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HIV Adherence Bottle Intervention Trial (HABIT): Randomized Study of an Advanced Smart-Pill Bottle Service

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BACKGROUND

- Excellent adherence is critical to successful antiretroviral therapy (ART) outcomes.
- A smart-pill bottle service (AdhereTech, New York, NY) prompts non-adherent patients to take medications via on-bottle prompts and text messages/phone calls and may improve adherence to ART.

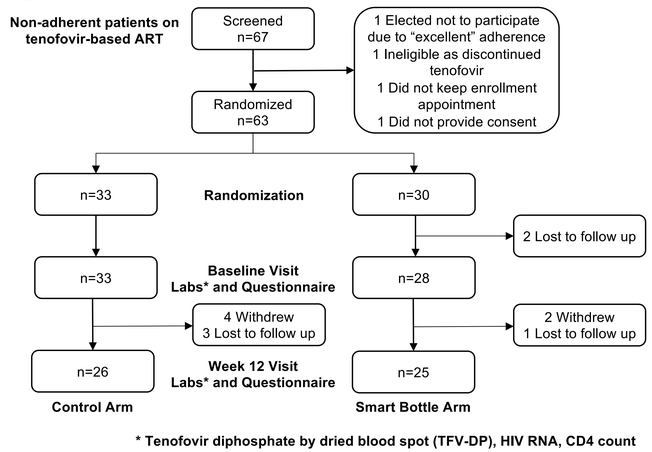
METHODS

- Adults with HIV taking a tenofovir (TFV)-containing ART regimen with suboptimal adherence (2 HIV RNA levels > 20 copies/mL during the prior year) were recruited from the the New York Presbyterian Hospital HIV practice (Center for Special Studies, CSS) and randomized to receive adherence counseling +/- the smart-pill bottle service for 12 weeks.
- Outcome measures (measured at baseline and Week 12):
  - Tenofovir diphosphate (TFV-DP) in dried blood spot (measures ~8 week average of TFV levels)
  - HIV RNA level
  - CD4 cell count
  - Self-reported adherence by standardized AIDS Clinical Trials Group (ACTG) Questionnaire

RESULTS

- Enrolled 63 participants (Figure 1):
  - 22% Female, 5% Transgender
  - 48% Black 25% Hispanic or Latino

Figure 1: CONSORT Diagram



In a Randomized Study of Diverse Participants with Suboptimal ART Adherence, the Smart-Pill Bottle Service was Associated with Higher Tenofovir Diphosphate Levels, a Quantitative Marker of Adherence

	Smart Bottle	Control	p
Baseline TFV-DP, *median [IQR] (fmol/punch)*	1230 [923;2066]	1108 [538;1886]	0.400
Week 12 TFV-DP, *median [IQR] (fmol/punch)*	1887 [816;2794]	1048 [504;1775]	0.035
Change in TFV-DP levels from baseline to week 12, median [IQR] (fmol/punch)			
Intention to treat (see Figure 2)	+252 [-167;946]	-41 [-327;214]	0.101
Excluding suspected drug-drug interactions *(n=3)*	+278 [-38;955]	-38 [-285;214]	0.038
Excluding unstable TFV-DP levels due to switch from TDF to TAF *(n=2)*	+252 [-106;880]	-41 [-327;214]	0.053
Excluding drug-drug interactions and unstable TFV-DP levels *(n=5)*	+278 [-32;946]	-38 [-285;214]	0.025
Secondary Outcomes			
Participants lost to follow up, *n (%)*	5 (17)	7 (22)	0.890
HIV RNA ≤20 copies/mL at week 12, *n (%)*	14 (58)	12 (46)	0.563
CD4 count, change from baseline to week 12, *median [IQR] (cells/μL)*	14 [-52;91]	-16 [-141;53]	0.356
Participants reporting missing ≥ 1 dose during the 4 days prior at week 12, *n(%)*	6 (25)	6 (23)	1.000

Note: Post-hoc analyses were performed to account for known differences in TFV-DP levels due to drug interactions attributed to use of ledipasvir/sofosbuvir in two participants and other suspected drug interactions in one additional participant and due to tenofovir alafenamide (TAF) use in 3 participants vs tenofovir disoproxil fumarate (TDF).

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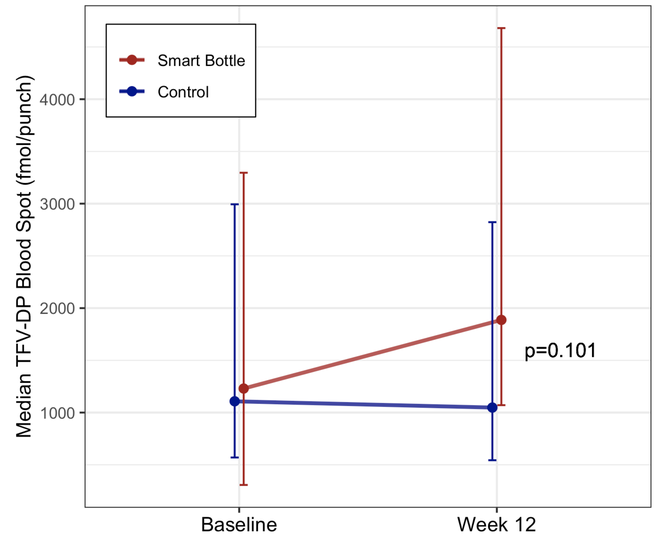
Figure 2: TFV-DP levels at Baseline and Week 12



CONCLUSIONS

- Use of an advanced smart-pill bottle was associated with higher TFV-DP levels (p=0.101), a quantitative marker of adherence, on the order of around one additional dose of TDF per week.
- In post-hoc analysis, removing potential confounders (drug-drug interactions and unstable drug levels due to ART changes from TDF to TAF) the service was associated with higher TFV-DP levels (p=0.038 and p=0.053 respectively)
- HIV RNA suppression rates, CD4 cell counts, and self-reported adherence rates (over the prior 4 days) were not different.
- The smart pill bottle service merits evaluation in a larger and longer clinical trial of ART and/or Pre-exposure Prophylaxis (PrEP).

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