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ORIGINAL PAPER

Psychometric Evaluation and Predictive Validity of an Adapted Adherence Self-Efficacy Scale for PrEP

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Abstract

Adherence to and sustainment of HIV pre-exposure prophylaxis (PrEP) are critical to its effectiveness. Adherence self-efficacy, i.e., confidence in one's ability to adhere to a particular medication, is a key psychological determinant of health behavior that strongly predicts HIV treatment adherence but has been understudied in PrEP research. This paper describes the psychometric evaluation and validation of the PrEP Adherence Self-Efficacy Scale (PrEP-ASES), adapted from the previously validated HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES). Data are drawn from two studies conducted at a community health center, one focused on gay and bisexual cisgender men and the other on transgender women. Factor analyses support a one-factor score (eigenvalue = 6.78) that explained 75.3% of the variance, with good test–retest reliability (rs > 0.40). In both studies, higher PrEP-ASES scores were associated with PrEP uptake, adherence, and sustainment. Findings support the utility of the PrEP-ASES in research and suggest the importance of addressing self-efficacy in PrEP programs and services.

Keywords HIV · Pre-exposure prophylaxis (PrEP) · Adherence · Persistence · Self-efficacy

Introduction

Pre-exposure prophylaxis (PrEP) for HIV prevention is a highly effective biomedical prevention medication and a proven and promising strategy for ending the HIV epidemic [1, 2]. Since its FDA approval in 2012, approximately one million people worldwide have benefitted from taking oral PrEP [3]. PrEP's effectiveness is dependent on patients' adherence to their chosen dosing strategy (e.g., daily or event-driven; with the most common strategy currently being daily oral PrEP in most countries), and on the health care systems' ability to support sustained use over time (e.g., by providing flexible visit scheduling, payment navigation services, or other assistance) [4–6]. Despite significant strides in PrEP implementation over the past 5 years, data indicate that we are far from reaching UNAIDS goals on a global level [7], and reveal stark inequities in PrEP uptake in the United States by both geographic location and race/ethnicity [8]. Given these challenges in uptake, supporting adherence and sustainment for individuals who are willing to start PrEP is critical. Multiple studies have demonstrated the importance of regular adherence to ensure PrEP effectiveness among daily PrEP users [9, 10].

To date, there are equivocal data about PrEP adherence, with some studies demonstrating high adherence rates and others demonstrating lower adherence rates [11–13]. Researchers have identified sociodemographic factors that are correlated with PrEP adherence and continuation and demonstrate that many systemic barriers affect sustainment among racially, socioeconomically, and otherwise marginalized individuals [11, 13, 14]. In addition to these social determinants of health, many psychosocial and treatment-related factors, such as PrEP and HIV stigma, risk perception, side effects, and logistics of daily life, have been identified as predictors of PrEP adherence [15]. Because individuals with low adherence or who discontinue PrEP

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may be vulnerable to HIV infection [11, 14], it is crucial that research identify social and psychological factors that can actively promote and support PrEP adherence and sustainment. Although structural-level and organizational-level interventions are necessary to end the HIV epidemic, psychological factors continue to be an important focus for clinical interventions as well [16].

One of the most prominent psychological constructs across individual-level theories of health behavior change that is both intervenable and especially relevant for effective prevention is adherence self-efficacy [17]. Adherence self-efficacy is defined as confidence in one's ability to adhere to a given treatment or medication [18–20], and has been demonstrated to be a strong predictor of adherence in a variety of contexts, including HIV treatment [21, 22]. In 2007, Johnson et al. published the HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES), a twelve-item self-report scale to measure this construct [18]. The HIV-ASES has robust internal consistency and test–retest reliability [18] and has been used in over 250 studies both nationally and internationally [23–25]. While adherence self-efficacy is correlated with several factors that also affect medication adherence, such as depression [26, 27], this psychological construct is one of the strongest correlates of HIV adherence [21] and has been identified as a modifiable factor that clinicians can influence among patients to enhance adherence and care outcomes [28].

While adherence self-efficacy has been thoroughly explored in HIV treatment, few studies have included measures of PrEP self-efficacy [29–31] and none have been thoroughly validated through psychometric evaluation. In order to address this gap, our research team adapted the HIV-ASES for PrEP use and used this measure in two PrEP implementation research projects with populations disproportionately impacted by HIV in the United States [32, 33]. This paper presents an analysis of this adapted scale to evaluate its psychometric qualities and its association with PrEP adherence (i.e., daily use as directed) and sustainment (i.e., sustained use over time) in these two samples, to demonstrate the reliability and validity of this scale for the measurement of PrEP adherence self-efficacy in future research.

Methods

Participants

The analyses presented in this study are based on a total of 578 HIV-negative participants from two separate studies conducted in collaboration with Callen-Lorde Community Health Center, a federally qualified health center (FQHC) serving lesbian, gay, bisexual, transgender, and queer (LGBTQ) communities in New York City: SPARK, a PrEP demonstration-implementation project (Study A, $N = 430$), and FIRED UP, an observational cohort study of transgender women and trans feminine individuals (TGW/TFI) (Study B, $N = 148$).

Study Procedures: Study A

SPARK participants were recruited through medical provider or counselor referral at the health center. Eligibility criteria included: (1) being 18 years of age or older, (2) negative HIV status, (3) sex recorded at birth of 'male,' and (4) met CDC criteria for PrEP eligibility [34], and/or expressed concern about potential HIV exposure in the next 3 months. Participants who screened eligible for the study completed a self-administered online survey and then were scheduled for an in-person study enrollment visit at the health center at which they decided whether or not they wanted to begin PrEP. Data were collected between January 2014 and May 2017. Detailed information about the study protocol has been published previously [35].

Study Procedures: Study B

FIRED UP was designed to understand and improve PrEP implementation efforts with TGW/TFI in a real-world setting. Study staff embedded within the health center identified eligible patients with upcoming healthcare appointments, and conducted screening, informed consent, and enrollment procedures at appointments. Eligibility criteria included (1) being 18 years of age or older, (2) negative HIV status, (3) sex recorded at birth of 'male,' and (4) gender identity of woman, transgender woman, trans feminine, non-binary, two-spirit, or gender non-conforming. The study was divided into two cohorts: (1) TGW/TFI who were PrEP patients at the clinic and had been prescribed once daily tenofovir disoproxil fumarate/emtricitabine, and (2) TGW/TFI who were patients at the clinic but were not currently or previously prescribed or using PrEP. Data were collected from November 2018 to May 2020. Additional study procedure information is available in a previous publication [36].

Measures: Study A

Demographics

Participants reported their age, race/ethnicity, gender, sexual orientation, education, and income.

PrEP Adherence Self-Efficacy (PrEP-ASES)

Participants completed a 9-item adapted version of the HIV Adherence Self-Efficacy Scale (HIV-ASES) [18], measuring confidence in one's ability to carry out behaviors important

to PrEP adherence, even in the face of adherence barriers. The adaptation stayed as faithful as possible to the original scale, primarily replacing the words "your treatment" with the words "PrEP" or "taking PrEP," (e.g., "Integrate your treatment into your daily routine" became "Integrate taking PrEP into your daily routine"). We deleted three scale items that referenced barriers or situations not relevant for PrEP (e.g., restrictions on meal timing or T-cell level drops). Response options ranged from 0 ("cannot do at all") to 10 ("completely certain can do")? Items were averaged for each participant, with higher scores indicating higher adherence self-efficacy. The full PrEP-ASES scale is presented in "Appendix".

In Study A, all participants completed the PrEP-ASES at baseline (i.e., before initiating PrEP), and participants who initiated PrEP completed the scale on all follow up surveys. Since all participants were PrEP-naïve at baseline, the baseline PrEP-ASES scale prompt language was framed to reflect hypothetical use, whereas the scale prompt language for follow up surveys among active PrEP users referenced current PrEP use (see "Appendix" for different scale prompts).

The following measures were identified for inclusion in validity analyses based on hypothesized associations with adherence self-efficacy.

PrEP Uptake

After completing the baseline visit, participants decided whether they wanted to take PrEP. Those who elected to take PrEP were given a prescription for PrEP medications, based on which we created a binary variable of PrEP Uptake (Yes/No).

PrEP Sustainment

PrEP sustainment was defined through five separate binary variables: four pertaining to each follow up time point (3, 6, 9, 12 months), and one pertaining to the overall study period. Participants were coded as "Yes" for sustainment at each follow up time point during which they attended a visit and received and filled a PrEP prescription. We also created a variable for "on PrEP continually", which was coded as "yes" if patients filled their prescriptions at 3, 6, and 9 months, and reported no interim PrEP cessations to clinicians or study staff between enrollment and their 12-month visit.

PrEP Adherence

Adherence was monitored using dried blood spot testing (DBS) at 3, 6, and 12-month follow-up visits. Results were dichotomized as TDF $\geq$ 700 fmol/punch versus lower levels, with the higher category having been found to indicate recent protective PrEP dosing, at $\geq$ 4 pills/week [37].

Perceived Sensitivity to Medications

At baseline, each participant completed the 5-item scale which assessed their sensitivity to medications [38]. Higher scores on this scale have been associated with greater experiences of medication side effects as well as greater intentional non-adherence to anti-retroviral therapy among individuals living with HIV [38, 39]. Response options ranged from 1 (strongly disagree) to 5 (strongly agree). Example item: "My body is very sensitive to medicines." Individual items were averaged to provide a total score where higher scores indicate higher perceived sensitivity to potential adverse effects of medicines. The scale demonstrated good psychometric properties in the sample ($\alpha = 0.92$).

Depressive and Anxious Symptoms

Participants completed two subscales of the Brief Symptom Inventory [40]. Specifically, participants completed the 6-item depressive and 6-item anxious symptoms subscales, which are part of the short (53-item) version of the Symptom Checklist 90-R. Both subscales demonstrated good psychometric properties in the current sample (anxious symptoms $\alpha = 0.87$; depressive symptoms $\alpha = 0.88$).

Measures: Study B

Demographics

Participants reported the same demographic information as in Study A.

PrEP Adherence Self-Efficacy (PrEP-ASES)

The same survey items were used to measure PrEP-ASES in Study B as were used in Study A. All participants completed the PrEP-ASES at enrollment, and participants who were PrEP users also completed the scale on follow up surveys. The survey prompt was worded to refer to hypothetical PrEP use in the non-PrEP cohort, and to refer to actual PrEP use in the PrEP cohort. See "Appendix" for prompt language.

The following measures were identified for inclusion in validity analyses based on hypothesized associations with adherence self-efficacy.

PrEP Rx Status

We created a binary variable based on PrEP prescription (Rx) status at enrollment. Participants with a PrEP prescription were coded as PrEP Rx = Yes, and participants who

were neither current nor former PrEP users were coded as PrEP Rx = No.

Self-reported PrEP Adherence

Participants were asked a question from a self-report measure of medication adherence: "In the last 30 days, how often did you take your PrEP medication exactly as prescribed by your doctor?" (6-point Likert-type scale, ranging from "Never" to "Always") [41]. In these analyses, this item was dichotomized into Always/Almost Always versus Usually/Sometimes/Rarely/Never.

PrEP Adherence: Urine TFV

Urine samples were collected from participants who reported having taken PrEP within the 7 days preceding their follow up study visit. Samples were analyzed using a liquid chromatography–tandem mass spectrometry (LC–MS/MS) urine assay with high sensitivity and specificity for tenofovir, performed by a third-party laboratory [42]. This assay has been validated, demonstrating high sensitivity and positive predictive value when compared to dried blood spots (DBS), as well as greater sensitivity than plasma-based measures [43–45]. It differentiates between high levels of urine TFV (> 1000 ng/mL), lower levels of urine TFV (10–1000 ng/mL), and the absence of detectable levels (< 10 ng/mL). High levels indicate having taken a pill in the last 7 days, and are a probable indicator for last pill within the last 2–3 days [43]. For these analyses, results are dichotomized as urine TFV > 1000 ng/mL vs. < 1000 ng/mL.

Perceived Sensitivity to Medications

Study B analyzed this construct using the same scale variable used in Study A.

Anxious Symptoms

Participants completed the Generalized Anxiety Disorder 7-item scale [46]. A total score is provided by summing ratings on a 4-point scale, 0 (not at all) to 3 (nearly every day). Example item: "Over the last 2 weeks, how often have you been bothered by the following problems? Feeling nervous, anxious or on edge." Depressive symptoms were included in the survey; however, due to a survey programming error, the results for this scale were incomplete and could not be analyzed.

Resilience Scale

Participants completed the 25-item Connor–Davidson Resilience scale [47]. A total score is calculated by summing ratings on a 5-point scale, 0 (not true at all) to 4 (true nearly all the time). Example item: "Please indicate how much you agree with the following statement: I am able to adapt when changes occur."

Data Analysis: Study A

First, we conducted an exploratory factor analysis (EFA) with data from a randomly selected sample of approximately half of the study participants. We used a principal axis factor method and oblique rotation (PROMAX) to assist us with identifying items with sufficient and adequate factor loadings (i.e., ≥ 0.40) [48, 49]. Factor retention was decided by examining eigenvalues, scree plot, and interpretability of factors. Specifically, factors with eigenvalues less than 1 and those with less than three items were not retained [48].

We then used MPlus 8.0 to conduct a Confirmatory Factor Analysis (CFA) of the 9-item scale with the data from the 225 baseline participants who did not overlap with the EFA sample. This sample size exceeded guidelines for deriving meaningful and interpretable models and fit indices in CFA [50]. Chi-square model fit criterion can lead to erroneous conclusions with criterion sensitivity to large samples (i.e., greater than 200), and has a tendency to indicate a significant probability level as sample size increases [51]. Therefore, model fit was evaluated by examining the root mean square error of approximation (RMSEA), the comparative fit index (CFI), and the standardized root-mean residual (SRMR). RMSEA values lower than 0.06, CFI values above 0.90, and SRMR values close to 0.08 all are indicative of good model fit [52]. We then conducted a CFA with only the participants who had adopted PrEP and completed the scale at their 3-month follow-up.

We assessed concurrent, predictive, and divergent validity, as well as test–retest reliability with all three PrEP-ASES time points (baseline, 3-months, and 6-months) in order to not only provide insight on PrEP-ASES in general, but also to better understand possible differences in the scale's behavior among naïve vs. experienced PrEP users. For concurrent and predictive validity, we calculated mean PrEP-ASES scores stratified by binary PrEP use indicators, using independent t-tests to determine statistically significant differences. Baseline scores were stratified by PrEP uptake, and both baseline and follow up scores were stratified by sustainment and adherence indicators. We assessed divergent validity by calculating Pearson's correlation coefficients and *p*-values between the three PrEP-ASES scores and the hypothesized correlates of adherence self-efficacy. To assess test–retest reliability, we calculated Pearson's correlation coefficients and conducted a repeated measures ANOVA with post hoc pairwise comparison.

Data Analysis: Study B

We assessed concurrent, predictive, and divergent validity for PrEP-ASES in FIRED UP by applying the same analytic methods used for Study B. For concurrent and predictive validity, ASES scores were stratified by binary PrEP use indicators, including PrEP Rx status among all participants, self-reported adherence among PrEP users, and urine TFV level among PrEP users. For divergent validity, we ran correlations between PrEP-ASES T1, T2, T3, and three hypothesized adherence self-efficacy correlates (perceived sensitivity to medications, anxious symptoms, and resiliency). Correlations between the three ASES scores were also used to assess test–retest reliability.

Results: Study A

Sample Characteristics

Participants ($N = 430$) ranged in age from 18 to 76 years ($M = 34.2$, $SD = 9.0$). Table 1 presents the demographic characteristics of the study sample by PrEP Uptake. Cisgender men comprised 96% of the total sample, and 4% were transgender women or non-binary individuals. The sample was diverse in regard to race/ethnicity with 10.5% ($n = 55$) identifying as non-Hispanic Black, 11.9% ($n = 51$) identifying as Hispanic/Latino/a/x, 49.8% identifying as non-Hispanic white ($n = 214$), 18.8% identifying as multiracial ($n = 81$), and 6.6% identifying as Asian ($n = 28$). Approximately 75% of the sample identified as gay ($n = 323$), 12.6% identified as bisexual ($n = 54$) and 9.5% identified as queer ($n = 41$). Approximately two-thirds of the sample had earned a bachelor's degree or higher and about two thirds also earned less than $50,000 annually. The only demographic correlate of PrEP uptake was gender identity, with a larger proportion of the PrEP decliners identifying as trans women, compared to PrEP adopters.

Construct Validity Analyses

Exploratory factor analysis from baseline data with the randomly selected half of the participants ($n = 222$) suggested that the one-factor model approximated multivariate normality as demonstrated by Kaiser–Meyer–Olkin value of 0.93 and a significant Bartlett's test of sphericity: $\chi^2(36) = 1765.34$, $p < 0.001$. Factor retention was decided by examining eigenvalues, scree plot, and interpretability of factors, which all suggested a one-factor solution (eigenvalue = 6.78, 75.3% of variance explained).

The results of the CFA of the baseline data also suggested that a one-factor model provided acceptable fit to the data, $\chi^2(27) = 146.75$, $p < 0.001$, CFI = 0.93, RMSEA = 0.04, SRMR = 0.05. As illustrated in Table 2, items loaded significantly onto one factor and the scale demonstrated good psychometric properties in both samples ($\alpha = 0.95$). Next, we fit a CFA to evaluate the one-factor solution among participants who decided to take PrEP at their 3-month follow-up visit, which also confirmed a one-factor model, $\chi^2(27) = 163.62$, $p < 0.001$, CFI = 0.90, RMSEA = 0.03, SRMR = 0.11.

Concurrent and Divergent Validity

To assess concurrent validity, we examined whether PrEP-ASES assessed at baseline distinguished between those who elected to use PrEP compared to those who did not. Findings were in line with our hypothesis, such that those who elected to take PrEP had higher PrEP-ASES scores compared to those who did not elect to take PrEP. Additionally, we examined whether PrEP-ASES at baseline, 3-months ($n = 280$), and 6-months ($n = 278$) were associated with sustained PrEP use and adherence. In line with our hypothesis, we found that compared to those who stopped PrEP, those who sustained PrEP use had significantly higher PrEP-ASES scores at 3-months and 6-months. Similarly, participants who demonstrated higher levels of PrEP adherence (i.e., TDF ≥ 700 fmol) over the 12-months of the study had significantly higher PrEP-ASES scores at 3-months and 6-months compared to those with lower TDF concentrations. PrEP use indicators were not associated with a difference in baseline PrEP-ASES scores. Table 3 presents these data.

Table 4 provides correlations of PrEP-ASES assessed at baseline, 3-months, and 6-months, and our divergent variables of interest. PrEP-ASES at all time points was negatively associated with Perceived Sensitivity to Medications and Depressive Symptoms assessed at baseline. Additionally, PrEP-ASES assessed at follow-up time points was negatively associated with Anxious Symptoms at baseline.

Test–Retest Reliability

We analyzed test–retest reliability among participants who initiated PrEP by first calculating Pearson's correlation coefficients between PrEP-ASES at each time point. All three time points demonstrated a significant positive correlation with one another, and this association was strongest between the two follow up measurements (3-month and 6-month ASES $r = 0.737$, $p < 0.001$, compared to $r < 0.35$, $p < 0.001$, for baseline paired with either follow up time) (see Table 4).

In addition, we performed a repeated measures ANOVA ($n = 266$) to assess mean ASES scores at baseline and at the two times after accumulating PrEP experience. Mauchly's test indicated that the sphericity assumption had been violated ($\chi^2(2) = 69.74$, $p < 0.001$), so we corrected degrees of freedom using Huynh–Feldt estimates of sphericity ($\varepsilon = 0.82$). The results showed that mean ASES

Table 1 Sample characteristics by study and PrEP status

	Study A: SPARK			Study B: FIRED UP		
	Declined PrEP	Accepted PrEP	χ^2, p value[b]	No PrEP Rx	PrEP Rx	χ^2, p value[b]
	n = 130	n = 300		n = 48	n = 100	
	N (%)	N (%)		N (%)	N (%)	
Gender identity[a]			7.98, 0.017[b]			0.01, 0.931
Transgender woman/woman	9 (6.9%)	5 (1.7%)		42 (87.5%)	88 (88%)	
Non-binary	1 (0.8%)	2 (0.7%)		6 (12.5%)	12 (12%)	
Cisgender man	120 (92.3%)	293 (97.7%)		–	–	
Race/Ethnicity			4.22, 0.574[b]			5.85, 0.430[b]
Non-Hispanic White	63 (49.6%)	151 (50.3%)		16 (33.3%)	22 (22%)	
Black	15 (11.8%)	30 (10.0%)		8 (16.7%)	16 (16%)	
Hispanic/Hispanic White[c]	12 (9.4%)	39 (13.0%)		13 (27.1%)	31 (31%)	
Asian	12 (9.4%)	16 (5.3%)		1 (2.1%)	5 (5%)	
Native Hawaiian/Pacific Islander	1 (0.8%)	1 (0.3%)		1 (2.1%)	1 (1%)	
Middle Eastern	2 (1.6%)	4 (1.3%)		1 (2.1%)	0 (0%)	
Multiracial	22 (17.3%)	59 (19.7%)		8 (6.7%)	25 (25%)	
Sexual identity[d]			5.10, 0.219[b]			30.80, < 0.001[b]
Gay	90 (70.3%)	233 (77.9%)		–	–	
Bisexual	20 (15.6%)	34 (11.4%)		11 (26.8%)	8 (8.9%)	
Queer	13 (10.2%)	28 (9.4%)		2 (4.9%)	14 (15.6%)	
Straight	3 (2.3%)	3 (1.0%)		13 (31.7%)	55 (61.1%)	
Uncertain	2 (1.6%)	1 (0.3%)		–	–	
Lesbian	–	–		9 (22.0%)	1 (1.1%)	
Pansexual	–	–		3 (7.3%)	9 (10.0%)	
Asexual	–	–		3 (7.3%)	3 (3.3%)	
Age			0.07, 0.995			12.46, 0.006
18–24 years of age	13 (10.2%)	29 (9.7%)		16 (33.3%)	34 (34%)	
25–29 years of age	32 (25.0%)	78 (26.0%)		13 (27.1%)	20 (20%)	
30–49 years of age	73 (57.0%)	169 (56.3%)		11 (22.9%)	43 (43%)	
50 years of age and older	10 (7.8%)	24 (8.0%)		8 (16.7%)	3 (3%)	
Education			0.74, 0.391			0.02, 0.883
Less than a bachelor's degree	39 (30.7%)	105 (35.0%)		34 (70.1%)	72 (72%)	
Bachelor's degree or higher	88 (69.3%)	195 (65.0%)		14 (29.2%)	28 (28%)	
Income			0.25, 0.874			1.45, 0.228
$0 to < $49,999	85 (67.7%)	198 (66.7%)		38 (79.2%)	86 (86.9%)	
$50,000+	41 (32.3%)	99 (33.3%)		10 (20.8%)	13 (13.1%)	

[a]Gender identity options differed between Study A and Study B. The "non-binary" category here captures participants who described their gender as genderqueer, gender non-conforming or non-binary in Study A, and who identified as trans feminine, non-binary, two-spirit, or gender non-conforming in Study B. Cisgender men were ineligible for participation in Study B

[b]Chi-squared p-values except cases which required Fisher's exact test (race/ethnicity and sexual identity for both studies, and gender identity for Study A)

[c]Includes individuals who indicated Hispanic ethnicity and White race, as well as individuals who declined to put a race other than Hispanic/Latino or who wrote in Hispanic/Latino as their race under "Other."

[d]Study A and Study B surveys included different response options for sexual orientation

scores significantly varied across the time points: $F(1.63, 432.42) = 160.60$, $p < 0.001$. Bonferroni post hoc tests indicated that in comparison to baseline PrEP-ASES ($M = 7.85$, $SD = 1.23$), scores were significantly higher at 3-months ($M = 9.14$, $SD = 1.29$, $p < 0.001$), and at 6-months ($M = 9.09$, $SD = 1.36$, $p < 0.001$). However, there was no significant difference between scores at 3-months and 6-months ($p = 1$). This aligns with our hypothesis that adherence self-efficacy would be higher after PrEP experience and indicates strong test–retest reliability among PrEP users (Data not shown).

Table 2 PrEP Adherence Self-Efficacy Scale: standardized factor loadings—SPARK (Study A)

Item stem: How confident are you that you can…	Baseline		3-Month follow-up
	EFA (N = 222)	CFA (N = 225)	CFA (N = 280)
…Stick to taking PrEP even when side effects begin to interfere with daily activities	0.68	0.64 (0.57, 0.71)	0.69 (0.53, 0.72)
…Integrate taking PrEP into your daily routine	0.88	0.83 (0.78, 0.94)	0.86 (0.79, 0.93)
…Integrate taking PrEP into your daily routine even if it means taking medications or doing other things in front of people who don't know you are taking PrEP	0.86	0.79 (0.74, 0.83)	0.81 (0.79, 0.84)
…Stick to your PrEP schedule even when your daily routine is disrupted	0.92	0.90 (0.87, 0.92)	0.88 (0.84, 0.92)
…Stick to your PrEP schedule when you aren't feeling well	0.92	0.92 (0.90, 0.94)	0.89 (0.88, 0.94)
…Continue taking PrEP even if it means doing so interferes with your daily activities	0.86	0.85 (0.82, 0.89)	0.81 (0.78, 0.89)
…Continue taking PrEP even when you are feeling discouraged about your sexual health	0.92	0.91 (0.89, 0.93)	0.85 (0.83, 0.89)
…Continue taking PrEP even when getting to your clinic appointments is a major hassle	0.86	0.83 (0.79. 0.87)	0.82 (0.79, 0.89)
…Continue taking PrEP even when people close to you tell you that they don't think it is doing any good	0.88	0.83 (0.79, 0.86)	0.83 (0.76, 0.88)
Eigenvalue	6.78	–	–
% of variance explained	75.3	–	–
Alpha	0.95	0.95	0.93

Results: Study B

Sample Characteristics

Participants ($N = 148$) ranged in age from 18 to 65 years ($M = 34$, $SD = 8.7$). Demographic data stratified by PrEP Rx status is found in Table 1. Almost 88% of the total sample identified as trans women or women, with the rest identifying as trans feminine, non-binary, two-spirit, or gender non-conforming. The sample was diverse in regard to race/ethnicity with 16.2% ($n = 24$) identifying as non-Hispanic Black, 29.7% ($n = 44$) identifying as Hispanic/Latino/a/x, 25.7% identifying as non-Hispanic white ($n = 38$), and 22.3% identifying as multiracial ($n = 33$). Approximately 46% of the sample identified as straight ($n = 68$), 12.8% identified as bisexual ($n = 19$) and 10.8% identified as queer ($n = 16$). Only 28% of the sample had earned a bachelor's degree or higher ($n = 42$), and 83.7% ($n = 124$) earned less than $50,000 annually. A greater proportion of participants who had received PrEP prescriptions at the health center identified as straight or queer compared to identifying as a lesbian or bisexual. A higher percentage of those with PrEP prescriptions were between the ages of 30–49, and a higher percentage of those who had not received PrEP prescriptions were aged 50 or older.

Concurrent and Predictive Validity

To assess concurrent validity, we examined whether PrEP-ASES at enrollment differed between those with PrEP prescriptions and those without. Findings supported our hypothesis, in that PrEP users had significantly higher T1 ASES scores. We also hypothesized that among those in the PrEP cohort, those with higher ASES scores at a given time point would have higher concurrent and future self-reported adherence and urine TFV, compared to those with lower ASES scores. Stratified ASES scores displayed patterns aligning with this hypothesis at all time points, some of which reached levels of statistical significance. Specifically, ASES T1 was significantly associated with self-reported adherence at T2 and T3, and with urine TFV at T3. ASES T2 was significantly associated with self-reported adherence at T2, and ASES T3 was significantly associated with both self-reported adherence and urine TFV at T3. Table 5 presents these data.

Divergent Validity and Test–Retest Reliability

Overall, correlation coefficients between ASES scores and the hypothesized divergent variables were low (ranging from − 0.163 to 0.179). The T1 ASES has a small but significant negative correlation with Perceived Sensitivity to Medications, and a small marginally significant positive association with resilience. In terms of test–retest reliability, the correlations between the ASES scores over time ranged between 0.417 and 0.505 and were all statistically significant. These results are shown in Table 4.

Discussion

This paper is the first, to our knowledge, to develop and test an adapted PrEP adherence self-efficacy scale. In two studies conducted in a community-based health center with priority populations, we found evidence for the reliability and divergent validity of the PrEP-ASES, and for its ability

Table 3 Concurrent and predictive validity of PrEP-ASES—SPARK (Study A)

	PrEP-ASES Baseline				PREP-ASES 3 Months				PrEP-ASES 6 Months			
	N	M (SD)	*t*	*p*[a]	N	M (SD)	*t*	*p*[a]	N	M (SD)	*t*	*p*[a]
PrEP uptake (baseline)			11.38	< 0.001			–	–			–	–
Yes	300	7.85 (1.24)			–	–			–	–		
No	130	5.54 (2.17)			–	–			–	–		
PrEP sustainment[b]												
PrEP Rx/pick-up at 3-month visit			-0.38	0.707			2.17	0.047			–	–
Yes	277	7.84 (1.24)			265	9.20 (1.09)			–	–		
No	23	7.94 (1.19)			15	7.54 (2.95)			–	–		
PrEP Rx/pick-up at 6-month visit			1.43	0.159			2.40	0.023			1.52	0.149
Yes	263	7.89 (1.22)			252	9.22 (1.03)			262	9.16 (1.20)		
No	37	7.55 (1.36)			28	8.06 (2.54)			16	8.10 (2.77)		
PrEP Rx/pick-up at 9-month visit			1.31	0.191			2.36	0.023			2.40	0.023
Yes	251	7.89 (1.23)			240	9.23 (1.03)			247	9.21 (1.15)		
No	49	7.64 (1.26)			40	8.38 (2.25)			31	8.21 (2.28)		
PrEP Rx at 12-month visit			0.84	0.400			2.63	0.011			2.37	0.022
Yes	233	7.88 (1.25)			226	9.25 (1.05)			231	9.22 (1.13)		
No	67	7.74 (1.21)			54	8.52 (1.95)			47	8.48 (2.06)		
On PrEP continually (full study)			1.09	0.278			3.36	0.001			2.93	0.005
Yes	217	7.90 (1.24)			210	9.30 (1.00)			217	9.26 (1.11)		
No	83	7.72 (1.21)			70	8.52 (1.85)			61	8.51 (1.91)		
PrEP adherence[b]												
TDF700 at 3-month visit			1.40	0.162			2.61	0.019			–	–
Yes	259	7.87 (1.21)			250	9.27 (1.00)			–	–		
No	21	7.48 (1.50)			17	7.90 (2.16)			–	–		
TDF700 at 6-month visit			0.41	0.680			3.37	0.002			2.98	0.006
Yes	237	7.89 (1.21)			226	9.32 (0.96)			237	9.29 (0.99)		
No	26	7.78 (1.35)			26	8.57 (1.08)			25	8.23 (1.75)		
TDF700 at 12-month visit			1.73	0.093			2.38	0.024			2.53	0.017
Yes	209	7.96 (1.16)			202	9.32 (0.96)			207	9.29 (1.04)		
No	28	7.40 (1.64)			27	8.64 (1.45)			28	8.55 (1.51)		

[a]Independent samples t-test *p*-values

[b]Among those who adopted PrEP at baseline

to predict PrEP adherence and sustainment. The two studies differed in terms of the gender composition of the sample, the years of data collection, and the type of patient (patients offered free PrEP through the study, vs. patients engaging in regular healthcare that may or may not involve PrEP). The fact that results were replicated in these diverse samples bodes well for the potential generalizability of these findings to additional populations.

Our analyses suggested that PrEP self-efficacy is best conceptualized as a single factor. The original ASES was conceptualized as comprising two subscales: integration and perseverance; but past research also suggests the utility of a single factor or total score for this measure [28, 53]. In both studies, PrEP-ASES scores demonstrated good test–retest reliability, with correlations strengthening over time among the new PrEP users in Study A.

In Study A, the PrEP demonstration project, higher baseline PrEP-ASES scores predicted PrEP uptake, and higher PrEP-ASES scores 3 months after PrEP initiation were significantly associated with both PrEP adherence, measured by TDF-levels in DBS testing, and PrEP sustainment, measured by PrEP prescription pick-up. These significant associations were sustained at every time-point in the study, and PrEP-ASES scores at 3 months predicted continuous PrEP use over the full 12-month follow-up period. In Study B, the naturalistic PrEP cohort study, higher PrEP-ASES scores were associated with greater self-reported PrEP adherence, both concurrently and at future visits. Participants with urine TFV levels above 1000 had higher PrEP-ASES scores in every instance, but these associations did not always reach statistical significance.

Table 4 Divergent validity of PrEP-ASES

Study A (SPARK)	1	2	3	4	5	6
1. PrEP-ASES (baseline)[a]	–					
2. PrEP-ASES (3-months)[b]	0.343***	–				
3. PrEP-ASES (6-months)[b]	0.327***	0.737***	–			
4. Perceived sensitivity to medications[a]	−0.329***	−0.122*	−0.164**	–		
5. Anxious symptoms[a]	−0.051	−0.148*	−0.148**	0.177***	–	
6. Depressive symptoms[a]	−0.108*	−0.153*	−0.174**	0.169***	0.744***	–
Study B (FIRED UP)	1	2	3	4	5	6
1. PrEP-ASES (T1)[a]	–					
2. PrEP-ASES (T2)[b]	0.484***	–				
3. PrEP-ASES (T3)[b]	0.417***	0.505***	–			
4. Perceived sensitivity to medications[a]	−0.163*	−0.128	−0.126	–		
5. Anxious symptoms[a]	−0.036	0.034	−0.067	0.240**	–	
6. Resilience scale[a]	0.158^	0.048	0.179	−0.094	−0.350***	–

***p < 0.001; **p < 0.01; *p < 0.05; ^p < 0.1

[a]Baseline variables are analyzed for all participants in each study

[b]ASES scores were collected at follow up only for participants who initiated PrEP at baseline in the SPARK study, and for participants who had a prescription to PrEP at enrollment in the FIRED UP study

Table 5 Concurrent and predictive validity of PrEP-ASES—FIRED UP (Study B)

	PrEP-ASES T1				PrEP-ASES T2				PrEP-ASES T3			
	N	M (SD)	*t*	*p*[a]	N	M (SD)	*t*	*p*[a]	N	M (SD)	*t*	*p*[a]
PrEP user (enrollment)			3.48	< 0.001			–	–			–	–
Yes	100	8.05 (2.11)			–	–			–	–		
No	48	6.42 (2.88)			–	–			–	–		
PrEP adherence—self-report[b]												
Always/almost always at T2			2.57	0.039			3.62	< 0.001			–	–
Yes	62	8.35 (2.14)			61	8.61 (1.77)			–	–		
No	14	7.23 (1.26)			14	6.46 (2.06)			–	–		
Always/almost always at T3			2.83	0.006			0.84	0.404			2.75	0.017
Yes	56	8.35 (2.02)			54	8.10 (2.01)			56	8.60 (1.34)		
No	12	6.45 (2.52)			11	7.52 (2.55)			12	6.71 (2.29)		
PrEP adherence—urine[b]												
TFV > 1000 at T2			0.93	0.357			1.63	0.108			–	–
Yes	50	8.43 (1.95)			49	8.50 (1.89)			–	–		
No	14	7.88 (2.04)			14	7.50 (2.37)			–	–		
TFF > 1000 at T3			2.11	0.040			1.03	0.318			2.87	0.011
Yes	40	8.49 (1.83)			40	8.41 (1.90)			40	8.69 (1.11)		
No	15	7.15 (2.72)			13	7.67 (2.39)			15	7.00 (2.17)		

[a]Independent samples t-test *p*-values

[b]Among PrEP users

Not surprisingly, PrEP-ASES scores were negatively associated with perceived sensitivity to medications, and this association was stronger at baseline, compared to follow-up, especially for participants in Study A who were initiating PrEP. The PrEP-ASES demonstrated divergence from other measures previously associated with adherence, including anxiety, depression and resilience.

Taken together, these results support the utility of the PrEP-ASES for use in PrEP-related research, as well as the importance of the concept of PrEP self-efficacy in clinical

encounters. Many of the items in the PrEP-ASES represent abilities that can be taught or supported by behavioral interventions in health care settings. For example, patients can be taught strategies for integrating PrEP into their daily routines, for sticking to their PrEP schedule even when their daily routine is disruptive, and for navigating frustrations or negative emotions that might impact PrEP use. Research suggests that presenting patients with specific coping strategies can increase self-efficacy [54–57], which may have significant positive impacts on health behavior and outcomes. Using a consistent measure of PrEP self-efficacy may improve the evaluation of interventions aimed at increasing PrEP self-efficacy and enable researchers to understand the relative impact of different intervention strategies.

The analyses above are subject to several limitations. Although the studies were conducted with different patient populations and at different times, both were conducted in the same community-based health center in New York City. This community health center is a highly supportive environment for LGBTQ+ patients and has a robust PrEP program, so these findings might not necessarily generalize to differing patient populations or settings. Our studies did not include cisgender women and transgender men, who have both been systematically under-represented in PrEP prescriptions and programs. More research is needed on the psychological and social predictors of PrEP adherence and sustainment in these populations. It should be noted that longer-acting injectable cabotegravir has potential to mitigate adherence (though not sustainment) concerns; however, many individuals may find this option less desirable because of financial, logistic, or other concerns and may continue to elect oral PrEP.

Despite these limitations, these data indicate that the PrEP-ASES is a useful tool for understanding PrEP adherence and sustainment. Interventions and programs to support PrEP use in clinical settings should pay careful attention to the role of self-efficacy in patients' behavior and should build upon strategies designed to enhance and support self-efficacy to ensure the success of PrEP in achieving Ending the Epidemic goals.

Appendix

PrEP Adherence Self-Efficacy Scale (PrEP-ASES)

Standard Language for Active PrEP Users (See Prompt Language Below for Other Types of Participants)

The following questions are about situations that can occur while taking PrEP. Think about the different situations that are listed below, and tell us how confident you feel that you can…

1. Stick to taking PrEP even when side effects begin to interfere with daily activities?
2. Integrate taking PrEP into your daily routine?
3. Integrate taking PrEP into your daily routine even if it means taking medications or doing other things in front of people who don't know you are taking PrEP?
4. Stick to your PrEP schedule even when your daily routine is disrupted?
5. Stick to your PrEP schedule when you aren't feeling well?
6. Continue taking PrEP even if it means doing so interferes with your daily activities?
7. Continue taking PrEP even when you are feeling discouraged about your sexual health?
8. Continue taking PrEP even when getting to your clinic appointments is a major hassle?
9. Continue taking PrEP even when people close to you tell you that they don't think it is doing any good?

Response options:

0	Cannot do at all
1	
2	
3	
4	
5	Moderately certain can do
6	
7	
8	
9	
10	Completely certain can do

Scale Prompt Language for Participants Considering Initiating or Being Offered PrEP

The following questions are about situations that can occur while taking PrEP. Think about the different situations that are listed below, and tell us how confident you feel you are that you would be able to do these things <u>if you decided to take PrEP</u>...

Scale Prompt Language for Participants Not Using PrEP

The following questions are about situations that can occur while taking PrEP. Think about the different situations that are listed below, and tell us how confident you feel you are that you would be able to do these things <u>if you were taking PrEP...</u>

Scoring instructions Take mean response value across all non-missing items

Note There is also an optional preamble that was adapted from the original HIV-ASES scale and can be placed in the survey text prior to the scale prompt, if desired. This preamble was used in Study A only, in the paper above.

The following questions are about situations that could occur while you are taking PrEP. PrEP treatment can involve different things for different people. Sometimes, this might refer to taking medications, and other times it could refer to other things that you do to deal with taking medications, such as diet and exercise or taking vitamins. So, in these questions, when we ask you about "taking PrEP," we are talking not only about the medication, but also other things that make up your self-care.

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Data Availability The datasets generated and analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request, as per CUNY protocols for data transfer.

Code Availability Not applicable.

Declarations

Conflict of interest The authors declare they have no conflict of interest.

Ethical Approval Both studies reported in this paper were reviewed in accordance with ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments and were approved by the Institutional Review Board of the City University of New York.

Consent to Participate Informed consent was obtained from all individual participants included in the study.

Consent for Publication Not applicable.

References

1. CDC. Pre-exposure prophylaxis (PrEP). Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention; 2021.
2. Fauci AS, Redfield RR, Sigounas G, Weahkee MD, Giroir BP. Ending the HIV epidemic: a plan for the United States. JAMA. 2019;321(9):844–5.
3. Samuel K. Nearly a million have started taking PrEP worldwide—only a third of UNAIDS' 2020 target. NAM AIDSmap [Internet]. 2021. Available from: https://www.aidsmap.com/news/feb-2021/nearly-million-have-started-taking-prep-worldwide-only-third-unaids-2020-target.
4. Cornelisse VJ, Lal L, Price B, Ryan KE, Bell C, Owen L, et al editors. Interest in switching to on-demand HIV pre-exposure prophylaxis (PrEP) among Australian users of daily PrEP: an online survey. Open forum infectious diseases. Oxford: Oxford University Press US; 2019.
5. Jongen VW, Reyniers T, Ypma ZM, van der Loeff MFS, Davidovich U, Zimmermann HM, et al. Choosing event-driven and daily HIV pre-exposure prophylaxis—data from two European PrEP demonstration projects among men who have sex with men. J Int AIDS Soc. 2021;24(8):e25768.
6. Cohen SE, Kelley CF. Is the United States ready for event-driven human immunodeficiency virus preexposure prophylaxis? Oxford: Oxford University Press US; 2020. p. 256–8.
7. Segal K, Fitch L, Riaz F, Rodrigues J, Warren M. The evolution of oral PrEP access: tracking trends in global oral PrEP use over time. HIV Research for Prevention (HIVR4P) virtual conference, abstract OA11.01, 2021.
8. Sullivan PS, Satcher Johnson A, Pembleton ES, Stephenson R, Justice AC, Althoff KN, et al. Epidemiology of HIV in the USA: epidemic burden, inequities, contexts, and responses. Lancet. 2021;397(10279):1095–106.
9. Haberer JE, Baeten JM, Campbell J, Wangisi J, Katabira E, Ronald A, et al. Adherence to antiretroviral prophylaxis for HIV prevention: a substudy cohort within a clinical trial of serodiscordant couples in East Africa. PLoS Med. 2013;10(9): e1001511.
10. Fonner VA, Dalglish SL, Kennedy CE, Baggaley R, O'reilly KR, Koechlin FM, et al. Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. AIDS (London, England). 2016;30(12):1973.
11. Marcus JL, Hurley LB, Hare CB, Nguyen DP, Phengrasamy T, Silverberg MJ, et al. Preexposure prophylaxis for HIV prevention in a large integrated health care system: adherence, renal safety, and discontinuation. J Acquir Immune Defic Syndr. 2016;73(5):540.
12. Allison BA, Widman L, Stewart J, Evans R, Perry M. Adherence to pre-exposure prophylaxis in adolescents and young adults: a systematic review and meta-analysis. J Adolesc Health. 2022;70(1):28–41.
13. Yun K, Xu J-J, Zhang J, Li J-M, Hu Q-H, Chu Z-X, et al. Female and younger subjects have lower adherence in PrEP trials: a meta-analysis with implications for the uptake of PrEP service to prevent HIV. Sex Transm Infect. 2018;94(3):163–8.
14. Hojilla JC, Hurley LB, Marcus JL, Silverberg MJ, Skarbinski J, Satre DD, et al. Characterization of HIV preexposure prophylaxis use behaviors and HIV incidence among US adults in an integrated health care system. JAMA Netw Open. 2021;4(8):e2122692.
15. Sidebottom D, Ekström AM, Strömdahl S. A systematic review of adherence to oral pre-exposure prophylaxis for HIV—how can we improve uptake and adherence? BMC Infect Dis. 2018;18(1):1–14.
16. Gamarel KE, King WM, Operario D. Behavioral and social interventions to promote optimal HIV prevention and care continua

outcomes in the United States. Curr Opin HIV AIDS. 2022. https://doi.org/10.1097/COH.0000000000000717.
17. Glanz KE, Rimer BK, Viswanath K. Health behavior: theory, research, and practice in health behavior. 5th ed. Hoboken: Wiley; 2015.
18. Johnson MO, Neilands TB, Dilworth SE, Morin SF, Remien RH, Chesney MA. The role of self-efficacy in HIV treatment adherence: validation of the HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES). J Behav Med. 2007;30(5):359–70.
19. Bandura A. Human agency in social cognitive theory. Am Psychol. 1989;44(9):1175.
20. Bandura A. Regulation of cognitive processes through perceived self-efficacy. Dev Psychol. 1989;25(5):729.
21. Nafradi L, Nakamoto K, Schulz PJ. Is patient empowerment the key to promote adherence? A systematic review of the relationship between self-efficacy, health locus of control and medication adherence. PLoS ONE. 2017;12(10): e0186458.
22. Sevelius JM, Carrico A, Johnson MO. Antiretroviral therapy adherence among transgender women living with HIV. J Assoc Nurses AIDS Care. 2010;21(3):256–64.
23. Batey DS, Whitfield S, Mulla M, Stringer KL, Durojaiye M, McCormick L, et al. Adaptation and implementation of an intervention to reduce HIV-related stigma among healthcare workers in the United States: piloting of the FRESH workshop. AIDS Patient Care STDS. 2016;30(11):519–27.
24. Nakimuli-Mpungu E, Musisi S, Katabira E, Nachega J, Bass J. Prevalence and factors associated with depressive disorders in an HIV+ rural patient population in southern Uganda. J Affect Disord. 2011;135(1–3):160–7.
25. Zhu Y, Wu J, Feng X, Chen H, Lu H, Chen L, et al. Patient characteristics and perceived health status of individuals with HIV and tuberculosis coinfection in Guangxi, China. Medicine. 2017;96(14):e6475.
26. Johnson MO, Dilworth SE, Taylor JM, Darbes LA, Comfort ML, Neilands TB. Primary relationships, HIV treatment adherence, and virologic control. AIDS Behav. 2012;16(6):1511–21.
27. Eller L, Rivero-Mendez M, Voss J, Chen W, Chaiphibalsarisdi P, Iipinge S, et al. Depressive symptoms, self-esteem, HIV symptom management self-efficacy and self-compassion in people living with HIV. AIDS Care. 2014;26(7):795–803.
28. Nokes K, Johnson MO, Webel A, Rose CD, Phillips JC, Sullivan K, et al. Focus on increasing treatment self-efficacy to improve human immunodeficiency virus treatment adherence. J Nurs Scholarsh. 2012;44(4):403–10.
29. Qu D, Zhong X, Lai M, Dai J, Liang H, Huang A. Influencing factors of pre-exposure prophylaxis self-efficacy among men who have sex with men. Am J Mens Health. 2019;13(2):1557988319847088.
30. Mueses-Marín HF, Alvarado-Llano B, Torres-Isasiga J, Camargo-Plazas P, Bolívar-Rocha MC, Galindo-Orrego X, et al. Scales to assess knowledge, motivation, and self-efficacy for HIV PrEP in Colombian MSM: PrEP-COL study. AIDS Res Treat. 2021. https://doi.org/10.1155/2021/4789971.
31. Walsh JL. Applying the information–motivation–behavioral skills model to understand PrEP intentions and use among men who have sex with men. AIDS Behav. 2019;23(7):1904–16.
32. Poteat T, Malik M, Scheim A, Elliott A. HIV prevention among transgender populations: knowledge gaps and evidence for action. Curr HIV/AIDS Rep. 2017;14(4):141–52.
33. Halkitis PN, Wolitski RJ, Millett GA. A holistic approach to addressing HIV infection disparities in gay, bisexual, and other men who have sex with men. Am Psychol. 2013;68(4):261.
34. CDC. Pre-exposure prophylaxis for the prevention of HIV infection in the United States: a clinical practice guideline. CDC; 2014.
35. Golub SA, Fikslin RA, Goldberg MH, Peña SM, Radix A. Predictors of PrEP uptake among patients with equivalent access. AIDS Behav. 2019;23(7):1917–24.
36. Starbuck L, Golub SA, Klein A, Harris AB, Guerra A, Rincon C, et al. Transgender women and PrEP care: high PrEP adherence in a real-world health care setting in New York City. J Acquir Immune Defic Syndr. 2022. https://doi.org/10.1097/QAI.0000000000002915.
37. Grant RM, Anderson PL, McMahan V, Liu A, Amico KR, Mehrotra M, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. Lancet Infect Dis. 2014;14(9):820–9.
38. Horne R, Faasse K, Cooper V, Diefenbach MA, Leventhal H, Leventhal E, et al. The perceived sensitivity to medicines (PSM) scale: an evaluation of validity and reliability. Br J Health Psychol. 2013;18(1):18–30.
39. Kalichman SC, Katner H, Hill M, Ewing W, Kalichman MO. Perceived sensitivity to medicines and the experience of side-effects: understanding intentional medication nonadherence among people living with HIV. Psychol Health Med. 2021. https://doi.org/10.1080/13548506.2021.1960391.
40. Derogatis LR, Melisaratos N. The brief symptom inventory: an introductory report. Psychol Med. 1983;13(3):595–605.
41. Wilson IB, Lee Y, Michaud J, Fowler FJ, Rogers WH. Validation of a new three-item self-report measure for medication adherence. AIDS Behav. 2016;20(11):2700–8.
42. Daughtridge G, Hebel S, Larabee L, Patani H, Cohen A, Fischl M, et al., editors. Development and clinical use case of a urine tenofovir adherence test. 2019 HIV Diagnostics Conference Abstract; 2019.
43. Koenig HC, Mounzer K, Daughtridge GW, Sloan CE, Lalley-Chareczko L, Moorthy GS, et al. Urine assay for tenofovir to monitor adherence in real time to tenofovir disoproxil fumarate/emtricitabine as pre-exposure prophylaxis. HIV Med. 2017;18(6):412–8.
44. Patel RR, Amico KR, Harrison LC, Al E. Associations between urine tenofovir levels and pharmacy measures for PrEP adherence. Miami Beach: International Association of Providers of AIDS Care (IAPAC); 2017.
45. Patel RR, Lalley-Chareczko L, Harrison LC, Anderson P, Amico KR, Presti R, et al. Evaluating urine with dried blood spots to assess tenofovir levels for PrEP adherence. Paris: International AIDS Society; 2017.
46. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166(10):1092–7.
47. Connor KM, Davidson JR. Development of a new resilience scale: the Connor–Davidson Resilience Scale (CD-RISC). Depress Anxiety. 2003;18(2):76–82.
48. Raykov T, Marcoulides GA. Introduction to psychometric theory. London: Routledge; 2011.
49. Ferrando Piera PJ, Lorenzo Seva U. Program FACTOR at 10: origins, development and future directions. Psicothema. 2017;29(2):236–40.
50. Hau KT, Marsh HW. The use of item parcels in structural equation modelling: non-normal data and small sample sizes. Br J Math Stat Psychol. 2004;57(2):327–51.
51. Schumacker RE, Lomax RG. A beginner's guide to structural equation modeling. London: Psychology Press; 2004.
52. Yu C-Y. Evaluating cutoff criteria of model fit indices for latent variable models with binary and continuous outcomes. Los Angeles: University of California; 2002.
53. Brown JL, Littlewood RA, Vanable PA. Social-cognitive correlates of antiretroviral therapy adherence among HIV-infected

individuals receiving infectious disease care in a medium-sized northeastern US city. AIDS Care. 2013;25(9):1149–58.
54. Ironson G, Weiss S, Lydston D, Ishii M, Jones D, Asthana D, et al. The impact of improved self-efficacy on HIV viral load and distress in culturally diverse women living with AIDS: the SMART/EST Women's Project. AIDS Care. 2005;17(2):222–36.
55. Chesney MA, Chambers DB, Taylor JM, Johnson LM, Folkman S. Coping effectiveness training for men living with HIV: results from a randomized clinical trial testing a group-based intervention. Psychosom Med. 2003;65(6):1038–46.
56. Damush T, Kroenke K, Bair M, Wu J, Tu W, Krebs E, et al. Pain self-management training increases self-efficacy, self-management behaviours and pain and depression outcomes. Eur J Pain. 2016;20(7):1070–8.
57. Mansouri P, Ghadami M, Najafi SS, Yektatalab S. The effect of self-management training on self-efficacy of cirrhotic patients referring to transplantation Center of Nemazee Hospital: a randomized controlled clinical trial. Int J Community Based Nurs Midwifery. 2017;5(3):256.