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ConceptPrEP-on-Demand: Digital, on-Demand HIV Prevention and Contraceptive Delivery Intervention for Adolescent Girls and Young Women in Southwestern Kenya

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ABSTRACT

Background: Adolescent girls and young women (AGYW) in sub-Saharan Africa experience high rates of HIV infection and unintended pregnancy, yet continuation of pre-exposure prophylaxis (PrEP) and non-barrier contraception remains suboptimal. Digital health interventions (DHIs) offer promise for improving access and autonomy, but their effectiveness in sustaining prevention behaviours remains not well established.

Objectives: To evaluate the acceptability, feasibility, and 6-month continuation of PrEP and non-barrier contraceptive use among AGYW using ConceptPrEP-on-demand, a digital, on-demand HIV prevention and contraceptive delivery intervention, compared with standard facility-based care.

Methods: We conducted a prospective quasi-experimental pilot study between February and December 2023 among 205 AGYW aged 16 to 24 years in Kisumu County, Kenya, at two health facilities providing primary-level sexual and reproductive health services. Participants self-selected into the digital intervention or the standard-of-care arm in a non-randomised 1:1 allocation (104 digital; 101 standard). The digital platform provided tele-counselling, online ordering of SRH commodities, and discreet delivery. The standard-of-care arm received clinic-based PrEP according to the Kenya national guidelines. Structured surveys were administered at baseline, 3 months, and 6 months post-enrolment via REDCap. Primary outcomes were continuation of PrEP and non-barrier contraceptive methods at 3 and 6 months. Secondary outcomes included intervention acceptability and predictors of continuation. Data were analysed using descriptive statistics and multivariable Poisson regression with generalised estimating equations (GEE) using an exchangeable working correlation structure and robust standard errors. Analyses were performed in Stata 18.1, with statistical significance set at $P<.05$.

Results: Among 205 participants (104 digital, 101 standard), PrEP continuation at 6 months was lower in the digital arm (34.4%) compared with the standard-of-care arm (72.0%) ($P<.001$). Contraceptive continuation also declined in the digital arm (84.5% vs. 94.7%, $P=.036$). Multivariable analysis showed that participants in the standard arm were 31% more likely to continue PrEP (adjusted IRR,1.31; 95% CI, 1.05 to1.63). Acceptability of the digital intervention was high, with 85.1% expressing interest in future use.

Conclusion: These hypothesis-generating findings suggest that digital, on-demand platforms in this context may require accountability mechanisms and adaptive support to sustain prevention behaviours. Future adequately powered randomized trials are needed to confirm these signals.

BACKGROUND

Adolescent girls and young women (AGYW) in sub-Saharan Africa face significant drop-off in continuation of HIV pre-exposure prophylaxis (PrEP) and contraceptive use. Despite high needs, AGYW comprise less than 10% of the population but account for approximately 20% of new HIV infections[1] and face a high risk of unintended pregnancy.[2] Unfortunately, many do not continue with these prevention methods.[3,4] Oral PrEP is highly effective when taken consistently, yet low persistence and poor adherence have limited its impact on reducing HIV incidence among young women.[5] Similarly, adolescent contraceptive users have the highest discontinuation rates of any age group, even though they still wish to avoid pregnancy.[6]

In Kenya, the adolescent contraceptive discontinuation rate is approximately 35%,[2] with side effects being the leading cause of discontinuation.[4] Globally, about 41% of people stop PrEP within 6 months of initiation. Discontinuation of PrEP is even more common (around 72% at six months) among predominantly heterosexual populations that include young women.[7]

Digital health interventions (DHIs) that enable people to direct and support their own sexual and reproductive health (SRH) and HIV care and prevention, with or without a provider, as part of "self-care" are supported and promoted by the World Health Organization (WHO).[8,9] Digitally enabled self-care has the potential to improve the user experience by providing more convenient, more informative, and more cost-effective services.[10] DHIs have also been found to be feasible and acceptable to youth, including sexual and gender minority youth.[11,12] However, many digital services for AGYW remain siloed, disease-specific, tailored to adult women, and limited to education and referral.[13] Observational studies suggest that combining digital health communication with online product ordering can improve contraceptive continuation,[14] and a UK trial of digital STI testing services doubled testing uptake in the intervention group.[15]

Despite this promise, evidence on whether DHIs sustain complex preventive behaviours such as PrEP and contraceptive continuation among AGYW in low- and middle-income settings remains limited.[16,17] The WHO Global Strategy on Digital Health calls for more contextualised evidence on what works, for whom, and under what conditions.[18] *ConceptPrEP-on-demand* was developed to address this evidence gap. The intervention, co-designed with AGYW, healthcare providers, and male partners in western Kenya through a human-centred design (HCD) process, combines digital counselling, online ordering, and discreet delivery of HIV prevention and contraceptive commodities. The detailed qualitative and co-design findings from the formative HCD phase are available separately and are currently under review for publication. The primary aim of this pilot study was to evaluate the acceptability, feasibility, and 6-month continuation of PrEP and non-barrier contraceptive use among AGYW using *ConceptPrEP-on-demand* compared with standard facility-based care. The secondary aim was to identify socio-demographic, behavioural, and clinical predictors of continuation, and to assess participant acceptability of individual platform components.

METHODS

Study Design and Period

We conducted a prospective quasi-experimental pilot study to evaluate the feasibility, acceptability, and preliminary outcomes of *ConceptPrEP-on-demand* , a digital, on-demand HIV and contraceptive delivery intervention, compared with standard facility-based care in southwestern Kenya. Enrollment ran from 13 February 2023 to 08 May 2023, with the last 6-month follow-up visit completed on 31 December 2023.

Intervention Development

The intervention was grounded in the Unified Theory of Acceptance and Use of Technology (UTAUT),[19] which views user behaviour as shaped by performance expectancy, effort expectancy, social influence, and facilitating conditions. UTAUT was selected because it provides a useful framework for understanding uptake and engagement with digital health technologies, particularly where perceived usefulness, ease of use, and enabling conditions may influence utilisation of digital sexual and reproductive health services among AGYW. *ConceptPrEP-on-demand* was designed using HCD methods and the British Design Council's Double Diamond model.[20,21] Formative qualitative work included 20 in-depth interviews with AGYW, 10 in-depth interviews with healthcare workers, and two focus group discussions with male partners. Insights from this phase informed content design, delivery preferences, product bundling, and communication strategies; full qualitative findings are reported separately.

The resulting intervention offered a digitally enabled, user-centred service package. Participants could access text-based counselling through WhatsApp or SMS from trained clinicians, allowing flexible and confidential engagement. The platform also enabled online ordering of a bundled range of SRH commodities, including oral PrEP, emergency contraception, self-injectable medroxyprogesterone, pregnancy and HIV self-testing kits, condoms, and STI treatment. All products were delivered discreetly in a user-customised kit to a safe and confidential pickup location. In alignment with national guidelines, participants were required to attend a single clinic visit for provider-led PrEP initiation to ensure appropriate clinical oversight. Participants in the standard-of-care arm received clinic-based PrEP services in accordance with Kenya's national guidelines, including in-person nurse-led counselling, HIV testing, risk assessment, and quarterly clinic visits for medication refills and adherence monitoring.[22]

Study Setting

The study was conducted in Kisumu County, Kenya, at two health facilities (one urban and one peri-urban) that provide primary-level SRH services. The site was selected because of: existing cohorts of HIV-negative adolescents using STI services; clinical research centres with established programmes and trained staff; and a documented high burden of STIs, HIV, and unintended pregnancy among AGYW in this region.[2,23,24]

Sample Size

Sample size estimation was based on the primary outcome of PrEP persistence at 6 months. Using findings from the KEN SHE study, which reported a 35% persistence rate in the standard-of-care arm and is consistent with regional estimates, we powered the study to detect an absolute 15-percentage-point increase in PrEP persistence associated with the *ConceptPrEP-on-demand* intervention. Assuming a two-sided alpha of 0.05, 80% power, and a standard deviation of 10%, a total sample size of 200 participants was considered sufficient to detect this difference.

Study Population, Inclusion and Exclusion Criteria

We enrolled 205 AGYW aged 16 to 24 years, sampling purposively. The AGYW who had participated in the formative HCD phase were excluded from the pilot to support generalisability. Only one participant was enrolled per site per day to avoid clustering effects, as young women often present for PrEP and other SRH services in groups. Inclusion criteria were: (1) aged 16 to 24 years (2) willing and able to provide informed consent or assent (3) willing to undergo HIV testing (4) reported sexual activity within the past 3 months (5) interest in taking PrEP (actual PrEP uptake was not required) (6) residence in the Kisumu region and (7) ownership of a

mobile phone. We excluded AGYW with a confirmed HIV diagnosis at enrolment.

Allocation

After eligibility confirmation and a standardised briefing on both arms, participants self-selected into the *ConceptPrEP-on-demand* digital arm or the clinic-based standard-of-care arm. Allocation was therefore non-randomised; the resulting distribution was 104 (50.7%) in the digital arm and 101 (49.3%) in the standard-of-care arm. We did not stratify, match, or use propensity scoring at enrolment, but assessed baseline balance post hoc.

Procedures and Data Collection

Trained research staff administered structured surveys at baseline, 3 months, and 6 months via REDCap, capturing socio-demographics, sexual behaviour, partner characteristics, PrEP and contraceptive use, depressive symptoms (using the Patient Health Questionnaire–2 items on anhedonia and low mood), and intervention acceptability (System Usability Scale).[25] Additional clinical and pharmacy data on PrEP refills, HIV-status, contraceptive use, and pregnancy outcomes were abstracted from existing electronic records, including data captured through the *ConceptPrEP-on-demand* platform. HIV testing was performed at enrolment and at each follow-up visit using the national rapid test algorithm (Determine HIV-1/2, then First Response HIV 1-2.O if positive, with confirmatory testing according to the Kenya MoH guidelines). Participants who tested positive were referred to ART services as per national protocols. Engagement with the ConceptPrEP-on-demand platform was characterized using back-end records of tele-counseling consultations and app-based product orders for the digital-model users registered during the study period. Product orders include all commodity bundles requested through the platform (PrEP refills, self-injectable medroxyprogesterone, condoms, and pregnancy and HIV self-test kits). Tele-counselling consultations include all chat-based engagements initiated by participants with the study nurse.

Outcome Definitions

Primary outcomes were continuation of PrEP and non-barrier contraceptive use at 3 and 6 months. PrEP continuation was defined as self-reported use within the 30 days prior to the survey visit, corroborated where available by pharmacy refill data from the platform and from clinic records. Contraceptive continuation was defined as self-reported use of any non-barrier method within the same 30-day window. Participants with confirmed discontinuation, missed visits without reported use, or those lost to follow-up at the relevant time-point were classified as non-continuers.

Statistical Analysis

Categorical variables were summarised as numbers (percentages) and compared across study arms using Pearson's chi-square or Fisher's exact test, as appropriate. Continuous variables were summarised as mean (standard deviation) or median (interquartile range, IQR) and compared using the Student's *t*-test or Mann–Whitney U test.

We used univariable and multivariable Poisson regression with a log link to identify correlates of PrEP and contraceptive continuation. To account for within-participant repeated measures at 3 and 6 months, models were fitted using generalised estimating equations (GEE) with an exchangeable working correlation structure and robust (sandwich) standard errors. Variables with a univariable P value≤.05 together with variables selected a priori based on theoretical and clinical relevance (including study arm), were considered for inclusion in the multivariable model. Prior studies have shown that depressive symptoms (anhedonia and low mood, from the PHQ-2) may reduce motivation, self-efficacy, and adherence to preventive health interventions, thereby potentially influencing continuation outcomes.[26,27] Therefore, multivariable models were retained based on both theoretical reasoning and observed associations in the bivariable analysis.

For the PrEP continuation model, candidate variables included study arm, age group, marital status, residence setting, travel time to clinic, employment status, living arrangement, depressive symptoms, partner HIV status knowledge, receipt of gifts or money, PrEP disclosure, condom use frequency, study participation disclosure, perceptions regarding PrEP protection, and concerns about PrEP side effects. For the contraceptive continuation model, candidate variables included study arm, age, marital status, residence setting, travel time to clinic, living arrangement, depressive symptoms, condom use, PrEP disclosure, concurrent sexual partnership, perceptions regarding PrEP safety, concerns about PrEP side effects, and social disclosure variables. A complete list of candidate variables tested and retained in each model.

Two-way interaction terms were tested in each model. For PrEP continuation we tested the interactions of study arm by marital status, study arm by condom use, and study arm by partner HIV status knowledge. For contraceptive continuation we tested the interactions of study arm by marital status, study arm by consistent condom use, and study arm by depressive symptoms. None of the interaction terms reached statistical significance and none were retained. A backward elimination procedure was applied to refine the final models, retaining variables most strongly associated with the outcome. Statistical significance was defined as P<.05 and 95% confidence intervals are provided throughout. Multivariable analyses produced adjusted IRRs (aIRRs) with 95% confidence intervals. Standardised mean differences (SMD) were computed to complement P-value-based comparisons of baseline characteristics in the full sample and to assess whether differential attrition shifted baseline balance in the Month 6 completer subset. An absolute SMD above 0.10 was considered to indicate meaningful between-arm imbalance independent of sample size. All analyses were performed in Stata version 18.1 (StataCorp LLC, College Station, Texas, USA).[28]

Ethical Considerations

All participants provided written informed consent prior to enrolment. For participants aged 16 to 17 years, additional parental or caregiver consent was obtained alongside the adolescent's assent, in accordance with ethical standards for involving minors in research. The study protocol received ethical approval from the

Scientific and Ethics Review Unit (SERU) of the Kenya Medical Research Institute (KEMRI) (KEMRI/SERU/CMR/P00175/4328).

RESULTS

Baseline Characteristics

The study enrolled 205 participants, with 104 (50.7%) in the digital arm and 101 (49.3%) in the standard-of-care arm (Table 1). The median age was 21 years (IQR: 20 to 23), with no significant difference between arms. Most participants were single without a steady partner (62.9%), with similar distribution across arms. Over half lived in urban areas (54.2%), and around one-third in semi-urban settings. Travel time to the clinic differed statistically significantly between arms (P=.013), with more participants in the digital arm reaching the clinic in under 30 minutes. Occupational status was comparable across arms (39.2% students, 28.4% employed, 32.4% unemployed). While between-arm P values were non-significant for most characteristics, standardised mean differences identified imbalance (absolute SMD above 0.10) on six variables: age, marital status, residence setting, travel time to clinic, occupation, and living arrangement (Table 1).

TABLE 1: Baseline Socio-demographic Characteristics of the Study Population (N=205)

Variables	Study Arm Digital Arm	Standard of Care	Total	*P Value*	SMD
Total	104 (50.7%)	101 (49.3%)	205 (100%)		
Age in years	22 (20-23)	21 (20-23)	21 (20-23)	.133	0.210
What is your marital status					0.229
Single with no steady partner	66 (63.5%)	63 (62.4%)	129 (62.9%)	.261	
Single with a steady partner	35 (33.7%)	30 (29.7%)	65 (31.7%)		
Married or once married	3 (2.9%)	8 (7.9%)	11 (5.4%)		
Do you live in a rural, semi-urban, or urban setting?					0.177
Rural	14 (13.7%)	13 (12.9%)	27 (13.3%)	.453	
Semi-urban	29 (28.4%)	37 (36.6%)	66 (32.5%)		
Urban	59 (57.8%)	51 (50.5%)	110 (54.2%)		
How long did it take you to get to the clinic today?					0.421
< 30 minutes	59 (56.7%)	43 (42.6%)	102 (49.8%)	.013	
30-60 minutes	38 (36.5%)	56 (55.4%)	94 (45.9%)		
>60 minutes	7 (6.7%)	2 (2.0%)	9 (4.4%)		
What is your job/occupation					0.196
Student	39 (37.5%)	41 (41.0%)	80 (39.2%)	.379	
Employed	34 (32.7%)	24 (24.0%)	58 (28.4%)		
Unemployed	31 (29.8%)	35 (35.0%)	66 (32.4%)		
With whom do you live with					0.252
Parents	55 (52.9%)	56 (55.4%)	111 (54.1%)	.361	
Other family members	23 (22.1%)	28 (27.7%)	51 (24.9%)		
Male partner	22 (21.2%)	16 (15.8%)	38 (18.5%)		
Other	4 (3.8%)	1 (1.0%)	5 (2.4%)		

Abbreviation key: SMD, standardised mean difference.
Notes: *P* values continuous variables. from Pearson chi-square or Fisher exact test for categorical variables and from Student t-test or Mann-Whitney U test for Standardised mean differences for each baseline variable, in both the full sample and the Month 6 completer subset

Baseline Sexual Behaviour

Sexual behaviour and disclosure patterns were broadly similar across study arms (Table 2). Participants reported a median of two current sexual partners and similar frequency of intercourse with main and casual partners. Most (74.8%) did not know their partners' HIV status. Condom use varied: 42.9% reported no use with main partners, 28.0% occasional use, and 29.2% consistent use; condom use with casual partners was 25.4%. Approximately 42.4% reported having exchanged sex for money, goods, or services in the past 6 months. One-third (34.1%) reported that their partner held more sexual relationship power. A pregnancy history was reported by 36.1% of participants, and 36.6% disclosed PrEP use to someone.

PrEP and Contraceptive Continuation

At 3 months, PrEP continuation was higher in the standard-of-care arm than in the digital arm (71% vs. 58%; P=.050; Table 3, Figure 1). By 6 months, the difference had widened: 72% in the standard arm versus 34% in the digital arm continued PrEP (P<.001). In contrast, at 3 months, contraceptive continuation did not differ between arms. However, by 6 months contraceptive continuation was statistically significantly higher in the standard arm (95% vs. 85%; P=.036).

Overall retention at Month 6 was 171 of 205 enrolled participants (83%), with differential attrition by arm: 75 of 101 standard-arm participants (74%) and 96 of 104 digital-arm participants (92%) completed Month 6

assessment (Table 3). In the Month 6 completer subset, the baseline imbalance pattern was largely preserved and was further amplified for marital status, occupation, and living arrangement.

Multivariable Analysis: Factors Associated with PrEP Continuation

In the adjusted GEE model (Table 4), participants in the standard-of-care arm were 31% more likely to continue PrEP than those in the digital arm (aIRR,1.31; 95% CI, 1.05 to1.63; *P*=.015). Married or previously married participants had a 41% higher likelihood of continuing PrEP than those who were single with no steady partner (aIRR,1.41; 95% CI, 1.12 to 1.78; *P*=.003). Participants who were unsure of their partner's HIV status had a 62% higher likelihood of continuing PrEP (aIRR,1.62; 95% CI, 1.27 to 2.08; *P*=.001).

In the adjusted GEE model for contraceptive continuation (Table 5), married or previously married participants were more likely to continue contraceptives than those single with no steady partner (aIRR,1.10; 95% CI, 1.03 to 1.17; *P*=.005). Participants who reported consistent condom use had a 13% reduced likelihood of continuing non-barrier contraceptives (aIRR, 0.87; 95% CI, 0.77 to 0.99; *P*=.034). Those reporting some days of anhedonia (PHQ-2 item) had a small increase in contraceptive continuation (aIRR,1.08; 95% CI, 1.02 to1.15; *P*=.005). Participants whose travel time to clinic was 30 to 60 minutes were more likely to continue contraceptives than those with shorter travel time (aIRR, 1.09, 95% CI: 1.01 to 1.17; *P*=.021). There was no significant difference between digital and standard arms in adjusted contraceptive continuation (aIRR,1.04; 95% CI, 0.97 to 1.11; *P*=.249).

Among the 104 digital-arm participants, the intervention demonstrated high acceptability across components. A majority (61.0%) used the intervention on three or more occasions, and 66.0% had used it again since their last recorded episode. Clinic initiation (99.0%), meeting with a digital provider (98.9%), HIV self-testing (99.0%), pregnancy testing (98.9%), partner STI treatment (96.8%), and clinic-based follow-up for complications (97.9%) were each rated as acceptable or very acceptable by almost all users. Self-injection of medroxyprogesterone had somewhat lower acceptability, with 22.3% rating it as neutral, unacceptable, or very unacceptable; nonetheless, 84.0% rated it acceptable or very acceptable. When asked about future use, 85.1% expressed interest in accessing the intervention outside the study. Among digital-arm participants, 55.3% reported that this model would make them more likely to remain on PrEP than standard in-clinic services, while 36.2% felt less likely (Figure 2).

Platform Engagement Among Digital-arm Participants

Among the 184 digital-model users registered on the ConceptPrEP-on-demand platform during the study period, 12 (6.5%) ever initiated a tele-counselling consultation with a study nurse, and 94 (51.1%) ever placed a product order through the platform. The remaining 90 users (48.9%) had no recorded platform activity beyond initial registration. Among the 94 active orderers, the median order count was 3 (IQR 2 to 7). Platform-level ordering activity peaked at 102 orders in June 2023 and declined steeply thereafter, with 268 orders placed between May and July 2023, 151 between August and October, and only 7 from November 2023 onwards.

TABLE 2: Baseline Sexual Behavioural Characteristics of the Study Population (N=171)

Variables	Study arm Digital Arm n (%)	Standard of Care n (%)	Total n (%)	*P Value*
Total	104 (50.7%)	101 (49.3%)	205 (100.0%)	
How many sexual partners do you have currently?	2 (2-3)	2 (1-3)	2 (2-3)	.891
Frequency or sexual intercourse with main partner	2 (1-3)	2 (1-3)	2 (1-3)	.421
Frequency or sexual intercourse with casual partner	1 (0-2)	1 (0-2)	1 (0-2)	.771
To your knowledge, do any of your sexual partners have HIV?				
No	31 (30.1%)	20 (20.2%)	51 (25.2%)	.106
Don't know	72 (69.9%)	79 (79.8%)	151 (74.8%)	
How many times was a condom used with main partner				
Not at all	30 (37.5%)	39 (48.1%)	69 (42.9%)	.327
Sometimes	23 (28.7%)	22 (27.2%)	45 (28.0%)	
All the time	27 (33.8%)	20 (24.7%)	47 (29.2%)	
How many times was a condom used with casual partner				
No	77 (74.0%)	76 (75.2%)	153 (74.6%)	.842
Yes	27 (26.0%)	25 (24.8%)	52 (25.4%)	
Sex in exchange for money, goods and services in the past 6 months				
No	61 (58.7%)	57 (56.4%)	118 (57.6%)	.748
Yes	43 (41.3%)	44 (43.6%)	87 (42.4%)	
Partner has more sexual relationship power				
No	71 (68.3%)	64 (63.4%)	135 (65.9%)	.459
Yes	33 (31.7%)	37 (36.6%)	70 (34.1%)	

Continue

TABLE 2: Continued

Variables	Study arm Digital Arm n (%)	Standard of Care n (%)	Total n (%)	*P Value*
Ever been pregnant				
No	64 (61.5%)	67 (66.3%)	131 (63.9%)	.475
Yes	40 (38.5%)	34 (33.7%)	74 (36.1%)	
Does anyone know you will be (are) taking PrEP				
Yes	33 (31.7%)	42 (41.6%)	75 (36.6%)	.143
No	71 (68.3%)	59 (58.4%)	130 (63.4%)	
Does anyone know about your participation in the study				
Yes	68 (65.4%)	67 (66.3%)	135 (65.9%)	.886
No	36 (34.6%)	34 (33.7%)	70 (34.1%)	

TABLE 3: Proportion of Participants Continuing on PrEP and Contraception at Month 3 and Month 6 by the Study Group

		Month 3 Standard	Digital	*P Value*	Total	Month 6 Standard	Digital	*P Value**
Continue on PrEP at Month				.050				<.001
No	36% (72)	29% (29)	43% (43)		49% (84)	28% (21)	66% (63)	
Yes	64% (128)	71% (70)	58% (57)		51% (87)	72% (54)	34% (33)	
Total	n=200	n=99	n=101		n=171	n=75	n=96	
Continue on Contraceptive				.617				.036
No	8% (16)	7% (7)	9% (9)		11% (19)	5% (4)	15% (15)	
Yes	92% (183)	93% (92)	91% (91)		89% (153)	95% (71)	85% (82)	
Total	n=199	n=99	n=100		n=172	n=75	n=97	

Note: The Month 6 PrEP analysis denominator (n=171) and the Month 6 contraceptive analysis denominator (n=172) differ by a single digital-arm participant who had contraceptive data at Month 6 but not PrEP data.
*Chi-square test of independence or Fisher's exact test *P* values

TABLE 4: Multivariable Analysis of Factors Associated with PrEP Continuation

	aIRR	95% CI	*P Value*
Which arm of the study has the participant chosen?			
Digital Arm	1.00		
Standard of Care	**1.31**	**[1.05, 1.63]**	**.015**
Marital status			
Single with no steady partner	1.00		
Single with a steady partner	0.93	[0.72, 1.19]	.538
Married or once married	**1.41**	**[1.12, 1.78]**	**.003**
To your knowledge, do any of your sexual partners have HIV?			
No	1.00		
Don't know	**1.62**	**[1.27, 2.08]**	**.001**
How many times was a condom used?			
Not at all	1.00		
Sometimes	0.91	[0.74, 1.14]	.422
All the time	0.71	[0.49, 1.03]	.072

Abbreviation: aIRR, Adjusted Incidence Rate Ratio
Bold aIRR and *P* values indicate statistical significance at $P<.05$.

TABLE 5: Multivariable Analysis of Factors Associated with Contraceptive Continuation

	aIRR)	95% CI	*P Value*
Which arm of the study has the participant chosen?			
Digital Arm	1.00		
Standard of Care	1.04	[0.97, 1.11]	.249
Marital status			
Single with no steady partner	1.00		
Single with a steady partner	1.03	[0.95, 1.12]	.465
Married or once married	**1.10**	**[1.03, 1.17]**	**.005**
Safe sex (consistent condom use with both main and casual partners)			
No	1.00		
Yes	**0.87**	**[0.77, 0.99]**	**.034**
Little interest or pleasure in doing things?			
Not at all	1.00		
Several days	**1.08**	**[1.02, 1.15]**	**.005**
More than half the days	0.73	[0.43, 1.27]	.266
Nearly every day	0.91	[0.70, 1.17]	.462
How long did it take you to get to the clinic today?			
<30 minutes	1.00		
30-60 minutes	**1.09**	**[1.01, 1.17]**	**.021**
>60 minutes	1.01	[0.79, 1.28]	.960

Abbreviation key: aIRR, adjusted incident rate ratio.
Bold aIRR and P values indicate statistical significance at $P<.05$.

FIGURE 1: PrEP and Contraceptive Continuation at 3 and 6 Months by Study Arm

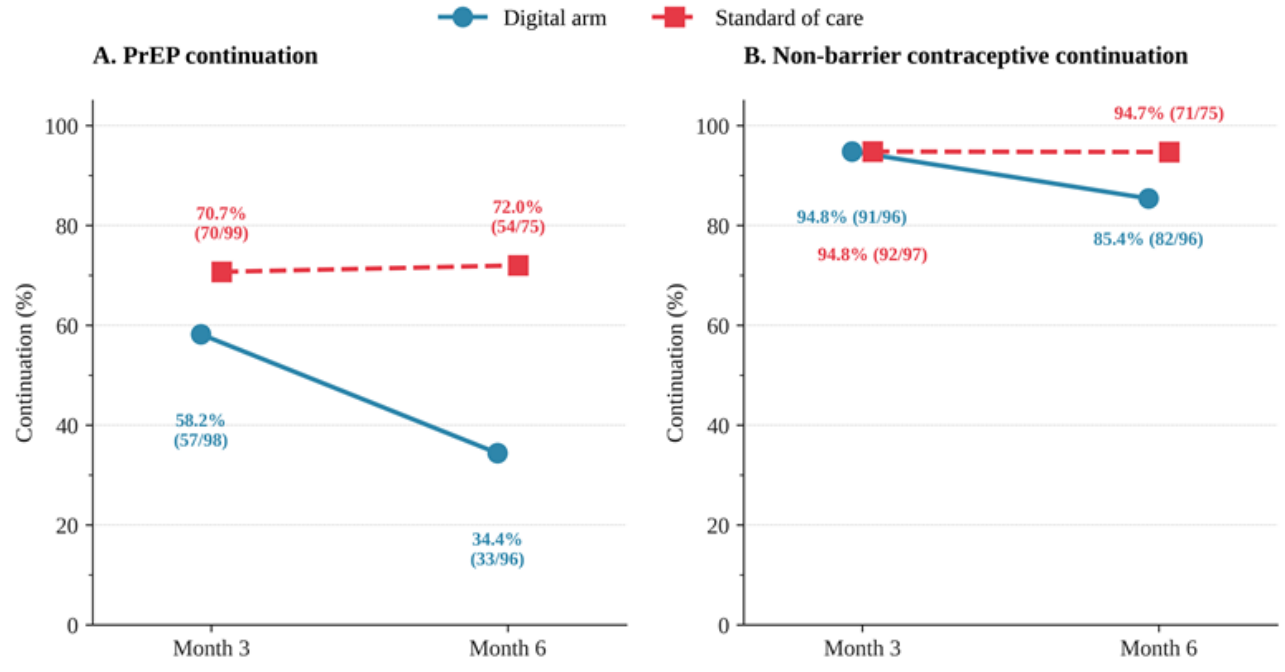
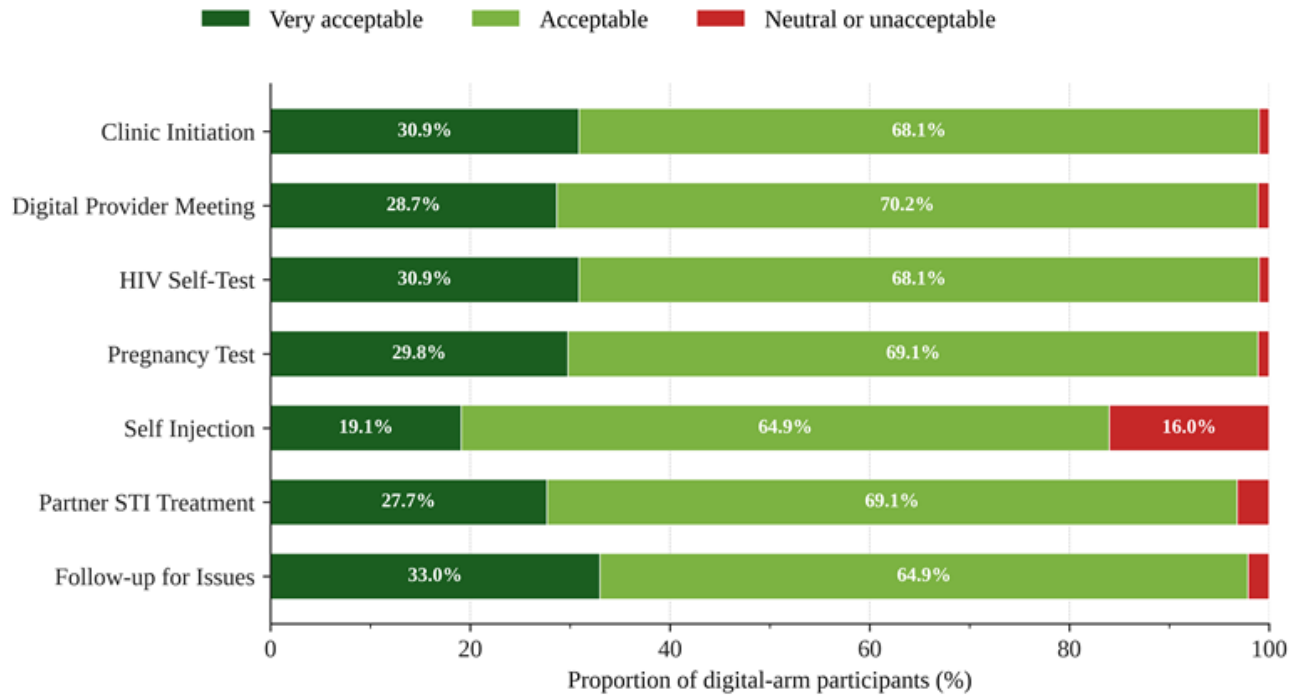


FIGURE 2: Acceptability of the ConceptPrEP-on-demand Digital Intervention



DISCUSSION

This study evaluated the continuation of PrEP and contraception among AGYW in a pilot digital health intervention, *ConceptPrEP-on-demand* , compared with standard facility-based care. Although the intervention showed high acceptability and increased service utilization, it did not effectively sustain continued use, especially for PrEP, when compared with standard care. The decline in platform ordering after the fifth month of follow-up parallels the steep drop in PrEP continuation between Month 3 and Month 6 in the digital arm shown in Table 3. These patterns indicate that while the platform provided transactional access to the product, it lacked ongoing behavioral support. These findings reflect a well-documented gap in DHIs for AGYW, in which favorable attitudes at a moment in time do not consistently translate into sustained use, since acceptability instruments do not capture the social, structural, and motivational pressures that govern ongoing engagement.[1,29]

Despite the intervention's design around accessibility, AGYW in the digital arm disengaged at higher rates over time. By month 6, continuation of PrEP in the digital arm was markedly lower compared with the standard of care while contraceptive continuation also declined. Several factors in the literature may explain this. The AGYW value interpersonal support, whether from peer mentors or trusted providers, to reinforce adherence and provide emotional or motivational counselling. Digital-only platforms may fail to replicate these elements of trust, encouragement, empathy, personalised problem-solving and accountability that a trained counsellor or supportive clinician can provide. Research exploring attitudes towards effectiveness of digital interventions shows that there is a genuine concern about a lack of accountability in digital interventions which can lead to low motivation and dropout.[30,31] The limited personal connection inherent in most digital health tools can hinder the building of supportive relationships with health care providers that encourage ongoing use.[31,32] In a Kenyan randomised controlled trial, for instance, daily SMS adherence reminders (the MPYA study) proved ineffective at improving PrEP adherence among young women, in the context of overall low pill-taking behaviour.[33] In contrast, a randomised controlled trial in Rwanda found that a purely digital sexual health platform modestly increased contraceptive use, but outcomes improved statistically significantly when the platform was paired with in-person peer support sessions.[34] These findings suggest that simple DHIs alone may not overcome deeper issues of motivation, communication and understanding.[35-37]

Emerging literature posits that AGYW at risk of HIV or unintended pregnancy, and who may benefit from PrEP or contraception, often require differentiated support pathways rather than a uniform, one-size-fits-all approach. In our study, the lack of a dynamic triage system within the digital platform likely limited its ability to adapt to varying user needs. While the intervention offered real-

time telehealth consultation, it did not incorporate risk scoring or behavioural triggers to differentiate support, such as flagging disengagement or hesitancy for escalation to more personalised follow-up. Programmes such as the PrEP SMART study in South Africa have explored the effectiveness of multi-component, stepped adherence support, in which non-responders to digital nudges (SMS or WhatsApp) are escalated to counselling and mentor-led interventions.[26,38,39] Such designs acknowledge that some AGYW may need personal coaching in addition to technology-based support. The absence of such adaptive functionality in our platform may help explain why certain services, such as self-injection, which requires a higher degree of behavioural agency, saw lower continuation.

Our intervention was grounded in the UTAUT, which informed the focus on performance expectancy, effort expectancy, and facilitating conditions.[19] However, our findings suggest that UTAUT alone may be insufficient to explain long-term behavioural persistence. Beyond digital delivery-specific limitations, AGYW face a range of behavioural and structural barriers that drive PrEP and contraceptive discontinuation, even when interventions are in place.[40] These include stigma and restrictive social norms, lack of partner or family support, perceived low risk of HIV or pregnancy, concerns about side effects, the burden or inconvenience of methods, and systemic access barriers such as cost, distance to clinics, and negative provider attitudes.[1,4,40] Evidence from HIV treatment and care programmes suggests that differentiated, tailored models, responsive to behavioural, motivational, and structural contexts, are critical to sustained engagement with prevention services among AGYW in sub-Saharan Africa.[41,42] This has led to growing support for a prevention-effective adherence framework, which aligns PrEP use with periods of actual risk and recognises alternative prevention strategies as valid, adaptive choices.[43,44]

A behavioral economics perspective complements these frameworks and can help explain the observed persistence gap. The intention-action gap, in which positive intentions to practice health-protective behaviors don't always translate into ongoing action, aligns with our data: acceptability scores reflect intentions, while continuation measures actual behavior.[45] Present bias, the tendency to prioritize immediate costs, such as pill burden, side effects, and stigma, over distant benefits, and decision fatigue, the gradual depletion of self-control from repeated daily choices, are both amplified in digital self-care models that rely on the user, rather than a clinician, to anchor future benefits at each decision point.[46,47] Therefore, upcoming digital interventions for AGYW might benefit from incorporating explicit nudges, default options, or commitment devices to lessen the need for sustained self-motivation.

Strengths and limitations of the Study

This study offers several methodological strengths. It employed a quasi-experimental design with real-world implementation in a high-priority population of AGYW in Kisumu, Kenya, enhancing both internal and contextual validity.[48] The co-creation of the digital intervention using HCD and the Double Diamond model ensured cultural and contextual relevance,[21,49] and the inclusion of both digital and standard-of-care arms allowed for meaningful comparative analysis. However, the study has some limitations. The main limitation is the lack of random allocation: participants self-selected their preferred follow-up modality thus introducing potential selection bias. Standardized mean differences revealed baseline imbalance between arms which was present even in the Month 6 completer subset, indicating that differential attrition did not correct for these baseline differences. It is plausible that the differential attrition between arms (24% standard versus 8% digital at Month 6) likely inflated the apparent advantage of standard care if those retained were preferentially the most motivated subset. Prevention motivation and self-efficacy were not systematically measured, limiting our ability to formally evaluate potential selection bias. As a result, the differences observed between groups should be considered exploratory associations rather than definitive evidence of the intervention's effectiveness.

The lack of qualitative follow-up limited our insights into why participants stopped engaging or disengaged digitally. Future studies should explore why AGYW disconnect from digital prevention tools despite finding them acceptable, focusing on factors such as perceived accountability, trust, privacy concerns, changing HIV risk perceptions, digital fatigue, and unmet support needs. Additionally, the single geographic region, relatively small sample, and the six-month follow-up period may limit the generalisability and the ability to assess long-term outcomes such as pregnancy or HIV seroconversion.

A formal economic evaluation of the intervention was not conducted. ConceptPrEP-on-demand may be more resource-intensive than SMS-only digital prevention interventions, because it incorporates tele-counselling, commodity bundling, and direct-to-user delivery. Future implementation and scale-up work should include costing and cost-effectiveness analyses, and consider how the digital and delivery infrastructure can be embedded within existing health systems to support scalability. Lastly, the intervention's reliance on a digital platform may also have excluded AGYW without consistent phone access, which could further limit the external validity of the findings to AGYW with stable digital access.

CONCLUSION

In this quasi-experimental pilot study, ConceptPrEP-on-demand was highly acceptable but PrEP continuation was lower in the digital arm than in standard care. Because of the non-randomised design, these findings are hypothesis-generating and should not be read as definitive comparative effectiveness. Our work is consistent with the possibility that, without integrated accountability and adaptive support, digital engagement alone may not be enough to sustain preventive behaviours and that these interventions work best as part of a broader support system rather than an independent alternative. Ultimately, reversing the attrition trend among AGYW will demand not only technological solutions but also community, health system, and policy-level changes that empower young women to continue protecting their health over the long term. For Ministries of Health and implementation partners across sub-Saharan Africa, these findings argue against deploying digital HIV prevention

platforms for AGYW as stand-alone replacements for facility-based services. National HIV prevention strategies and differentiated service delivery frameworks should clearly define how digital tools and clinic-based services are integrated, include accountability measures within digital systems, identify and address disengagement, and monitor retention and enrollment as part of routine program oversight. Further randomised and mixed-methods studies are needed to better understand which components of digital prevention interventions support long-term engagement.

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