



ELSEVIER

---



---

 JOURNAL OF  
 ADOLESCENT  
 HEALTH
 

---



---

www.jahonline.org

Original article

## Reaching Adolescent Girls and Young Women With HIV Self-Testing and Contraception at Girl-Friendly Drug Shops: A Randomized Trial in Tanzania

Lauren A. Hunter, Ph.D.<sup>a,\*</sup>, Aarthi Rao, M.B.A.<sup>b</sup>, Sue Napierala, Ph.D.<sup>c</sup>, Atuganile Kalinjila, B.A.<sup>d</sup>, Agatha Mnyippembe, B.A.<sup>d</sup>, Kassim Hassan, B.A.<sup>d</sup>, Stefano M. Bertozzi, M.D.<sup>a</sup>, Rashid Mfaume, M.D.<sup>e</sup>, Prosper Njau, M.D.<sup>d,f</sup>, Jenny X. Liu, Ph.D.<sup>g,1</sup>, and Sandra I. McCoy, Ph.D.<sup>a,1</sup>

<sup>a</sup> School of Public Health, University of California, Berkeley, Berkeley, California<sup>b</sup> Cityblock Health, Boston, Massachusetts<sup>c</sup> RTI International, Berkeley, California<sup>d</sup> Health for a Prosperous Nation, Dar es Salaam, Tanzania<sup>e</sup> Shinyanga Regional Medical Office, Shinyanga, Tanzania<sup>f</sup> National AIDS Control Program, Ministry of Health, Community Development, Gender, Elderly, and Children, Dar es Salaam, Tanzania<sup>g</sup> Institute for Health and Aging, Bixby Center for Global Reproductive Health, University of California, San Francisco, San Francisco, California

Article history: Received February 3, 2022; Accepted August 17, 2022

Keywords: Adolescent girls and young women; HIV self-testing; Contraception; Drug shops; Human-centered design; Tanzania

---

 A B S T R A C T

**Purpose:** We hypothesized that an intervention designed to create girl-friendly drug shops would increase access to sexual and reproductive health products and services among adolescent girls and young women (AGYW) (ages 15–24 years) in Tanzania.

**Methods:** We conducted a four-month randomized trial at 20 drug shops in Shinyanga, Tanzania from August–December 2019 to determine if the *Malkia Klabu* (“Queen Club”) intervention increased AGYW patronage and the provision of HIV self-testing (HIVST), contraception, and health facility referrals to AGYW (primary outcomes). Drug shops were randomized 1:1 to the intervention or comparison arm. All shops were provided with OraQuick HIVST kits to give to AGYW for free. Intervention shops implemented *Malkia Klabu*, a loyalty program for AGYW created using human-centered design through which AGYW could also access free contraception. We compared outcomes in intention-to-treat analyses using shop observations and shopkeeper records.

**Results:** By endline, shops implementing *Malkia Klabu* had higher AGYW patronage than comparison shops (rate ratio: 4.4; 95% confidence interval: 2.0, 9.8). Intervention shops distributed more HIVST kits (median per shop: 130.5 vs. 58.5,  $P = .02$ ) and contraceptives (325.5 vs. 7.0,  $P < .01$ ) to AGYW and provided more referrals for HIV, family planning, or pregnancy services combined (3.5 vs. 0.5,  $P = .02$ ) than comparison shops.

**Discussion:** The *Malkia Klabu* intervention increased AGYW patronage and the provision of HIVST kits, contraception, and referrals to AGYW at drug shops, despite HIVST kits being freely available at all participating shops. Enhancing drug shops with girl-friendly services may be an effective strategy to reach AGYW with sexual and reproductive health services.

---

 IMPLICATIONS AND CONTRIBUTION

Engaging drug shops in Tanzania to specialize in delivering highly tailored, “girl-friendly” services may be an effective strategy to bolster young women’s access to HIV testing and family planning services.

**Conflicts of interest:** The authors have no conflicts of interest to declare.

**Trials registry:** ClinicalTrials.gov, NCT04045912.

**Data statement:** Deidentified datasets used in analyses and accompanying R script files will be publicly available at the time of publication at the following link: <https://github.com/lauren-hunter/addo>.

\* Address correspondence to: Lauren A. Hunter, University of California, Berkeley School of Public Health, 2121 Berkeley Way #5302, Berkeley, California 94720.

E-mail address: [lahunter@berkeley.edu](mailto:lahunter@berkeley.edu) (L.A. Hunter).

<sup>1</sup> Co-senior authors.

© 2022 Society for Adolescent Health and Medicine. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Adolescent girls and young women (AGYW) (ages 15–24 years) in Tanzania experience barriers to sexual and reproductive health (SRH) services that may compromise their long-term health and wellbeing [1]. Although young women bear a disproportionate burden of HIV infection and unintended pregnancy [2,3], stigma related to young women's sexual behavior, misinformation about contraception, prohibitive transportation costs, long wait times at clinics, and concern about unfriendly health providers may constrain young women's demand for SRH services [1,4,5]. While no government policies directly prohibit the provision of family planning services to adolescents, some healthcare providers may believe minors are ineligible or require parental consent to receive contraception [6–8]. HIV testing is freely available at public health facilities in Tanzania, yet nearly half of HIV-positive young women remain undiagnosed [9]. To accelerate progress toward ending the HIV/AIDS epidemic, Tanzania lowered the age of consent for HIV testing to 15 years and legalized HIV self-testing (HIVST) in 2019 [10]. Evidence from other countries in sub-Saharan Africa demonstrates that HIVST is highly acceptable to youth, who value the increased convenience and confidentiality it affords [11–13], but little is known about how to ensure that young women will be able to access HIVST kits once they are widely available.

Community drug shops may be one effective distribution channel through which to reach young women with SRH services, including HIVST and contraception [14,15]. In Tanzania, privately owned drug shops called Accredited Drug Dispensing Outlets (ADDOs) greatly outnumber health facilities and pharmacies, are ubiquitous in many communities, and enable widespread access to quality assured pharmaceuticals [16–18]. These small businesses, often operated by women, are authorized to dispense certain essential prescription medicines (e.g., common antimicrobials), as defined by a government list [16]. Alongside other medicines and health products, many ADDOs provide SRH products and services such as contraceptives (i.e., condoms, combined oral contraception, levonorgestrel oral emergency contraception), pregnancy tests, informal counseling, and health facility referrals. Notably, although contraceptive services are free at public health facilities, 21% of women in Tanzania obtained their most recent contraceptive method from private sector drug shops [19], and young women were more likely than older women to rely on private sector method providers [20].

For these reasons, expanding and improving the delivery of SRH services offered by drug shops in Tanzania may mitigate some barriers to access among young women. However, demand for SRH services at drug shops among young women may be stymied by fear of discriminatory treatment by shopkeepers, lack of awareness of and/or misconceptions about available SRH products, and pervasive social norms regarding the (in)appropriateness of SRH products for unmarried young women [21,22]. Thus, novel demand-creation strategies may be necessary to amplify young women's access to SRH services at drug shops.

We employed the established, iterative process of human-centered design (HCD) to develop *Malkia Klabu* ("Queen Club"), a comprehensive loyalty program intervention to motivate

young women to obtain HIVST kits and other SRH services at ADDOs while simultaneously meeting the professional and financial needs of drug shopkeepers [21]. To test the feasibility of our intervention as a precursor to a larger trial, we conducted a four-month pilot randomized trial at privately owned drug shops in Tanzania through which we newly introduced HIVST kits in ADDOs. We hypothesized that enhancing drug shops with the *Malkia Klabu* intervention would increase AGYW patronage and the provision and uptake of HIVST kits, contraception, and health facility referrals for AGYW.

## Methods

### Study design and setting

We conducted a parallel arm randomized controlled trial at 20 ADDOs (drug shops) in Shinyanga, Tanzania, a resource-limited, semi-rural region where we introduced OraQuick HIVST kits in ADDOs. OraQuick, the first HIVST kit to be pre-qualified by the World Health Organization, is an oral fluid screening test that displays high accuracy in the hands of lay users [23]. Although HIVST was legalized in Tanzania in 2019, HIVST kits are not yet registered or widely available outside of research settings [10]. In Shinyanga, the HIV prevalence is 5.1% among young women, more than twice the prevalence among young men (2.0%), and 34% of women aged 15–19 years have begun childbearing, underscoring the importance of the proposed research [19,24].

This study was approved by the National Institute of Medical Research in Tanzania and the Human Research Protection Program at the University of California, San Francisco with the University of California, Berkeley Committee for Protection of Human Subjects in reliance. The trial was preregistered (ClinicalTrials.gov: [NCT04045912](https://clinicaltrials.gov/ct2/show/study/NCT04045912)). We report the findings as per the Consolidated Standards of Reporting Trials Statement checklist [25].

### Participants

We randomly selected drug shops from four administrative wards in the Shinyanga Region using a registry of ADDOs provided by the Municipal Pharmacist. The Municipal Pharmacist contacted drug shop owners using phone numbers from the registry and informed them that they would be invited to participate in a study. After this first contact, research staff called shop owners to provide information about the study and, if interested, arrange to meet to obtain informed consent. Owners from all participating drug shops provided written informed consent.

The inclusion criteria for drug shop owners were: (1) at least 18 years of age, (2) owns an ADDO, (3) willing to offer HIVST kits and AGYW-friendly services at their shop, and (4) provides written informed consent for the study. The exclusion criteria were: (1) less than 18 years of age, (2) owns a drug shop that is not government-accredited, (3) unwilling to offer HIVST kits and/

or AGYW-friendly services at their drug shop, and (4) does not provide informed consent. As participating shops were selected from four neighboring wards within a small geographic area, there was a potential overlap in the communities they served. We ceased recruitment upon reaching the desired sample size of 20 drug shops.

### Randomization and blinding

Drug shops were randomly assigned 1:1 to the intervention or comparison arm through a participatory randomization process intended to increase study engagement. Specifically, at an HIVST training which representatives from all shops attended, each shopkeeper drew a colored ball from an opaque bag in front of all attendees to obtain their study arm assignment. Randomization was stratified by administrative ward. Due to the nature of the intervention, it was not feasible to blind participants or researchers implementing the intervention or assessing the outcomes.

### Outcomes

Our study had four primary outcomes:

1. AGYW patronage: The number and proportion of AGYW customers observed by research staff during shop observations.
2. Contraceptive distribution: The number and type of contraceptive products (i.e., condoms, oral contraception, emergency contraception) that shopkeepers reported distributing to AGYW customers during the study period.
3. Health facility referrals: The number of referrals for SRH services (i.e., family planning, prenatal, and HIV testing/treatment services) that shopkeepers reported providing to AGYW customers during the study period.
4. HIVST kit uptake: The number of HIVST kits that shopkeepers reported distributing to AGYW customers during the study period.

In addition, access to pregnancy tests emerged as an important feature of “girl-friendly” drug shops among AGYW during the design process for the intervention. Thus, although not pre-registered, we assessed pregnancy test distribution via shopkeepers’ report as a secondary outcome.

Participants were encouraged to contact the research team if any adverse events occurred. Research assistants also asked about adverse events as part of study close-out procedures.

### Procedures

Upon recruitment, shopkeepers completed surveys about shop operations, their sociodemographic characteristics, and their attitudes toward providing SRH services to young women. For shops where the owner was not involved in day-to-day shop operations, we obtained written informed consent from the shop’s primary employee to complete the survey.

Regardless of study arm, all participating drug shops completed a half-day group training on HIVST, in which local health officials reviewed HIV/AIDS information; explained the purpose of HIVST; led a hands-on demonstration of the OraQuick HIVST kit; and guided shopkeepers through interactive

discussions (e.g., brainstorming ways to prevent social harms among customers), role plays (e.g., pairing up to practice explaining various test results to a customer), and quizzes. Shopkeepers received an HIV referral plan for customers who required linkage to confirmatory testing or treatment. Throughout the four-month intervention period, all shops were freely supplied with OraQuick HIVST kits by the study to provide to AGYW for free and a separate supply of HIVST kits that they could sell to non-AGYW customers (not included in the present analysis) [26]. As distribution was restricted to research settings, OraQuick HIVST kits were only locally available at participating study shops during the study period.

In addition, drug shops assigned to the intervention arm implemented a multifaceted loyalty program, *Malkia Klabu* (“Queen Club”), designed for AGYW using HCD and motivational strategies based on behavioral economics (design process described elsewhere) [21]. In brief, participating intervention shops invited AGYW customers to join the *Malkia Klabu* loyalty program to earn mystery prizes (e.g., lotion, menstrual pads) through repeat purchases. At any time, program members could point at symbols on the back of the loyalty card (Figure A1) to discreetly request free SRH products (i.e., HIVST kits, condoms, oral contraception, emergency contraception, and pregnancy tests) without hassle or fear of denial. Intervention shops were also given an SRH display containing sample products, contraceptive method informational cards, and a computer tablet with SRH videos for interested customers to watch (i.e., a video on how to use the HIVST kit and videos of young Tanzanian women discussing their preferred contraceptive methods). Intervention shopkeepers completed a half-day group training on contraceptive counseling for AGYW facilitated by local health officials, which reviewed modern contraceptive methods and principles of adolescent-friendly service provision. Shopkeepers were reimbursed weekly for contraceptives and pregnancy tests provided to AGYW at prespecified fixed amounts reflective of typical local retail prices (i.e., 1,500 TSh [\$0.65] for three condoms; 2,000 TSh [\$0.86] for oral contraception; 6,000 TSh [\$2.58] for emergency contraception; and 1,000 TSh [\$0.43] for pregnancy tests). Unlike HIVST kits, shops were not directly stocked with these products by the study.

Throughout the study, research staff visited all shops weekly to count and restock HIVST kits (both arms) and *Malkia Klabu* supplies (intervention arm only). Additional visits were conducted whenever shops contacted the research team to request restocking.

We relied upon three sources of data to evaluate the *Malkia Klabu* intervention:

1. Shop observations: Research staff conducted shop observations at baseline (before randomization), midline (after 2–3 months), and endline (after 3–4 months) to assess AGYW patronage in participating drug shops. Each observation period entailed a three-hour continuous time block during which research staff documented all customers entering the shop, including their apparent gender and age and products/referrals received. We randomly sampled five observation day/time blocks (e.g., Wednesday from 10 A.M. to 1 P.M.) per shop per time point, corresponding to up to 15 observations per shop across the study period (Figure A2). The sampling algorithm required that each set of five day/time blocks included at least one weekend, weekday, morning, and afternoon observation to increase comparability between shops. If a shop was closed during a

scheduled observation, the observation was attempted on the same day/time block in the subsequent week(s).

2. Customer logs: Participating shopkeepers were trained to fill standardized customer logs provided by the study that tracked transactions with female customers who appeared to be aged 15–24 years (i.e., AGYW), including provision of HIVST kits; other SRH products (i.e., condoms, oral contraception, emergency contraception, and pregnancy tests); and health facility referrals for HIV, family planning, and/or pregnancy services. Research staff reviewed and collected completed logs during weekly restocking visits.

3. Administrative stocking records: Research staff maintained administrative records of HIVST kits stocked in each shop and counted remaining HIVST kits during weekly restocking visits; these records were used to validate shopkeepers' logs of HIVST kit distribution.

### Statistical analyses

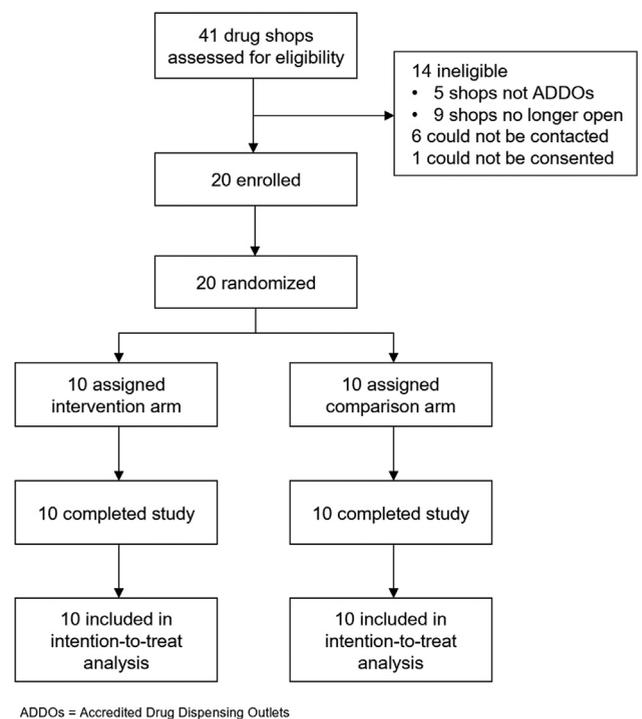
Data from all participating drug shops were included in intention-to-treat analyses. We conducted two types of analyses to estimate the effects of the intervention on the primary and secondary outcomes. First, we used negative binomial regression to estimate rate ratios comparing the rate of AGYW patronage between study arms via a difference-in-differences approach [27]. Models included administrative ward to account for stratified randomization, shops as random effects to account for clustering of observations by shop, and log-duration of observation as an offset term [28]. To assess the robustness of our modeling approach, we also ran alternative models (1) using shop fixed effects in lieu of random effects and (2) using zero-inflated negative binomial regression. Our findings remained consistent and, thus, we present only the first approach.

Second, we compared the mean and median number of HIVST kits, contraceptives, pregnancy tests, and SRH referrals provided over the study period per shop by study arm using *t*-tests and Kruskal–Wallis tests [29]. We also present several post hoc secondary analyses conducted to examine the stability of our findings. Specifically, we reran all analyses of SRH product and referral provision excluding one outlier (an intervention shop that accounted for 51% of SRH products and referrals provided in the intervention arm) and reran analyses of HIVST kit provision using administrative stocking records rather than customer logs. We also calculated descriptive statistics for SRH products and referrals provided to AGYW during post-randomization (midline and endline) shop observations by study arm. While shop observations were not a primary source of data on product/referral provision (due to the low number of SRH-related customer interactions expected to take place during observation windows), these data were used to assess whether trends observed in shopkeeper-reported customer logs are supported by direct observations made by research staff.

Formal power calculations were not performed for this feasibility trial. Analyses were conducted in R, version 4.1.0 [30].

### Results

We randomly selected 41 drug shops, of which 34% were ineligible and 15% could not be contacted (Figure 1). Of the 21 shops that were eligible and could be contacted between July 22 and August 14, 2019, 20 (95%) consented to participate; 10 were



**Figure 1.** Trial profile for the randomized trial evaluating the *Malkia Klabu* intervention.

randomized to each arm. All completed the study through the predetermined date of December 31, 2019 (four months after implementation) and were included in analyses. Shops were 1.4 kilometers apart on average (range: 0.04 kilometers–3.7 kilometers). Three-quarters of participating shopkeepers were female (Table 1). Many shopkeepers (60%) had medical training outside of their role at the shop, primarily in nursing or midwifery, and most participating drug shops (85%) were staffed by only one person. At the time of recruitment, most shops sold condoms (80%) and daily oral contraception (75%) but only 20% of shops sold emergency contraception.

In baseline shop observations conducted before randomization, drug shops averaged one AGYW customer per three-hour observation with no differences in AGYW patronage by study arm (Figure 2, Table 2, Figure A3). At midline, intervention drug shops implementing *Malkia Klabu* had somewhat higher AGYW patronage relative to comparison shops (rate ratio [RR]: 1.47; 95% confidence interval [CI]: 0.65, 3.32). By endline, the rate of AGYW patronage at intervention shops was 4.38 times that of comparison shops (95% CI: 1.96, 9.77). In contrast, trends in patronage by non-AGYW customers over the study period did not differ by study arm (Table 2). Thus, the percentage of AGYW customers in intervention shops increased over the study period (17% at baseline vs. 39% at endline), while the percentage of AGYW customers in comparison shops remained steady (12% at baseline vs. 11% at endline).

Based on shopkeeper-completed customer logs, the 10 intervention shops distributed more HIVST kits (1,456 vs. 596), contraceptives (6,649 vs. 199 products), and pregnancy tests (1,822 vs. 281) and made more referrals for SRH services (661 vs. 67) to AGYW during the study period than the 10 comparison arm shops (Figures A4, A5). The mean and median number of

**Table 1**

Baseline characteristics of 20 shopkeepers and drug shops participating in the randomized trial evaluating the *Malkia Klabu* intervention

	Comparison arm (n = 10)	Intervention arm (n = 10)	Combined arms (n = 20)
Gender, n (%)			
Female	8 (80%)	7 (70%)	15 (75%)
Male	2 (20%)	3 (30%)	5 (25%)
Age (years), mean (SD)	38.7 (15.7)	48.5 (15.3)	43.6 (15.9)
Education, n (%)			
Primary school	2 (20%)	1 (10%)	3 (15%)
Any secondary school	4 (40%)	3 (30%)	7 (35%)
Diploma course	1 (10%)	4 (40%)	5 (25%)
Other certificate	3 (30%)	2 (20%)	5 (25%)
Years worked in a drug shop, mean (SD)	9.0 (6.1)	14.7 (13.6)	11.8 (10.7)
Medical training beyond shop, n (%)			
Doctor	0 (0%)	1 (10%)	1 (5%)
Nurse or professional midwife	4 (40%)	4 (40%)	8 (40%)
Other	2 (20%)	1 (10%)	3 (15%)
None	4 (40%)	4 (40%)	8 (40%)
Owens participating shop, n (%)	4 (40%)	8 (80%)	12 (60%)
Response to: "Unmarried women should be ashamed to ask their provider for contraceptives," n (%)			
Strongly agree or agree	3 (30%)	2 (20%)	5 (25%)
Undecided	1 (10%)	0 (0%)	1 (5%)
Disagree or strongly disagree	6 (60%)	8 (80%)	14 (70%)
Response to: "Unmarried women should not be given contraceptives because they should not be having sex," n (%)			
Strongly agree or agree	2 (20%)	2 (20%)	4 (20%)
Undecided	1 (10%)	1 (10%)	2 (10%)
Disagree or strongly disagree	7 (70%)	7 (70%)	14 (70%)
Location of shop <sup>a</sup> , n (%)			
Ward 1	3 (30%)	3 (30%)	6 (30%)
Ward 2	3 (30%)	3 (30%)	6 (30%)
Ward 3	2 (20%)	2 (20%)	4 (20%)
Ward 4	2 (20%)	2 (20%)	4 (20%)
No. of people who work in shop, n (%)			
1 person	10 (100%)	7 (70%)	17 (85%)
2 people	0 (0%)	2 (20%)	2 (10%)
3 people	0 (0%)	1 (10%)	1 (5%)
Years shop in business <sup>b</sup> , mean (SD)	8.2 (8.1)	9.0 (7.7)	8.6 (7.7)
Shop sells condoms, n (%)	10 (100%)	6 (60%)	16 (80%)
Shop sells oral contraception, n (%)	9 (90%)	6 (60%)	15 (75%)
Shop sells emergency contraception, n (%)	1 (10%)	3 (30%)	4 (20%)
No. of customers last work shift <sup>c</sup> , mean (SD)	27.7 (15.2)	20.0 (11.5)	24.1 (13.8)
No. of AGYW customers last work shift, mean (SD)	7.7 (4.8)	7.5 (7.5)	7.6 (6.1)

AGYW = adolescent girls and young women (ages 15–24 years); No. = number; SD = standard deviation.

<sup>a</sup> Randomization stratified by administrative ward.

<sup>b</sup> Missing: two drug shops in comparison arm.

<sup>c</sup> Missing: one drug shop in intervention arm.

SRH products and referrals provided to AGYW per shop over the four-month study period were higher among intervention shops than comparison shops (Table 3).

Notably, emergency contraception comprised 69% of contraception that shopkeepers reported providing to AGYW in intervention shops, compared to 20% of contraception provided to AGYW by comparison shops. This was partially attributable to one outlying shop, which accounted for 65% of emergency contraception and 55% of all contraception distributed in the intervention arm (Figure A6). Counterintuitively, the increase in

variance caused by this positive outlier reduced the significance of *t*-tests comparing mean contraceptive product distribution by study arm (Table 3). In post hoc secondary analyses excluding this shop, HIVST kit and contraceptive distribution remained higher in the intervention arm, with all mean comparisons reaching statistical significance due to reduced variance (Table A1). However, this shop accounted for 77% of SRH referrals in the intervention arm, and when excluded, differences in SRH referral by study arm were attenuated.

In secondary analyses, differences in HIVST kit distribution were similar when using data from administrative stocking records rather than shopkeepers' logs (Table A2), and during post-randomization shop observations, more contraceptives were provided to AGYW in intervention shops than comparison shops (26 vs. 2), although referrals were similar (4 vs. 3) (Table A3).

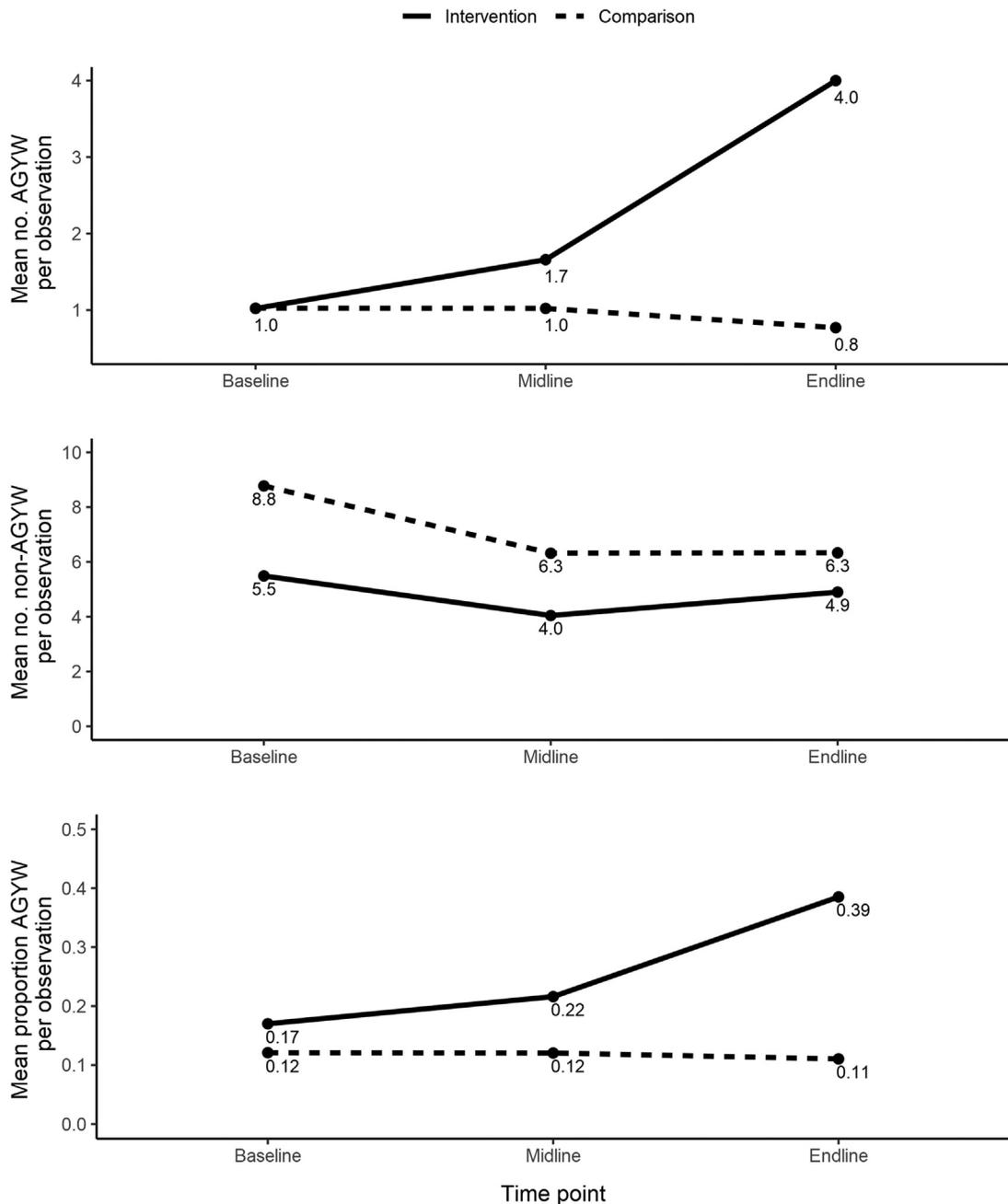
No adverse events were reported over the study period.

## Discussion

The *Malkia Klabu* intervention was associated with increased distribution of HIVST kits, contraceptives, and health facility referrals to young women in drug shops. In the absence of the intervention, comparison shops distributed nearly 600 HIVST kits to young women over the study period, suggesting that free provision of HIVST kits in drug shops may lead to uptake even when young women are not otherwise incentivized to access SRH services. However, drug shops that offered *Malkia Klabu* distributed more than twice as many HIVST kits and 33 times as many contraceptive products as comparison shops during the study, demonstrating the potential value of comprehensive interventions to create girl-friendly drug shop environments.

*Malkia Klabu* drew upon myriad complementary approaches to promote, optimize, and expand the range of SRH products and services available to AGYW. The intervention was designed to act upon both demand-side and supply-side barriers to services (e.g., by normalizing SRH product provision to AGYW among participating shopkeepers). Several intervention components were specific to contraception, such as additional training for shopkeepers on AGYW-friendly contraceptive service provision, free contraceptive products for AGYW club members, nonverbal pathways through which AGYW could discreetly request contraceptive products, and hands-on contraceptive displays with informational videos. However, unlike HIVST kits (which were free in both study arms), it is not possible to disentangle the effect of contraceptive subsidies from the other intervention components. Regardless, the dramatic increase in contraceptive distribution at intervention shops suggests that implementing programs that are tailored to young women in drug shops may be an effective strategy through which to reach them with contraceptive products.

Notably, emergency contraception accounted for most of the contraceptive products distributed to young women at intervention shops. This finding aligns with existing research suggesting that emergency contraception is especially desirable to young women, who may prefer methods that can be used postcoitally or on an as-needed basis [31,32]. The high demand for emergency contraception observed among young women in drug shops may offer the opportunity to build upon these shop interactions by integrating timely HIV-related interventions (e.g., bundling emergency contraception with condoms, postexposure prophylaxis, and/or an HIVST kit). Fostering trusted relationships between young women and shopkeepers may also pave the way



**Figure 2.** Patronage of adolescent girls and young women (AGYW) compared to other customers (non-AGYW) at 20 drug shops, assessed via multiple three-hour shop observations per shop, by time point and study arm.

for shopkeepers to link AGYW to more proactive methods for HIV and pregnancy prevention, such as pre-exposure prophylaxis and an expanded selection of contraceptive options, including long-acting reversible contraception.

When designing *Malkia Klabu*, we sought to move beyond surface-level service availability to understand and address the complex structural and sociocultural factors that interact to determine young women's engagement with health services. There has been increasing interest by the global health community in applying HCD to solve public health challenges, including SRH challenges faced by young women in

sub-Saharan Africa. Despite HCD's growing use as a tool for global health [33], few HCD-derived programs have been formally evaluated, a gap we sought to address through the present study. This study's rigor is bolstered by the random selection of drug shops from a government registry, high participation rates among contacted shops, randomization of shops into study arms, and no loss to follow-up among participating shops. Although only shops that were willing to offer AGYW-friendly services were eligible to participate, all but one shop that met the other eligibility criteria and could be contacted enrolled in the study, limiting potential bias due to

**Table 2**

Patronage of adolescent girls and young women compared to other customers at 20 drug shops during three-hour shop observations by time point and study arm

	Baseline	Midline	Endline	Midline/endline combined
Total no. of observations (range per shop)				
Comparison arm	40 (2–5)	44 (3–5)	48 (4–5)	92 (8–10)
Intervention arm	45 (3–5)	47 (4–5)	49 (4–5)	96 (9–10)
Mean no. of AGYW per observation (SD)				
Comparison arm	1.03 (1.14)	1.02 (1.27)	0.77 (1.22)	0.89 (1.24)
Intervention arm	1.02 (1.22)	1.66 (2.87)	4.00 (5.24)	2.85 (4.39)
Mean no. of non-AGYW per observation (SD)				
Comparison arm	8.78 (8.00)	6.32 (4.71)	6.33 (5.77)	6.33 (5.26)
Intervention arm	5.49 (3.50)	4.04 (3.50)	4.90 (3.86)	4.48 (3.69)
Mean proportion AGYW per observation <sup>a</sup> (SD)				
Comparison arm	0.12 (0.13)	0.12 (0.12)	0.11 (0.21)	0.12 (0.17)
Intervention arm	0.17 (0.19)	0.22 (0.28)	0.39 (0.31)	0.31 (0.31)
RR (95% CI) <sup>b</sup> : No. of AGYW				
Comparison arm	Reference	Reference	Reference	Reference
Intervention arm	1.03 (0.50, 2.13)	1.47 (0.65, 3.32)	4.38 (1.96, 9.77)	2.81 (1.34, 5.91)
RR (95% CI) <sup>b</sup> : No. of non-AGYW				
Comparison arm	Reference	Reference	Reference	Reference
Intervention arm	0.74 (0.47, 1.15)	0.99 (0.70, 1.41)	1.09 (0.77, 1.53)	1.04 (0.77, 1.41)

AGYW = adolescent girls and young women (ages 15–24 years); CI = confidence interval; No. = number; RR = rate ratio; SD = standard deviation.

<sup>a</sup> Number of AGYW customers ÷ total number of customers, excluding 12 observations with zero customers.<sup>b</sup> Estimated via difference-in-differences approach using negative binomial regression models adjusted for ward with random effects for shops and log-duration of observation as an offset term.

self-selection. In combination, these strengths increase the likelihood that the drug shops included in each study arm are representative of drug shops within the targeted communities. In addition, HIVST kits were free to AGYW in both study arms, allowing for direct comparison of HIVST kit distribution between study arms. Finally, data on AGYW patronage were collected via repeated, systematic observations by research staff at randomly determined times, reducing information bias.

One potential limitation of the study is our reliance on visual assessment of customer age by both research staff conducting shop observations and shopkeepers completing customer logs. As the study was designed to reduce hassle and stigma experienced by AGYW at drug shops, this approach was chosen to avoid potentially intrusive questioning of AGYW customers. However, this increases the potential for misclassification of AGYW customers. The use of shopkeeper-completed customer logs to assess the distribution of HIVST kits, other SRH products, and health facility referrals raises other limitations. Shopkeepers' record-keeping is of uncertain and likely variable quality, and because shopkeepers were not blinded, measurement error may be differential by study arm. For example, shopkeepers in the intervention arm, who received more products and reimbursements via the study, may have been more motivated to record product distribution and referrals to AGYW, biasing the results in favor of the intervention. However, because research staff provided all participating shops with HIVST kits, we were able to triangulate research staff's own administrative records on HIVST kits stocked at shops during weekly stocking visits with shopkeepers' customer logs to evaluate the degree to which their record-keeping aligned with our own; we found high concordance. Nevertheless, our reliance on shopkeeper customer logs to measure other SRH product distribution and referrals remains a limitation. We did not collect data on customers' use of HIVST or contraception after leaving the shop or their uptake of shopkeeper referrals for confirmatory HIV testing or other facility based services. Thus, we cannot ascertain the effect of the intervention on HIV diagnoses or other downstream SRH outcomes among AGYW.

To contextualize the findings of this trial, we conducted a mixed-method evaluation to better understand various stakeholders' experiences with the intervention. Through in-depth interviews with AGYW customers, shopkeepers, and HIV referral counselors, we found high acceptability of HIVST provision at drug shops and evidence that multiple intervention features drawn from behavioral economics worked in concert to motivate AGYW and shopkeepers' engagement with *Malkia Klabu* [34,35]. Future studies are needed to evaluate the performance of this intervention in other settings and to develop strategies to efficiently tailor the intervention to local contexts during broader implementation. This pilot trial included only 10 intervention shops, all located within the specific context in which the intervention was designed. The small size of this study made it possible to provide shops with extensive support while they implemented the multifaceted intervention components. However, we noted significant heterogeneity in intervention shops' performance, with several shops standing out as high and low responders. While we can qualitatively describe preliminary characteristics associated with performance level in this limited sample (e.g., a high-performing shop was located near a secondary school and had an enthusiastic shopkeeper), a larger-scale implementation is necessary to quantitatively evaluate which factors are most predictive of performance.

Although this pilot provides strong preliminary evidence of the *Malkia Klabu* intervention's feasibility and acceptability, additional research is needed to understand its adaptability, scalability, and downstream impacts. Accordingly, our next step is to conduct a five-year cluster randomized trial and mixed-method implementation science study among drug shops in two regions of Tanzania (NCT05357144). Through this larger-scale implementation, we will evaluate *Malkia Klabu's* effects on the number of HIV diagnoses and antenatal care registrations (i.e., as a proxy for pregnancies) among AGYW at the population level, link these outcomes to demand-side pathways leading to impact (e.g., recent HIV testing, met need for contraception), and identify supply-side factors influencing effectiveness (e.g., shop implementation models). In parallel, we will explore strategies

**Table 3**

Number of sexual and reproductive health products and health facility referrals provided to adolescent girls and young women during the four-month study period by study arm

	Comparison arm shops (n = 10)	Intervention arm shops (n = 10)	P value*
HIV self-test kits			
Total	596	1,456	
Mean per shop (SD)	59.6 (30.4)	145.6 (107.6)	.03
Median per shop (Q1, Q3)	58.5 (43.8, 70.0)	130.5 (97.0, 166.3)	.02
Condoms			
Total	123	1,289	
Mean per shop (SD)	12.3 (25.8)	128.9 (142.7)	.03
Median per shop (Q1, Q3)	1.0 (0.0, 7.8)	92.5 (58.3, 111.8)	<.01
Daily oral contraception			
Total	36	773	
Mean per shop (SD)	3.6 (5.3)	77.3 (60.5)	<.01
Median per shop (Q1, Q3)	1.0 (0.3, 5.5)	74.0 (31.0, 128.8)	<.01
Emergency contraception			
Total	40	4,587	
Mean per shop (SD)	4.0 (4.9)	458.7 (904.4)	.15
Median per shop (Q1, Q3)	2.0 (0.0, 6.5)	148.5 (72.0, 332.3)	<.01
Contraception (all)			
Total	199	6,649	
Mean per shop (SD)	19.9 (27.4)	664.9 (1,073.5)	.09
Median per shop (Q1, Q3)	7.0 (1.0, 33.0)	325.5 (210.5, 539.0)	<.01
Pregnancy tests			
Total	281	1,822	
Mean per shop (SD)	28.1 (29.0)	182.2 (236.0)	.07
Median per shop (Q1, Q3)	16.5 (5.8, 43.0)	136.0 (87.8, 164.3)	<.01
HIV referrals			
Total	2	82	
Mean per shop (SD)	0.2 (0.4)	8.2 (20.0)	.24
Median per shop (Q1, Q3)	0 (0.0, 0.0)	0 (0.0, 3.5)	.19
Family planning referrals			
Total	49	495	
Mean per shop (SD)	4.9 (15.1)	49.5 (120.0)	.27
Median per shop (Q1, Q3)	0.0 (0.0, 0.0)	2.0 (0.3, 19.3)	.03
Pregnancy referrals			
Total	16	84	
Mean per shop (SD)	1.6 (4.0)	8.4 (17.8)	.27
Median per shop (Q1, Q3)	0.0 (0.0, 1.0)	1.0 (0.3, 3.3)	.14
Referrals (all)			
Total	67	661	
Mean per shop (SD)	6.7 (19.1)	66.1 (157.5)	.27
Median per shop (Q1, Q3)	0.5 (0.0, 1.8)	3.5 (1.0, 23.8)	.02

Q1 = first quartile; Q3 = third quartile; SD = standard deviation.

\* P value for comparison of means by Welch's two-sample *t*-test, for comparison of medians Kruskal–Wallis rank-sum test.

for sustainability as scaling *Malkia Klabu* will likely require streamlining the intervention to the core components most critical for its success and identifying the minimum levels of support and product subsidies necessary for shops to effectively implement and sustain it.

### Acknowledgments

This work was supported by the National Institute of Mental Health [Liu/McCoy R34MH116804]. The authors gratefully

acknowledge Ms. Moza Chitela, Dr. Nancy Padian, Dr. Ntuli Kapologwe, Dr. Elizabeth Shekalaghe, Dr. Angela Ramadhani, Dr. Betty Shayo, Mr. Godfrey Ngonela, the Shinyanga Regional Health Management Team, the Pharmacy Council of Tanzania, and Population Services International for their contributions to this study. This study was presented at the International AIDS Conference (AIDS 2020).

### Supplementary Data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jadohealth.2022.08.013>.

### Funding source

The funder had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

### References

- [1] World Health Organization (WHO) Regional Office for Africa. Report of an adolescent health services barriers assessment (AHSBA) in the United Republic of Tanzania: With a Focus on Disadvantaged Adolescents. Brazzaville, Republic of the Congo: WHO Regional Office for Africa. 2019. <https://apps.who.int/iris/bitstream/handle/10665/324924/9789290234302-eng.pdf>. Accessed October 30, 2020.
- [2] Fleischman J, Peck K. Addressing HIV risk in adolescent girls and young women. Washington DC, USA: Center for Strategic and International Studies (CSIS). 2015. <https://iogt.org/wp-content/uploads/2015/03/Addressing-HIV-Risk-in-Adolescent-Girls-and-Young-Women-CSIS-Report.pdf>. Accessed October 30, 2020.
- [3] Hubacher D, Mavranzouli I, McGinn E. Unintended pregnancy in sub-Saharan Africa: Magnitude of the problem and potential role of contraceptive implants to alleviate it. *Contraception* 2008;78:73–8.
- [4] Nyblade L, Stockton M, Nyato D, Wamoyi J. Perceived, anticipated and experienced stigma: Exploring manifestations and implications for young people's sexual and reproductive health and access to care in North-Western Tanzania. *Cult Health Sex* 2017;19:1092–107.
- [5] Tumlinson K, Okigbo CC, Speizer IS. Provider barriers to family planning access in urban Kenya. *Contraception* 2015;92:143–51.
- [6] Mwakawanga DL, Mkonyi E, Mushy SE, et al. Would you offer contraception to a 14-year-old girl? Perspectives of health students and professionals in Dar es Salaam, Tanzania. *Reprod Health* 2021;18:245.
- [7] Bylund S, Målvist M, Peter N, Herzog van Wees S. Negotiating social norms, the legacy of vertical health initiatives and contradicting health policies: A qualitative study of health professionals' perceptions and attitudes of providing adolescent sexual and reproductive health care in Arusha and Kilimanjaro region, Tanzania. *Glob Health Action* 2020;13:1775992.
- [8] Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC). National Adolescent Health and Development Strategy 2018–2022. Dar Es Salaam, Tanzania: MoHCDGEC; 2018.
- [9] Tanzania Commission for AIDS (TACAIDS), Zanzibar AIDS Commission (ZAC). Tanzania HIV Impact Survey (THIS) 2016–2017: Final Report. Dar es Salaam, Tanzania: TACAIDS and ZAC. 2018. [https://phia.icap.columbia.edu/wp-content/uploads/2019/06/FINAL\\_THIS-2016-2017\\_Final-Report\\_\\_06.21.19\\_for-web\\_TS.pdf](https://phia.icap.columbia.edu/wp-content/uploads/2019/06/FINAL_THIS-2016-2017_Final-Report__06.21.19_for-web_TS.pdf). Accessed October 30, 2020.
- [10] UNAIDS. United Republic of Tanzania lowers age of consent for HIV testing. 2019. <https://www.unaids.org/en/resources/presscentre/featurestories/2019/november/united-republic-of-tanzania-lowers-age-of-consent-for-hiv-testing>. Accessed October 30, 2020.
- [11] Indravudh PP, Sibanda EL, d'Elbée M, et al. 'I will choose when to test, where I want to test': Investigating young people's preferences for HIV self-testing in Malawi and Zimbabwe. *AIDS* 2017;31:S203.
- [12] Pettifor A, Lippman SA, Kimaru L, et al. HIV self-testing among young women in rural South Africa: A randomized controlled trial comparing clinic-based HIV testing to the choice of either clinic testing or HIV self-testing with secondary distribution to peers and partners. *EclinicalMedicine* 2020;21.
- [13] Njau B, Covin C, Lisasi E, et al. A systematic review of qualitative evidence on factors enabling and deterring uptake of HIV self-testing in Africa. *BMC Public Health* 2019;19:1289.
- [14] Liu J, Prach LM, Treleaven E, et al. The role of drug vendors in improving basic health-care services in Nigeria. *Bull World Health Organ* 2016;94:267–75.

- [15] Sudhinaraset M, Ingram M, Lofthouse HK, Montagu D. What is the role of informal healthcare providers in developing countries? A systematic review. *PLoS ONE* 2013;8:e54978.
- [16] Embrey M, Vialle-Valentin C, Dillip A, et al. Understanding the role of accredited drug dispensing Outlets in Tanzania's health system. *PLoS ONE* 2016;11:e0164332.
- [17] Rutta E, Liana J, Embrey M, et al. Accrediting retail drug shops to strengthen Tanzania's public health system: An ADDO case study. *J Pharm Policy Pract* 2015;8:23.
- [18] Tanzania Food and Drugs Authority (TFDA). Improving access to essential medicines in Tanzania: Role of the ADDO program. Dar es Salaam, Tanzania: TFDA. 2015. <https://www.pc.go.tz/files/The%20ADDO%20Program%20%20Story-%20Feb%202015.pdf>. Accessed October 30, 2020.
- [19] Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) [Tanzania Mainland], Ministry of Health (MoH) [Zanzibar], National Bureau of Statistics (NBS), Office of the Chief Government Statistician (OCGS), ICF International. Tanzania Demographic and Health Survey and Malaria Indicator Survey (TDHS-MIS) 2015–16. Dar es Salaam, Tanzania, and Rockville, Maryland, USA: MoHCDGEC, MoH, NBS, OCGS, and ICF. 2016. <https://dhsprogram.com/pubs/pdf/fr321/fr321.pdf>. Accessed October 30, 2020.
- [20] Dennis ML, Radovich E, Wong KLM, et al. Pathways to increased coverage: An analysis of time trends in contraceptive need and use among adolescents and young women in Kenya, Rwanda, Tanzania, and Uganda. *Reprod Health* 2017;14:130.
- [21] Hunter LA, McCoy SI, Rao A, et al. Designing drug shops for young women in Tanzania: Applying human-centred design to facilitate access to HIV self-testing and contraception. *Health Policy Plan* 2021;czab084.
- [22] Sieverding M, Schatzkin E, Shen J, Liu J. Bias in contraceptive provision to young women among private health care providers in South west Nigeria. *Int Perspect Sex Reprod Health* 2018;44:19–29.
- [23] World Health Organization (WHO). Guidelines on HIV self-testing and partner notification: Supplement to consolidated guidelines on HIV testing services. Geneva, Switzerland: WHO. 2016. <https://apps.who.int/iris/bitstream/handle/10665/251655/9789241549868-eng.pdf?sequence=1>. Accessed October 30, 2020.
- [24] Tanzania Commission for AIDS (TACAIDS), Zanzibar AIDS Commission (ZAC), National Bureau of Statistics (NBS), Office of the Chief Government Statistician (OCGS), and ICF International. Tanzania HIV/AIDS and Malaria Indicator Survey 2011–12. Dar es Salaam, Tanzania: TACAIDS, ZAC, NBS, OCGS, and ICF. 2013. <https://dhsprogram.com/pubs/pdf/ais11/ais11.pdf>. Accessed October 30, 2020.
- [25] Moher D, Schulz KF, Altman DG. The CONSORT statement: Revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001;357:1191–4.
- [26] Chiu C, Hunter LA, McCoy SI, et al. Sales and pricing decisions for HIV self-test kits among local drug shops in Tanzania: A prospective cohort study. *BMC Health Serv Res* 2021;21:434.
- [27] Wing C, Simon K, Bello-Gomez RA. Designing difference in difference studies: Best practices for public health policy research. *Annu Rev Public Health* 2018;39:453–69.
- [28] Diez-Roux AV. Multilevel analysis in public health research. *Annu Rev Public Health* 2000;21:171–92.
- [29] Kruskal WH, Wallis WA. Use of ranks in one-Criterion variance analysis. *J Am Stat Assoc* 1952;47:583–621.
- [30] R Core Team. R: A Language and environment for statistical computing. 2021. <https://www.R-project.org/>. Accessed October 30, 2020.
- [31] Both R. Emergency contraceptive use in Addis Ababa, Ethiopia: Challenging common assumptions about young people's contraceptive practices. *Reprod Health Matters* 2015;23:58–67.
- [32] Rokicki S, Merten S. The context of emergency contraception use among young unmarried women in Accra, Ghana: A qualitative study. *Reprod Health* 2018;15:212.
- [33] Bazzano AN, Martin J, Hicks E, et al. Human-centered design in global health: A scoping review of applications and contexts. *PLOS ONE* 2017;12:e0186744.
- [34] Liu J, Chiu C, Hunter L, et al. Designing an effective intervention to increase uptake of HIV and pregnancy prevention services at drug shops in Tanzania: Integrating behavioral economics and human-centered design to motivate behavior change. *Virtual: 2021 International Health Economics Association (iHEA) World Congress*; 2021.
- [35] Cabrera A, Willard-Grace R, Bykhovsky C, et al. Stakeholder experiences of an intervention for provision of HIV self-testing kits and contraception to adolescent girls and young women in privately-owned drug shops in sub-Saharan Africa. In: *IAS 2021 Abstract Book*. International AIDS Society; 2021.