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Novel Latent Profile Analysis of a Test of Concept, Stigma Intervention to Increase PrEP Uptake

Among Black Sexual Minority Men

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RUNNING HEAD: STIGMA INTERVENTION FOR PREP USE

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ABSTRACT

Background: Pre-exposure prophylaxis (PrEP) has demonstrated efficacy for HIV prevention, yet uptake of PrEP among populations in urgent need of prevention tools (*e.g.*, Black sexual

minority men [BSMM]) is limited, and stigma and medical mistrust remain strong barriers to accessing PrEP. Purpose: To evaluate a test of concept brief intervention to address stigma and medical mistrust as barriers to PrEP uptake using novel latent profile analysis. Methods: Participants (N=177) residing in the southeastern US were randomized to one of four arms to establish the potential impact of a brief, stigma focused counseling intervention (referred to as Jumpstart) to increase PrEP uptake. We estimated intervention effect size (Cramer's V) for PrEP uptake and then explored differential intervention effects across latent profiles of psychosocial barriers to PrEP use. Results: The intervention resulted in small, but meaningful effect size, with self-reported PrEP uptake increasing across Jumpstart conditions with the control condition reporting 24% uptake and Jumpstart plus text/phone calls (the most intensive intervention arm) reporting 37% uptake, and a similar pattern emerging for biologically confirmed PrEP use. Among participants 30 and older, Jumpstart participants were more likely to move to a post-intervention profile with fewer barriers than control participants and reported the highest uptake of PrEP. Conclusions: Addressing social/emotional barriers to PrEP uptake is an essential component of bridging the gap between advances being made in biomedical forms of HIV prevention, and establishing and supporting access to those advances.

Key Words: PrEP uptake, Black sexual minority men, brief interventions

HIV disproportionately burdens Black/African Americans who represent 42% of new HIV cases annually, yet they account for 13% of the US population (1). Furthermore, Black

sexual minority men (BSMM) continue to be the foremost group affected by HIV in the US. It is estimated that with current transmission rates, one out of two BSMM will test positive for HIV within their lifetime (2, 3). Furthermore, pre-exposure prophylaxis (PrEP) has demonstrated high efficacy for HIV prevention in clinical trials and observational studies among sexual minority men (SMM) (4, 5), and therefore, has the potential to be a highly effective tool in halting the HIV epidemic among BSMM.

Although PrEP is highly effective for preventing HIV transmission, it is not sufficiently reaching BSMM (6, 7). Estimates demonstrate that uptake of PrEP is higher among White SMM – a population with declining HIV incidence – compared to Black SMM – a population with increasing HIV incidence (8). This disparity in PrEP use further contributes to the existing ethnic/racial disparities currently observed in HIV transmission (9, 10). Similar to the HIV treatment and care cascade (11), Kelley et al. (12) proposed the PrEP Care Cascade for sexually active BSMM and demonstrated that even with optimistic estimates of PrEP uptake, considerable work remains in linking BSMM to ongoing PrEP care (13, 14).

The stigmatization of PrEP for HIV prevention undermines efforts to promote PrEP use, and has proven to be a strong barrier to PrEP uptake (13, 15). Anticipated stigma regarding PrEP use from potential sex partners has been highlighted as a barrier to using PrEP among SMM (16, 17). Further, mistrust towards medical institutions and/or pharmaceutical industries is a strong driver of stigma and also serves as a barrier to PrEP use (18). Prior work with BMSM has identified robust relationships between stigmatizing beliefs about PrEP use, mistrust of medical institutions, and actual interest in starting PrEP (19, 20).

Although stigma and medical mistrust are robust barriers to engagement in HIV care current CDC PrEP guidelines do not offer specific guidance in these areas. The *CDC PrEP* Copyright © 2023 Wolters Kluwer Health, Inc. Unauthorized reproduction of this article is prohibited.

Practice Guidelines do highlight the need to better understand the barriers to and motivations for using PrEP (21), but interventions that address these areas are limited. More specifically, the guidelines highlight stigma related barriers, but do not offer further instruction for addressing these challenges. Brief interventions to address psychosocial barriers, including stigma, to improve HIV-related health outcomes have been demonstrated as feasible and cost efficient, and have shown significant impact on sexual risks and preventing sexually transmitted infections (STI) (22). Advances in the utility of brief interventions have not, however, been applied to accessing healthcare for PrEP uptake.

The current study was an initial test of concept for an intervention that focused on determining the potential efficacy of a brief, counseling intervention to increase PrEP uptake by addressing stigma around PrEP use and PrEP-related medication beliefs among BSMM atrisk for HIV. We also incorporated a novel analytic approach to determine the impact of the intervention on sample subgroups that were identified based on subgroupings of PrEP psychosocial beliefs. The intervention was adapted from the HIV stigma framework (23) which elucidates the relationships between stigma drivers (stereotypes, prejudice, and discrimination) and stigma mechanisms (internalized, enacted, and anticipated stigmas). Components of the HIV stigma framework were used, specifically, to inform brief intervention counseling content in order to address stigma related barriers to PrEP uptake among BSMM.

METHODS

Participants and Settings. Participants were 177 individuals residing in and around Atlanta, GA, recruited via social media (e.g., Facebook and Instagram) and through participant

referral. Enrollment occurred between November 2019 and August 2020, and follow-ups were completed by January 2021. All study protocols received Institutional Review Board approval and the trial was registered in the clinical trials registry-clinicaltrials.gov (NCT-04201327). Study entry criteria included: 18 years of age or older, assigned male sex at birth, report condomless anal sex in the past year, report no current PrEP use, report HIV negative/unknown status, and report that last HIV test was more than 3 months ago.

Study procedures. Participants provided written informed consent for study enrollment. All study activities occurred virtually using either an online survey program (REDCap) or video chat with project staff. HIV testing was conducted using OraQuick HIV 1/2 antibody tests (OraSure Technologies). Using randomization software, all participants testing HIV negative were assigned to one of four intervention conditions: (1) PrEP information only (control condition), (2) the experimental, brief counseling intervention (Jumpstart, described below), (3) Jumpstart plus text message check ins, or (4) Jumpstart plus text message and phone call checkins. Given the stepped nature of the intensity of the intervention arms and because rates of PrEP uptake are largely established, we employed an unequal allocation of intervention arm (1:2:2:2). Text messages and phone call check-ins occurred primarily in the first four weeks following the intervention. Participants also completed 1-, 2-, and 4-month follow-up surveys (Figure 3). We report on uptake of PrEP use at any follow-up time point, and we report on data from baseline (pre-intervention), and 1-month follow-up (post-intervention) for latent profile analyses of psychosocial barriers to PrEP use. Participants received \$220 for completing study activities.

Intervention Counseling

Jumpstart Brief Counseling. Participants randomized to Project Jumpstart counseling received approximately 45-minutes of stigma focused counseling delivered over one session.

Using strategies consistent with client-centered counseling (24, 25), motivational interviewing (26), and a semi-structured interviewing styles, participants were asked to discuss their perspective on factors that influence their engagement in HIV prevention strategies (27)(28). Counseling and follow-up text messages and phone calls were delivered virtually. Counselors were trained in motivation interviewing. Text message and phone call (10-15 minutes) check-ins consisted of asking participants if they needed help with reaching their PrEP related goals set in the counseling session.

Measures

Primary outcome

PrEP uptake. PrEP uptake was assessed using biological testing and self-report from follow-up measures. Participants who self-reported any PrEP use in the 4 months post-intervention were asked to provide a urine sample for assay testing using UrSure (UrSure, Inc, Boston, MA). Test results were interpreted dichotomously and included presence or absence of tenofovir.

Secondary outcomes

Psychosocial barriers to PrEP uptake. Seven measures of psychosocial barriers to PrEP uptake were measured at pre-intervention and at immediate post-intervention (one month from baseline). All items were measured on a 6-point Likert scale ranging from strongly disagree to strongly agree. Anticipated PrEP stigma was measured with a mean scale of three items regarding expectations about how the participant would be treated if they used PrEP ($\alpha = .76$) (19). PrEP stereotypes were measured with a mean scale of ten items regarding beliefs about PrEP users or related behaviors ($\alpha = .81$) (19). Negative PrEP beliefs were measured with a mean scale of three items regarding a participant's beliefs about how taking PrEP might

negatively impact their life (α = .80) (29). *PrEP conspiracy beliefs* were measured with a mean scale of three items regarding mistrust of PrEP providers and developers (α = .86) (19). *Medical mistrust* was measured with a mean scale of three items about personal and global mistrust of healthcare providers (α = .83) (30-32). *PrEP contextual barriers* were measured with a mean scale of nine items related to access, interpersonal barriers, and confidentiality barriers (α = .77) (33). *Low social support* was measured with five items related to social support for PrEP use from friends, family, and sexual partners. All social support items were reverse coded to create a mean scaled score for low support (α = .86). Normal distribution of all psychosocial barrier variables was confirmed using skewness and kurtosis thresholds of \pm 2 (34, 35). Psychosocial barriers scales were scored for any participants who provided data on at least one item in each scale.

Analysis Plan

Overall and age-stratified tests of preliminary efficacy. To check for effective randomization, differences in pre-intervention demographic characteristics (education, income, employment, gender, sexual orientation, relationship status) and prior PrEP use were examined across conditions using chi-square tests. No differences across conditions were detected. For the current study we used X^2 tests to estimate effect sizes (Cramer's V) for PrEP uptake across intervention conditions and stratified by age. This approach was determined due to limitations of the sample size and the focus on testing preliminary efficacy. Based on a binary outcome and a four-arm intervention, we followed work by Kim (36) (small >.06, medium >.17; large >.29) for recommended thresholds for interpreting effect sizes. Analyses were then repeated and stratified by age (below 30, and 30 and over). Findings were reported by age due to the well-established relationship between patterns of HIV transmission and age, in particular, for BSMM (1, 37).

Tests of intervention impact varying by subgroups. We used latent profile analyses (LPA) to assess whether the impact of intervention varied by subgroups characterized by groupings of psychosocial PrEP belief measures. We used LPA (31) to identify profiles indicated by patterns of seven co-occurring psychosocial barriers to PrEP uptake. LPA allows for the identification of subgroups (i.e., profiles) with shared patterns of characteristics. LPA produces two types of estimates: (1) latent profile membership prevalences and (2) item-response means or estimates of the item-level indicators (i.e., psychosocial PrEP barriers) within profiles. Pre-intervention model selection was based on information criteria (AIC, BIC, a-BIC), entropy, profile size, and interpretability (38). Item-response variances were restricted to be equal across profiles. After selecting the best-fitting pre-intervention model, the immediate post-intervention model was selected using the same steps. To examine measurement invariance in latent profile structure between pre- and immediate post-intervention models we compared latent profile measurement structure stratified by time, and then contrasted model fit parameters between latent profiles with measurement structure constrained and unconstrained across times. In latent profile analysis, data were retained for participants who provided data for at least one psychosocial barrier at baseline.

To examine whether transitions differed by treatment and by age group, transitions were estimated for the full sample and then stratified by condition (simplified to any intervention versus control) within age groups. Probability of transition for participants under 30 was limited and therefore movement was only further investigated among participants 30 years of age and older. SAS version 9.4 and Mplus version 8.4 were used for analyses.

RESULTS

Sample Description

The majority of participants reported more than a high school diploma (76%), an income of \$20,000 and over (56%), being employed (76%), and male gender identity (96%). All participants identified as Black with 37% also identifying as African American, 4% as Afro-Caribbean, 3% as African, 2% as Afro-Jamaican (Table 1).

Intervention Impact

Overall intervention impact on self-reported PrEP uptake resulted in a small effect size, though non-significant, with this outcome increasing across Jumpstart conditions with the control condition reporting 24% uptake, Jumpstart only reporting 29% uptake, Jumpstart plus text messaging reporting 34% uptake, and Jumpstart plus text/phone calls reporting 37% uptake. We note a 43% increase in the likelihood of uptake in the Jumpstart text/phone call arm relative to the control condition. A similar pattern was observed when analyzing the overall intervention effect size on the PrEP biological test results - the percent of participants' biological confirmation of PrEP use increased as intervention intensity increased (Table 2).

Findings stratified by age reveal similar patterns to those that were observed across the entirety of the sample, yet we also note a large effect, though non-significant, when examining the percent of individuals biologically testing positive for PrEP among participants aged 30 and over, with 20% of the control condition sample, 22% of Jumpstart only, 56% of Jumpstart plus text messaging, and 58% of Jumpstart plus phone calls testing positive for PrEP use (Table 2). Note, biological testing for PrEP use only occurred among individuals self-reporting PrEP use.

Latent Profiles of Psychosocial PrEP Barriers

Profile membership prevalence and item-response means are visualized in Figure 1. The first profile, named **Low Emotional Barriers** (44% prevalence), was characterized overall by below average levels on all psychosocial PrEP barriers. The second profile, named **Concerns**

about HIV Prevention (39% prevalence), was characterized by elevated PrEP conspiracy beliefs, medical mistrust, and negative PrEP beliefs, but with below average anticipated stigma. For this profile, barriers to PrEP uptake were concentrated on concerns towards medicine and medical establishments, but not on how participants would be treated by others for using PrEP. The third profile, named **Experience Complex Barriers** (17% prevalence), was characterized by above average levels of psychosocial PrEP barriers (with exception of medical mistrust), with especially elevated levels of anticipated PrEP stigma.

To extend the LPA longitudinally, the same model selection steps were replicated using the first follow-up post intervention. Comparison of models with 3-profile model post-intervention with pre-intervention data provided evidence of the same three profiles at both times (i.e., stable latent profile measurement structure, minimization of model fit criteria, more trustworthy, well-identified solution, in the latent model constrained to be equal across times). Post-intervention 4- and 5-profile models provided similar decision-making information as pre-intervention with very small or redundant profiles emerging after the 3-profile model. There were no differences among profiles in intervention arm assignment pre-intervention.

Latent Transitions in Profiles of Psychosocial PrEP Barriers

Parameter estimates for latent transitions in profile membership from pre- to post-intervention are shown in the bottom of Figure 1. Transition probabilities in Figure 1 represent stability in profile membership: probability of belonging to the same profile post-intervention was 88% for Low Emotional Barriers, 92% for Concerns about HIV Prevention, and 75% for Experience Complex Barriers. For example, participants in Experience Complex Barriers pre-intervention had a 21% probability of transitioning to Concerns about HIV Prevention post-intervention and a 4% probability of transitioning to Low Emotional Barriers post-intervention.

Under age 30. Probability of transition between profiles for participants under age 30 was near zero in both the treatment and control conditions, indicating little change and more stability in profile membership from pre- to post-intervention in both conditions.

Age 30 and over. As shown in Figure 2, among participants aged 30 and older, there were visible differences in transition probabilities between conditions (i.e., control versus Jumpstart conditions). Experience Complex Barriers membership stability was more common in the control condition than in the Jumpstart conditions (79% vs. 60%), and stability in Low Emotional Barriers was less common (41% vs. 92%). Further, among participants in Low Emotional Barriers, there was 60% probability of transitioning to Experience Complex Barriers in the control condition and only 4% probability of the same transition in all the Jumpstart conditions. Among participants in Experience Complex Barriers, there was a 21% probability of moving to either Concerns about HIV Prevention or Low Emotional Barriers in the control group and a combined 40% probability of the same transitions in the Jumpstart conditions. Together, these results suggest more desired change (movement out of Experience Complex Barriers and stability in Low Emotional Barriers) in the Jumpstart conditions relative to the control condition for participants age 30 and older. In addition, participants age 30 and older experiencing these two transitions reported the highest percentage of PrEP uptake, 37% for stable Low Emotional Barriers and 40% for participants with the transition from Experience Complex Barriers to Concerns about HIV Prevention.

DISCUSSION

Findings from the current study suggest important utility of providing additional support for improving engagement in PrEP access among individuals at elevated risk for HIV. Although findings from the current study need to be replicated with larger samples, the demonstrated

preliminary results warrant further research into understanding how stigma focused interventions can impact PrEP uptake (39). Data from our sample suggest beneficial patterns of not only brief intervention counseling, but a beneficial pattern of providing additional and ongoing support for accessing PrEP uptake through post-intervention check-ins.

For the current analysis, we incorporated a novel approach to examining intervention effects, thereby demonstrating how subgroups of BSMM characterized by complex patterns of psychosocial barriers to PrEP use shifted through a stigma-related PrEP intervention. We used latent profile and transition analysis to identify complex patterns of barriers and to compare preto post-intervention transitions in these patterns between control and intervention arms. Although it is known that prior research has incorporated this approach (e.g., (40, 41)) and related approaches such as identifying mediators of intervention effects (e.g., (42)), on the whole, interventions are typically evaluated solely between arms with little consideration of differential results among subgroups. The main consequence of this latter approach is that it does not capture how subgroups respond to the intervention and the resultant effects of the intervention. More traditional approaches may adjust for baseline differences, but they do not adjust for subgroup differences in the patterns of response.

We note in our analyses that shifts in patterns of psychosocial PrEP barriers from pre- to post-intervention were more favorable in the Jumpstart intervention conditions than in the control condition, for participants over age 30. Among individuals experiencing a pattern of elevated, co-occurring psychosocial barriers (*i.e.*, the Experience Complex Barriers profile), fewer participants in Jumpstart remained in this profile post-intervention compared to the control condition. We also show that transitioning from the profile with the most complex barriers and highest level of stigma (*i.e.*, Experiencing Complex Barriers) resulted in a higher likelihood of

reporting PrEP use relative to individuals who were stable in or transitioned to the Experience Complex Barriers. When reviewing the sample as a whole, the most common pre- to post-intervention profile transition occurred among participants in the Experiencing Complex Barriers profile – 21% of these individuals moved into the Concerns about HIV Prevention profile which is characterized by below average anticipated stigma when compared with the larger sample. It's possible that by virtue of being involved in any arm of the study participants gained heightened awareness of HIV prevention needs resulting in an overall shift on items making up this profile over time.

Historically, HIV transmission rates have varied by age and in recent data (*i.e.*, 2019) (43) we have observed the greatest number of diagnoses among individuals between the ages of 25-29, and increases in diagnoses among individuals 13-24, 35-44, and 45-55. HIV transmission remains a concern across the lifespan of BSMM, even as needs or interests in HIV transmission may change throughout the lifetime (*e.g.*, special issue on topic(44)). Our analyses were stratified by age, we noted similar patterns of intervention effects across age groups. However, effect sizes were stronger with our age 30 and over group. There is evidence that PrEP use increases with age (45) and, although there exist important qualifiers (e.g., neurocognitive status, co-morbid diagnoses) (46), HIV related health care access markers tend to improve with age (47). We do, however, caution that these patterns need to be evaluated with larger samples and evaluated with inferential statistics. Literature suggests that younger SMM have less experience with routine healthcare (48) and unmet medical needs when compared to heterosexual youth (49) and transitioning from adolescent care to adult care can prove complicated for some (50), which may help explain the relatively small transition in this group. Additionally, the stability among the Concerns about HIV Prevention profile in transition analyses may support findings of a

recent qualitative study of younger BSMM who initiated PrEP, which found that challenges to PrEP use included PrEP related stigma in addition to ongoing concerns about side effects (51). It is therefore possible that PrEP related outcomes will improve with age regardless of intervention provided.

As for study limitations, findings are limited to a sample of BSMM reporting sexual risk taking and residing in the southern US. The small sample size precluded the use of parametric statistics and is based in assumptions of latent profile analysis (e.g., local dependence), and therefore, needs replication with larger sample sizes. Biological testing of PrEP using UrSure is limited to only a short-term period of time (approximately 48 hours). Social desirability bias, in particular, around stigma may impact self-report measures. It is also important to consider larger socioeconomic factors that impact the likelihood of accessing PrEP. Education and income levels among the participants were varied and suggest the need for taking these factors into consideration when developing interventions. Likewise, it is important to consider how structural approaches that address stigma, medical mistrust, and social support can also be implemented to increase PrEP uptake.

Novel approaches to engaging BSMM in PrEP care, such as the intervention described here, offer a feasible and low-burden approach for addressing unmet psychosocial needs when engaging in HIV prevention. Efforts to slow and eradicate the HIV epidemic in the US and globally remain an urgent need, and critical and comprehensive approaches to prevention must be prioritized. Our post-intervention effects suggest that targeting PrEP-related stigma through a brief counseling session may be an effective and cost-saving means of increasing access to PrEP uptake (52). Those who received the most comprehensive package (e.g., stigma-focused counseling plus text message and phone call check-ins) showed the strongest patterns of increase

in PrEP uptake. Addressing stigma as a barrier to PrEP will be an essential element of interventions focused on increasing PrEP use. Broader scale testing of Project Jumpstart across the southeastern US is warranted as rates of HIV and the need to address stigma related barriers (53-55) in this region remain a critical priority (56).



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Table 1Full Sample and Age Stratified Demographic Summary

	Ove	erall	Unde	er 30	30)+
	n	%	n	%	n	%
Education					\	
High School or Less	42	23.7	16	23.4	26	23.01
More than High School	135	76.3	48	76.6	87	76.9
Income						
Under \$20,000	77	43.5	35	54.7	42	37.2
\$20,000 and Over	100	56.5	29	45.3	71	72.8
Employment						
Unemployed	43	24.3	14	21.9	29	25.7
Employed	134	75.7	50	88.1	84	74.3
Gender						
Cisgender man	170	96.0	60	93.8	110	97.4
Other gender identities ^a	7	4.0	4	6.2	3	2.6
Sexual Orientation						
Same-Gender Loving	30	16.7	3	4.7	27	23.9
Gay or homosexual	100	56.5	40	62.5	60	53.1
Bisexual	41	23.2	17	26.6	24	21.2

Heterosexual	3	1.7	1	1.6	2	1.8
Missing	3	1.7	3	4.7	0	0.0
Married						
Yes	9	5.1	0	0.0	9	8.0
No	168	94.9	64	100.0	104	92.0

Note. Besides sexual orientation, no other demographic variables had any missingness. ⁴Other gender identities included trans woman, female, and other write-in responses.



 Table 2

 PrEP Uptake and Adherence Differences, and Effect Sizes across Jumpstart Intervention Conditions

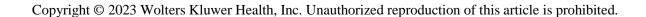
	PrEP Uptake							PrEP Biological Test Results						
	No Uptake		Uptake		Effect Size		Unconfirmed Confirmed			firmed		Effect Size		
	n	%	n	%	χ2 (p)	V (df)	n	%	n	%	χ2 (p)	V (df)		
Full Sample ¹								>						
Control	19	76.0	6	24.0	1.62 (.65)	.10 (3)*	4	66.7	2	33.3	1.61 (.66)	.17 (3)**		
Jumpstart							,							
only	36	70.6	15	29.4			10	66.7	5	33.3				
Jumpstart				A										
Text	33	66.0	17	34.0			9	52.9	8	47.1				
Jumpstart														
Call	32	62.7	19	37.3			9	47.4	10	52.6				
			V											
Under Age														

30^{2}												
Control	6	85.7	1	14.3	1.46 (.69)	.15 (3)*	0	0.0	1	100.0	1.47 (.69)	.26 (3)**
Jumpstart												
Only	11	64.7	6	35.3			3	50.0	3	50.0		
Jumpstart								X				
Text	14	63.6	8	36.4			5	62.5	3	37.5		
Jumpstart												
Call	11	61.1	7	38.9			4	57.1	3	42.9		
							P					
Age 30+ ³												
Control	13	72.2	5	27.8	0.87 (.83)	.09 (3)*	4	80.0	1	20.0	4.40 (.22)	.35 (3)***
Jumpstart												
Only	25	73.5	9	26.5			7	77.8	2	22.2		
Jumpstart												
Text	19	67.9	9	32.1			4	44.4	5	55.6		
Jumpstart	21	63.6	12	36.4			5	41.7	7	58.3		

	11						
Ca							
Cu.							

Note. *Small effect; ***Medium Effect; ***Large Effect according to Kim, 2017 (36). ¹PrEP uptake, *n* = 177; PrEP test results, *n* = 57.

²PrEP uptake, n = 64; PrEP test results, n = 22. ³PrEP uptake, n = 113; PrEP test results, n = 35.



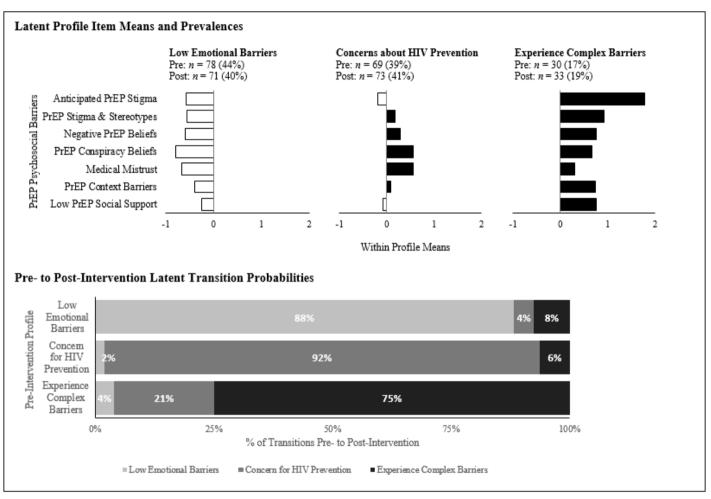
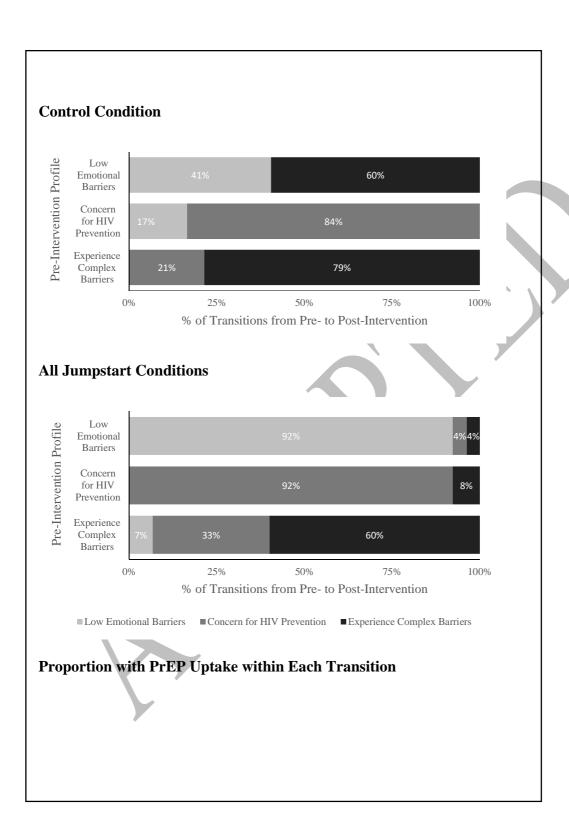


Figure 1. Latent Profiles of PrEP Barriers with Mean Indicator Probabilities and Pre- to Post-Intervention Latent Transition Probabilities. Overall sample included here.



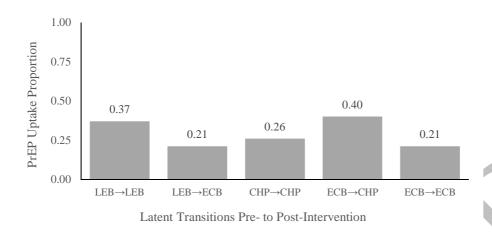


Figure 2. Latent Transitions Pre- to Post-Intervention and Differences in PrEP Uptake Across Transitions for Participants Age 30 Years Old and Over. Overall n = 113 (Control n = 18; JumpStart n = 95). Transitions with n > 5 are included for PrEP uptake summary. LEB = Low Emotional Barriers. CHP = Concerns about HIV Prevention. ECB = Experience Complex Barriers.

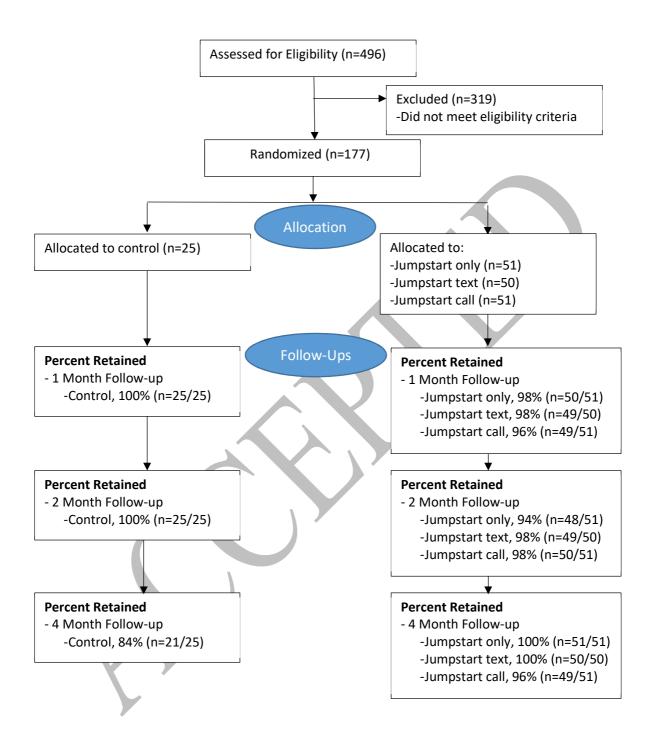


Figure 3. CONSORT Flow Diagram.

