.13	<0.001	4.82%	0.89	0.14	<0.001	5.24%
Sense of future (0-8)	0.51	0.093	<0.001	5.67%	0.49	0.077	<0.001	5.44%
Sexual pleasure (0-12)	1.28	0.21	<0.001	9.85%	0.66	0.18	<0.001	5.08%

¹ 2,050 unique participants comprising 3,459 participant-waves

² 2,053 unique participants comprising 3,586 participant-waves

³ Bonferroni adjusted alpha critical value cut off: p<0.00625

⁴ Each line a separate regression model; each model adjusted for district, location, remoteness, school type, and number of students

Table 3.5: Difference-in-difference effects of the SKILLZ intervention on SRE overall score and subscales with imputed items among sexually active AGYW, SKILLZ Study in Zambia, 2022

	Midline ¹				Endline ²			
	D-i-D β	SE	p-value ³	% change	D-i-D β	SE	p-value ³	% change
Overall SRE score (Range: 0-92)⁴	7.78	1.17	<0.001	8.46%	4.64	0.93	<0.001	5.04%
Subscales⁴								
Parental support (0-16)	0.94	0.34	0.006	5.53%	0.16	0.33	0.64	0.94%
Comfort talking with partner (0-12)	1.04	0.35	0.003	8.00%	0.52	0.25	0.036	4.00%
Choice of partners, marriage, and children (0-12)	0.51	0.21	0.013	3.92%	0.49	0.17	0.003	3.77%
Sexual safety (0-16)	1.9	0.26	<0.001	11.18%	0.89	0.34	0.009	5.24%
Self-love (0-16)	0.94	0.20	<0.001	5.53%	1.20	0.19	<0.001	7.06%
Sense of future (0-8)	0.58	0.16	<0.001	6.44%	0.36	0.12	0.003	4.00%
Sexual pleasure (0-12)	1.76	0.30	<0.001	13.54%	0.99	0.26	<0.001	7.62%

¹ 830 unique participants comprising 1,399 participant-waves

² 833 unique participants comprising 1,484 participant-waves

³ Bonferroni adjusted alpha critical value cut off: p<0.00625

⁴ Each line a separate regression model; each model adjusted for district, location, remoteness, school type, and number of students

Table 3.6: Difference-in-difference effects of the SKILLZ intervention on SRE overall score and subscales among per-protocol sample, SKILLZ Study in Zambia, 2022

	Midline ¹				Endline ²			
	D-i-D β	SE	p-value ³	% change	D-i-D β	SE	p-value ³	% change
Overall SRE score (Range: 0-92)⁴	7.56	0.76	<0.001	8.22%	6.64	0.72	<0.001	7.22%
Subscales⁴								
Parental support (0-16)	0.82	0.24	0.001	4.82%	0.61	0.19	0.001	3.59%
Comfort talking with partner (0-12)	1.03	0.24	<0.001	7.92%	0.84	0.19	<0.001	6.46%
Choice of partners, marriage, and children (0-12)	0.84	0.13	<0.001	6.46%	0.94	0.15	<0.001	7.23%
Sexual safety (0-16)	1.66	0.23	<0.001	9.76%	1.53	0.27	<0.001	9.00%
Self-love (0-16)	1.02	0.14	<0.001	6.00%	1.11	0.15	<0.001	6.53%
Sense of future (0-8)	0.58	0.097	<0.001	6.44%	0.59	0.08	<0.001	6.56%
Sexual pleasure (0-12)	1.56	0.20	<0.001	12.00%	1.02	0.18	<0.001	7.85%

¹ 1,750 unique participants comprising 3,026 participant-waves

² 1,754 unique participants comprising 3,138 participant-waves

³ Bonferroni adjusted alpha critical value cut off: $p < 0.00625$

⁴ Each line a separate regression model; each model adjusted for district, location, remoteness, school type, and number of students

Table 3.7: Difference-in-difference effects of the SKILLZ intervention on SRE overall score and subscales using an instrumental variable analysis, SKILLZ Study in Zambia, 2022

	Midline ¹				Endline ²			
	D-i-D β	SE	p-value ³	% change	D-i-D β	SE	p-value ³	% change
Overall SRE score (Range: 0-92)⁴	6.01	0.81	<0.001	6.53%	5.08	0.84	<0.001	5.52%
Subscales⁴								
Parental support (0-16)	1.16	0.23	<0.001	6.82%	0.8	0.23	0.001	4.71%
Comfort talking with partner (0-12)	0.29	0.25	0.249	2.23%	0.46	0.25	0.067	3.54%
Choice of partners, marriage, and children (0-12)	0.80	0.17	<0.001	6.15%	0.89	0.17	<0.001	6.85%
Sexual safety (0-16)	0.68	0.28	0.017	4.00%	0.83	0.29	0.004	4.88%
Self-love (0-16)	1.50	0.18	<0.001	8.82%	1.35	0.19	<0.001	7.94%
Sense of future (0-8)	0.89	0.12	<0.001	9.89%	0.71	0.12	<0.001	7.89%
Sexual pleasure (0-12)	0.70	0.26	0.007	5.38%	0.037	0.25	0.88	0.28%

¹ Instrumental variable analysis leverages all 2,053 participants over two time points (4,306 units)

² Bonferroni adjusted alpha critical value cut off: p<0.00625

³ Each line a separate regression model; each model adjusted for district, location, remoteness, school type, and number of students

Table 3.8: Difference-in-difference effects of the SKILLZ intervention on SRE overall score and subscales controlling for month of enrollment, SKILLZ Study in Zambia (n=1,422), 2022

	Midline ¹				Endline ²			
	D-i-D β	SE	p-value ³	% change	D-i-D β	SE	p-value ³	% change
Overall SRE score (Range: 0-92)⁴	6.31	0.76	<0.001	6.86%	5.20	0.71	<0.001	5.59%
Subscales⁴								
Parental support (0-16)	0.66	0.22	0.003	3.88%	0.46	0.2	0.022	2.71%
Comfort talking with partner (0-12)	0.89	0.22	<0.001	6.85%	0.65	0.17	<0.001	5.00%
Choice of partners, marriage, and children (0-12)	0.65	0.14	<0.001	5.00%	0.77	0.16	<0.001	5.92%
Sexual safety (0-16)	1.34	0.22	<0.001	7.88%	1.23	0.27	<0.001	7.24%
Self-love (0-16)	0.85	0.13	<0.001	5.00%	0.91	0.14	<0.001	5.35%
Sense of future (0-8)	0.51	0.094	<0.001	5.67%	0.5	0.078	<0.001	5.56%
Sexual pleasure (0-12)	1.28	0.21	<0.001	9.85%	0.67	0.18	0.001	5.15%

¹ 2,050 unique participants comprising 3,459 participant-waves

² 2,053 unique participants comprising 3,586 participant-waves

³ Bonferroni adjusted alpha critical value cut off: $p < 0.00625$ ⁴ Each line a separate regression model; each model adjusted for district, location, remoteness, school type, and number of students, as well as month of enrollment

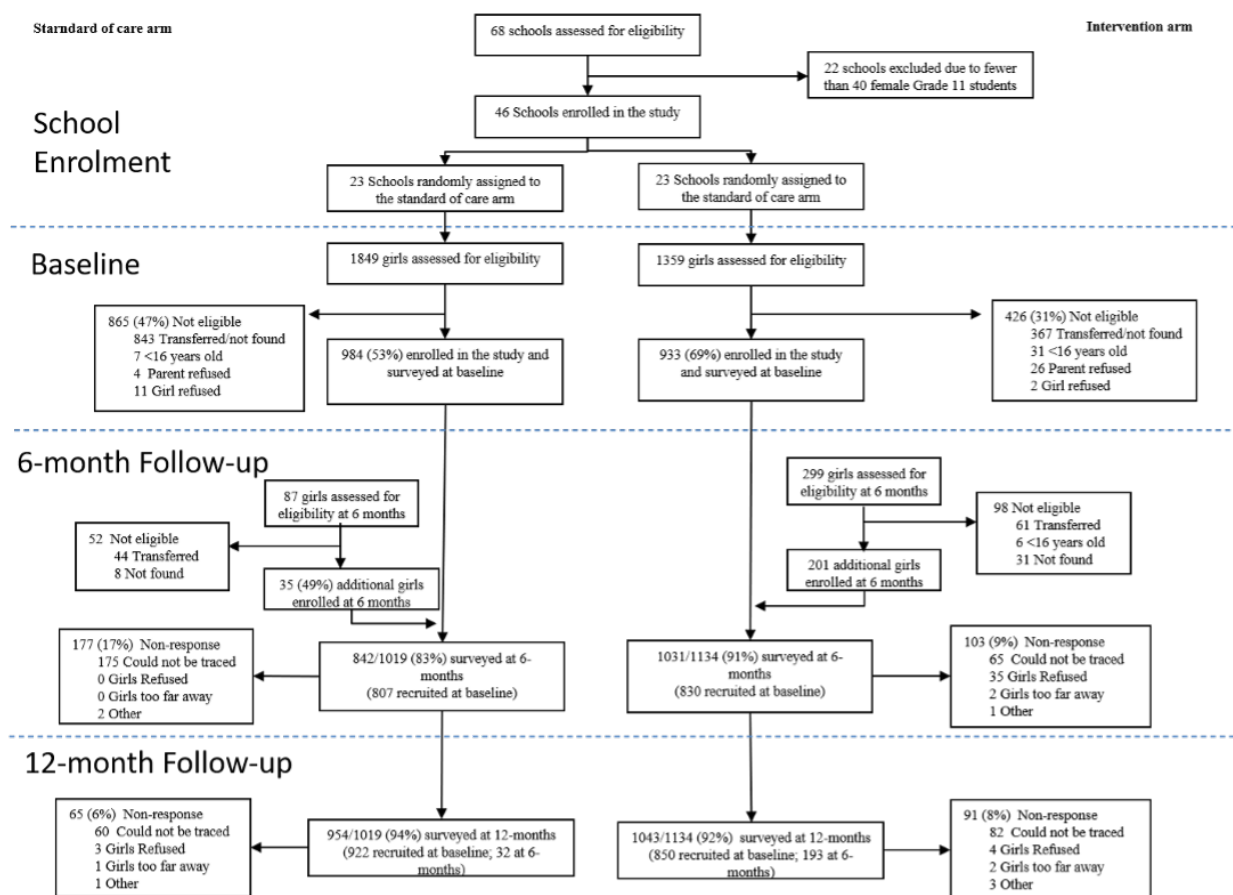
Table 3.9: Fully adjusted difference-in-difference effects of the SKILLZ intervention on SRE overall score and subscales, SKILLZ Study in Zambia, 2022

	Midline ¹				Endline ²			
	D-i-D β	SE	p-value ³	% change	D-i-D β	SE	p-value ³	% change
Overall SRE score (Range: 0-92)⁴	6.36	0.78	<0.001	6.91%	5.19	0.73	<0.001	5.64%
Subscales⁴								
Parental support (0-16)	0.67	0.22	0.002	3.94%	0.43	0.2	0.03	2.69%
Comfort talking with partner (0-12)	0.89	0.22	<0.001	6.85%	0.65	0.17	<0.001	5.42%
Choice of partners, marriage, and children (0-12)	0.67	0.14	<0.001	5.15%	0.76	0.17	<0.001	6.33%
Sexual safety (0-16)	1.33	0.22	<0.001	7.82%	1.25	0.27	<0.001	7.81%
Self-love (0-16)	0.87	0.13	<0.001	5.12%	0.91	0.14	<0.001	5.69%
Sense of future (0-8)	0.53	0.093	<0.001	5.89%	0.5	0.079	<0.001	6.25%
Sexual pleasure (0-12)	1.27	0.21	<0.001	9.77%	0.69	0.18	<0.001	5.75%

¹ 2,041 unique participants comprising 3,441 participant-waves

² 2,046 unique participants comprising 3,572 participant-waves

³ Bonferroni adjusted alpha critical value cut off: $p < 0.00625$ ⁴ Each line a separate regression model; each model adjusted for district, location, remoteness, school type, and number of students, month of enrollment, age, employment, and ever sexually active

Figure 3.1: Study CONSORT^{1, 2}¹ Designed by Calvin Chiu and Chama Mulubwa²There are fewer enrolled participants at the 6-month follow-up in control schools because implementation of the study was staggered across schools. The decision to increase enrollment occurred prior to the baseline survey round in 15/23 schools but only 9/23 intervention schools, resulting in higher participant recruitment at baseline in more control schools and less need for additional enrolment at the 6-month follow-up.

3.7 Supplementary Materials

Table 3.10: **SRE Individual items and subscale**

Subscale	Question
Comfort talking with partner	1. If I had a romantic partner, I would feel comfortable talking about whether or not I want to have children with them.
	2. If I had a sexual partner, I would feel comfortable telling that person if I wanted to use a method to protect against infection or pregnancy, even when they did not want to.
	3. If I had a romantic partner, I would feel comfortable voicing disagreements with them.
Choice of partners, marriage, and children	4. I can freely choose if I get married.
	5. I can freely choose who I marry.
	6. I have the power to control if and when I have children.
Parental support	7. I have a parent or guardian who would help me with my problems and troubles if I needed.
	8. I have a parent or guardian who accepts me as I am.
	9. I have a parent or guardian who trusts me to make the right decisions.
	10. I have a parent or guardian who helps me achieve my goals in life.
Sexual safety	11. I am able to do the things I want to do without worrying about my safety.
	12. Walking down the street, I feel like my body is my own.
	13. I do not feel afraid that I will be forced to do something sexually when I do not want to
	14. I feel safe in my current living situation.
Self-love	15. I like myself.
	16. I am worthy of love.
	17. I know my body well.
	18. My body belongs to me.
Sense of future	19. I can imagine what my future will be like.
	20. I have an idea of how I can eventually reach my goals.
Sexual pleasure	21. My sexual needs or desires are important.
	22. I think it would be important to focus on my own pleasure as well as my partner's during sexual experiences.
	23. I expect to enjoy sex.

¹ Response options: Not at all true (0), A little true (1), Moderately true (2), Very true (3), Extremely true (4)

Table 3.11: Sociodemographic characteristics of original study recruits at first survey round by missing status, SKILLZ Study in Zambia, 2022

	Complete Case ¹ (n=1,202)	Missing $\leq 25\%$ (n=1,739)	Missing $> 25\%$ (n=178)	Total (n=1,917)
Age, median (IQR)	17.0 (16.0, 18.0)	17.0 (16.0, 18.0)	17.0 (16.0, 18.0)	17.0 (16.0, 18.0)
Marital status				
Unmarried	1,098 (95.6%)	1,566 (95.5%)	149 (98.0%)	1,715 (95.7%)
Married or divorced	51 (4.4%)	74 (4.5%)	3 (2.0%)	77 (4.3%)
Currently does any job or tasks to earn money	311 (25.9%)	440 (25.3%)	46 (26.0%)	486 (25.4%)
Mother's educational attainment				
N/A	21 (1.9%)	33 (2.1%)	3 (2.2%)	36 (2.1%)
Primary or less	499 (45.0%)	707 (45.1%)	68 (50.4%)	775 (45.5%)
Some or complete secondary	361 (32.6%)	513 (32.7%)	39 (28.9%)	552 (32.4%)
Post-secondary	227 (20.5%)	314 (20.0%)	25 (18.5%)	339 (19.9%)
Has access to a functional mobile phone	695 (57.9%)	984 (56.9%)	66 (38.2%) ³	1,050 (55.2%)
Food insecure	374 (31.3%)	523 (30.4%)	56 (32.6%)	579 (30.6%)
Ever had sexual intercourse	297 (24.8%)	391 (22.7%) ²	18 (5.4%) ³	409 (21.6%)
Overall SRE score, median (IQR)	60.0 (51.0, 68.0)	58.0 (49.0, 66.0)	–	58.0 (49.0, 66.0)
Parental support, median (IQR)	12.0 (10.0, 13.0)	12.0 (10.0, 13.0)	–	12.0 (10.0, 13.0)
Comfort talking with partner, median (IQR)	7.0 (4.0, 9.0)	6.0 (3.0, 9.0)	–	6.0 (3.0, 9.0)
Choice of partners, marriage, and children, median (IQR)	9.0 (9.0, 11.0)	9.0 (8.0, 11.0)	–	9.0 (8.0, 11.0)
Sexual safety, median (IQR)	8.0 (5.0, 11.0)	7.0 (4.0, 10.0)	–	7.0 (4.0, 10.0)
Self-love, median (IQR)	12.0 (12.0, 15.0)	12.0 (12.0, 15.0)	–	12.0 (12.0, 15.0)
Sense of future, median (IQR)	6.0 (6.0, 8.0)	6.0 (6.0, 8.0)	–	6.0 (6.0, 8.0)
Sexual pleasure, median (IQR)	6.0 (3.0, 9.0)	5.0 (2.0, 8.0)	–	5.0 (2.0, 8.0)
Arm				
Control	668 (55.6%)	911 (52.4%)	73 (41.0%)	984 (51.3%)
Intervention	534 (44.4%)	828 (47.6%) ²	105 (59.0%) ³	933 (48.7%)
School type				
Co-ed	1,085 (90.3%)	1,576 (90.6%)	160 (89.9%)	1,736 (90.6%)
Girls-only	117 (9.7%)	163 (9.4%)	18 (10.1%)	181 (9.4%)
District				
Chilanga	236 (19.6%)	330 (19.0%)	25 (14.0%)	355 (18.5%)
Chongwe	151 (12.6%)	212 (12.2%)	28 (15.7%)	240 (12.5%)
Kafue	181 (15.1%)	263 (15.1%)	31 (17.4%)	294 (15.3%)
Lusaka	634 (52.7%)	934 (53.7%)	94 (52.8%)	1028 (53.6%)

¹ Among those with 100% completion of SRE; ² Indicates a statistically significant difference compared to the 0% missing sample (n=1202) using a chi-squared test of independence; ³ Indicates a statistically significant difference compared to the $\leq 25\%$ sample (n=1739) using a chi-squared test of independence

Table 3.12: By arm and survey round summary statistics for overall SRE scale and subscales across the three groups of participants per item missingness status, SKILL Study, Zambia, 2022

		Survey round 1		Survey round 2		Survey round 3	
		Intervention	Control	Intervention	Control	Intervention	Control
		Among complete cases (0% missingness) mean (SD)					
Overall SRE score		59.3 (13.0)	59.6 (13.7)	67.2 (13.5)	62.2 (14.0)	67.5 (13.2)	63.2 (14.8)
Subscales							
Parental support		11.3 (3.3)	11.4 (3.2)	12.2 (3.3)	11.6 (3.7)	12.0 (3.4)	11.6 (3.7)
Comfort talking with partner		6.8 (3.5)	6.7 (3.4)	7.9 (3.4)	7.0 (3.8)	8.3 (3.1)	7.4 (3.5)
Choice of partners		9.1 (2.4)	9.1 (2.4)	9.7 (2.3)	9.5 (2.3)	9.7 (2.2)	9.3 (2.6)
Sexual safety		7.7 (3.8)	7.6 (4.1)	9.2 (3.8)	8.0 (4.0)	9.2 (4.1)	8.1 (4.2)
Self-love		12.6 (2.8)	12.8 (2.8)	13.8 (2.5)	13.4 (2.8)	13.8 (2.3)	13.2 (2.8)
Sense of future		6.2 (1.7)	6.4 (1.6)	6.8 (1.4)	6.6 (1.6)	6.8 (1.3)	6.5 (1.6)
Sexual pleasure		5.6 (3.5)	5.6 (3.5)	7.6 (3.3)	6.2 (3.7)	7.8 (3.3)	7.1 (3.5)
		Among those with $\leq 25\%$ missingness, mean (SD)					
Overall SRE score		57.0 (13.3)	58.1 (13.4)	65.0 (13.4)	60.4 (14.0)	66.3 (13.4)	61.7 (14.9)
Subscales							
Parental support		11.3 (3.3)	11.4 (3.2)	12.2 (3.2)	11.7 (3.7)	12.0 (3.5)	11.6 (3.7)
Comfort talking with partner		6.2 (3.7)	6.2 (3.6)	7.3 (3.7)	6.6 (3.8)	7.8 (3.4)	7.0 (3.7)
Choice of partners		8.7 (2.6)	9.0 (2.4)	9.6 (2.3)	9.3 (2.5)	9.8 (2.2)	9.2 (2.7)
Sexual safety		7.2 (3.9)	7.4 (4.0)	8.9 (3.9)	7.6 (4.1)	9.0 (4.2)	7.8 (4.2)
Self-love		12.5 (2.8)	12.7 (2.9)	13.8 (2.5)	13.3 (2.8)	13.8 (2.4)	13.2 (3.0)
Sense of future		6.2 (1.7)	6.4 (1.6)	6.8 (1.4)	6.5 (1.6)	6.8 (1.3)	6.5 (1.6)
Sexual pleasure		4.8 (3.6)	5.0 (3.5)	6.5 (3.7)	5.4 (3.7)	7.1 (3.5)	6.4 (3.7)
		Multiple imputation estimated mean (SE) ¹					
Overall SRE score		59.7 (0.34)	59.4 (0.39)	66.3 (0.36)	61.6 (0.38)	66.6 (0.37)	62.6 (0.43)
Subscales							
Parental support		11.3 (0.10)	11.5 (0.10)	12.1 (0.092)	11.4 (0.11)	11.9 (0.10)	11.5 (0.10)
Comfort talking with partner		7.0 (0.10)	6.5 (0.10)	7.8 (0.10)	7.2 (0.11)	8.0 (0.091)	7.3 (0.11)
Choice of partners,		8.9 (0.067)	9.0 (0.073)	9.6 (0.063)	9.2 (0.072)	9.63 (0.064)	9.2 (0.079)
Sexual safety		8.2 (0.12)	7.7 (0.12)	9.3 (0.11)	8.3 (0.13)	9.3 (0.12)	8.2 (0.13)
Self-love		12.3 (0.071)	12.7 (0.085)	13.6 (0.072)	13.0 (0.088)	13.6 (0.072)	13.1 (0.091)
Sense of future		6.1 (0.050)	6.4 (0.051)	6.7 (0.042)	6.3 (0.051)	6.7 (0.041)	6.5 (0.050)
Sexual pleasure		6.0 (0.11)	5.5 (0.11)	7.2 (0.10)	6.2 (0.11)	7.4 (0.10)	6.8 (0.11)

¹ Using mi estimate; thus SE rather than SD reported

Table 3.13: Sociodemographic characteristics at first survey round among those with missing visits,¹ SKILLZ Study in Zambia, 2022

	Missing midline (n=280)	Missing endline (n=156)	Total ¹ (n=1,917)
Age, median (IQR)	18 (17, 18) ²	17.5 (16.5, 18.5) ²	17.0 (16.0, 18.0)
Marital status			
Unmarried	248 (93.6%)	129 (94.9%)	1,715 (95.7%)
Married or divorced	17 (6.4%)	7 (5.2%)	77 (4.3%)
Currently does any job/tasks to earn money	81 (29.0%)	40 (27.6%)	486 (25.4%)
Mother's educ. attainment			
N/A	5 (2.0%)	3 (2.3%)	36 (2.1%)
Primary or less	118 (47.0%)	66 (50.0%)	775 (45.5%)
Some or complete secondary	84 (33.5%)	35 (26.5%)	552 (32.4%)
Post-secondary	44 (17.5%)	28 (21.2%)	339 (19.9%)
Has access to a functional mobile phone	166 (59.9%)	75 (52.1%)	1050 (55.2%)
Food insecure	104 (38.0) ³	48 (33.8%)	579 (30.6%)
Ever had sexual intercourse	114 (41.8%) ³	47 (32.9%) ³	409 (21.6%)
Overall SRE score, median (IQR)	55.0 (45.5, 65)	53.0 (42.0, 64.0) ²	58.0 (49.0, 66.0)
Parental support, median (IQR)	12.0 (10.0, 13.0) ²	12.0 (10.0, 13.0)	12.0 (10.0, 13.0)
Comfort talking with partner, median (IQR)	7.0 (3.0, 9.0)	6.0 (3.0, 9.0)	6.0 (3.0, 9.0)
Choice of partners, marriage, and children, median (IQR)	9.0 (7.0, 10.0) ²	9.0 (8.0, 10.0)	9.0 (8.0, 11.0)
Sexual safety, median (IQR)	7.0 (4.0, 10.0)	7.5 (4.5, 11.0)	7.0 (4.0, 10.0)
Self-love, median (IQR)	12.0 (12.0, 14.0) ²	12.0 (12.0, 14.5)	12.0 (12.0, 15.0)
Sense of future, median (IQR)	6.0 (6.0, 8.0) ²	6.0 (6.0, 8.0)	6.0 (6.0, 8.0)
Sexual pleasure, median (IQR)	5.0 (3.0, 8.0)	5.0 (3.0, 8.0)	5.0 (2.0, 8.0)
Arm			
Control	177 (63.2%)	65 (41.7%)	984 (51.3%)
Intervention	103 (36.8%) ³	91 (58.3%) ³	933 (48.7%)
School type			
Co-ed	239 (85.4%)	144 (92.3%)	17,36 (90.6%)
Girls-only	41 (14.6%) ³	12 (7.7%)	181 (9.4%)
District			
Chilanga	44 (15.7%)	22 (14.1%)	355 (18.5%)
Chongwe	40 (14.3%)	20 (12.8%)	240 (12.5%)
Kafue	49 (17.5%)	35 (22.4%)	294 (15.3%)
Lusaka	147 (52.5%)	79 (50.6%)	1028 (53.6%)

¹ Of the original recruits

² Indicates a statistically significant difference using a T-test compared to the total sample (n=1917)

³ Indicates a statistically significant difference using a chi-squared test of independence compared to the total sample (n=1917)

Table 3.14: Sociodemographic characteristics of original study recruits at first survey round, SKILLZ Study in Zambia (n=1,917), 2022

	Control (n=984)	Intervention (n=933)	Total (n=1,917)
Age, median (IQR)	17.0 (16.0, 18.0)	17.0 (16.0, 18.0)	17.0 (16.0, 18.0)
Marital status			
Unmarried	897 (95.7%)	818 (95.7%)	1,715 (95.7%)
Married or divorced	40 (4.3%)	37 (4.3%)	77 (4.3%)
Currently does any job/tasks to earn money	288 (29.3%)	198 (21.3%)	486 (25.4%)
Mother's educ. attainment			
N/A	15 (1.7%)	21 (2.6%)	36 (2.1%)
Primary or less	407 (45.8%)	368 (45.2%)	775 (45.5%)
Some or complete secondary	287 (32.3%)	265 (32.6%)	552 (32.4%)
Post-secondary	179 (20.2%)	160 (19.7%)	339 (19.9%)
Has access to a functional mobile phone	567 (57.9%)	483 (52.4%)	1050 (55.2%)
Food insecure	327 (33.5%)	252 (27.5%)	579 (30.6%)
Ever had sexual intercourse	217 (22.4%)	192 (20.8%)	409 (21.6%)
Overall SRE score, median (IQR)	57.0 (47.0, 66.0)	55.0 (45.0, 64.0)	56.0 (46.0, 66.0)
Parental support, median (IQR)			
Comfort talking with partner, median (IQR)	12.0 (10.0, 13.0)	12.0 (10.0, 13.0)	12.0 (10.0, 13.0)
Choice of partners, marriage, and children, median (IQR)	6.0 (3.0, 9.0)	6.0 (3.0, 9.0)	6.0 (3.0, 9.0)
Sexual safety, median (IQR)	9.0 (8.0, 11.0)	9.0 (8.0, 10.0)	9.0 (8.0, 11.0)
Self-love, median (IQR)	7.0 (4.0, 10.0)	7.0 (4.0, 10.0)	7.0 (4.0, 10.0)
Sense of future, median (IQR)	12.0 (12.0, 16.0)	12.0 (12.0, 15.0)	12.0 (12.0, 15.0)
Sexual pleasure, median (IQR)	6.0 (6.0, 8.0)	6.0 (6.0, 8.0)	6.0 (6.0, 8.0)
School type			
Co-ed	834 (84.8%)	902 (96.7%)	1736 (90.6%)
Girls-only	150 (15.2%)	21 (3.32%)	181 (9.44%)
District			
Chilanga	190 (19.3%)	165 (17.7%)	355 (18.5%)
Chongwe	70 (7.1%)	170 (18.2%)	240 (12.5%)
Kafue	234 (23.8%)	60 (6.4%)	294 (15.3%)
Lusaka	490 (49.8%)	538 (57.7%)	1,028 (53.6%)
Phase			
Phase A	984 (100%)	933 (100%)	1,917 (100%)
Phase B	—	—	—
Sessions Attended out of 12, median (IQR)	—	11 (9, 12)	11 (9, 12)
School in Urban Area (out of 46)	10 (43.5%)	12 (52.2%)	22 (47.8%)
Median N of grade 10 students at school	139 (88, 298)	250 (107, 364)	116 (62, 297)
Median distance (km) from dist. education board	9.5 (6, 30.5)	8 (5, 32)	16 (6, 41)

Table 3.15: Difference-in-difference effects of the SKILLZ intervention on SRE overall score and subscales among original baseline recruits, SKILLZ Study in Zambia, 2022

	Midline ¹				Endline ²			
	D-i-D β	SE	p-value ³	% change	D-i-D β	SE	p-value ³	% change
Overall SRE score (Range: 0-92)⁴	6.58	0.74	<0.001	7.15%	5.18	0.68	<0.001	5.63%
Subscales⁴								
Parental support (0-16)	0.66	0.22	0.003	3.88%	0.42	0.2	0.034	2.47%
Comfort talking with partner (0-12)	1.03	0.22	<0.001	7.92%	0.67	0.17	<0.001	5.15%
Choice of partners, marriage, and children (0-12)	0.69	0.14	<0.001	5.31%	0.74	0.16	<0.001	5.69%
Sexual safety (0-16)	1.38	0.23	<0.001	8.12%	1.21	0.27	<0.001	7.12%
Self-love (0-16)	0.86	0.13	<0.001	5.06%	0.89	0.13	<0.001	5.24%
Sense of future (0-8)	0.52	0.094	<0.001	5.78%	0.51	0.079	<0.001	5.67%
Sexual pleasure (0-12)	1.38	0.21	<0.001	10.62%	0.72	0.18	<0.001	5.54%

¹ 1,348 unique participants comprising 2,204 participant-waves

² 1,350 unique participants comprising 2,293 participant-waves

³ Bonferroni adjusted alpha critical value cut off: $p < 0.00625$ ⁴ Each line a separate regression model; each model adjusted for district, location, remoteness, school type, and number of students

Table 3.16: Difference-in-difference effects of the SKILLZ intervention on SRE overall score and subscales among those sexually active at baseline, SKILLZ Study in Zambia, 2022

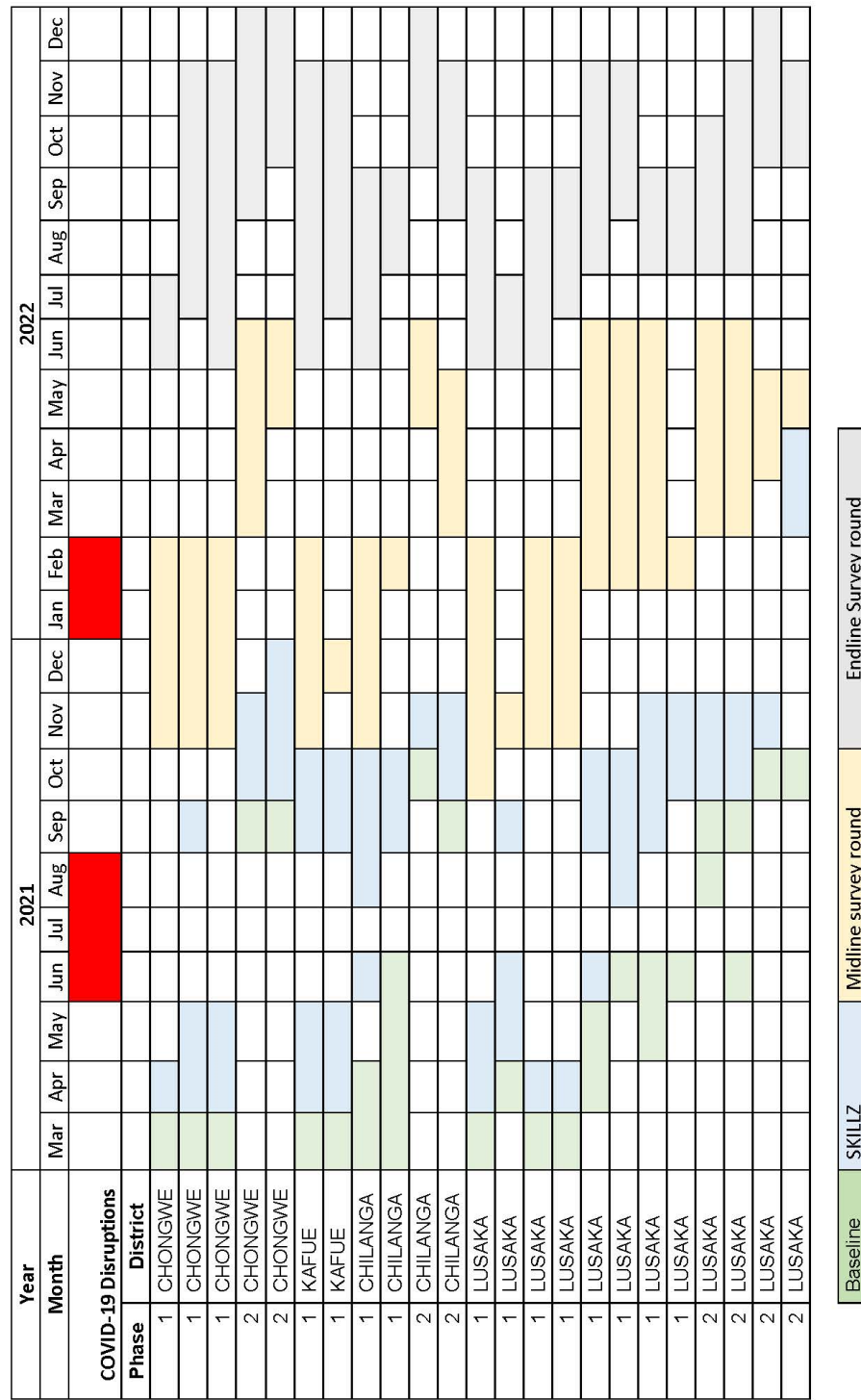
	Midline ¹				Endline ²			
	D-i-D β	SE	p-value ³	% change	D-i-D β	SE	p-value ³	% change
Overall SRE score (Range: 0-92)⁴	7.96	1.72	<0.001	8.65%	3.67	1.53	0.017	3.99%
Subscales⁴								
Parental support (0-16)	1.19	0.583	0.041	7.00%	-0.016	0.47	0.973	-0.09%
Comfort talking with partner (0-12)	0.76	0.43	0.078	5.85%	0.41	0.39	x ⁴	3.15%
Choice of partners, marriage, and children (0-12)	0.66	0.26	0.013	5.08%	0.30	0.23	0.2	2.31%
Sexual safety (0-16)	2.11	0.48	<0.001	12.41%	0.45	0.56	0.42	2.65%
Self-love (0-16)	0.79	0.32	0.014	4.65%	0.99	0.25	<0.001	5.82%
Sense of future (0-8)	0.6	0.22	0.006	6.67%	0.35	0.19	0.069	3.89%
Sexual pleasure (0-12)	1.79	0.45	<0.001	13.77%	1.14	0.36	0.001	8.77%

¹ 399 unique participants comprising 673 participant-waves

² 404 unique participants comprising 734 participant-waves

³ Bonferroni adjusted alpha critical value cut off: $p < 0.00625$ ⁴ Each line a separate regression model; each model adjusted for district, location, remoteness, school type, and number of students

Figure 3.2: Timeline of Data Collection and Implementation of SKILLZ at each school



Appendix 1: Overview of the 12 sessions of SKILLZ workshops

- 1. Join the SKILLZ Girl Team!**
 - a) Team Identity
 - b) Team Contract
- 2. I Matter!**
 - a) I Matter
- 3. Understanding Gender!**
 - a) Defining YOU!
 - b) SKILLZ Soccer
- 4. Me & My Body**
 - a) Me & My Body
 - b) I Am Beautiful!
- 5. Healthy Relationships**
 - a) Healthy & Unhealthy Relationships
 - b) Team Handball
- 6. Healthy Communication**
 - a) Know Your Rights
 - b) SKILLZ to Say 'NO!'
- 7. Avoid Risks!**
 - a) Risk Field
- 8. Winning Combination**
 - a) Winning Combination
- 9. Rights and Responsibilities**
 - a) Advocate for Yourself!
 - b) SKILLZ Soccer
- 10. Build Your Team!**
 - a) Find the Ball

- b) My Supporters

11. Let's Get Tested!

- a) Explain HIV Testing
- b) Healthy Living
- c) Supporting

12. Goal Setting

- a) Goal Setting
- b) Go for Goal

Conclusion

AGYW remain disproportionately affected by HIV and unintended pregnancy in east and southern Africa, which is precipitated by low sexual and reproductive empowerment (SRE), poor reproductive autonomy, and inequitable gender views. This disparity is bolstered by multiple well-documented programming and implementation gaps, including stigma, fear of being perceived as promiscuous or living with HIV, and poor provider treatment. These, in turn, are compounded by general low-awareness and education about HIV preventative and SRH promoting services. Given that adolescence is a crucial period in the life course when substantial gender programming takes place, the development of interventions to promote sexual and reproductive empowerment, and related domains of reproductive autonomy and gender equity, during this developmental period may in turn influence a host of positive downstream sexual health behaviors, including seeking out PrEP.

Chapter 1 evaluates the impact of a school-based digital, SRH intervention program on inequitable gender views and reproductive autonomy among school-age Rwandan AGYW. The study was designed after a formative research phase centering the voices of AGYW and using Human-Centered Design. AGYW from schools assigned to the CyberRwanda facilitated implementation model experienced small improvements in inequitable gender views and reproductive autonomy; no effect was observed among AGYW at CyberRwanda self-service schools. The outcomes evaluated in Chapter 1 are on the causal pathway to the parent study primary outcomes of modern contraception use, delayed initiation of childbearing, and HIV testing uptake. The findings reported in Chapter 1 highlight the complexity in measuring reproductive autonomy among AGYW, while also suggesting that the more complex, facilitated implementation model, with both structured and unstructured access to digital content, as well as in-person, peer-led group activities to promote deeper engagement with the intervention, can move the needle, albeit slightly, on reproductive autonomy and inequitable gender views.

Chapter 2 describes the formative research, subsequent study design, and results of a discrete choice experiment (DCE) and is the first study, to my knowledge, to evaluate preferences for potential implementation models for newer PrEP modalities and their distribution specifically for AGYW. The DCE reveals that AGYW in the high HIV-burdened setting of western Tanzania prefer injectable, low out-of-pocket user cost, and what might be perceived as “girl-

friendly” PrEP whereby PrEP is delivered by young female providers (compared to older providers of any sex). Further, the results highlight low PrEP knowledge, but high levels of interest once informed. While the DCE was a hypothetical exercise with forced choice options (i.e., AGYW were forced to choose between two random options, known as ”alternatives”), 89% of AGYW reported that, if the option they chose was actually available, they would initiate PrEP via this option. While preferences for PrEP among other key populations for HIV prevention are well-studied, this study specifically provides timely evidence regarding desired PrEP implementation models for this key and underreached population for PrEP in Tanzania. Given that this DCE will precede the approval of the two newest forms of PrEP (the vaginal ring and long-acting injectable PrEP), it is possible that, in close collaboration with partners at the Ministry of Health, these findings could be timed to influence actual implementation models for these new methods as they become approved and available in country. Upon availability of these newer PrEP products, future studies can evaluate whether the newer modalities, implemented per the preferences of AGYW outlined in Chapter 3, can effectively close the gap on adherence and continuation of PrEP, and subsequently, HIV acquisition, among AGYW.

Similar to Chapter 1, Chapter 3 evaluates the impact of a peer-led, sports-based program (‘SKILLZ’) for empowering in-school Zambian AGYW. I found that the intervention had small to moderate impacts on SRE, which were magnified among ever sexually active AGYW and those AGYW who attended more than eight of twelve sessions. SRE is on the causal pathway to the parent study primary outcomes of contraceptive uptake and HIV testing. The results show that the intervention was effective at improving sexual and reproductive autonomy, and that this success may have been underpinned by high rates of engagement in the twelve sessions offered. This is in contrast to null findings on the outcomes of HIV and pregnancy incidence as well as HIV testing from the similar CRCT evaluating SKILLZ implementation in schools in South Africa,[232], where just 27.8% of the enrolled AGYW graduated from the program (compared to 89.6% in Zambia). This juxtaposition highlights the importance of both attendance and an understanding of AGYW desires for programming to ensure successful fidelity to the intervention and in turn, measurable impact on the outcomes of interest.

Chapter 1 and 3 demonstrate the impact of school-based sexual health and empowerment interventions for AGYW through two unique means: digital health and sport-based programming. Both interventions focused on AGYW around the average age of sexual debut in SSA (age 16) and had interactive, peer-led components to foster trust, confidentiality, and camaraderie amongst the AGYW. Similarly, measurement of the sexual and reproductive empowerment and reproductive autonomy domains were unique features of these chapters, as each utilized relatively novel measures with their own unique limitations and strengths for this population. These measurement characteristics provide guidance on the relevance of these measures for AGYW in SSA and insights on future directions in their measurement among AGYW.

In conclusion, the three chapters of this dissertation demonstrate that rigorous, high-quality epidemiological research methods combined with youth-involved and centered design methodology can be used to improve upstream determinants of SRH and HIV health, including SRE, autonomy, and inequitable gender views (Chapters 1, 3), as well as understand AGYW preferences around potential HIV prevention programming (Chapter 2). Further, the intervention studies evaluated in Chapters 1 and 3 demonstrate that such youth-designed school-based interventions not only impact upstream determinants of SRH behaviors and outcomes, but do so at a developmentally critical period for gender programming for AGYW, which may have great potential for subsequent health benefits throughout the life course. Finally, the three studies highlight unique and innovative approaches, via digital health (Chapter 1), evaluation of preferences (Chapter 2), and sports (Chapter 3), to quantify both potential PrEP programming as well as multidimensional concepts such as gender equity and reproductive empowerment.

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