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Validation of HIV Pre-Exposure Prophylaxis (PrEP) Medication Scales with Youth on PrEP: PrEP Confidence Scale and PrEP Difficulties Scale

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Abstract

Pre-exposure prophylaxis (PrEP) is a lifesaving medical intervention that protects against human immunodeficiency virus (HIV), but to date, PrEP uptake has been limited. PrEP utilization and adherence among youth, including stigmatized and highly vulnerable young sexual and gender minorities, have been exceptionally low across all regions, leading to preventable HIV transmission. Considering the scientific value of measuring and understanding predictors or associations of PrEP adherence, our study team validated two scales: a PrEP Difficulties Scale and a PrEP Confidence Scale tested within the Adolescent Trials Network P3 study (2019-2021). Data from sexual and gender minorities who were prescribed PrEP across nine domestic sites were evaluated (N=235). Descriptive statistics, exploratory factor analysis, and correlation coefficients are reported herein. Results for the PrEP Difficulties Scale vielded a four-factor solution (Disclosure, Health Effects, Logistics, and Cost), and results for the PrEP Confidence Scale produced a three-factor solution (Scheduling, Distraction, and Planning). Factor loadings and Cronbach's alphas suggested good internal consistency for both scales. PrEP Confidence Scale subscales were correlated with PrEP adherence, and subscales of both scales were associated with dimensions of social support and PrEP-related stigma. Given the persistence of preventable HIV infections among key populations, multi-level barriers and facilitators to medication adherence, and expansion of PrEP modalities, the PrEP Difficulties Scale and PrEP Confidence Scale have the potential to enhance intervention, exploratory, and mechanistic HIV prevention research. ClinicalTrials.gov Identifier: NCT03320512.

Keywords: HIV, PrEP, pre-exposure prophylaxis, self-efficacy, scale development, scale validation, difficulties, confidence, disclosure

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Introduction

PRE-EXPOSURE PROPHYLAXIS (PrEP) is a biomedical advancement that protects against human immunodeficiency virus (HIV).¹ Daily oral tenofovir disoproxil fumarate with emtricitabine was originally approved as PrEP for adults by the US Food and Drug Authority (FDA) in 2012; 6 years later, in 2018, the FDA approved this same formulation for youth weighing at least 35 kg,^{2.3} and in December 2021, the FDA approved long-acting injectable cabotegravir (CAB-LA) for use as PrEP.⁴

Even though PrEP has been available for over a decade, uptake has been slow and research suggests that an array of barriers, ranging from personal to structural, can limit PrEP acceptance and adherence.^{1,2,5–7} Alarmingly, PrEP uptake and adherence among young sexual and gender minorities, a group that is highly stigmatized, vulnerable, and holds the highest rates of new HIV infection domestically and globally, have been exceptionally low, potentially fueling ongoing preventable HIV transmission.

Understanding barriers and facilitators to PrEP, particularly among priority populations that are disproportionately affected by the HIV epidemic, is of high importance.^{1,5,6} However, to do so, scientific, practice, and clinical communities would benefit from standardized and validated tools to assess multiple types of difficulties or promoters that produce confidence to use PrEP.

Key among difficulties to starting and adhering to PrEP are concerns related to disclosure, safety and long-term health effects, environmental considerations, logistics of taking a medication, and financial costs, particularly among adolescents and emerging adults.^{8–11} In contrast, facilitators to PrEP uptake as well as adherence to HIV treatment include selfefficacy and personal motivation that can be operationalized as one's ability to take action, or being sufficiently empowered, leading to PrEP confidence.^{12,13}

While these difficulties and elements of confidence have been explored for individual effects on PrEP and are relevant across populations and settings,^{3,5,6} to our knowledge, there are no existing validated scales to assess PrEP difficulties or confidence in PrEP-experienced youth. These multi-faceted, often multi-level, constructs are critical in assessing the likelihood of patients' successful adherence to PrEP, as well as being informative for HIV prevention intervention research that aims to stop HIV spread through PrEP uptake.^{14,15}

To address this scientific gap, under the auspices of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NIH/NICHD)-funded Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN), we conducted the Prepared, Protected, emPowered (P3: ATN protocol 142) intervention trial within which we developed and tested a PrEP Confidence Scale and a PrEP Difficulties Scale.¹⁶

In response to our research question: "Can PrEP difficulties and confidence be measured scientifically?" we present a statistical validation of these two scales.

Methods

Parent study

The P3 study tested the impact of mobile application use among young men who have sex with men (YMSM) and young transgender women who have sex with men (YTWSM), aged 16–24 years, through a nationwide, three-arm, randomized controlled trial, with assessments at baseline, after 3 months (end of intervention phase), and after 6 months (postintervention phase).¹⁶ PrEP confidence and difficulties were secondary outcomes measured at all three points of data collection.

Informed consent and ethics review

The Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Prepared, Protected, emPowered (P3: ATN protocol 142) informed assent/consent documents and related modifications were reviewed and approved by the University of North Carolina at Chapel Hill (UNC) Institutional Review Board (IRB, #17-1951).

Data and participants

The study sample included English-speaking US-residing YMSM and YTWSM, aged 16–24 years, from the P3 baseline data. All participants were on PrEP or had been previously prescribed PrEP and expressed intent to restart in the upcoming week (N=235). Participants accessed PrEP services at nine partner clinics with multi-state catchment areas in Atlanta, Georgia; Boston, Massachusetts; Bronx, New York; Chapel Hill, North Carolina; Charlotte, North Carolina; Chicago, Illinois; Houston, Texas; Philadelphia, Pennsylvania; and Tampa, Florida.

Scale measures

PrEP Difficulties Scale. The PrEP Difficulties Scale consists of 15 items rated on a 4-point Likert scale, ranging from 1=not at all concerned to 4=very concerned, with higher scores indicating greater difficulties. Sample items are "Having to talk to a healthcare provider about my sex life," "The long-term effects of PrEP on my health," and "Getting transportation to PrEP appointments or for laboratories." The possible range of scores for this scale is 15–60. For each subscale, composite scores are calculated using the mean of the items.

PrEP Confidence Scale. Adapted from the HIV Medication Taking Self-Efficacy Scale,¹⁷ the PrEP Confidence Scale was developed to assess self-confidence in the ability to take and adhere to oral PrEP medications. Participants responded to 11 items rated on a 10-point Likert scale (where 1=not confident and 10=totally confident), with higher scores reflecting more confidence. Sample items included "Keep PrEP appointments," "Follow plan for taking PrEP," and "Take PrEP at work or school," with each item starting with "How confident are you that you can..."

The possible range of scores for the full PrEP Confidence Scale is 10–110. Composite scores are calculated using the mean of the items in each subscale.

Validation measures

Youth PrEP-related Stigma Scale. The Youth PrEP Stigma Scale was used to measure dimensions of PrEP-related stigma (i.e., disapproval by others, enacted PrEP stigma, and PrEP user stereotypes). The scale consists of 19 items rated on a 4-point Likert scale, ranging from 1 = strongly disagree to 4 = strongly agree, with higher scores reflecting greater levels of PrEP-related stigma. Sample items included "I worry my friends will find out that I take PrEP," "I have experienced

physical violence because I am taking PrEP," and "I worry people will assume I sleep around if they know I take PrEP." Cronbach's alpha coefficient is 0.92 for the entire scale.

Community PrEP norms. Community norms related to taking PrEP (community PrEP stigma) were assessed with three items of the Community PrEP Norms Scale rated on a 4-point Likert scale (from 1=strongly disagree to 4= strongly agree). Items are, "People taking PrEP are portrayed poorly in the media and online," "People in my community talk poorly about people taking PrEP," and "I think I am not following the 'rules' of my community if I take PrEP."

Cronbach's alpha was 0.72 in the current study.

PrEP adherence. PrEP medication adherence was assessed with the two questions, "How many of the last 7 days did you take your PrEP medication?" (i.e., adherence to PrEP weekly; response options: 0-7 days) and "In the last month, what percent of the time did you take your PrEP as prescribed (once a day)?" (i.e., adherence to PrEP monthly; response options: 0= none of the time to 100% = all of the time).

We separately dichotomized these variables by using a cutoff as nonadherent (0=3 or less days/week) versus adherent (1=4 or more days/week) for adherence to PrEP weekly and nonadherent (0=less than 60%) versus adherent (1=60% or more) for adherence to PrEP monthly.

Social support and well-being. Dimensions of social support, specifically emotional support, informational support, and instrumental support, were assessed with four items for each dimension adapted from Hahn et al.'s study.¹⁸ Items are rated on a 5-point Likert scale (1 = never to 5 = always), with higher scores reflecting higher social support. Sample items included "I have someone who will listen when I need to talk," "Have someone to give me advice about a crisis," and "Have someone to help you if confined to bed."

In the current study, Cronbach's alpha was 0.94 for emotional support, 0.96 for informational support, and 0.94 for instrumental support. We also collected Patient-Reported Outcomes Measurement Information System (PROMIS) outcomes, a set of person-centered measures that evaluate mental health, physical health, and social health among both adults and children.^{19,20}

Statistical analyses

First, descriptive statistics for the sample were calculated. To determine the factor structure of the PrEP Difficulties Scale and PrEP Confidence Scale, exploratory factor analyses (principal component analysis with varimax rotation) were employed. In factor analyses, the decision about how many factors to retain was made based on communality (0.30 or greater for each item), factor loadings (0.40 or greater),²¹ and eigenvalue (1.0 or greater).²²

Second, we calculated Cronbach's alpha coefficients to assess internal consistencies of whole scale and subscale scores. Last, Pearson's correlation analysis²³ was performed to examine the relationships that the PrEP Confidence Scale and PrEP Difficulties Scale have with related study variables (i.e., PrEP-related stigma, community PrEP norms, PrEP adherence, and social support).

In the analyses, composite scores are calculated using the mean of the scores in the total or subscale. Baseline data were analyzed with the Statistical Package for the Social Sciences (version 22; SPSS, Inc., Chicago, IL, USA).

Results

Sample demographics

Descriptive statistics for the sample are shown in Table 1. Mean age was 21.6 years, with a standard deviation of 1.95 years. About 23% identified as African American or

TABLE 1. DESCRIPTIVE STATISTICS OF STUDY
PARTICIPANTS (N=235)

| Variables | M (SD) or N (%) |
|----------------------------------|--------------------|
| Age, years | 21.60 (1.95) |
| Hispanic or Latinx | |
| Yes | 66 (28.1) |
| No | 169 (71.9) |
| Race | |
| American Indian/Alaskan Native | 9 (3.8) |
| Asian | 21 (8.9) |
| Black | 54 (23.0) |
| White | 145 (61.7) |
| Other | 1 (0.4) |
| Decline to answer | 14 (6.0) |
| Gender | |
| Female | 2(0.9) |
| Male | 215(915) |
| Transgender woman or | 9 (3.8) |
| transfeminine |) (5.0) |
| Genderqueer gender | 22(94) |
| nonconforming or nonbinary | 22 ().1) |
| Decline to answer | 1(04) |
| | 1 (0.1) |
| Sexual identity | 10((70, 1)) |
| Gay or same gender loving | 180(79.1) |
| Bisexual | $\frac{2}{(11.5)}$ |
| Queer | 18(7.7) |
| Straight or neterosexual | 2(0.9) |
| Pansexual | 2 (0.9) |
| Income (past 30 days) | |
| \$0-\$999 (\$0-\$11,999/year) | 102 (43.3) |
| \$1000–\$4999 (about \$12,000– | 100 (42.5) |
| \$59,999/year) | |
| \$5000 or more (about \$60,000 | 11 (4.7) |
| or more/year) | () |
| Don't know or declined to answer | 22 (9.3) |
| Income level | |
| Low | 123 (52.3) |
| Middle | 90 (38.3) |
| High | 7 (3.0) |
| Decline to answer | 15 (6.4) |
| Insurance | |
| No insurance | 26 (11.1) |
| Independent insurance | 89 (37.9) |
| Parent/guardian's | 119 (50.6) |
| Decline to answer | 1 (0.4) |
| | - (0) |
| On PrEP | 235(05.7%) |
| Restarting PrEP | 10(4.3%) |
| Nosunting 11L1 | IU (T.J/0) |

PrEP, pre-exposure prophylaxis; SD, standard deviation.

| | | Factor loadir | ıgs | |
|---|------------|----------------|-----------|------|
| Items | Disclosure | Health effects | Logistics | Cost |
| Having to talk to the health care provider about my sex life | 0.75 | | | |
| Having to talk to the health care provider about PrEP | 0.72 | | | |
| Friends finding out that I am on PrEP | 0.70 | | | |
| Sexual partners finding out I am on PrEP | 0.68 | | | |
| Family members finding out I am on PrEP | 0.65 | | | |
| The long-term effects of PrEP on my health | | 0.73 | | |
| Possibility that PrEP might not provide complete protection | | 0.69 | | |
| Possibility that if I become HIV+, certain meds will not work | | 0.65 | | |
| Experiencing side effects | | 0.62 | | |
| Having to remember to take the medication every day | | 0.58 | | |
| Getting transportation to PrEP appointments or for laboratories | | | 0.84 | |
| Returning for PrEP follow-up appointments or for laboratories | | | 0.82 | |
| Getting PrEP prescription refills | | | 0.54 | |
| Using insurance to get coverage for PrEP costs | | | | 0.87 |
| Getting the cost of PrEP covered | | | | 0.87 |
| Eigenvalue | 4.96 | 1.82 | 1.61 | 1.13 |
| Variance explained | 33.09 | 12.14 | 10.75 | 7.53 |

TABLE 2. FACTOR LOADINGS FOR PRE-EXPOSURE PROPHYLAXIS DIFFICULTIES SCALE ITEMS

HIV, human immunodeficiency virus.

Black and about 62% identified as White. Over a quarter (28%) were Hispanic or Latinx. The majority (92%) were of male gender and 79% reported being gay or same gender loving.

Nearly half reported a monthly income that indicated poverty; specifically, 43% reported a monthly income of under \$1000 a month (about \$12,000 annually); 235 (96%) were currently on PrEP and 10 (4%) were previously on PrEP and intended to restart PrEP within a week.

PrEP Difficulties Scale and PrEP Confidence Scale factors

Two separate factor analyses were performed to identify the factor structure of the PrEP Difficulties Scale and PrEP Confidence Scale. First, for the PrEP Difficulties Scale, Bartlett's test of sphericity²⁴ was significant [χ^2 (105)= 1546.883, p < 0.001)] and the Kaiser–Meyer–Olkin (KMO) value was 0.78, indicating the data's suitability for factor analytic procedures. Second, factor analysis results revealed that a four-factor solution best fit the data, with eigenvalues of 1.0 or greater, communalities above 0.30, factor loadings ranging from 0.55 to 0.87, and total variance of 63.51. Table 2 displays all factor loadings and variances explained for each factor.

As for the PrEP Confidence Scale, Bartlett's test of sphericity was significant [χ^2 (171)=2929.135, p < 0.001)] and the KMO value was 0.85, suggesting data's suitability for factor analysis. Results of the factor analysis yielded a threefactor solution, with eigenvalues of 1.0 or greater, communalities above 0.30, factor loadings ranging from 0.69 to 0.84, and total variance of 68.48 (see Table 3).

Reliability of scales

Internal consistency coefficients for the two scales were calculated. For the PrEP Difficulties Scale, Cronbach's alpha coefficients were 0.72 for Disclosure, 0.74 for Health Effects, 0.82 for Logistics, 0.94 for Cost, and 0.84 for the entire scale.

For the PrEP Confidence Scale, Cronbach's alpha coefficients for each subscale were 0.87 for Scheduling, 0.77 for Distraction, and 0.57 for Planning. Cronbach's alpha for the combined subscales was 0.87.

Validity of scales

As shown in Table 4, subscales of both the PrEP Difficulties Scale (i.e., Disclosure, Health Effects, Logistics, and

TABLE 3. FACTOR LOADINGS FOR PRE-EXPOSURE PROPHYLAXIS CONFIDENCE SCALE ITEMS

| | Fe | actor loadings | 5 |
|--|---------------|----------------|--------------|
| Items | Scheduling | Distraction | Planning |
| Take PrEP on a weekend | 0.79 | | |
| Take PrEP on a weekday | 0.78 | | |
| Take PrEP when schedule changes | 0.70 | | |
| Take PrEP while traveling | 0.70 | | |
| Take PrEP when out with friends | 0.70 | | |
| Take PrEP at work/school | 0.68 | | |
| Take PrEP when having side effects | | 0.84 | |
| Take PrEP when having a crisis | | 0.76 | |
| Take PrEP when drinking or using drugs | | 0.70 | |
| Keep PrEP medical | | | 0.78 |
| Follow a plan for taking PrEP | | | 0.70 |
| Eigenvalue Variance explained | 5.16 46.95 | 1.29 11.75 | 1.07 9.77 |

| | -0.11 -0.03 | 9 0.66** 3** 0.02 | 0.05 | I | | | |
|--|---------------|----------------------|--------------|---------|----------|---------|--------|
| $-0.04 -0.17^{*} 0.08 0.24^{**}$ | 0.22** 0.1: | 5* 0.01 | 0.02 0.46 | | | | |
| -0.12 -0.15* -0.13* 0.13* | 0.16* 0.13 | 5* -0.23** | -0.29** 0.0 | 4 -0.02 | I | | |
| -0.18^{**} -0.17^{**} -0.17^{*} 0.11 | 0.16* 0.13 | 2 -0.17* | -0.25** 0.00 | 0.01 | 0.76** | | |
| $-0.12 -0.17^{**} -0.24^{**} 0.14^{*}$ | 0.10 0.10 | 0.0- 0 | -0.07 0.02 | 4 0.14* | 0.37** 0 | .50** | |
| 0.08 -0.07 0.15* -0.00 | 0.07 0.0 | 1 0.00 | -0.00 0.0- | 7 0.13 | 0.01 0 |).03 –(| 0.06 — |

^aDichotomized variable. PCS, PrEP Confidence Scale; PDS, PrEP Difficulties Scale.

Cost) and PrEP Confidence Scale (i.e., Scheduling and Distraction) were correlated with PrEP-related stigma.^{*} Similarly, PrEP Difficulties Scale subscales (i.e., Disclosure, Health Effects, and Logistics) were correlated with community PrEP norms.

Results suggest that subscales of both the PrEP Difficulties Scale and PrEP Confidence Scale have good construct validity. Moreover, the PrEP Confidence Scale subscales were correlated with both PrEP adherence weekly and PrEP adherence monthly. We also found significant correlations between PrEP Difficulties Scale and PrEP Confidence Scale subscales and social support dimensions.

Discussion

The purpose of this study was to explore the internal consistency and external validity of the newly developed PrEP Difficulties Scale and PrEP Confidence Scale, evaluated in a population of PrEP-experienced youth (e.g., currently taking PrEP or about to restart). Results provide evidence for the concurrent validity of both the PrEP Confidence Scale and PrEP Difficulties Scale.

Our study sample was racially diverse, with roughly 40% non-White or Hispanic participants who predominantly identified as gay. To our knowledge, this study is the first to validate scales for PrEP confidence and difficulties, and it is a rare PrEP scales validation study to verify newly developed PrEP scales with PrEP-experienced youth.

For the PrEP Difficulties Scale, we found that our key factors/constructs yielded a four-factor solution (i.e., Disclosure, Health Effects, Logistics, and Cost). For the PrEP Confidence Scale, we found that our key factors/constructs yielded a three-factor solution (i.e., Scheduling, Distraction, and Planning).

Both scales produced strong factor loadings. Validation analysis results indicate that both scales have good construct validity. PrEP Confidence Scale subscales were correlated with self-reported PrEP adherence, and subscales of both scales were associated with dimensions of social support.

While validated scales to assess PrEP difficulties and confidence are a new scientific contribution, these constructs have been validated within HIV-focused scales and leveraged broadly across HIV care research. For example, there are multiple self-efficacy for HIV antiretroviral medication adherence scales that are routinely used to ascertain confidence and capability, and similarly, HIV medication adherence barriers scales (our corollary being difficulties) are also applied across diverse populations and settings.^{12,17,25,26}

Further, subscale constructs within the PrEP Difficulties Scale and PrEP Confidence Scale, such as disclosure and cost, are routinely included as stand-alone measures in PrEP research.^{27–29} By validating the multi-factor PrEP Difficulties Scale and PrEP Confidence Scale, in a racially diverse national sample of PrEP-experienced YMSM and YTWSM, we offer pragmatic tools for use in clinical care and HIV prevention research.

Limitations should be considered when extending findings. Data analyzed are cross-sectional and therefore restrict our ability to ascertain causal associations. Our sample is predominantly White, limiting our ability to explore racial differences related to difficulties and confidence in taking PrEP. The PrEP Confidence Scale is informed by the HIV Medication Taking Self-Efficacy Scale,¹⁷ thereby extending the orientation of people living with HIV to those who are not.

We are unaware of other scales for PrEP confidence and difficulties; therefore, convergent and discriminant analyses are limited. We found that internal consistency of the Planning subscale in the PrEP Confidence Scale was slightly lower than the acceptable level of reliability coefficient (i.e., 0.60), likely due to the small number of items included.³⁰ Further evaluation could provide more definitive evidence for reliability of the Planning subscale in and of itself (compared with the full scale). These scales should be tested in adult populations on PrEP.

Last, both scales focused on oral prep regimens (during the time of testing, CAB-LA was not FDA approved); thus, questions to address confidence and difficulties specific to long-acting nonoral formulations remain unanswered.

Our results indicate that the PrEP Confidence Scale and PrEP Difficulties Scale, presented herein, are valid instruments for use with groups prescribed PrEP and highlight special considerations for youth who may be on or considering PrEP. For example, social support is critically important to most marginalized populations, but youth, by virtue of their development stage, may be particularly affected, indicating that PrEP uptake may be improved through an increase in PrEP confidence, mechanistically through enhanced social support.

Additionally, sexual identity disclosure concerns are often exacerbated for youth, particularly those who live at home or are on their parents' or guardians' health insurance, since to be prescribed PrEP, one is required to complete laboratory blood work that could alert the primary insurance holder through explanation of benefits statements.

Future HIV prevention research should incorporate these scales into larger studies and clinical trials focusing on PrEP uptake and adherence. The growing array of PrEP options underscores the value of addressing difficulties while concurrently bolstering confidence to protect against HIV acquisition and transmission.

HIV prevention interventions that address PrEP-related difficulties and evaluate confidence offer promising opportunities to address the HIV epidemic among those who are willing to accept PrEP for HIV prevention, particularly highpriority adolescents, youth, and emerging adults.

^{*}We also conducted three nonparametric analyses to compare PrEP Difficulties Scale and PrEP Confidence Scale scores by age group [i.e., >18 years (N=22) and 18–24 years (213)]; race [i.e., Black (N=54) and White (N=140)]; and insurance [no insurance (N=26), independent insurance (N=89), and guardian's insurance (119)]. The PrEP Difficulties Scale-Cost scores of youth aged 18-24 years (M=2.43, SD=1.16) were higher than those of youth aged <18 years (M=1.41, SD=0.70). A Mann–Whitney U test indicated that this difference was statistically significant (U=1160.00,z=-3.99, p<0.001). Black youth (M=2.39, SD=0.67) scored significantly higher on the PrEP Difficulties Scale-Health Effects than White youth (M=2.18, SD=0.61), indicated through Mann-Whitney U test results (U=3085.50, z=-1.99, p<0.05). The Kruskal–Wallis H test was conducted to examine the differences in the PrEP Difficulties Scale and Confidence Scale scores according to insurance status. Results suggested differences in PrEP Difficulties Scale–Cost scores, H(2) = 6.72, p < 0.05. Post hoc comparisons using Bonferroni correction indicated that there was no significant difference in PrEP Difficulties Scale-Cost scores between youth having different insurance statuses (all p values >0.05)

Authors' Contributions

L.B.H.-W. is the senior author and parent study Principal Investigator. H.B. is the lead author on this article. L.B.H.-W. and H.B. jointly conceptualized the study in consultation with A.C.M.-B. and K.E.M. I.Y. conducted all quantitative analyses. All authors contributed to the writing and revising of the article.

Consent to Participate

All participants agreed to participate and provided informed consent.

Availability of Data and Material

Data are available upon request through the University of North Carolina at Chapel Hill (UNC) BATLab through the study Principal Investigator, Dr. Lisa Hightow-Weidman.

Code Availability

Data are available upon request from the P3 Protocol Chair and senior author on this article, Dr. Lisa B. Hightow-Weidman. Code is available upon request from our quantitative lead, Dr. İbrahim Yiğit.

Author Disclosure Statement

No competing financial interests exist.

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