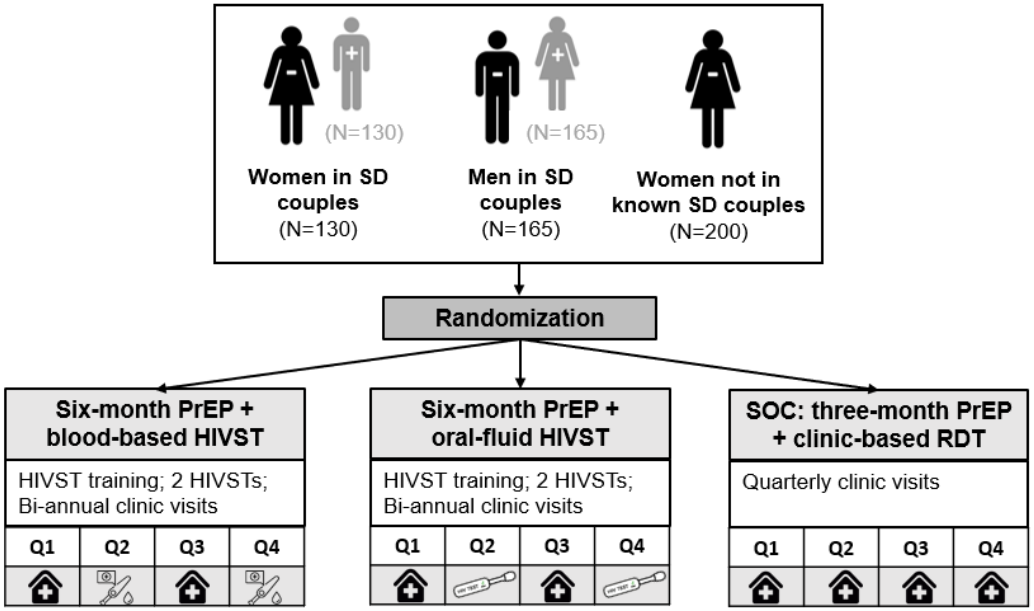
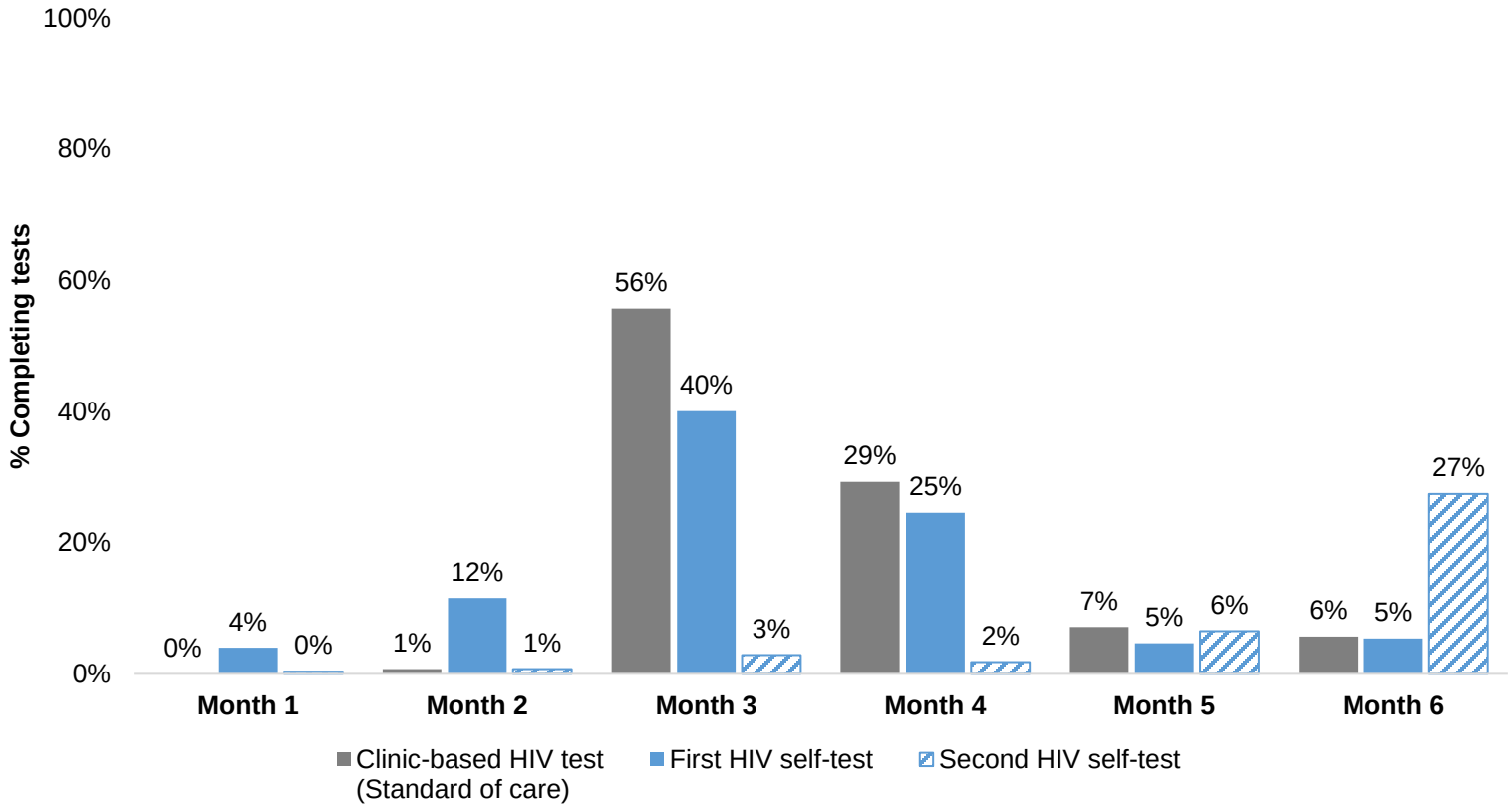



**Supplemental Figure 1. Study design of the six-month PrEP dispensing + interim HIVST randomized implementation trial**

**Abbreviations:** HIV self-testing (HIVST); pre-exposure prophylaxis (PrEP); serodifferent (SD); rapid diagnostic testing (RDT)




**Supplemental Figure 2. Timing of clinic-based HIV testing (SOC arm, N=140) or HIV self-testing (combined intervention arm, N=274) among participants returning for their six-month visit**

*Among participants in the combined intervention arm, data was missing on the timing of the first HIV self-test for 22 participants and second HIV self-test for 7 participants.

**Supplemental Table 1. Primary outcomes by study arm among men in HIV serodifferent couples and women in HIV serodifferent couples**

| Outcome | Standard of care | Oral-fluid + Blood-based HIVST[1] | Oral-fluid HIVST[1] | Blood-based HIVST[1] | Overall |
|---|---|---|---|---|---|
| **Men in HIV serodifferent couples** | **55** | **110** | **54** | **56** | **165** |
| Returned to clinic[2] | 49 (89·1%) | 91 (82·7%) | 46 (85·2%) | 45 (80·4%) | 140 (84·9%) |
| Tested for HIV | 49 (89·1%) | 90 (81·8%) | 46 (85·2%) | 44 (78·6%) | 139 (84·2%) |
| Refilled PrEP | 46 (83·6%) | 84 (76·4%) | 43 (79·6%) | 41 (73·2%) | 130 (78·8%) |
| Adherent (any TFV-DP detected) | 45 (81·8%) | 75 (68·2%) | 37 (68·5%) | 38 (67·9%) | 120 (72·7%) |
| **Women in HIV serodifferent couples** | **44** | **86** | **43** | **43** | **130** |
| Returned to clinic[2] | 36 (81·8%) | 74 (86·1%) | 38 (88·4%) | 36 (83·7%) | 110 (84·6%) |
| Tested for HIV | 36 (81·8%) | 73 (84·9%) | 38 (88·4%) | 35 (81·4%) | 109 (83·9%) |
| Refilled PrEP | 33 (75·0%) | 70 (81·4%) | 35 (81·4%) | 35 (81·4%) | 103 (79·2%) |
| Adherent (any TFV-DP detected) | 29 (65·9%) | 57 (66·3%) | 28 (65·1%) | 29 (67·4%) | 86 (66·2%) |

**Abbreviations:** HIV self-testing (HIVST); pre-exposure prophylaxis (PrEP); tenofovir-diphosphate (TFV-DP)

[1]Participants randomized to these intervention arms received six-month PrEP dispensing + interim HIVST (either oral-fluid or blood-based) with biannual clinic visits.

[2]We included all follow-up visits assigned as six-month visits by study staff; the window for these visits closed two weeks prior to the next scheduled visit date, which as at nine months for participants randomized to the standard-of-care group and 12 months for participants randomized to one of the intervention arms.

**Supplemental Table 2. Sub-group analysis of primary outcomes for participants <30 years and ≥30 years; percentages by study arm and effect size estimates using 1-sided 95% and 97·5% confidence intervals**

| | Standard of care | Oral-fluid + Blood-based HIVST[1] | Oral-fluid + Blood-based HIVST[1] vs. Standard of care | Oral-fluid + Blood-based HIVST[1] vs. Standard of care |
|---|---|---|---|---|
| **Participants <30 years old** | **N=52** | **N=111** | **RD (1-sided 95% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** |
| Returned to clinic[2] | 45 (86·5%) | 90 (81·1%) | | |
| Tested for HIV | 45 (86·5%) | 90 (81·1%) | -5·69% (-15·37%) | -5·69% (-17·22%) |
| Refilled PrEP | 43 (82·7%) | 82 (73·9%) | -8·79% (-19·72%) | -8·79% (-21·82%) |
| Adherent (any TFV-DP detected) | 26 (50·0%) | 55 (49·6%) | -1·49% (-14·24%) | -1·49% (-16·68%) |
| **Participants ≥30 years old** | **N=114** | **N=218** | **RD (1-sided 95% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** |
| Returned to clinic[2] | 95 (83·3%) | 187 (85·8%) | | |
| Tested for HIV | 95 (83·3%) | 184 (84·4%) | 1·50% (-5·51%) | 1·50% (-6·86%) |
| Refilled PrEP | 91 (79·8%) | 175 (80·3%) | 1·08% (-6·53%) | 1·08% (-7·98%) |
| Adherent (any TFV-DP detected) | 69 (60·5%) | 145 (66·5%) | 4·67% (-4·32%) | 4·67% (-6·05%) |

**Abbreviations:** HIV self-testing (HIVST); pre-exposure prophylaxis (PrEP); tenofovir-diphosphate (TFV-DP); risk difference (RD); confidence interval (CI)

[1]Participants randomized to these intervention groups received six-month PrEP dispensing + interim HIVST (either oral-fluid or blood-based) with biannual clinic visits.

[2]We included all follow-up visits assigned as six-month visits by study staff; the window for these visits closed two weeks prior to the next scheduled visit date, which as at nine months for participants randomized to the SOC arm and 12 months for participants randomized to one of the intervention arms.

[4]Risk differences (RDs) measured using binomial regression models with identity links, adjusted for study population at enrollment (e.g., men in HIV serodifferent couples, women in HIV serodifferent couples, and women singly enrolled).

**Supplemental Table 3. Sensitivity analyses for primary outcomes among all study participants; percentages by study arm and effect size estimates using 1-sided 95% and 97·5% confidence intervals**

| | Standard of care | Oral-fluid + Blood-based HIVST[1] | Oral + Blood HIVST[1] vs. Standard of care | Oral + Blood HIVST[1] vs. Standard of care |
|---|---|---|---|---|
| **Sensitivity analysis 1. "On-time" retention** | **N=166** | **N=329** | **RD (1-sided 95% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** |
| Returned to clinic (on-time)[2] | 132 (79·5%) | 233 (70·8%) | | |
| Tested for HIV | 132 (79·5%) | 230 (69·9%) | -9·48% (-16·08%) | -9·48% (-17·34%) |
| Refilled PrEP | 127 (76·5%) | 218 (66·3%) | -10·28% (-17·16%) | -10·28% (-18·48%) |
| Adherent (any TFV-DP detected) | 89 (53·6%) | 186 (56·5%) | 2·26% (-5·27%) | 2·26% (-6·71%) |
| **Sensitivity analysis 2. Adherence threshold** | **N=166** | **N=329** | **RD (1-sided 95% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** |
| Returned to clinic[3] | 140 (84·3%) | 277 (84·2%) | | |
| Adherent (≥700 fmol/punch) | 67 (40·4%) | 137 (41·6%) | 2·67% (-4·57%) | 2·67% (-5·95%) |

**Abbreviations:** HIV self-testing (HIVST); pre-exposure prophylaxis (PrEP); tenofovir-diphosphate (TFV-DP); risk difference (RD); confidence interval (CI)

[1]Participants randomized to these intervention groups received six-month PrEP dispensing + interim HIVST (either oral-fluid or blood-based) with biannual clinic visits.

[3]Our definition of "on-time" clinic visits included those returning to the scheduled six-month visit not more than 21 days after the target date at 180 days.

[3]We included all follow-up visits assigned as six-month visits by study staff; the window for these visits closed two weeks prior to the next scheduled visit date, which as at nine months for participants randomized to the SOC arm and 12 months for participants randomized to one of the intervention arms.

[4]Risk differences (RDs) measured using binomial regression models with identity links, adjusted for study population at enrollment (e.g., men in HIV serodifferent couples, women in HIV serodifferent couples, and women singly enrolled).

**Supplemental Table 4. Effect size estimates for HIV testing, PrEP refilling, and PrEP adherence using 1-sided 97·5% confidence intervals, by study population and intervention groups**

| | Oral-fluid + Blood-based HIVST[1] vs. Standard of care | Oral-fluid HIVST[1] vs. Standard of care | Blood-based HIVST[1] vs. Standard of care | Oral-fluid HIVST[1] vs. Blood-based HIVST[1] |
|---|---|---|---|---|
| **All participants (N=495)** | **RD (1-sided 97·5% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** |
| Returned to clinic[2] | | | | |
| Tested for HIV | -1·15% (-7·99%) | 0·72% (-6·98%) | -3·24% (-11·33%) | 3·96% (-4·07%) |
| Refilled PrEP | -2·60% (-10·08%) | -1·18% (-9·77%) | -4·31% (-13·12%) | 3·07% (-5·82%) |
| Adherent (any TFV-DP detected) | 2·37% (-6·47%) | -0·62% (-10·62%) | 4·67% (-5·39%) | -5·74% (-16·11%) |
| **HIV serodifferent couples[3] (N=295)** | **RD (1-sided 97·5% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** |
| Returned to clinic[2] | | | | |
| Tested for HIV | -2·81% (-11·43%) | 0·42% (-9·20%) | -6·43% (-16·86%) | 6·79% (-3·60%) |
| Refilled PrEP | -1·19% (-10·96%) | 0·28% (-10·86%) | -3·13% (-14·61%) | 3·33% (-8·08%) |
| Adherent (any TFV-DP detected) | -7·98% (-18·67%) | -8·37% (-20·89%) | -7·84% (-20·28%) | -0·63% (-13·76%) |
| **All women[3] (N=330)** | **RD (1-sided 97·5% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** | **RD (1-sided 97·5% CI lower bound)[4]** |
| Returned to clinic[2] | | | | |
| Tested for HIV | 2·06% (-6·58%) | 3·51% (-6·22%) | 0·76% (-9·28% ) | 2·74% (-6·95%) |
| Refilled PrEP | -0·26% (-9·54%) | 0·35% (-10·30%) | -1·21% (-12·00%) | 1·53% (-9·22%) |
| Adherent (any TFV-DP detected) | 12·01% (0·93%) | 7·19% (-5·49%) | 16·29% (3·62%) | -9·26% (-22·16%) |

**Abbreviations:** confidence interval (CI); HIV self-testing (HIVST); pre-exposure prophylaxis (PrEP); risk difference (RD); tenofovir-diphosphate (TFV-DP)

Risk differences (RDs) measured using binomial regression models with identity links, adjusted for study population at enrollment (e.g., men in HIV serodifferent couples, women in HIV serodifferent couples, and women singly enrolled).

[1]Participants randomized to these intervention arms received six-month PrEP dispensing + interim HIVST (either oral-fluid or blood-based) with biannual clinic visits.

[2]We included all follow-up visits assigned as six-month visits by study staff; the window for these visits closed 2 weeks prior to the next scheduled visit date, which as at nine months for participants randomized to the SOC arm and 12 months for participants randomized to one of the intervention arms.

[3]The sub-group HIV serodifferent couples included all men and women enrolled in HIV serodifferent couples (N=295). The sub-group all women included both women enrolled in HIV serodifferent couples and women singly enrolled (N=330).

[4]In our non-inferiority analyses, we interpreted one-sided 97·5% CIs above -10% as non-inferior.