Published in final edited form as:

J Acquir Immune Defic Syndr. 2018 May 01; 78(1): 34–42. doi:10.1097/QAI.0000000000001637.

Mobile Health Intervention to Reduce HIV Transmission: A Randomized Trial of Behaviorally Enhanced HIV Treatment as Prevention (B-TasP)

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Abstract

Objectives—We conducted a randomized clinical trial to test a mobile health (mHealth) behavioral intervention designed to enhance HIV treatment as prevention (B-TasP) by simultaneously increasing combination antiretroviral therapies (cART) adherence and improving the sexual health of people living with HIV.

Methods—A cohort of sexually active men ($n = 383$) and women ($n = 117$) living with HIV were enrolled. Participants were baseline assessed and randomized to either: (a) B-TasP adherence and sexual health intervention or (b) general health control intervention. Outcome measures included HIV-RNA viral load, cART adherence monitored by unannounced pill counts, indicators of genital tract inflammation (GTI), and sexual behaviors assessed over 12-months.

Results—Eighty-six percent of the cohort was retained for 12-months follow-up. The B-TasP intervention demonstrated significantly lower HIV RNA, $OR = 0.56$, $p = .01$, greater cART adherence, $Wald \chi^2 = 33.9$, $p = .01$, and fewer indicators of GTI, $Wald \chi^2 = 9.36$, $p = .05$, over the follow-up period. Changes in sexual behavior varied, with the B-TasP intervention showing lower rates of substance use in sexual contexts, but higher rates of condomless sex with non-HIV positive partners occurred in the context of significantly greater beliefs that cART reduces HIV transmission.

Conclusions—Theory-based mHealth behavioral interventions can simultaneously improve cART adherence and sexual health in people living with HIV. Programs aimed to eliminate HIV transmission by reducing HIV infectiousness should be bundled with behavioral interventions to maximize their impact and increase their chances of success.

Keywords

HIV Prevention; Treatment as Prevention; HIV infectiousness

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Conflicts

The authors declare no conflicts of interest.

INTRODUCTION

The success of combination antiretroviral therapies (cART) in suppressing viral replication has transformed HIV infection from a life-threatening disease with 100% mortality into a chronic, long-term, medically manageable condition. There is definitive evidence that sustained HIV suppression in the absence of genital tract inflammation (GTI), principally caused by sexually transmitted co-infections (STI), nearly eliminates the risk of HIV transmission (1–6). Increasing cART coverage can reduce HIV infections at the population-level by as much as 50% (7), and the potential impact of treatment on slowing HIV epidemics has led to ambitious policies to eliminate HIV infections, particularly the WHO's 90-90-90 initiative (8). The success of cART-based prevention strategies, known as treatment as prevention (TasP), are however limited by non-adherence and untreated STI. Poor linkage to care, cART non-adherence and background GTI may account for the failure of efforts to scale-up cART to achieve reductions in HIV transmission in some settings (9, 10).

The correlation between HIV RNA in various compartments (i.e., blood plasma and genital tract fluids) is low (11, 12) and appears dependent on specific cART regimens, drug penetration into the genital tract immune compartment, and patient adherence. In addition, local viral shedding caused by inflammatory processes (13, 14) can further suppress the correlation between viral RNA in blood plasma versus genital tract fluid. Sexual risks for STI are linked to cART non-adherence by a cluster of common determinants, including: conditions of poverty, substance use, and mental health problems (15–18). Behavioral interventions aimed at simultaneously increasing cART adherence and reducing sources of GTI may therefore enhance the impact of TasP (19, 20).

Effective interventions for improving cART adherence focus on cognitive-behavioral skills and strategies to resolve individual, situational, and structural barriers (21). Cognitive-behavioral skills-building techniques are also central to the most effective sexual health interventions (22, 23), which focus on preventing and treating sources of GTI, particularly STI. Both controlling HIV replication in blood plasma with suppressive cART and avoiding genital tract activation of leukocytes that stimulate HIV shedding (24), can synergize to reduce HIV transmission. Unfortunately, few studies have tested integrative approaches to simultaneously increase cART adherence and improve sexual health of people living with HIV.

The CDC's Compendium of Evidence-Based Interventions includes one behavioral intervention designed for use with TasP (25). The intervention is grounded in cognitive-behavioral skills building and aims to resolve challenges to accessing care, adhering to cART, and maintaining sexual health through condom use and engaging with sexual health services (26). The integrated adherence-sexual health intervention included elements found in previous interventions that targeted adherence and sexual health separately (27, 28). Results showed the integrated intervention significantly reduced HIV viral load, increased cART adherence, and reduced new STI diagnoses. Despite promising outcomes, the CDC disseminated integrated adherence-sexual health intervention requires multiple facility-based small group sessions, making it an effective intervention of limited use. In contrast, mobile

health (mHealth) interventions have the flexibility and reach to overcome the challenges of repeated visits to a clinic or other facilities. While mHealth interventions are generally thought to improve access to care for patients living in rural areas, advances in telecommunications also remove barriers to care such as stigma-related concerns, time constraints, and lack of transportation that patients in urban centers also face. Behavioral health interventions are adaptable to fit low-cost mHealth platforms and thereby expand access to evidence-based services (29). Here we report the outcomes of a randomized clinical trial designed to test the effects of an mHealth adaptation of the CDC disseminated integrated cART adherence and sexual health intervention to behaviorally enhance TasP (B-TasP) (26).

METHODS

Setting and participants

Enrolled participants included 383 men and 117 women living with HIV in Atlanta, GA; a priority setting as CDC estimates that 1 in 51 Georgians will become HIV infected (30). The trial was launched in October, 2012, enrollment closed in December, 2014, and follow-ups were completed in January, 2016. Recruitment occurred by notifying AIDS service providers and infectious disease clinics about the study opportunity, distributing brochures to local HIV services, and word-of-mouth. Interested persons phoned the research site to schedule an intake appointment. The trial entry criteria were age 18 or older, proof of positive HIV status, and being sexually active as defined by at least one sexual occasion reported during the 28-day run-in period.

Ethical review

The trial was registered with [ClinicalTrials.gov](https://clinicaltrials.gov), identifier NCT 01752777. All study protocols were approved by the University of Connecticut IRB and a Certificate of Confidentiality was obtained from the National Institutes of Health. There were no adverse events observed in this trial.

Overview of intervention conditions

The trial tested one active intervention with one parallel active contact-matched comparator. Both arms were structurally matched in that they delivered single two-hour workshops with approximately 8–10 participants and two co-facilitators, followed by four one-on-one bi-weekly cellphone-delivered coaching sessions. The content of the B-TasP intervention and the comparison were non-overlapping. The group facilitators/phone-coaches received weekly supervision to review sessions and assure adherence to the intervention protocol.

B-TasP enhancement intervention

The experimental condition in this trial was adapted from ‘In The Mix’, an evidence-based 7-session small group (7–10 participants) intervention tested in a randomized trial and adopted by CDC for dissemination (25). *In The Mix* was grounded in Social Cognitive Theory of behavior change (31) and provides a unified approach to improving medication adherence and reducing sexual transmission risk behaviors. To fit an mHealth delivery format, we consolidated all of the group process activities and reformatted the skills-building

components for cellphone-delivered coaching sessions. The single two-hour workshop concentrated on interactive components that required social-facilitation and peer support. For example, a core activity of the original intervention asked participants to wear vision disorienting goggles to simulate intoxication while filling a pillbox with mints and then applying a condom to a penis model.

All other intervention components were reconfigured for individualized delivering by cellphone. The one-on-one coaching sessions included a brief personalized assessment of recent experiences gaining access to health care, addressing barriers to staying in care, challenges to taking cART, sexual decisions, emotions, and relationships. Each session included content directed at addressing the links between mood, situational contexts, social relations and substance use in relation to HIV health care, cART adherence, and sexual behaviors. Decisional balance exercises and problem-solving activities focused on treatment adherence and sexual risks for STI in the context of viral load. In each session, sexual decision-making was placed within scenarios of individually tailored challenges such as substance use, mood/depression, relationship status, viral load, and HIV disclosure. Effective decisions regarding medication management and sexual health strategies were the focus of each session.

Contact-matched general health condition

The control arm was a contact-matched non-contaminating supportive health intervention. Participants received a single two-hour small group workshop focused on how to access quality health information, identifying early signs of cancer with self-examination, improving nutrition, exercise, and stress management. The four one-on-one phone sessions were intended to control for interventionist contact and remind participants to monitor their health goals and reinforced their health behaviors.

Outcome measures

Audio-computer assisted self-interviews (ACASI)—The ACASI asked participants their demographics, health care status, and alcohol use (32, 33). To assess sexual health, participants were asked whether they had experienced three symptoms of GTI in the previous three months; specifically, unexplained genital discharge, genital pain, and genital ulcers. Participants also reported whether they had been diagnosed with an STI, specifically gonorrhea, chlamydia, syphilis, herpes simplex virus, or trichomoniasis. GTI symptoms and STI diagnoses were dichotomously coded as present (1) or not present (0) and summed to create respective indexes. Three-month time-frames were selected to provide non-overlapping coverage of symptoms and diagnoses over the follow-up intervals.

At baseline and subsequent quarterly assessments, participants indicated whether they had used 14 common strategies for improving medication adherence identified from previous research (32, 33). The adherence strategies endorsed were summed as a composite score that was internally consistent ($\alpha=.70$). Finally, we assessed sexual infectiousness beliefs using five questions that asked about whether HIV treatments make sex safer and whether an undetectable HIV viral load alleviates concerns about HIV transmission. Responses were made on a five-point scale; “Strongly agree” to “Strongly disagree” (34) ($\alpha=.70$).

HIV viral load—Baseline HIV viral load and CD4 counts were collected using participant assisted medical records abstraction. Participants were provided with a form to request their doctor's office for the results and dates of their most recent (within three months) viral load tests and CD4 cell counts. These data were obtained directly by the participant from their care provider and required the provider's office stamp or signature to assure authenticity. Providers used viral load testing with a range of sensitivities for detecting viral activity. For baseline descriptive purposes HIV RNA levels below 100 copies/ml were defined as undetectable (35). At the 12-month assessment, blood samples were collected at the project offices using standard phlebotomy. Whole blood specimens were collected and plasma viral load was determined by the Amplicor HIV-1 Monitor test (Roche Diagnostics, Indianapolis, IN).

Urine tests for drug use and genital tract inflammation—We conducted an FDA approved multi-panel urine dip-test to detect common illicit drug use (Redwood Toxicology Labs - Reditest-12). We also tested urine samples for leukocyte esterase as a marker for genital tract inflammation (36–38). Because leukocyte esterase urine dip tests are of uncertain reliability with women due to self-collection contamination, analyses of leukocyte test results were restricted to male participants (39).

Antiretroviral adherence and HIV care visits—Participants consented to monthly unannounced cellphone-based pill counts over 12-months. Unannounced pill counts are reliable and valid in assessing medication adherence when conducted in homes (40) and on cellphones (41, 42). In this study we conducted unannounced cellphone-based pill counts using study-provided cellphones. Pill counts allow for calculating adherence as the ratio of pills counted relative to pills prescribed, taking into account the number of pills dispensed. We used 85% of cART taken to define a clinically relevant level of adherence and non-adherence in descriptive analyses (43). The proportion of cART taken (continuous variable) was used for outcome analyses. For HIV care provider visits, participants were asked about appointments kept and missed during each monthly phone assessment. We summed the number of visits across the monthly assessments to yield the number of visits occurring over 12-months.

Sexual behavior—We used an interactive text-diary assessment to collect daily sexual behavior assessments. Brief (nine-question) daily were delivered using interactive short message system (SMS) response. Electronic diaries provide reliable data collection of socially sensitive behaviors (44–46). Participants received a text-prompt to initiate and answer questions about their sexual activity during the previous day. The daily questions asked about whether participants had sex yesterday. Specifically, participants indicated partner type (regular, casual), partner HIV status, condom use by self or partner, and substance use by self and partner. Each behavior was dichotomous, indicating that it had occurred (coded 1) or not occurred (coded 0). The data were stored on a central secured server. Sexual behavior assessments were administered in blocks of 14 consecutive days with 21 days between blocks. Sexual behaviors were aggregated across the 14 days within nine blocks, providing nine post-randomization repeated measures of sexual behavior (46).

Sample size

Based on previous intervention research (26), a moderate effect size ($d=.35$) was used to calculate statistical power for viral load, cART adherence and sexual health outcomes. We assumed 85% retention and estimated a final sample of 210 in each of the two conditions for primary outcomes to achieve 90% chance of detecting differences.

Randomization and blinding

Following a 30-day run-in period that collected baseline assessments, participants were randomly assigned to conditions. Allocation was accomplished using condition codes generated by an automated randomizer. The project manager used the randomization list to assign participants to conditions. Randomization was not breached throughout the trial. Recruitment, screening, office-based assessment and cellphone assessment staff remained blinded to condition throughout the study and interventionists never conducted assessments.

Statistical analyses

Outcome analyses used an intent-to-treat approach where all available data were included regardless of exposure to the intervention sessions. Primary and secondary outcome analyses used generalized linear models (GLM) for 12-month viral load counts and generalized estimating equations (GEE) with unstructured working correlation matrixes for monthly adherence pill counts, adherence strategies, care appointments and blocks of sexual behaviors. Poisson distributions were modeled for all count data (e.g., sexual behaviors, adherence strategies, care provider visits). For treatment adherence, we included baseline viral load (detected vs. undetected) as a moderating variable to inform potential for reductions in infectiousness. We used an available data approach to missing values with standard estimations in GLM and GEE. Logistic regression tested for intervention effects on all dichotomous GTI and STI outcomes. Infectiousness beliefs were analyzed using two (conditions) $\times$ four repeated measures multivariate analyses of variance (MANOVA). All outcome analyses controlled for baseline scores and participant gender. In addition, to avoid confounding duration of infection with HIV suppression, we also controlled for years since testing HIV positive in the analyses of viral load. Condition, time of assessment, and condition $\times$ time interactions were entered as model effects. Planned contrasts for least significant differences were used to test for simple effects.

RESULTS

Participant enrollment and retention

The flow of participants through the run-in period and clinical trial is summarized in Figure 1. Of the 1,076 participants enrolled in the run-in study, 500 were sexually active during the 28-day run-in period and accepted enrollment in the trial. Participant retention over the 12-months was 87% for viral load, leukocyte testing, final ACASIs, and electronic sexual behavior assessments, and 86% for unannounced pill counts. There were no indications of differential attrition and randomization resulted in condition equality for all participant characteristics and outcome measures (see Table 1).

Baseline chart abstracted viral load showed that 150 (30%) participants had detectable virus. A total of 68 (12%) participants were not taking cART at baseline. Among those taking cART, the mean baseline adherence for the sample was 88.4% (SD=17.4). In addition, 107 (21%) participants had at least one GTI symptom at baseline and 124 (25%) had been diagnosed with an STI in the previous 3-months (see Table 2).

HIV suppression, GTI and STI indicators

Results for HIV RNA copies/ml (viral load) showed that the effect of the intervention on 12-month HIV RNA testing, controlling for baseline viral load and number of years since testing HIV positive, was significant, adj OR=0.56, $p=.01$, 95%CI 0.55–0.57 (see Table 2). The B-TasP intervention reduced viral burden by 2917 copies/ml relative to an overall reduction of 60 copies/ml in the comparison group. Participants in the B-TasP intervention were also significantly less likely to report GTI symptoms than the comparison condition at the 9-month follow-up, adj OR=0.54, $p=.05$, 95%CI 0.29–0.99. For STI diagnoses, the B-TasP intervention had significantly fewer new STI diagnoses treated at the 3-month follow-up, adj OR=0.21, $p=.04$, 95%CI 0.04–0.98. Finally, results for leukocyte tests showed a significant condition by time interaction, Wald X^2 (df=3)=9.36, $p=.05$. Subsequent models showed that men in the B-TasP intervention were less likely to have positive urine leukocyte results than the comparison intervention at the 3-month follow-up, adj OR=0.23, $p=.01$, 95%CI 0.07–0.76.

cART adherence, adherence strategies and HIV care provider visits

Results showed a significant 3-way interaction for intervention condition by baseline viral suppression by time, Wald X^2 (df=19)=33.9, $p=.01$. Among participants with baseline detectable virus (Figure 2, panel A), the B-TasP intervention demonstrated greater adherence across follow-up assessments, with subsequent tests showing significant differences at time points proximal to the intervention as well as during the final months of follow-up. In contrast, there were no significant intervention effects for participants with baseline undetectable viral load (see Figure 2, panel B). Results also showed a significant intervention effect for treatment adherence strategies at the 3-month follow-up, Wald X^2 =4.26, $p=.04$ (see Table 3). In addition, participants receiving the B-TasP intervention reported significantly more HIV care provider visits over the follow-up period, Wald X^2 =3.89, $p=.04$.

Sexual behaviors

Results for sexual behavior assessments over the 9-blocks of follow-up text messaging are shown in Table 3. For condomless intercourse with discordant partners, the condition by time interaction was significant, Wald X^2 =18.80, $p=.01$; the B-TasP intervention demonstrated lower rates early in the follow-ups. However, this pattern reversed with higher rates of condomless intercourse occurring among the B-TasP condition in the later follow-ups. Results for substance use in the context of sex indicated a trend, Wald X^2 =14.64, $p=.06$; participants in the B-TasP intervention had lower rates of substance use in the context of sex over the follow-up period.

Results also indicated a significant effect of the intervention on infectiousness beliefs, $F(3, 418)=4.0$, $p=.01$; participants receiving the B-TasP intervention demonstrated greater endorsement of infectiousness beliefs than the comparison condition. Planned comparisons showed the differences were significant at the 3-month and 12-month follow-ups.

DISCUSSION

Nearly one in three sexually active HIV positive persons in this trial evidenced detectable HIV RNA at baseline and one in four had at least one baseline indicator of GTI or STI diagnosis. Results of this trial extend previous findings that demonstrate theory-based behavioral interventions effectively increase cART adherence and reduce GTI of people living with HIV (25). Participants who received the B-TasP intervention demonstrated consistently higher cART adherence and had lower HIV burden after 12-months. The effects of the intervention on adherence were most pronounced for participants who were not viral suppressed at baseline. While the intervention effect for unsuppressed individuals is clear and consistent, it is not optimized; mean adherence for the intervention group never approached 90%. Improved treatment adherence was supported by uptake of behavioral strategies for cART adherence and a greater number of HIV care visits.

To our knowledge this is the first behavioral intervention trial to measure potential infectiousness outcomes with leukocyte esterase, a known biomarker for GTI (47). Participants in the B-TasP intervention also reduced their use of alcohol and other drugs in sexual contexts to a greater degree than control participants. Differences between conditions in condomless sex with HIV serodiscordant partners indicated a mixed pattern of outcomes that may best be explained by shifts in infectiousness beliefs. Participants in the B-TasP intervention significantly increased their beliefs that individuals are less sexually infectious when their blood plasma viral load is suppressed. Thus, as participants became less infectious (lower viral burden and less GTI) they reduced their condom use with HIV susceptible partners (increased condomless sex) in unison with increased compensatory beliefs (infectiousness beliefs). The results also indicated that cART adherence among individuals with detectable HIV viral load improved and was sustained. However, average adherence remained sub-optimal. Taken together, the B-TasP intervention demonstrated reductions in HIV infectiousness in a sexually active cohort of men and women living with HIV. However, greater intervention intensity and duration may be needed to increase the magnitude, durability and sustainability of the observed outcomes. It is important to note that the number of sessions delivered in this intervention was not empirically determined. It is possible that more sessions may have resulted in a greater impact for some participants, while others may have sufficiently improved with fewer sessions. Dose determination trials are needed for behavior interventions aimed to improve TasP outcomes.

The strengths of this trial include its randomized design, high-rates of participant retention, inclusion of biological endpoints, and state of the science behavioral measures. The trial is, however, limited by only including a single follow-up point for HIV viral load. In addition, we did not include biological testing specifically for incident STI and urinary leukocyte esterase as a marker for GTI was only used with men. The small to medium observed effect sizes should also be considered when weighing the value of the intervention. In addition,

while the intervention was delivered mostly by cellphone it was not entirely mHealth as it included one facility-based small group session. This model is more accessible than multiple facility-based group sessions, but does still require bringing patients together for a single group. Finally, our trial was geographically constrained to a single southeastern US city. With these strengths and limitations in mind, the current findings support the importance of accompanying behavioral interventions to bolster the public health impact of TasP with the aim of eliminating HIV transmission.

Acknowledgments

The authors thank Cindy Merely, Brandi Welles, Ginger Hoyt, and Tamar Grebler for the contributions to this trial.

Sources of Funding: This research was supported by grants from the National Institute on Drug Abuse (NIDA) R01-DA033067 (Kalichman) and National Institute of Allergy and Infectious Diseases P30-AI050409 (Schinazi).

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Figure 1.

Flow of participants through the randomized trial. cART = antiretroviral therapy, Block = 14-days of electronic sexual behavior text message assessments.

Detectable Viral Load at Baseline

A

Undetectable Viral Load at Baseline

B

Figure 2.

Twelve-month cART adherence rates in participants with baseline detectable (panel A) and baseline undetectable (Panel B) viral load.

Table 1

Demographic characteristics and baseline values for integrated B-TasP and comparison interventions.

Characteristic	B-TasP Intervention (N = 250)		Comparison Condition (N = 250)		χ^2	p
	N	%	N	%		
Gender					0.64	.42
Men	196	78	187	75		
Women	54	22	63	25		
Transgender	8	3	15	6	2.16	.15
Race						
African-American	221	91	224	90	4.65	.19
White	13	5	16	6		
Other race	10	4	9	4		
Unemployed	76	31	77	31	1.26	.73
Income < \$10,000	149	61	159	64	0.33	.56
Tested drug positive	135	56	121	47	2.25	.13
Alcohol use in past month	168	69	154	62	0.39	.53
Knows CD4	168	69	155	62	2.56	.11
Knows viral load	142	58	156	62	0.91	.34
Chart abstracted CD4 <200	38	16	33	14	0.57	.44
Times hospitalized for HIV					4.00	.55
none	144	59	136	54		
1-2	57	24	69	28		
3+	43	17	45	18		
Renal disease	8	3	14	6	1.56	.21
Hepatitis-C positive	25	10	30	12	0.73	.39
<85% cART adherent	65	30	47	22	3.60	.06
Detectable HIV viral load	77	32	73	29	0.36	.55
	M	SD	M	SD	t	
Age	43.7	10.4	44.9	10.1	1.3	.19
Years education	12.8	1.8	12.7	8.2	0.9	.36

Characteristic	B-TasP Intervention (N = 250)		Comparison Condition (N = 250)		χ^2	p
	N	%	N	%		
Years since testing HIV+	12.9	8.5	13.7	8.2	1.0	.32
Chart abstracted CD4 count ^a	491.7	289.4	526.8	289.7	1.3	.19
Viral load copies/ml	7,491.8	49,143.8	14,189.8	86,025.6	1.1	.27
HIV symptoms	4.0	3.5	4.3	3.7	0.9	.92
cART adherence	87.7	16.9	89.2	17.9	1.2	.23
Adherence strategies	5.29	3.02	5.29	2.64	0.4	.68
Sex Behaviors	M	SD	M	SD	t	p
Infectiousness beliefs	2.18	0.80	2.22	0.83	0.56	.57
Number of days with sexual activity ^a	3.41	2.79	3.58	3.14	0.63	.52
New sex partners ^a	0.73	1.21	0.70	1.35	0.21	.83
Number regular sex partners ^a	2.13	2.40	2.28	2.72	0.66	.50
Condomless sex with an HIV serodiscordant partner ^a	1.06	1.61	1.05	1.80	0.08	.93
Substance use during sex ^a	1.08	1.69	1.09	2.15	0.31	.75
Substance use during condomless sex ^a	0.56	1.10	0.41	0.92	0.30	.76

Note: B-TasP = Behavioral enhancement of treatment as prevention; M = mean, SD = standard deviation, cART = combination antiretroviral therapy;

^alog10 transformed values used for parametric tests.

Blood plasma viremia and genital tract inflammation marker outcomes for B-TasP Intervention and Comparison Condition.

Table 2

	B-TasP Intervention (N = 250)		Comparison Condition (N = 250)		OR	p	95%CI
	M	SD	M	SD			
12-Month viral load	5,325.7	30,789.8	11,913.8	83,841.7	0.56	.01	0.55–0.57
Change in RNA copies	–2917.5		–60.9				
GTI symptoms	N	%	N	%			
Baseline	54	22	53	21			
3-month	44	20	43	18	1.43	.25	0.77–2.61
6-month	33	14	31	13	1.13	.70	0.59–2.15
9-month	30	13	43	19	0.54	.05	0.29–0.99
12-month	28	12	28	12	0.95	.88	0.48–1.87
STI Diagnoses							
Baseline	58	24	66	26			
3-month	46	18	49	20	0.21	.04	0.04–0.98
6-month	35	14	39	16	0.79	.46	0.44–1.42
9-month	32	13	37	15	0.68	.65	0.12–3.62
12-month	25	10	29	12	0.48	.44	0.08–2.99
Leukocytes (Men)							
Baseline	20	11	19	10			
3-month	5	3	15	9	0.23	.01	0.07–0.76
6-month	15	8	8	5	1.70	.36	0.54–5.33
9-month	12	7	5	3	3.36	.10	0.87–13.04
12-month	15	9	3	5	1.32	.57	0.49–3.56

Note: B-TasP = Behavioral enhancement of treatment as prevention; M = mean, SD = standard deviation, OR = odds ratio; STI = sexually transmitted infections, GTI = genital tract inflammation; Baselines viral loads shown in Table 1; Odds ratios refer to events occurring in the B-TasP condition relative to the comparison condition.

Table 3

Sexual behavior, care appointments, adherence strategies, and infectiousness beliefs outcomes for B-TasP intervention and Comparison conditions.

Behavior	B-TasP Intervention (N = 250)		Comparison Condition (N = 250)		Wald X ²	p
	M	Se	M	Se		
Condomless HIV discordant sex						
2-month ^a	0.69	0.05	0.54	0.04	4.84	.028
4-month	0.43	0.04	0.62	0.05	8.98	.003
5-month	0.45	0.04	0.52	0.04	1.12	.289
6-month	0.34	0.03	0.39	0.04	0.75	.379
7-month	0.44	0.04	0.46	0.04	0.08	.777
9-month	0.50	0.04	0.37	0.03	5.97	.015
10-month	0.46	0.04	0.41	0.04	0.73	.390
11-month	0.42	0.04	0.44	0.04	0.07	.791
12-month	0.50	0.04	0.36	0.04	5.19	.023
Substance use during condomless sex						
2-month ^a	0.32	0.05	0.27	0.04	3.38	.066
4-month	0.17	0.03	0.27	0.04	3.56	.059
5-month	0.20	0.03	0.24	0.05	1.32	.249
6-month	0.14	0.02	0.25	0.04	6.05	.014
7-month	0.19	0.03	0.24	0.04	1.00	.315
9-month	0.16	0.03	0.28	0.07	3.20	.073
10-month	0.16	0.03	0.25	0.04	4.63	.031
11-month	0.16	0.03	0.25	0.04	5.26	.022
12-month	0.21	0.04	0.18	0.05	0.12	.722
Number of HIV Care Appointments kept over follow-up period	4.04	0.13	3.7	0.12	3.89	.049
Adherence Strategies						
	M	SD	M	SD		
3-month	5.42	2.77	4.93	2.68	4.26	.040
6-month	5.12	2.78	5.02	2.71	2.94	.081
9-month	4.71	2.83	4.72	2.83	0.02	.890

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Behavior	B-TasP Intervention (N = 250)		Comparison Condition (N = 250)		Wald X ²	p
	M	Se	M	Se		
12-month	5.36	3.36	5.14	3.11	0.02	.890
F						
Infectiousness beliefs					4.00	.003
3-month	2.40	0.87	2.19	0.86	4.70	.013
6-month	2.33	0.87	2.22	0.87	1.69	.198
9-month	2.41	0.91	2.25	0.82	3.612	.058
12-month	2.54	0.97	2.29	0.88	7.356	.007

Note:

^atime point is post-baseline and during intervention period;

B-TasP = Behavioral enhancement of treatment as prevention; M = mean, Se = standard error; SD = standard deviation, Baselines shown in Table 1