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# Efficacy of daily text messaging to support adherence to HIV pre-exposure prophylaxis (PrEP) among stimulant-using men who have sex with men

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## Abstract

Men who have sex with men (MSM) who use stimulants are at increased risk for HIV infection. Adherence to pre-exposure prophylaxis (PrEP) reduces the risk of HIV infection. We evaluated the efficacy of the individualized Texting for Adherence Building (iTAB) intervention for PrEP adherence compared to standard of care (SoC) among 119 MSM who use stimulants (cocaine, methamphetamine and/or other amphetamine) from the California Collaborative Treatment Group 595 randomized control trial. Three ordered levels of PrEP adherence (non-adherence, adequate adherence, and near-perfect adherence) were compared between intervention arms across study visits (weeks 12 and 48) using ordinal logistic regressions. The effect of intervention arm was not significant in the final model; however, there was a 38% decrease in odds (OR=0.62, $p$=.023) of having near-perfect adherence (versus non-adherence or adequate adherence) at week 48 compared to week 12, indicating a significant effect of time. In a follow-up analysis examining week 48 only, logistic regression examining PrEP adherence showed that receiving iTAB (compared to SoC) trended towards higher odds of near-perfect adherence relative to adequate adherence (OR=2.48, $p$=.061). Higher HIV knowledge resulted in higher odds (OR=1.72, $p$=.020) of near-perfect adherence (versus non-adherence or adequate adherence). HIV knowledge may influence PrEP adherence, and most notably, the iTAB intervention may support near-perfect adherence relative to adequate adherence.

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### Keywords

PrEP; men who have sex with men (MSM); text-based intervention; stimulants; substance use

Stimulant use is a well-documented risk behavior for HIV infection among men who have sex with men (MSM; Hoenigl et al., 2016). Numerous studies have found MSM who use stimulants to report higher numbers of sexual partners and more engagement in condomless anal sex than non-stimulant using MSM (Mimiaga et al., 2018). Further, beyond sexual risk, stimulant use introduces the risk of HIV transmission through the potential for injection drug use (Vlahov et al., 2010).

Pre-exposure prophylaxis (PrEP) with daily oral tenofovir disoproxil fumarate and emtricitabine (TDF/FTC) is highly effective for preventing HIV acquisition (Spinner et al., 2016). Specifically, TDF/FTC PrEP reduces the risk of HIV infection by 42% compared to no PrEP use, and by 68% in those who achieve near-perfect PrEP adherence (i.e., ≥ 90% doses taken; Moore et al., 2018). Stimulant use, inclusive of methamphetamine (meth), cocaine, and other recreationally-used stimulants (e.g., abuse of prescription amphetamines), negatively impacts PrEP adherence (Okafor et al., 2020). To reap the public health benefits of PrEP, interventions are needed to support PrEP adherence among people who use stimulants.

Text messaging interventions show efficacy for supporting medication adherence (Finitsis, Pellowski, & Johnson, 2014). In a large trial involving 398 men who have sex with men (MSM), a personalized text messaging system (i.e., the individualized Texting for Adherence Building intervention; iTAB) showed efficacy for supporting durability of near-perfect PrEP adherence (Moore et al., 2018). In this secondary analysis, we aim to examine whether MSM who use stimulants were more likely to achieve near-perfect PrEP adherence if they received iTAB versus standard of care (SoC).

## Methods

### Study Setting

The CCTG 595 Text Messages to Support Adherence to PrEP In At-Risk for HIV Individuals (TAPIR) study was a 48-week randomized controlled trial (RCT) of iTAB versus SoC to support adherence to daily TDF/FTC PrEP. The CCTG group enrolled participants at four medical centers from February 2013 to February 2015. Participants were followed for a minimum of 48 weeks ending in February 2016. The study protocol received institutional review board approval, and participants provided written, informed consent.

### Eligibility *Criteria*

Eligible participants were English- or Spanish-speaking HIV-uninfected MSM and transgender women (age >18 years). Eligible participants also had acceptable laboratory values in the past 30 days, and an increased risk for HIV acquisition as determined by 1) >1 HIV-infected sexual partner for >4 weeks; 2) condomless anal intercourse with >3 male sex partners who were HIV positive or of unknown HIV status during the previous

3 months; or 3) condomless anal sex with >1 male partner and an STI diagnosis during the previous 3 months. Exclusion criteria included active hepatitis B infection, inability to provide informed consent, and presence of a medical condition or use of a medication that may interfere with study participation. For the present sub-study, we examined only cisgender MSM who endorsed stimulant use (cocaine, meth, or other recreationally-used amphetamines) in the past three months on the Structured Clinical Interview for DSM disorders (SCID; First, 1997) screening assessment administered at the baseline study visit.

## Study and Intervention Design

Participants were randomized 1:1 to receive either iTAB or SoC. Study personnel who assisted participants with setting up iTAB were different from the study personnel who later administered study assessments, therefore, study personnel with continued engagement with participants were blinded to participant intervention arm. Development and refinement of the iTAB intervention has previously been described (Montoya et al., 2014; Moore et al., 2018). In brief, participants receive automated daily text messages. The content of the text messages was adapted based on feedback received from focus group participants consisting of MSM prior to enrollment of participants in the TAPIR study. During study enrollment, participants selected health promotion (e.g., “We care about u and your health”) and factoid-type (e.g., “On average, you breathe 23,000 times a day”) message stems. Each message stem was accompanied with a prompt to take PrEP that could also be personalized (e.g., “Pls take ur small blue pill”). Participants were then prompted to respond with a single letter indicating whether or not they took PrEP on that specific day (“Reply: Y) Took, N) Didn’t, P) Postpone”).

## Study Procedures and Measures

Study visits occurred at baseline and weeks 4, 12, 24, 36, and 48. DBS concentrations for intracellular TFV-DP was performed at week 12 and the last study visit following week 12 (week 24, 36, or 48) to characterize PrEP adherence: nonadherence (TFV-DP levels <719 fmol/punch), adequate adherence (TFV-DP levels 719–1245 fmol/punch), and near-perfect adherence (TFV-DP levels ≥1246 fmol/punch).

Screening for STIs were completed at baseline and every 3–6 months. Participants also completed measures on sexual risk, depression symptoms (PHQ-9; Kroenke, Spitzer, & Williams, 2001), substance use (Drug Abuse Screening Test, DAST), and HIV knowledge (measure items assessed participants’ knowledge of how HIV can and cannot be transmitted; Carey & Schroder, 2002).

## Statistical Analyses

In the current sub-study, 119 participants who endorsed stimulant use (cocaine, meth, or other recreationally-used amphetamines) and two visits (i.e., week 12 and week 48) were included in analyses. Demographics, employment, sexual desire and risk scale, relationship, HIV knowledge, depression symptoms (PHQ-9 total score), and substance use at baseline were compared between iTAB and SoC arms using Student t-tests for continuous variables or Fisher’s exact test for categorical variables. Three ordered levels of PrEP adherence (i.e., non-adherence, adequate adherence, and near-perfect adherence) were compared between

intervention arms across study visits (i.e., weeks 12 and 48) using mixed-effects ordinal logistic regressions. First, the interaction effect of the intervention arm and study visit on PrEP adherence was assessed (Model 1). Next, an additive model to examine the main effects of intervention arm and study visit on PrEP adherence was conducted (Model 2). If the interaction term from Model 1 was not statistically significant, it would not be retained in Model 2 or other subsequent models. The variables differing between intervention arms at $p<.20$ were included in the model of PrEP adherence, along with intervention arm and study visit (Model 3). The final model of PrEP adherence was determined using backward stepwise selection, such that variables were retained in the model as covariates if they continued to contribute to the model at $p<.20$ (Model 4). As a follow-up analysis, a logistic regression model was evaluated to assess whether proportions of near-perfect adherence (relative to adequate adherence) differed between the two intervention arms at week 48. The significance level $\alpha$ was set to 5%, and all statistical analyses were performed using R version 3.6.3 (R Core Team, 2020).

## Results

Table 1 presents demographic characteristics and risk behavior data by intervention arm. The intervention arms were comparable on demographic variables (i.e., age, education, ethnicity/race, income), relationship status, sexual desire and risk, substance use, and depression symptoms ($p>.05$). Compared to the SoC arm, the iTAB arm had more participants employed (35.1% vs. 11.5%, $p=.004$) and greater HIV knowledge (5.50 vs. 3.00, $p=.001$). There was a trend towards a greater proportion of participants endorsing cocaine use in the SoC arm ($p=0.100$) and a greater proportion of participants endorsing meth use in the iTAB arm ($p=.099$).

Ordinal logistic regression modeling revealed that among all MSM who use stimulants, no significant interaction between intervention arm and study visit was detected (Model 1 in Table 2), indicating no effect of intervention arm (iTAB vs. SoC) on change of PrEP adherence from week 12 to week 48. The interaction term was removed from the model, and the additive effects of intervention arm and study visit on the ordered levels of PrEP adherence were examined (Model 2 in Table 2). Model 2 showed there was a 38% decrease in the odds of having near-perfect adherence (versus non-adherence or adequate adherence) at week 48 compared to week 12 (OR=0.62, $p=.03$). At week 12, 6 (6.82%) participants demonstrated non- adherence, 39 (44.3%) adequate adherence, and 43 (48.9%) near-perfect adherence. At week 48, 16 (18.2 %) participants demonstrated non-adherence, 36 (40.9%) adequate adherence, and 36 (40.9%) near-perfect adherence. We observed a reduction in the proportion of participants demonstrating near-perfect adherence from week 12 to week 48 in the SoC arm (48.9% to 33.3%) but not the iTAB arm (48.8% at both study weeks).

The variables univariably associated with PrEP adherence (i.e., employment, DAST total, HIV knowledge, cocaine use, and meth use in Table 1; $p$'s$<.20$) were included in the multivariable model (Model 3 in Table 3). With backward stepwise selection, HIV knowledge and meth use were retained in the model as covariates (Model 4 in Table 4). There was a 40% decrease in the odds of having near-perfect adherence (versus non-adherence or adequate adherence) at week 48 compared to week 12 (OR=0.60, $p=.023$)

indicating a significant effect of study visit (i.e., time). Further, higher HIV knowledge resulted in higher odds of near-perfect adherence (versus non-adherence or adequate adherence; OR=1.72, $p$=.020), indicating that more HIV knowledge is associated with higher adherence (Mean= 3.18, 4.11, 4.99 for non-adherence, adequate adherence, and near-perfect adherence, respectively).

In a follow-up logistic regression analysis, MSM had a trend towards higher odds of near-perfect adherence relative to adequate adherence at week 48 (OR=2.48, $p$=.061) if they received iTAB versus SoC.

## Discussion

MSM who use stimulants represent a group highly susceptible to HIV transmission, both through engagement in risk activity (e.g., unprotected sex, potential for injection drug use) as well as poor adherence to PrEP (Mimiaga et al., 2018; Okafor et al., 2020). Thus, MSM who use stimulants represent a group for which consistent adherence to a PrEP regimen is particularly important. In our subanalysis of the CCTG 595 study, we found duration of time in study (i.e., completion of the 48-week study), regardless of treatment arm (i.e., SoC versus iTAB) to be associated with higher odds of near-perfect PrEP adherence. We further found greater HIV knowledge to be negatively associated with odds of near-perfect PrEP adherence.

Among MSM who use stimulants, stimulant use has been purported to negatively influence participants' ability to take PrEP as prescribed and/or recommended to confer protection against HIV (Hojilla et al., 2018; Oldenburg et al., 2016). Further, stimulant use has been qualitatively reported to introduce adherence barriers such as forgetfulness and disruptions to daily routines (Storholm, Volk, Marcus, Silverberg, & Satre, 2017). However, in one published analysis of the CCTG 595 trial that collapsed the intervention arms, stimulant use was not associated with poorer PrEP adherence when compared to no stimulant use (Hoenigl et al., 2018). The present study extends these findings by focusing on the subset of participants who reported stimulant use and examining whether PrEP adherence differed by intervention arm. In univariate tests by specific substance (i.e., meth, cocaine, amphetamines), we found the proportion of near-perfect adherence to be higher among MSM receiving iTAB (compared to SoC) for individuals who use cocaine and amphetamines. Although our models did not find meth use to significantly predict odds of PrEP adherence, meth use trended towards significance in our final model. No other substance use was statistically associated with PrEP adherence in our models.

Our findings suggest that receipt of the iTAB intervention trends towards greater PrEP adherence. Although we observed an overall reduction in the proportion of participants demonstrating near-perfect adherence from week 12 to week 48, there was not a reduction in the proportion of near-perfect adherence among the iTAB arm (only a reduction in proportion of individuals achieving near-perfect adherence in the SoC arm, 48.9% to 33.3%, versus the iTAB arm's 48.8% proportion of near-perfect adherence). Further, we observed all MSM to trend towards higher odds of near-perfect adherence relative to adequate adherence at week 48 (but not near-perfect adherence relative to non-adherence). Taken

together, one possible explanation for these findings is that for participants with adequate adherence, receipt of the iTAB intervention may provide an additional level of support needed to achieve near-perfect adherence.

We found HIV knowledge to be a significant predictor of odds of PrEP adherence, such that higher HIV knowledge was associated with higher adherence. Our findings are supported by those of other HIV preventions studies among MSM and individuals using substances (Bazzi et al., 2018; Blair et al., 2022). In one particular study of PrEP-eligible MSM, greater HIV knowledge was associated with significantly increased odds of PrEP use (Blair et al., 2022). Similarly, willingness to take PrEP was associated with an awareness of increased risk among individuals who inject drugs (Bazzi et al., 2018). Finally, drawing on several years of PrEP implementation, Nunn et al. (2017) have proposed a PrEP continuum of care that underscores the importance of HIV risk awareness to support PrEP use among individuals at-risk for HIV transmission.

There were limitations to the present analyses. First, the sample size of this subanalysis was small, and limited to stimulant-using MSM, limiting our ability to generalize these findings to other substances and populations. Second, considering our finding of and explanation for HIV knowledge influencing odds of PrEP adherence, collecting data on perceived risk would lend more support and insight to this finding. Third, we have limited details on the specific “other recreationally-used amphetamines” that participants used, limiting insight to the substance use patterns of these individuals. Fourth, although this study period is longer than that of many existing studies, an increased time on the intervention as well as examination of post-trial PrEP adherence may be helpful in determining the longer-term efficacy of the iTAB intervention. Future directions include a larger, longer study of iTAB to support PrEP adherence among MSM who use meth, as well as a more in-depth inquiry on the substances participants use.

MSM who use stimulants represent ideal candidates for PrEP. Our study is relevant to supporting PrEP adherence by examining an individualized text messaging intervention as means to supports to PrEP adherence. Although more research is needed, our results provide preliminary evidence that HIV knowledge may influence PrEP adherence, and further, that engagement in research may be supportive of PrEP adherence.

## Conflicts of Interest and Source of Funding:

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**Table 1.**

Baseline characteristics by intervention arm (iTAB *vs.* SoC)

| | **iTAB (n=58)** | **SoC (n=61)** | ***p*** |
|---|---|---|---|
| Proportion male sex, % | 100% | 100% | - |
| Age, median (IQR) | 32.5 (28.0 –34.6) | 32.0 (28.0–35.2) | .69 |
| Education [some college or more], n (%) | 54 (93.1%) | 59 (96.7%) | .43 |
| Hispanic ethnicity, n (%) | 18 (31.6%) | 14 (23.3%) | .30 |
| Race | | | .70 |
| White, n (%) | 44 (80.0%) | 44 (74.6%) | |
| African American, n (%) | 6 (10.9%) | 11 (18.6%) | |
| Asian, n (%) | 3 (5.45%) | 2 (3.39%) | |
| Other/Unknown, n (%) | 2 (3.64%) | 2 (3.39%) | |
| Employed, n (%) | 20 (35.1%) | 7 (11.5%) | **.004** |
| Income [≥$2,000/month], n (%) | 32 (68.1%) | 44 (77.2%) | .38 |
| Relationship status [single], n (%) | 27 (65.9%) | 31 (67.4%) | 1.00 |
| Sexual desire total, median (IQR) | 16.0 (12.0, 15.3) | 15.0 (11.0, 14.9) | 0.58 |
| Median DAST-10 (IQR) | 3 (3–5) | 3 (2–4.5) | .11 |
| Sexual Risk Scale | 76 (13) | 74.7 (13.6) | .58 |
| HIV Knowledge[a], median (IQR) | 5.50 (3.00–5.55) | 3.00 (2.00–3.62) | **0.001** |
| PHQ9 total, median (IQR) | 6.00 (2.00–6.16) | 5.00 (2.00–5.44) | 0.38 |
| Cocaine use (yes), n (%) | 24 (41.4%) | 35 (57.4%) | 0.100 |
| Meth use (yes), n (%) | 35 (60.3%) | 27 (44.3%) | 0.099 |
| Other amphetamine use (yes), n (%) | 18 (31.0%) | 15 (24.6%) | 0.54 |

Notes:

[a]square-root transformation prior to comparison analysis

DAST-10 = Drug Abuse Screening Test-10 (self-reported screen of drug use); PHQ9 = Patient Health Questionnaire-9 (depression severity measure); Sexually Transmitted Infections screened: chlamydia, gonorrhea, syphilis.

At week 12, eight participants were lost to follow up (iTAB lost n=5, SoC lost n=3). By week 48, 29 participants were lost to follow up (iTAB lost n=14, SoC lost n=15).

**Table 2.**

Difference in adherences between the two arms over time were assessed using ordinal logistic regression.

| Model | Predictor | OR (95% CI) | *p*-value |
|---|---|---|---|
| **MODEL 1** | | | |
| | Arm (ref. iTAB) | 1.74 (0.41, 7.33) | 0.45 |
| | Visit (ref. week 12) | 0.79 (0.45, 1.39) | 0.41 |
| | Arm x Visit | 0.63 (0.27, 1.46) | 0.28 |
| **MODEL 2** | | | |
| | Arm (ref. iTAB) | 0.87 (0.44, 1.73) | 0.70 |
| | Visit (ref. week 12) | 0.62 (0.40, 0.95) | 0.029* |
| **MODEL 3** | Arm (ref. iTAB) | 1.49 (0.71, 3.13) | 0.30 |
| | Visit (ref. week 12) | 0.59 (0.38, 0.92) | 0.02* |
| | Employment (ref. unemployed) | 0.59 (0.24, 1.49) | 0.27 |
| | DAST total, a | 0.70 (0.29, 1.68) | 0.42 |
| | HIV Knowledge total, a | 1.67 (1.02, 2.72) | 0.041* |
| | Cocaine use (ref. no) | 1.12 (0.51, 2.48) | 0.78 |
| | Meth use (ref. no) | 1.96 (0.84, 4.59) | 0.12 |
| **MODEL 4** | Arm (ref. iTAB) | 1.37 (0.65, 2.86) | 0.41 |
| | Visit (ref. week 12) | 0.60 (0.39, 0.93) | 0.023* |
| | HIV Knowledge total, a | 1.72 (1.09, 2.72) | 0.020* |
| | Meth use (ref. no) | 1.73 (0.87, 3.46) | 0.12 |

Note: Ref = reference group.