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Engaging and supporting youth to promote adherence success (EASYPAS): A cognitive behavioral intervention for youth living with HIV

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Adolescents and young adults (youth), ages 13 to 24 years, represented 21% of the 39,782 HIV infections reported during 2016 in the United States, with a disproportionate prevalence in ethnic, minority youth (Centers for Disease Control and Prevention, 2017). Antiretroviral therapy (ART) has been recommended for all people living with HIV infection (PLWH; U.S. Department of Health and Human Services, 2017). However, youth living with HIV (YLWH) face substantial difficulties with ART adherence, in comparison to adult counterparts, resulting in poor health outcomes such as treatment failure and risk of sexual transmission to seronegative partners (Wong, Zucker, Fernandes, & Cennimo, 2016; Wood, Lowenthal, Lee, Ratcliffe, & Dowshen, 2017). Adherence research is an important component of effective HIV treatment and care, but to date, there is a paucity of evidence describing targeted behavioral interventions for YLWH (Shaw & Amico, 2016), including studies designed to examine the influence of technology on adherence behavior (Navarra et al., 2017).

Guided by the PRECEDE PROCEED model of health education and promotion (Green & Kreuter, 1991), the aims of our pilot study were to (a) test the feasibility and acceptability of

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a cognitive behavioral intervention (CBI), *Engaging and Supporting Youth to Promote Adherence Success (EASYPAS) among YLWH ages 16-24 years of age*; and (b) evaluate the impact of *EASYPAS* on adherence to ART, health beliefs and knowledge regarding HIV disease and treatment adherence, ART self-management skills, and appraisal skills of HIV/ART health-related information accessed via Internet sources.

Methods

We completed a pilot feasibility study, using a one-group study design with a convenience sample. The *EASYPAS* intervention was guided by the PRECEDE-PROCEDE Model of health promotion (Green & Kreuter, 1991) with predisposing, enabling, and reinforcing factors targeted for intervention during three consecutive *EASYPAS* Sessions.

Setting and Sample

After approval by the affiliated Columbia University Medical Center institutional review board, recruitment of eligible participants was conducted from January 2016 to August 2016, at an academic, outpatient, HIV health center located in northern Manhattan, New York, USA, where comprehensive health care is provided to YLWH, ages 13 to 29 years, including social work and psychiatric care. YLWH with perinatal and behaviorally-acquired HIV were eligible for study participation with specific inclusion criteria as follows: ages 16 to 24 years, English speaking, knew about HIV status, prescribed ART for at least 3 months, self-reported adherence to ART of less than 100% during past month, detectable quantitative HIV serum viral load (> 48 copies/mL) one or more times during past 3 months, and absence of major neurocognitive deficits, allowing for completion of survey measures. Informed consent or assent were obtained from all study participants in accordance with the regulations of the designated institutional review board.

Recruitment

Recruitment efforts, based on our previous work (Navarra, Neu, Toussi, Nelson, & Larson, 2014) included posting flyers and regularly scheduled visits by the study team to the HIV clinic during clinic hours. Participants expressing interest were screened for study eligibility by the site principal investigator (PI) and, if inclusion criteria were met, informed consent was obtained by the PI or Co-PI.

Study Variables

Primary study variables and associated survey measures are illustrated in Table 1. Survey measures were psychometrically sound with demonstrated reliability and validity including application with PLWH. The potential for low literacy was recognized in the design of the *EASYPAS* intervention, and education was tailored to the median literacy level of the group. A medical record data extraction tool was used to collect and record relevant demographic, psychosocial, and HIV clinical data (i.e., viral load).

Adherence Measure

The primary outcome of our study was adherence to ART, as measured with 3-day self-reported adherence estimates. An average missed dose calculation (Garvie, Wilkins, & Young, 2010) was computed after collecting and recording adherence estimates.

Internet Appraisal Skills

Participant internet appraisal skills were assessed by presenting three government and three non-government online sources of HIV/ART health related information via a laptop computer (i.e., <http://www.cdc.gov/actagainstaids/campaigns/hivtreatmentworks>, <http://i-base.info/qa/5015>). Participants were asked to categorize each website as a *trustworthy* or *not trustworthy* source of online information with a rationale for the classification. For the purposes of scoring, reliability of an HIV website was defined as one with current, objective content from an authority in the management of PLWH. Responses were audio recorded for later transcription and data analysis.

EASYPAS Intervention

Implementation of EASYPAS occurred during August 2016, and included three consecutive, 60-minute, weekly group sessions delivered by the PI with the assistance of a trained research assistant (RA). Sessions were conducted in a private conference room, and on site at the clinical agency. Refreshments were provided, and clinic social work staff offered transportation vouchers for travel to and from the clinic. A trained member of the study team regularly delivered reminders (text messages, phone calls), in support of study retention. A summary of each EASYPAS group session is provided below.

EASYPAS - Session 1.—Session 1 emphasized *predisposing factors* or the influence of knowledge, beliefs, and perceptions for motivation to adhere. Knowledge of HIV treatment and related beliefs, perceived barriers and facilitators of ART adherence, and strategies for effective ART self-management were discussed.

EASYPAS - Session 2.—Session 2 targeted the *enabling factors* or the skills and resources needed to adhere. Tools to promote adherence success (i.e., alarms, pharmacy prepackaging of ART) were presented. Available support systems were considered, and role-playing for communication with health care providers was demonstrated by the study team.

EASYPAS - Session 3.—Session 3 was directed to *reinforcing factors* contributing to sustained, positive behavioral change operationalized as the development of internet appraisal skills. Participants were provided with a method to evaluate websites presenting HIV health and treatment information, called the SCORE System (O'Connell, Kaur, Ramchandani, & Navarra, 2016). Guidelines from the National Institutes of Health (2011) and the U.S. National Library of Medicine (2014) were adapted and modified to develop this tool.

Data Collection/Study Procedures

Data collection of the primary study variables (Table 1) was performed by the PI with the assistance of an RA. The Mini-Mental Health State Exam (Folstein, Folstein, & McHugh,

1975) was used to screen for neurocognitive deficits (Lyon, McCarter, & D'Angelo, 2009; Navarra et al., 2014). Time for completion of survey measures and appraisal of online HIV resources was approximately 45 minutes. Compensation included a \$20 (USD) gift card for each group session attended and at the 12-week follow-up for viral load and adherence assessments. Audio recordings of EASYPAS group sessions and assessment of Internet appraisal skills were transcribed by a trained RA.

Data Analysis

Data were imported into IBM SPSS Statistics, version 22.0 (IBM Corp, 2013). We computed descriptive statistics to summarize characteristics of the study population, including scores on all survey instruments, adherence estimates, participant response rates to group sessions, recruitment, and overall retention and attrition rates. Appraisals of government and other online HIV treatment sites, as well as specific sites, were compared by generalized estimating equation (GEE) analysis. GEE was appropriate because the websites were repeated measures (i.e., 6 ratings nested for each participant) and the rating was *Yes/No* (after recoding *don't know* to *No*). Audio recording of the three EASYPAS sessions were analyzed using content analysis with the unit of analysis being the written transcript. Data from narrative text were organized into meaning units, condensed meaning units and codes. Categories were created to identify common threads (Graneheim & Lundman, 2004). Because this was an exploratory study with a small sample size and attrition of participants, comparison of primary study variables before and after the EASYPAS intervention would not have produced meaningful results.

Results

The final sample included 13 perinatally ($n = 7$) or behaviorally ($n = 6$) infected YLWH, enrolled from December 2016 through July 2017. Demographics and HIV characteristics are summarized in Table 2. HIV Treatment Knowledge and Beliefs about Medications Scores are shown in Table 3.

Internet Appraisal Skills

During the individual assessment, government websites were more likely to be rated as reliable than other websites ($p = .0009$), but differences between specific sites were not significant after adjustment to p -values for multiple comparisons. The most common subjective responses for rating a website as reliable were affiliation with the government and website layout. A rating of unreliability was assigned for mixed reasons with website layout again being cited as important factors.

Stigma, Secrecy, Conspiracy Beliefs, and Substance Use

Content analysis of EASYPAS group sessions demonstrated data elements consistent with internalized HIV-related stigma, secrecy and non-disclosure, conspiracy beliefs, and substance use. Participants discussed feeling “dirty,” “disgusting,” or being perceived as “a hoe or slut.” The need for non-disclosure of HIV seropositive status was depicted. “I did not tell nobody my status cuz people gonna judge.” “I always hide my medicines cuz my friends come over.” Beliefs “of a cure” were conveyed “but they just ain’t saying anything yet.”

Daily marijuana use for support with ART administration and adherence was also described, “I roll a blunt and then I’ll take my pill.”

Feasibility and Acceptability of EASYPAS

Five of the 13 enrolled participants completed one or two of the scheduled group sessions; no participants completed all three sessions. Participants attending one or two EASYPAS sessions described the content as helpful and informative. Due to the small sample size and challenges with study retention, we were unable to gather preliminary estimates of whether the intervention was likely to have an impact on study variables.

Discussion

The challenges of conducting adherence research with a high-risk cohort of YLWH was clearly highlighted by our low study recruitment and retention rates, irrespective of providing reminders, transportation, food, and compensation to participants. Our experience differed from findings of a 12-session (group and individual) behavioral intervention designed to increase HIV knowledge and disease management including adherence, and decrease risk reduction among perinatally and behaviorally YLWH (Chandwani, Abramowitz, Koenig, Barnes, & D’Angelo, 2011). In that study, mean attendance for the seven group sessions delivered in clinical settings was 4.7 ($SD = 2.5$; Chandwani et al., 2011). However, Chandwani et al. (2011) reported an intervention completion estimate of 23.1% for the combined 12 (group and individual) sessions, further highlighting the complexities of conducting intervention research with YLWH.

One plausible explanation for the observed difference with group session attendance by EASYPAS participants was the presence of co-morbid risk factors for poor engagement/retention in care, namely internalized stigma (Turan et al., 2017), substance use/abuse (Hartzler et al., 2018), psychiatric illnesses (Rooks-Peck et al., 2018), and low literacy (U.S. Department of Health and Human Services, 2017). Internalized stigma and depressive symptomatology have been associated with poor engagement in care including adherence to health care visits (Rice et al., 2017). The EASYPAS group sessions were conducted on site at the HIV clinic, and the location may have contributed to stigma and/or served as an unwanted reminder of having HIV. Moreover, treating clinicians served a dual role as members of the EASYPAS research team, as research and clinical activities occurred in the same location. These conditions may have contributed to a blurring of the lines (Pagano-Therrien & Sullivan-Bolyai, 2017), with participants not distinguishing clinical research from clinical care. It is equally important to note that the racial and ethnic minority status of enrolled participants may have also contributed to mistrust and stigma, thereby impeding research participation (George, Duran, & Norris 2014).

To the best of our knowledge, this was one of the first studies to report the Internet appraisal skills of YLWH. Participants in our study were more likely to rate government sites as reliable in comparison to other sites. However, we do not have evidence that any specific website was more likely to be rated as reliable than another specific website. The lack of differences between specific sites may have been due to the small number of raters ($N = 13$) and noteworthy differences between specific sites could emerge with more raters.

Knowledge and Beliefs

Baseline HIV treatment knowledge scores were inadequate, despite provision of routine HIV education at the clinic. HIV treatment knowledge is an important target for intervention, as knowledge has been associated with treatment outcomes (Jones, Cook, Rodriguez, & Waldrop-Valverde, 2013). Perceived threat related to non-adherence was low in EASYPAS participants, and may be partially explained by developmental features of adolescence (i.e., invulnerability) and denial. Beliefs and perceptions represent another important target for assessment and intervention, given the association between higher levels of perceived threat of illness and ART adherence for YLWH (Garvie et al., 2011).

Limitations

The primary study limitations of the EASYPAS pilot were small sample size and high number of non-completers.

Conclusion

In this sample of YLWH participants, an adherence intervention delivered at an HIV clinical care setting was not feasible, irrespective of minimizing structural barriers for attendance. Adherence struggles do not typically present in isolation; they more commonly represent a symptom of underlying psychosocial distress, as observed in our sample. Co-morbidities associated with suboptimal adherence in YLWH such as stigma, depression, and substance use/abuse warrant intervention, and are an essential component of advancing the HIV adherence research agenda. Evidence-based strategies to overcome recruitment and retention barriers and increase representation of ethnic minorities living with HIV in clinical trials are also needed. Finally, given the dominant role of technology in the lives of modern youth, technology-enabled interventions offer great promise by allowing for privacy and flexibility, thereby serving to minimize stigma and improve access to health care and research opportunities.

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Table 1

Conceptualization and Measurement of Primary Study Measures

Concept	Variable	Definition	Measure
Health Beliefs	Beliefs About Medications	Beliefs regarding HIV illness & ART	Beliefs About Medications Scale (Riekert & Drotar, 2002)
HIV Treatment Knowledge	Knowledge of ART	Cognitive knowledge of HIV illness and related ART	HIV Treatment Knowledge Scale (Balfour et al., 2007)
Literacy	Functional Literacy	Grade level reading skills	Rapid Estimate of Adult Literacy Medicine-teen (Davis et al., 2006)
Media Literacy (Feuerstein, 1999)	Internet appraisal skills of HIV/ART related content	Critical responses of health information content obtained via media sources	Content analysis of participant responses (Graneheim & Lundman, 2004); Generalized estimating equation (GEE) analysis
Adherence	ART Adherence	Extent to which participants adhere to prescribed HIV ART regimen	3-day self-report of missed doses (Garvie, Wilkins, & Young, 2010)

Note. ART = antiretroviral therapy.

Table 2*Characteristics of Study Population (N =13)*

Characteristic	n (%) or M (SD)
Age (years)	22.0 (2.0)
Gender	
Male	7 (53.8)
Female	6 (46.2)
Race/ethnicity	
African American/Black	7 (53.8)
Hispanic/Latino	2 (15.4)
Mixed race/ethnicity	4 (30.8)
Mode of HIV transmission	
Horizontal	6 (46.2)
Perinatal	7 (53.8)
Sexual orientation	
Heterosexual	9 (69.2)
Gay/lesbian	3 (23.1)
Bisexual	1 (7.7)
Education	
Some high school	7 (53.8)
High school or equivalent	3 (23.1)
Some college	3 (23.1)
REALM-teen score	
5 th grade and below	1 (7.7)
6 th -7 th grade	3 (23.1)
8 th -9 th grade	3 (23.1)
10 th grade and higher	6 (46.2)
Employment status	
Full time	1 (7.7)
Part time	4 (30.8)
Unemployed	8 (61.5)
Current residence	
Biological family	7 (53.8)
Friend/partner	4 (30.8)
Alone	2 (15.4)
Current substance use	
Alcohol	2 (15.4)
Marijuana	5 (38.5)
Polysubstance use	4 (30.8)
None	2 (15.4)
Current smoker	
Yes	2 (15.4)

Characteristic	<i>n</i> (%) or <i>M</i> (<i>SD</i>)
No	11 (84.6)
Current psychiatric diagnosis ^a	
Yes	8 (61.5)
No	5 (38.5)
Insurance	
Private	2 (15.4)
Medicaid	7 (53.8)
Other	4 (30.8)
Total time in care	
< 3 years	5 (38.5)
3-8 years	5 (38.5)
> 8 years	3 (23.1)
Total time on ART	
< 1 year	2 (15.4)
1-5 years	6 (46.2)
> 5 years	5 (38.5)
Time on current ART	
< 6 months	3 (23.1)
6-11 months	3 (23.1)
12-24 months	2 (15.4)
> 24 months	5 (38.5)
Daily pill burden	1.8 (1.2)
Pre-intervention adherence ^b	
< 100% reported adherence	5 (38.5)
100% reported adherence	7 (53.8)
HIV biomarkers	
CD4+ T cell (cells/mm ³)	470.5 (265)
Serum viral load (copies/mL)	18,576.8 (32,651.4)

Note. *M* = mean; *SD* = standard deviation; ART = antiretroviral therapy; REALM = Rapid Estimate of Adult Literacy in Medicine.

^aPsychiatric diagnoses include major depressive disorders, bipolar disorders, other mood disorders, cannabis abuse, and personality disorders.

^bReported adherence could not be obtained for one participant because of hospitalization.

Table 3*Beliefs about Medicine Scale (BAMS) and HIV Treatment Knowledge Scores (N =13)*

Total and Subscale Scores (Range)	<i>M</i> (<i>SD</i>)	<i>Median</i> (<i>range</i>)
Total beliefs composite score (53-371)	237.4 (26.6)	232 (204-284)
Positive outcome expectancy (20-140)	114.1 (15.5)	120 (79-131)
Negative outcome expectancy (13-91)	39.5 (14.6)	37 (16-66)
Perceived threat (13-91)	43.3 (14.9)	41 (20-68)
Intent to adhere (7-49)	40.4 (5.5)	42 (32-49)
HIV Treatment Knowledge Scale Scores	<i>M</i> (<i>SD</i>)	<i>Median</i> (<i>range</i>)
Total (0-21)	14.4 (3.0)	14 (8-20)

Note. *M*= mean; *SD*= standard deviation