

1. TITLE PAGE

Title of Project: Use of mHealth Technology for Supporting Symptom Management in Underserved Persons Living with HIV

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2. STRUCTURED ABSTRACT (250 word maximum). Include five headings: Purpose, Scope, Methods, Results, and Key Words

Purpose: This study aimed to examine the impact of a mHealth application (app) comprised of evidence-based self-care strategies on the symptom experience of PLWH.

Scope: Persons living with HIV (PLWH) are living longer but experiencing more adverse symptoms associated with the disease and its treatment.

Methods: We conducted a 12-week feasibility study with 80 PLWH who were randomized (1:1) to a mHealth app, mobile Video Information Provider (mVIP), with self-care strategies for improving 13 commonly experienced symptoms in PLWH or to a control app.

Results: Intervention group participants showed a significantly greater improvement than the control group in 5 symptoms: anxiety ($p = 0.001$), depression ($p = 0.001$), neuropathy ($p = 0.002$), fever/chills/sweat ($p = 0.037$), and weight loss/wasting ($p = 0.020$). Participants in the intervention group showed greater improvement in adherence to their antiretroviral medications ($p = 0.017$) as compared to those in the control group. In this 12-week trial, mVIP was associated with improved symptom burden and increased medication adherence in PLWH.

Key words: Symptom management, Mobile technology, mHealth, Self-care, Feasibility trial

3. PURPOSE (Objectives of the study)

The goal of this study is to facilitate the dissemination and implementation of PCOR using mHealth technology to improve self-management of adverse symptoms in persons living with HIV/AIDS (PLWH). This application, in response to RFA-HS-14-010, seeks to develop and evaluate the efficacy of incorporating validated symptom management strategies into a mHealth tool to improve symptom self-management for PLWH. Symptom management in PLWH is especially important because the US HIV epidemic continues to exact a huge toll, especially among AHRQ priority populations including racial, ethnic, and sexual minorities and low-income persons. HIV has evolved from an acute illness to a chronic illness and patients, especially those with co-morbid conditions, have multiple adverse symptoms that require attention, evaluation, treatment, and ongoing management. Notably, there is a growing population of older adults living with HIV. As PLWH age, they are more susceptible to co-morbid conditions and are more likely to be affected by adverse symptoms.

An individual's ability to self-manage the symptoms of his or her HIV illness has been shown to improve patient-centered outcomes and quality of life. In response to this need, a team of researchers at UCSF School of Nursing developed a paper-based symptom management manual with self-management strategies for 21 common HIV/AIDS symptoms (T32 NR0007081). The manual was validated in a 775-person RCT over three months at 12 sites. To facilitate uptake by PLWH, we developed and pilot tested the Video Information Provider (VIP), a web-based personal health record that delivers patient-centered tailored symptom management strategies for PLWH (P30NR010677-03S1). VIP provides tailored strategies to better manage symptoms and improve overall quality of life⁹. Once users log in, they are guided by an avatar (i.e., the VIP) through a series of questions ascertaining the nature and severity of their symptoms. After the evaluation is completed, the program recommends tailored strategies for meeting the user's self-reported symptoms. Results from our 3 month pilot study (N=42) study overwhelmingly demonstrated the feasibility of the use of this system.

In this study we incorporated PCOR findings from our VIP study based on earlier work into a mHealth application (mVIP) to inform health care decisions so that the clinical outcomes for PLWH are improved. Health care can be transformed by using mobile technologies to more rapidly and accurately assess and modify health-related behavior and biological states. In our proposed work, we will use smartphones to provide real-time feedback and access to important symptom management strategies (PCOR evidence) to tailor health information in real-time. The ubiquitous nature of mobile technologies, namely smartphones, in daily life has created opportunities for health-related applications that were not previously possible. As such mHealth technology has the potential to be a highly valuable tool in the management and prevention of chronic illnesses such as HIV. For instance, mHealth takes advantage of existing and expanding health information system infrastructure, speeds communication, and has low start-up costs. Therefore, mHealth can provide mechanisms for improving the efficiency and effectiveness of care while reducing administrative burden. Despite the growing use of mHealth technologies, many applications have not been rigorously evaluated and there remains limited evidence of their acceptability to intended users and impact on health care outcomes. Therefore, we will use qualitative ethnographic methods and user-centered human-computer interaction research methods to ensure that the mVIP meets the end-user's goals. The specific aims of this project are to:

- 1) Apply participatory design methods to incorporate PCOR evidence for HIV symptom management into a mobile health application (mVIP) for use in patient self-care.
- 2) Using a randomized design, examine the effect of mVIP as compared to an attention control group on primary outcomes of symptom frequency and intensity.

Hypothesis: Study participants who use the mVIP system to access symptom strategies are more likely to have decreased symptom frequency and intensity at the end of 12 weeks.

3) Guide by the PRECEDE-PROCEED model of health program planning and evaluation, examine HIV+ persons' perceptions of the predisposing, enabling, and reinforcing factors for mVIP use.

To improve outcomes for those most in need, our study activities are focused on communities with the greatest burden of HIV in the US, including racial and ethnic minorities and those of low socioeconomic status. Findings from this study have the potential to make scientific evidence more accessible to patients through the use of mHealth technology. Ultimately the incorporation of HIV symptom management strategies into patients' lives through the use of mHealth technologies has the potential to advance the effective dissemination and implementation of PCOR findings.

4. **SCOPE** (Background, Context, Settings, Participants, Incidence, Prevalence)

Background

HIV has evolved into a chronic disease supporting the need for symptom self-management. HIV has changed from an acute illness to a chronic disease. The success of HIV medications and treatments has significantly changed the course of the disease. While AIDS-related illnesses are no longer the primary threat, a new set of HIV-associated complications have emerged, resulting in a chronic disease that for many will span several decades of life. Treatment does not fully restore immune health and multi-morbidity is associated with HIV disease. In view of the change in the course of the disease, PLWH are living longer but experiencing more symptoms associated with the disease and its treatment. More than a quarter of adults with HIV are 50 years of age and older and the number is growing. As the population of PLWH ages, there is a sharply increased risk of poorer everyday functioning and HIV-related disability supporting the need to manage adverse symptoms in this population. Symptom management in PLWH has been shown to decrease symptom severity, improve quality of life, reduce disability, increase medication adherence, and promote health. Little is known about the use of mobile technology for managing PLWH's symptom burden. The proposed research expands upon our innovative and highly feasible pilot work in developing and testing a web-based tailored symptom reporting and self-management system to assist PLWH to improve patient-centered outcomes.

Symptom Self-Management Strategies for PLWH are Available to Help Manage Symptoms. Self-management for patients with chronic illness means assisting patients to improve their clinical outcomes and enjoy the best possible quality of life. Self-management involves helping patients set achievable goals and learn techniques of problem-solving that will improve their outcomes and quality of life. In HIV, much work has been documented regarding the use and relevance of various self-management strategies for symptom management for fatigue, neuropathy, anxiety, lipodystrophy, and depression. In their investigation of symptom occurrence in cancer, researchers found that symptoms do not occur alone but in clusters, illustrating an adverse synergism of multi-symptom occurrences in the symptom experience. The analysis of symptom occurrence and the influence of one symptom upon another provide a more nuanced representation of an individual's symptom experience for both the patient and their provider. Patients' symptom experiences and symptom management success are strongly related to HIV disease progression and adverse clinical profiles. The prevalence of individual signs and symptoms as well as the intensity of the symptoms have contributed to reduced adherence to medications, which increases the likelihood of resistance to medication regimens and exacerbation of symptoms. These factors may also reduce the physical and mental aspects of a person's quality of life.

Context

The ability to self-manage symptoms of HIV illness has been shown to improve patient-centered outcomes and quality of life. In response to this need, a team of researchers at UCSF School of Nursing developed a paper-based symptom management manual with self-management strategies for 21 common HIV/AIDS symptoms (T32 NR0007081). The manual, was validated in a 775-person RCT over three months at 12 sites. To facilitate uptake by PLWH, we developed and pilot tested the Video Information Provider (VIP), a web-based patient-centered tailored symptom management tool for PLWH (NINR P30NR010677-03S1). VIP provides tailored strategies to better manage symptoms and improve overall quality of life⁹. Once users log in, they are guided by an avatar (i.e., the VIP) through a series of questions ascertaining the nature and severity of symptoms. After the evaluation is completed, the program recommends targeted strategies for meeting the user's self-reported symptoms. Results from our 3 month pilot study (N=42) study overwhelmingly demonstrated the feasibility of the use of this system.

Mobile health (mHealth) offer an ideal platform for the implementation and dissemination of evidence-based strategies for HIV symptom management. mHealth is focused on the use of mobile information and communication technologies to support care delivery through meeting information, communication, and documentation needs of clinicians, patients, and other health care workers and facilitating health resource monitoring and management. Early applications of mobile

information and communication technologies in health care were provided through the use of handheld devices known as personal digital assistants (PDAs) that provided various information resources such as medication dictionaries or point-of-care decision support.³⁹ The ability to develop applications on mobile devices such as PDAs was limited due to lack of memory, screen space, poor graphical display, and inability to transfer data. Mobile technology has advanced, and current devices allow for more memory and data storage, full color graphical interfaces with video capability, wireless access and integration with cellular devices. In addition, the ubiquitous nature of mobile technologies in daily life has created opportunities for applications that were not previously possible. For instance, mHealth takes advantage of existing and expanding infrastructure, speeds communication, and has low start-up costs. Therefore, mHealth can provide mechanisms for improving the efficiency and effectiveness of care provided while reducing administrative burden.

Nonetheless, in most cases, mHealth technology is being developed without incorporating PCOR evidence in the conceptualization of mHealth tools, and most tools do not function in ways that accommodate the clinical use of new or existing PCOR evidence. Notably, there are currently thousands of apps for PLWH, yet these apps have not been developed using PCOR evidence and/or end-user design. Currently available apps for PLWH may be off the marketplace in a few years. For instance of the 55 apps for PLWH which were reported in Muessig's 2013 review, 15 are no longer available. Consequently, developmental research is needed to improve understanding of how mHealth tools can be appropriately designed, functionally operated, and effectively used by PLWH to enable PCOR evidence dissemination and implementation. Moreover, many of the mHealth innovations for PLWH that are emerging originated in developing countries and have not gone beyond the pilot stage or have not been rigorously evaluated. Despite the growing interest in mHealth apps, there remains limited evidence on their acceptability and impact on health care outcomes.

Of particular relevance to this application, use of mobile technology has had a huge impact on communication, access, and information/resource delivery to racial and ethnic minority groups. mHealth technology also has the potential to bridge a divide in healthcare delivery among these underserved groups. Ownership of a mobile device is more common among blacks than among whites (87% vs. 80%), and blacks are among the most active users of the mobile Internet and take advantage of a much greater range of mobile phone features than whites. Similarly, Latinos are just as likely as other Americans to own a smartphone and go online from a mobile device. Latino internet users are more likely than white internet users to go online using a mobile device (76% vs. 60%).

Settings

Our main sites for recruitment were:

- 1) Comprehensive Health Program at Columbia University/NY Presbyterian Hospital provides primary care, HIV specialty care and care coordination services to over 2,000 HIV+ patients. 95% of individuals are of either Black or Latino background and women represent half of the overall population. In addition, the program has 28 direct clinical providers, 8 social workers, and 10 additional care coordinators.
- 2) AIDS Service Center (ASC) is a multiservice community organization for HIV+ patients and persons at risk for HIV. ASC has more than 90 staff, 85 peer interns, and more than 1,800 clients who come to ASC for services each year. In addition, another 18,000 people are reached through the peer education and community outreach initiatives of ASC.
- 3) Gay Men's Health Crisis (GMHC) is a not-for-profit, volunteer-supported, community based organization committed to the fight against AIDS. The organization provides prevention and support services to over 10,600 individuals who are living with or affected by HIV/AIDS in NYC. The population is approximately 33% Black and 33% Latino.

Incidence

Due to the high incidence of HIV among racial and ethnic minority populations, it is appropriate to develop mHealth tools tailored to the needs of these populations. mHealth technology has the potential to address many of the health care needs of PLWH including symptom management. In response to these current issues, our proposal seeks to inform the development and testing a mobile application that will incorporate findings from PCOR studies to improve the outcomes of PLWH. The tool developed using this research has the potential to extend the impact and reach of health care for PLWH.

Prevalence

HIV imposes a significant burden on the health and quality of life of 1.1 million Americans living with the disease. The burden of HIV/AIDS is borne disproportionately by a growing number of racial and ethnic minorities and socioeconomically disadvantaged individuals. Significant racial disparities exist in HIV incidence and care in the US¹⁴⁻¹⁷. In 2011, 48.7% of new HIV diagnoses were among Blacks and 31.3% were among Latinos. Blacks represent approximately 14% of the US population, but accounted for an estimated 44% of new HIV infections in 2009. The HIV infection rate among Blacks is

almost eight times as high as that of Whites (69.9 v. 9.1 per 100,000). The HIV infection rate among Latinos was three times as high as that of Whites. In addition, HIV disease progression and survival are worse among racial/ethnic minority patients. This underscores the importance of this work which will be conducted with high-risk vulnerable PLWH. Our study sample will be recruited from HIV Medicaid clinics and community based organizations that are predominately comprised of minorities, so our study will be focused on those high-risk, minority and underserved PLWH. Our proposed intervention, mVIP, will be tailored to meet the needs of low-income minority PLWH.

Participants

A total of 80 PLWH were randomized and 76 subjects completed the study. 40 participants were randomized to the intervention group (40 allocated to intervention with one withdrawal). Table 1 summarizes demographic information for intervention and control groups. Mean age of intervention group participants was 50 years (SD 11.7) and the mean age of control group participants was 51 years (SD 9.0). Ages ranged from 23 to 72 years. Nearly half of the participants had an annual income of less than \$10,000/year. 90% of our study participants belonged to a racial or ethnic minority group. There were no statistically significant differences between study groups.

5. METHODS (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)

Study Design

This randomized, controlled study took place in New York City. Participants were recruited through flyers at a local HIV clinic and community based organizations, and through e-mail invitations. Research assistants assessed all respondents for eligibility over the phone. Eligible participants were English speaking; aged 18 years or older; diagnosed with HIV; experienced at least 2 of 13 HIV-related symptoms in the past week; had a cognitive state minimum score of 24 out of 30 as measured by the Mini-Mental State Examination (MMSE); and owned a smartphone or tablet. All participants completed written informed consent prior to the start of study activities.

Following enrollment, participants were randomized to each study arm. A randomization schedule was developed prior to the start of the trial. Study participants were randomized (1:1) to mVIP with self-care strategies (intervention group) or mVIP without self-care strategies (control group). Both groups received access to the mVIP app on their smart- phones. The PI created the allocation sequence through a computerized random number generator. This was a single- blinded study and the control group participants did not have access to the self-care strategies. Participation in the trial lasted 12 weeks; a follow-up survey was administered at our study site at the end of the study period.

Data Sources/Collection

Participants completed survey questions each week via the app (Fig. 2d) to report if they had experienced each of the 13 symptoms in the past week and how much each symptom bothered them in the past week. The symptom questions were based on the Revised Sign and Symptom Check-List for HIV (SSC-HIVrev). Participants were first asked if they experienced the symptom in the past 7 days (Yes or No). For each symptom selected, respondents were asked how much it bothered them (a little bit, somewhat, quite a bit, or very much). If a participant did not experience the symptom in the past week, then they were not asked how much it bothered them and were not given any strategies. If a participant reported bothersome symptoms, the app would deliver 3 self-care strategies for the participant to try that week. Figure 1 illustrates sample self-care strategies for each symptom. Each strategy was accompanied by a short (3–27 s) video to illustrate the strategy (Fig. 2e). At the end of the app session, participants were able to view a summary of their strategies (Fig. 2f). The app also included a reminder system that emailed participants at 7:30 pm on 7, 14, 18, and 21 days after their last use. The reminders included a link to the mVIP app so that users could easily access the app by clicking on the link.

Fig. 2 a mVIP shortcut, b Log-in, c Avatar selection, d Symptom assessment, e Animated video, f Summary of strategies



Intervention

Our study tested mVIP, which was designed to help PLWH self-manage their symptom experience. mVIP is a web-app optimized to run on a smartphone or tablet, and also capable of running on a desktop computer. It was developed through a rigorous user-centered design process described elsewhere, consisting initially of card sorting activities that informed the architecture of the symptoms and self-care strategies, followed by a heuristic evaluation with experts, and end-user usability testing in a laboratory setting. All features of the app were tested by the project team before enrolling study participants in the feasibility trial.

The mVIP app was comprised of 143 self-care strategies for 13 different symptoms. Symptoms included: (1) Anxiety, (2) Cough or shortness of breath, (3) Depression, (4) Diarrhea, (5) Difficulty falling or staying asleep, (6) Difficulty remembering, (7) Dizziness, (8) Fatigue, (9) Fever, chills, sweats, (10) Nausea or vomiting, (11) Neuropathy, (12) Skin problems, and (13) Weight loss or wasting. Sample self-care strategies can be found in Fig. 1.

Fig. 1 Sample self care strategies for 13 symptoms

Symptom	Example of re-worded self-care strategy
Anxiety	Attend a free support group offered in your community. Check if the group has a specific focus that interests you.
Cough or shortness of breath	Try controlled or paced breathing: The key is to inhale slowly and exhale through pursed lips while performing the work. Focus on breathing out slowly and evenly.
Depression	Avoid alcohol and other mood-altering non-prescription drugs (e.g. cocaine, speed) as these tend to make you sluggish later.
Diarrhea	Try these Supplements: Acidophilus or Metamucil™ (You can purchase these nutritional supplements at a health food or drug store). Share your plan to take nutritional supplements with your doctor/nurse before starting.
Difficulty falling or staying asleep	Do not exercise too close to bedtime – exercise at least 4-6 hours before going to bed.
Difficulty remembering	Use a date book to write down your appointments or schedule right away so you don't forget them later.
Dizziness	Rise slowly when waking up – sit up first, then stand.
Fatigue	Vegetables are a good source of vitamins, which can help you gain energy. Do not overcook vegetables since this makes them lose vitamins.
Fever, chills, sweats	Drink plenty of fluids (water, non-caffeinated beverages) – at least six 8-ounce glasses per day.
Nausea or vomiting	Do not lie down for at least 30 minutes after eating.
Neuropathy	Keep your hands/feet warm, but not so warm that they sweat.
Skin problems	Use a warm mist humidifier – dry air can irritate the skin.
Weight loss or wasting	Add instant breakfast drinks, milk shakes or other supplements to your diet and drink them any time of the day.

Upon enrollment, study participants installed a shortcut to the web-app on their home screen (Fig. 2a). Participants used this shortcut icon to log into mVIP (Fig. 2b), then selected an avatar (Fig. 2c) who guided them through the mVIP system. Participants were instructed to log in at least once per week and use the app to assess their symptoms and receive self-care strategies tailored to their symptom experience. Both study groups received the mVIP app but only intervention group participants received the self-care strategies. In addition to the text delivered by the self-care strategies, intervention group participants were able to view a short animated video which illustrated the self-care strategy.

Measures

Study participants completed a baseline survey comprised of demographic questions, PROMIS-29, RAND 36-item health survey, engagement with healthcare provider, antiretroviral therapy (ART) medication adherence using the Visual Analogue Scale (VAS) and CASE Adherence Index, number of medical visits, and usability through the Health-ITUES. All surveys were administered via Qualtrics software on either a laptop computer or iPad at our study site, the Columbia University School of Nursing. Study participants were instructed to use the app at least once per week, and symptom frequency and bothersomeness were collected via the app during each session. At the end of the 12 weeks, study participants were invited back to the study site to complete their follow-up questionnaire and receive compensation for completing the surveys each week. Participants had the opportunity to receive \$155 as total compensation. Participants

received \$30 for attending the baseline and \$40 for the follow-up visit. Participants received \$5 for each week they completed a survey using the app, and they received a bonus of \$25 for completion of all study components. All study activities were approved by the Columbia University Medical Center University Institutional Review Board.

Limitations

The technical capabilities of the app also created a number of limitations, which should be taken into consideration for future versions of the app. First, despite this being a smartphone app, participants wanted their reminders and login information sent via text instead of e-mail. Second, while the app provided a summary report of recommended self-care strategies for the intervention group, both study groups expressed their desire for reports of their symptoms and visualizations of their self-reported changes in symptoms over time. Finally, the self-care strategy videos did not contain sound and future versions of the app should incorporate videos that are longer and more dynamic.

There is also some limitation to the generalizability of our findings since we required individuals to possess a smartphone or tablet to be in the study. The most marginalized HIV patients likely do not have smartphones. On the other hand, an advantage to a web-based app is that individuals (assuming they own a phone/tablet) can connect using free wi-fi even if they do not have money to pay their cell phone bills, a frequent cause of service interruption.

6. RESULTS (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Principal Findings

Intervention group participants showed a significantly greater improvement than the control group in 5 symptoms: anxiety ($p = 0.001$), depression ($p = 0.001$), neuropathy ($p = 0.002$), fever/chills/sweat ($p = 0.037$), and weight loss/wasting ($p = 0.020$).

Outcomes

Overall Use of mVIP

Of the 80 participants who completed the baseline visit, 5 (6.3%) participants (1 control, 4 intervention group) did not use the mVIP app after the baseline visit. The mean number of times participants used the app during the study period was 18.2 times (SD 15.5). 18 (45.0%) intervention group participants and 19 (47.5%) control group participants used the app greater than 14 times during the 12-week trial. 32 (80.0%) intervention group participants and 35 (87.5%) control group participants used the app at least 11 times during the 12-week trial. 14 (35.0%) participants in the intervention group and 16 (40.0%) participants in the control group used the app at least once per week (within a strict 7-day period). There was no significant difference in app use between study groups.

Impact on Symptom Burden

Table 1 presents the frequency of participants who reported experiencing the symptom at baseline. Fatigue was the most frequently reported symptom ($n = 61$, 76.3%), followed by difficulty falling or staying asleep ($n = 59$, 74.7%), neuropathy ($n = 46$, 59.0%), anxiety ($n = 45$, 57.0%), and depression ($n = 43$, 53.8%). There was no significant difference in symptom frequency between study groups at baseline.

Table 1. Frequency of Symptoms at Baseline

Variable	Overall	Intervention	Control	Significance
	N = 80	N = 40	N = 40	(p-value)
Anxiety	45 (57.0%)	22 (56.4%)	23 (57.5%)	0.922
Cough or shortness of breath	37 (46.3%)	17 (42.5%)	20 (50.0%)	0.501
Depression	43 (53.8%)	25 (62.5%)	18 (45.0%)	0.116
Diarrhea	24 (30.4%)	13 (33.3%)	11 (27.5%)	0.573
Difficulty falling or staying asleep	59 (74.7%)	31 (77.5%)	28 (71.8%)	0.560
Difficulty remembering	40 (50.6%)	22 (55.0%)	18 (46.2%)	0.432
Dizziness	20 (25.6%)	12 (30.8%)	8 (20.5%)	0.300
Fatigue	61 (76.3%)	31 (77.5%)	30 (75.0%)	0.793
Fever, chills, or sweats	20 (25.0%)	10 (25.0%)	10 (25.0%)	1.000
Nausea or vomiting	15 (18.8%)	8 (20.0%)	7 (17.5%)	0.775
Neuropathy	46 (59.0%)	23 (59.0%)	23 (59.0%)	1.000
Skin problems	35 (44.3%)	19 (47.5%)	16 (41.0%)	0.562
Weight loss or wasting	20 (25.3%)	12 (30.0%)	8 (20.5%)	0.332

NOTE: Those who skipped a symptom question at baseline are excluded from percentages for that symptom

Table 2 provides a summary of the symptom burden results between baseline and follow-up. We conducted an intention-to-treat analysis. Compared with control group participants, intervention group participants had an improvement in 12 of 13 symptoms. Of these symptoms, intervention group participants showed a significantly greater improvement than the control group participants in 5 symptoms: anxiety ($p = 0.001$), depression ($p = 0.001$), neuropathy ($p = 0.002$), fever, chills, or sweats ($p = 0.037$), and weight loss or wasting ($p = 0.020$). There was a greater improvement in nausea or vomiting in the control group as compared to the intervention group but this was not significant.

Table 2. Difference Symptom Score Between the Intervention and Control Groups

	Score change from Baseline to Week 12				Difference between Arm 1 & Arm 2		
	Intervention		Control		Estimate	Standard Error	Significance (p-value)
	Score	Standard Error	Score	Standard Error			
Anxiety	-0.858	0.102	-0.318	0.118	-0.541	0.156	0.001
Cough or shortness of breath	-0.570	0.105	-0.421	0.122	-0.149	0.161	0.356
Depression	-0.540	0.106	-0.007	0.123	-0.533	0.163	0.001
Diarrhea	-0.240	0.092	-0.233	0.107	-0.007	0.141	0.962
Difficulty falling or staying asleep	-0.506	0.106	-0.433	0.122	-0.073	0.162	0.651
Difficulty remembering	-0.343	0.095	-0.169	0.110	-0.174	0.145	0.230
Dizziness	-0.319	0.083	-0.181	0.095	-0.138	0.126	0.275
Fatigue	-0.566	0.115	-0.563	0.132	-0.003	0.175	0.987
Fever, chills, sweats	-0.360	0.086	-0.084	0.099	-0.275	0.132	0.037
Neuropathy	-0.713	0.103	-0.228	0.119	-0.485	0.157	0.002
Skin problems	-0.219	0.091	-0.089	0.105	-0.130	0.139	0.349
Vomiting	-0.122	0.066	-0.185	0.077	0.063	0.101	0.534
Weight loss or wasting	-0.254	0.070	-0.004	0.081	-0.250	0.107	0.020

Secondary Outcomes

Table 3 illustrates the findings from our secondary outcome measures. Overall, participants rated the app as highly usable. There was almost no significant difference in health-related quality of life between study groups as measured by the PROMIS-29 and the RAND-36 Item Health Survey instruments. Higher scores on the RAND-36 indicate more favorable health states, thus a significantly higher pain score suggests that the intervention may have had a significant difference on improving self-reported pain in the intervention group as compared to the control group. Likewise, there was no significant difference between study groups in system usability. We measured adherence to ART using two adherence measures: VAS and the CASE Adherence Index. Both have been shown to be reliable and valid tools and there is no gold standard measure for ART adherence. We found a significant improvement in ART adherence as measured through the CASE adherence index in our intervention group as compared to our control group participants, but this difference was not detected when measuring adherence with the VAS.

Table 3. Difference in Difference of Secondary Outcome Measures

Variable	Estimate	Standard Error	Significance (p-value)
PROMIS-29			
Physical Function	0.79	1.25	0.529
Anxiety	1.71	1.68	0.312
Depression	-0.36	1.81	0.841
Fatigue	0.40	2.07	0.848
Sleep Disturbance	2.58	2.03	0.208
Satisfaction with Participation in Social Roles	0.72	2.29	0.754
Pain Interference	1.25	1.66	0.454
RAND-36 Item Health Survey 1.0			
Physical Functioning Scale	-3.06	7.27	0.675
Role Limitations due to Physical Health Scale	7.47	10.02	0.458
Role Limitations due to Emotional Problems Scale	3.50	9.91	0.725
Energy/Fatigue Scale	-1.00	4.09	0.807
Emotional Well-being Scale	1.48	3.73	0.693
Social Functioning Scale	-8.93	5.80	0.128
Pain Scale	-14.33	5.18	0.007
General Health Scale	-0.20	3.93	0.960
Physical Health Summary Scale	-0.93	4.47	0.836
Mental Health Summary Scale	-0.81	3.60	0.822
Engagement With Healthcare Provider			
Engagement with Healthcare Provider Scale	-2.52	2.19	0.252
Medication Adherence			
CASE Adherence Index	-1.51	0.62	0.017
Visual Analogue Scale	-4.88	5.06	0.338
Health-IT Usability Evaluation Scale (Health-ITUES)			
Overall	-0.07	0.23	0.743
Quality of Life	-0.28	0.20	0.166
Perceived Usefulness	0.03	0.26	0.899
Perceived Ease of Use	-0.07	0.26	0.803
User Control	-0.20	0.28	0.480

Healthcare Services Use

At the end of the trial, we asked participants to report their use of healthcare services in the past 30 days. Overall, healthcare services utilization was very low in both study groups. In summary, a total of 3 (8.1%) intervention group participants and 4 (10.3%) control group participants reported visiting the emergency room. A total of 2 (5.4%) intervention group participants and 1 (2.6%) control group participants reported being hospitalized. A total of 16 (43.2%) intervention group participants and 19 (48.7%) control group participants reported a medical office visit. Using Pearson's Chi squared test, there was no significant difference in healthcare services use between study groups

Focus Group Findings

A total of 14 themes were identified from the focus group transcripts. We organized the themes according to the three factors of the PRECEDE, component of the PRECEDE-PROCEED framework.

Predisposing factors

The five major themes related to predisposing factors, were: 1) ease of app use; 2) user-friendly functionality; 3) self-efficacy for symptom management; 4) design preference of illustrated strategies with videos; and 5) user-control (convenience vs. security). These predisposing factors and representative quotes are presented in Table 4. Codes were organized by positive, negative and neutral signs, and study group (i.e., intervention vs. control).

Table 4. Themes and Quotes of Predisposing Factors

Factor	Code	Quotes
P-1. Ease of app use		
Intervention group	Positive	<i>The questions (in the app) were all pretty much straightforward, easy to answer. Actually, the app was kind of simple to use, very simple. Totally easy...</i>
	Negative	---
	Neutral	---
Control group	Positive	<i>Once I got to the part where, you know, it was easy to get to start. Very easy for me.</i>
	Negative	---
	Neutral	---
P-2. User-friendly functionality		
Intervention group	Positive	<i>You guys give us a reminder. One day I did forget on Monday. It was Tuesday, Reminder said "You have to answer your questions." And, I could get right on top of it.</i>
	Negative	<i>I wanted to be able to go back and review my history just like when you go on the internet and it says, "Your History" and you go back, before you delete everything, you can go back and see it. That's what I thought it was going to do, but it didn't do that.</i>
	Neutral	<i>More choices (of Avatars) might be helpful? I guess maybe... I really didn't bother me either way.</i>
Control group	Positive	<i>I would get an email when I totally forgot. And, I'm like, "Oh, wow. They reminded me." I felt so good.</i>
	Negative	<i>I didn't like the avatar... I'm interested in really looking at their face and not the avatar. I want to see my face on my phone. I didn't want to see this cartoon.</i>
	Neutral	<i>The cartoon, it was okay, because I had to do something, so basically I had to get used to learning how to work it and I did that in a couple of days after she taught me.</i>

P-3. Self-efficacy for symptom management

Intervention group	Positive	<i>I got several symptoms like depression or not sleeping well and rush. And, I got all recommendations from the app and tried. It works!</i>
	Negative	---
	Neutral	<i>No meds. Just vitamins, working out, eating lots of fruits and whatever plan God has for me because he's in this, too. You understand what I'm saying? I respect the app, you know, but everything is not for everybody.</i>
Control group	Positive	<i>My experience while using the app, it gave me the power to control and monitor what was really going on with my body.</i>
	Negative	---
	Neutral	---

P-4. Design preference of illustrated strategies with videos

Intervention group	Positive	<i>Attractive videos. Exactly. All of them were cute. And, easy to understand (the strategies).</i>
	Negative	<i>The video didn't have any sound. So, I would just look at them and I'm like, "Why aren't they talking but they're moving." I want to hear something. I want to hear someone talking.</i>
	Neutral	---
Control group	Positive	---
	Negative	---
	Neutral	---

P-5. User-control (convenience vs. security)

Intervention group	Positive	<i>I didn't have a problem with password. I saved it. Every time I would go into Chrome and mVIP had already that password and it had the number (ID) and all I had to do was only sign in. That's it.</i>
	Negative	---
	Neutral	---
Control group	Positive	<i>9 out of 10 times, I forgot the password. The app had a little button that says: remember me. Therefore, I didn't have to remember my password. No need to remember. (convenience)</i>
	Negative	<i>For me, I never do that...If you have that "remember me" and somebody accesses your phone...let's say you have it on your bank account. They can immediately see what your bank account level is, they have access to your HIV thing. (security)</i>
	Neutral	---

Participants in both intervention and control groups perceived that mVIP was easy to use. A participant in the intervention group stated that, *"The questions (in the app) were all pretty much straightforward, easy to answer. Actually, the app was kind of simple to use, very simple. Totally easy..."*

Several participants in both groups thought that the app had user-friendly functionalities such as avatar selection, reminder emails, app instructions, and error messages. One participant stated that, *"I would get an email when I totally forgot. And, I'm like, "Oh, wow. They reminded me." I felt so good."* Meanwhile, a participant highlighted his expectation that mVIP app would include additional functionality which would allow end-users to upload their own pictures instead of selecting an avatar, describing that, *"I didn't like the avatar... I'm interested in really looking at their face and not the avatar. I want to see my face on my phone. I didn't want to see this cartoon."*

While both the intervention and control groups received symptom and intensity questions (e.g., did you have fatigue? If yes; how much did it bother you?), only the intervention group was provided with self-management strategies for the symptoms that bothered the participants. Participants in the intervention group expressed self-efficacy for managing HIV-related symptoms via the mVIP app. Relatedly, participants in the control group expressed their self-efficacy for symptom management by monitoring their symptoms through the use of the app. One participant stated that, *"My experience while using this easy app, it gave me the power to control and monitor what was really going on with my body."*

The app for the intervention group provided strategies using text and short animated videos. Several participants expressed that the animated videos were attractive and helpful for their better understandings of the strategies. Meanwhile, some participants suggested adding sound into the videos. One participant stated that, “*The video didn’t have any sound. So, I would just look at them and I’m like, “Why aren’t they talking but they’re moving.” I want to hear something. I want to hear someone talking.*”

Participants in both groups appreciated having the option of saving or not saving their password in accordance with an individual’s preference (convenience vs. security). A control group participant expressed a preference for saving a password stating that, “*9 out of 10 times, I forgot the password. The app had a little button that says: remember me. Therefore, I didn’t have to remember my password. No need to remember.*” On the contrary, however, another participant raised concerns about the security of the password, reflected on his experience when his smartphone was stolen, “*For me, I never do that...If you have that “remember me” and somebody accesses you phone...let’s say you have it on your bank account. They can immediately see what your bank account level is, they have access to your HIV thing.*”

Enabling factors

The four themes related to enabling factors influenced use of the app were: 1) information needs of symptom management; 2) symptom-tracking; 3) fit in lifestyle/schedule/living conditions; and 4) additional languages (e.g., Spanish). The enabling factors and representative quotations are presented in Table 5.

Table 5. Themes and Quotes of Enabling Factors

Factor	Code	Quotes
E-1. Information needs of symptom management		
Intervention group	Positive	<i>The suggestions they’re telling us to do is helping us. And, those are minor issues, but it can affect us a lot. Like, moving my bowels. I had a problem with that.</i>
	Negative	<i>But, after the first week of viewing everything, nothing changed. It was the same questions. It was the same video. I could have used a lot of other scenarios or more information to show me how to do things differently. Everything, after a while, everything it seems like it doesn’t work anymore... But, after doing it for 3 months it gets boring.</i>
	Neutral	<i>Every time I use it, sometimes I hit different things just to see what they would say in the symptoms or results.</i>
Control group	Positive	<i>And, my doctor that took my sample, they didn’t tell me nothing. But, I think it was telling me it’s what I’m eating. Doctor didn’t tell me that.</i>
	Negative	<i>I think the app lacks referral services. When you have a question with somebody experiencing depression and they could be experiencing it 5 days or more. That could be serious...You should have something there where they say, “If this is going on for the past 4 days maybe you need to seek medical attention or call 911” or something.</i>
	Neutral	---

E-2. Symptom-tracking

Intervention group	Positive	<i>The good thing about it (app) was that you can really go back to whatever you had, your progress was, and see what you did throughout the week.</i>
	Negative	<i>It's just like, I mean, I don't know, what I wanted to see more was like a calendar or like the frequency of how often I was experiencing certain symptoms rather than just like, these are the symptoms you've had in the past.</i>
	Neutral	---
Control group	Positive	<i>I found the app to help in terms of weekly stress because stress has very affected on everybody, including myself. So, it was important to be able to pinpoint the different type of stress that were happening. You should know what issues may occur. To be alert. To be aware.</i>
	Negative	---
	Neutral	---

E-3. Fit in my lifestyle/schedule/living conditions

Intervention group	Positive	<i>It's very convenient because I can use it almost anywhere. While I'm in public transportation, on the buses, at the clinic, at home...everywhere.</i>
	Negative	<i>I used app sometime...I couldn't use it because I had to move again and again. I didn't have a place to stay...</i>
	Neutral	<i>I only use it at home...when I get bored I just pick up the phone and go on anything. Just use it at home in privacy.</i>
Control group	Positive	<i>I use the app anywhere...I don't care who knows that I'm HIV positive. You either like me or you don't.</i>
	Negative	---
	Neutral	<i>It didn't make a difference to me. I didn't do it the same time, but I tried to do it basically the majority of the times when my alarm went off for me to take my medicine in the morning.</i>

E-4. Additional languages (e.g., Spanish)

Intervention group	Positive	---
	Negative	<i>I have a question. That is only for the studio (study)? Or, you're going to try to introduce that to the people? You know why? Because I suggest to use 2 languages.</i>
	Neutral	---
Control group	Positive	---
	Negative	---
	Neutral	---

Participants in the intervention group thought the mVIP app provided useful self-care strategies which were helpful for self-managing their HIV-related symptoms. The control group participants also reported needing information about symptom management, and they pointed out a lack of information on how to manage the symptom reported since the app provided to them did not suggest any strategies. One participant in the control group stated that, *"I think the app lacks referral services. When you have a question with somebody experiencing depression and they could be experiencing it 5 days or more. That could be serious...You should have something there where they say, "If this is going on for the past 4 days maybe you need to seek medical attention or call 911" or something"*. Nonetheless, the control group participants perceived the app to be useful because participants could self-monitor their symptoms using the app. One participant stated that, *"I found the app to help in terms of weekly stress because stress has very affected on everybody, including myself. So, it was important to be able to pinpoint the different type of stress that were happening. You should know what issues may occur. To be alert. To be aware."*

Several participants in both groups discussed the convenience of using the app at a place and time they preferred. An intervention group participant described that, *"It's very convenient because I can use it almost anywhere. While I'm in public transportation, on the buses, at the clinic, at home...everywhere."* On the other hand, a participant in

the intervention group disclosed housing instability as a barrier related to the app use stating that, “I only used app sometime...I couldn’t use it because I had to move again and again. I didn’t have a place to stay...”

Moreover, having additional languages was identified as one of enabling factors. A participant suggested that the app be offered in additional languages such as Spanish, specifically the participant questioned, “That is only for the study? Or, you’re going to try to introduce that to the people? You know why? Because I suggest to use 2 languages.”

Reinforcing factors

The five themes related to reinforcing factors were: 1) communication with healthcare providers; 2) individual-tailored information visualization; 3) social networking; 4) individual-tailored information quality; and 5) improvement in quality of life. The themes and quotes of reinforcing factors are reported in Table 6.

Table 6. Themes and Quotes of Reinforcing Factors

Factor	Code	Quotes
R-1. Communication with healthcare providers		
Intervention group	Positive	<i>I would discuss it with my doctor about that situation. I say, “Look at the app. Look at what happened to me. Look about my sleeping problem. Maybe we can change something in my medication.”</i>
	Negative	---
	Neutral	<i>I was discussing with my doctor about the app because, coincidentally, my visit to my doctor was during the study and she was just impressed about the app. That’s it.</i>
Control group	Positive	<i>It would be great if the doctors had access to see how often things are going on. I can show her this has been going on for a whole month, such and such. And she will see that he or she is responsible about taking care of themselves and what’s going on.</i>
	Negative	---
	Neutral	---
R-2. Individual-tailored information visualization		
Intervention group	Positive	---
	Negative	---
	Neutral	---
Control group	Positive	---
	Negative	<i>The one thing I want to say...about the graphic report of your symptoms, that would be great because then you can bring that to your doctor to share...</i>
	Neutral	---
R-3. Social networking		
Intervention group	Positive	<i>I showed a couple of my friends and I even gave them a couple of suggestions that the app gave me. They seemed to like it. It worked for them, so it was cool.</i>
	Negative	---
	Neutral	<i>I definitely showed it to my cousin. I was doing it there and she’s like, “That’s too many questions.” I was just showing her what I got, you know, showed her it and stuff and she said, “That’s too many questions.”</i>
Control group	Positive	---
	Negative	<i>I think you should create a network where we can network among each other with the app. You know you can respond to someone and you can say, “You know what? I’m feeling the same exact way today.” I think that’s what the app needs for me.</i>
	Neutral	---

R-4. Individual-tailored information quality

Intervention group	Positive	<i>I think it was pretty cool. The way it got me to switch out my routine a little bit. My sleeping routine...It kind of changed my routine up a little bit each time I logged in and I did the app. It was like a refresher to myself. It helped me.</i>
	Negative	<i>If you just got diagnosed with HIV between 1-5 years, this (strategy) is perfect. I've been diagnosed since 1989. There were a lot of suggestions that did work, but we can't just stick with one. More helpful hints. More quantity of suggestions and strategies for us (who were diagnosed with HIV a long time ago). I think it should be more personalized, like we said before because we all are different. I mean, you know. I may have something that they don't have. They may have something I don't have. Even though we have the same status, we go through daily different things.</i>
	Neutral	<i>I take medication for other areas, but as far as the app, I basically just took what I needed from it and the rest that didn't apply.</i>
Control group	Positive	<i>I like the app because there were some things that were listed in the app that I had no idea, you know, that were related to my HIV. So, it caused me to listen more closely to what's going on with me. So, I find the app very helpful.</i>
	Negative	<i>But, there's other health issues, too, that you all can put up there...The only thing I saw about diabetes was the tingling. There are other symptoms from diabetes, like you said, the blurred vision. I did it really quick. It was sort of too short.</i>
	Neutral	<i>I like collaborating on things that were said through others that took the app. I relate what you're saying. The app has things that each of us go through.</i>

R-5. Improvement in quality of life

Intervention group	Positive	---
	Negative	---
	Neutral	---
Control group	Positive	<i>The question, "have you had difficulty falling asleep" that was consistently true almost 3 or 4 days out of the week. One of the things that made me think, looking at my behavioral patterns, and now I literally will shut down my computer, I'll turn off the TV at least 15 or 20 minutes before going to bed, and now I haven't had that problem at all. Better life!</i>
	Negative	---
	Neutral	---

Several participants in both groups thought that the mVIP app could help them to better interact with their healthcare providers if they could share the information about their symptom status with a review function within the app. Users in the intervention group were able to review all of the self-care strategies when they used the app. This was noted as being useful since participants reported being able to better communicate their symptom experience to their healthcare providers. One participant described that, *"I would discuss it with my doctor about that situation. I say, 'Look at the app. Look at what happened to me. Look about my sleeping problem. Maybe we can change something in my medication.'"* Control group participants would also like to share their symptom status information with their healthcare providers suggesting individual-tailored information visualization such as a symptom report/summary. One participant stated that, *"The one thing I want to say...about the graphic report of your symptoms, that would be great because then you can bring that to your doctor to share..."*

In addition to communication with healthcare providers, participants in both groups mentioned the potential of the app for use as a social networking tool. Particularly, several participants in the control group thought that additional functionality of social networking to share feelings with other PLWH would be helpful. One participant said that, *"I think you should create a network where we can network among each other with the app. You know you can respond to someone and you can say, 'You know what? I'm feeling the same exact way today.' I think that's what the app needs for me."*

Regarding the quality of information provided within the app, several participants in the intervention group mentioned that it would be important for the app to be tailored to patient groups of varying years of diagnosis and to be tailored to more sensitive individuals. As HIV is considered a chronic disease, PLWH have been living with the common symptoms in their daily lives and have already tried various self-care strategies. They highlighted their desires for mVIP to include more symptoms and self-management strategies. One participant elucidated that, *“If you just got diagnosed with HIV between 1-5 years, this (strategy) is perfect. I’ve been diagnosed since 1989. There were a lot of suggestions that did work, but we can’t just stick with one. More helpful hints. More quantity of suggestions and strategies for us (who were diagnosed with HIV a long time ago).”* In addition, participants expressed their expectations for a more individualized self-tailoring symptom management app stating that, *“I think it should be more personalized, like we said before because we all are different. I mean, you know. I may have something that they don’t have. They may have something I don’t have. Even though we have the same status, we go through daily different things.”*

Participants in the control group reported improvements in their quality of life through use of the app. A participant mentioned that, *“The question, ‘have you had difficulty falling asleep’ that was consistently true almost 3 or 4 days out of the week. One of the things that made me think, looking at my behavioral patterns, and now I literally will shut down my computer, I’ll turn off the TV at least 15 or 20 minutes before going to bed, and now I haven’t had that problem at all. Better life!”*

Discussion

Multiple studies have addressed the potential benefits of mobile phone apps for patients with chronic illnesses. Though this study is small, it is one of the first trials to demonstrate even a short-term impact on symptom improvement in a randomized, controlled design. In particular, this study is one of the first randomized studies of a mobile app in a sample of persons who are almost all racial/ethnic minorities and from the lowest income groups in the US.

The intervention described here provides PLWH a mobile app to self-manage their symptoms and provides evidence-based self-care strategies to help them ameliorate their symptoms. It extends the current research in several important ways. First, this short duration study demonstrated that a sub-population exists who derives value from using mHealth technology for symptom self-management.

A larger, longitudinal study should be conducted to better understand how to sustain use over long periods of time in persons who can derive value from an intervention. Second, it will add to the body of literature on whether mHealth technology can be used for the dissemination of evidence-based strategies for persons living with a chronic illness. Third, it adds further support to the need for formative user-centered design during the conceptualization and development of mHealth technologies. Finally, it extends the literature on mHealth technology as a potentially effective tool for improving patient-reported outcomes in persons living with a chronic illness.

Importantly, we did detect an improvement in ART medication adherence using the CASE Adherence Index, although no significant association was found using the VAS. While both the CASE and the VAS are validated measures used to assess medication adherence, past research has suggested that Likert-type scales may yield more variable results in self-reports compared to global estimates of adherence. ART adherence and symptom management have been strongly linked in past research, which has shown that symptom interpretation can influence adherence to treatment regimens when, for example, symptoms are assumed to be medication side-effects or when their alleviation, persistence, or worsening after treatment initiation is used to assess therapeutic efficacy.

Past research has shown that untreated HIV, as well as ART side effects, can cause more symptoms. Unlike treatments for other illnesses, ART medications are more likely to contribute to greater discomfort, reinforcing the need for symptom management in the treatment cascade. Interestingly, 85% of our study sample was virologically suppressed at baseline and only 5% reported not being on ART. Therefore, even patients with well-controlled HIV report symptoms that affect quality of life, which has been shown in other studies. These findings further support the potential impact of the mVIP intervention for ameliorating symptoms and improving patient-reported outcomes. This is particularly relevant for PLWH who are virologically suppressed but are burdened by symptoms associated with their ART medications.

We did detect a significant improvement in the RAND-36 pain scale score in the intervention group. While this improvement is noteworthy, we acknowledge that since we examined a large number of similar outcomes measures for health-related quality of life, there is the potential for one of the scales to be significant because of random chance. Further consideration of health-related quality of life in our study demonstrates that the overall PROMIS scores at baseline in both study groups were only “mildly impaired,” making it difficult to detect a significant improvement in PROMIS scores since participants had relatively good health-related quality of life despite living with HIV. Likewise, the RAND-36 scores, another measure of health-related quality of life, were higher in our study sample than those for the general US population, making it difficult to demonstrate an intervention effect on a study sample who had generally good health-

related quality of life. Future intervention studies should evaluate the effect of these self-care strategies in people who are more symptomatic and who have lower health-related quality of life at baseline.

Another important note is that our study sought to assess the effect of overall usability of the app. Usability is the measure of the quality of a user's experience when interacting with a system, including their perceived usefulness and ease of use. In the case of our study, the Health-ITUES was used as a measure of usability. The Health-ITUES is a 20-item customizable usability evaluation instrument which has been validated for use with mHealth technology. This instrument is comprised of 4 subscales in addition to the overall user satisfaction: system impact, perceived usefulness, perceived ease of use, and user control. We would anticipate that there would be an improvement in overall user satisfaction, covering all of the constructs, in the intervention group at the end of the study. At the same time, we did not anticipate particularly perceived usefulness to increase in the control group, which it did. Participants in both study groups found the app to be useful in monitoring their symptom experience over time. As the mVIP app was initially developed through rigorous user-centered design processes, the overall user satisfaction scores were quite high at baseline, which reflects strong usability of mVIP. Given these findings and that both groups perceived the app as highly usable at baseline, it is not surprising that there was no significant difference in perceptions of usability between groups over time.

In regards to use of healthcare services and engagement with healthcare providers, we did not find a significant difference between groups. Given the short duration of our study and the relatively rare events of hospitalization and emergency room visits, these findings were not unexpected. Additional work evaluating mVIP's impact on use of health-care services over a longer study period may provide important information on healthcare use and costs to our health-care system. Similarly, the short study duration did not allow for adequate follow up to evaluate any effect on engagement with healthcare providers; current guidelines recommend that patients on ART visit their provider every 3–4 months. For adherent patients with consistently suppressed viral load and stable immunologic status for more than 2 years, provider visits can be extended to 6-month intervals.

Significance

Importantly, this app was designed employing earlier evidence from patient-centered outcomes research studies, which was a strength of the content of the app. In addition to the robustness of the content of the app, we employed rigorous user-centered design processes, which is in strong contrast to many of the extant mHealth apps on the marketplace. In particular, our design and development process adds to the rigor of current mHealth research given that our study population is comprised of racial and ethnic minority groups from the lowest income groups in the US. In short, our study sample is comprised of those persons who are most likely to suffer from disparities in healthcare yet are most likely to benefit from the mobile technology that we developed.

Our study sample is an especially important strength to our study given that past research on mobile technology has demonstrated that there are disparities in use of these technologies by African Americans. In contrast to this earlier work, we found no difference in use or outcomes related to racial/ethnic or any other sociodemographic characteristic of the study sample supporting the use of mHealth technology for bridging some of the current disparities in the delivery of healthcare.

Implications

Key elements of feasibility were successfully tested, including: acceptability, integration, demand, practicality, implementation, and limited efficacy testing. Acceptability was determined through high usability scores. Participants were able to integrate use of this app into the routines of their everyday lives. Demand for the intervention was assessed by gathering data on actual use which was quite high as described above. The practicality of this app is high given that healthcare providers do not need to interact with the technology. Finally, the potential for implementation of this app through its release to an app marketplace and the ability to download by targeted users is very practical. The use of mobile technology for symptom self-management holds promise, given the pervasive nature and penetration of mobile phones in our study population. Although the app was highly usable and showed preliminary efficacy, future study should consider the effect of this intervention over the long-term to demonstrate sustainability, evaluate implementation across other settings, and examine the use of this intervention in other languages.

Conclusion

The mVIP app was associated with improvement in symptoms and very strong usability. Findings from this study suggest that mobile apps have the potential to support aspects of patient-reported outcomes, including the symptom experience. Future work should use findings of this study to guide assessments of this intervention in other contexts, settings, and cultures in order to translate this intervention into the everyday lives of consumers.

7. LIST OF PUBLICATIONS and PRODUCTS.

Peer-Reviewed Publications:

- 1) Schnall R, Cho H, Weibel A. Predictors of Willingness to Use a Smartphone for Research in Underserved Persons Living with HIV. *International journal of medical informatics*. Mar 2017; 99: 53-59.
- 2) Cho H, Iribarren S, Schnall R. Technology-Mediated Interventions and Quality of Life for Persons Living with HIV/AIDS. A Systematic Review. *Applied clinical informatics*. 2017; 8(2):348-68.
- 3) Schnall R, Cho H, Mangone A, Pichon A, Jia H. Mobile Health Technology for Improving Symptom Management in Low-Income Persons Living with HIV. *AIDS Behavior*. Jan 2018 [epub; <https://doi.org/10.1007/s10461-017-2014-0>].
- 4) Schnall R, Cho H, Liu J. Health Information Technology Usability Evaluation Scale (Health-ITUES) for Usability Assessment of Mobile Health Technology: Validation Study. *JMIR mHealth and uHealth*. Jan 2018;6(1):e4.
- 5) Cho H, Yen P, Dowding D, Merrill J, Schnall R. Developing and Evaluating Mobile Health Applications: A Methodology for a Multi-Level Usability Evaluation. *Journal of Biomedical Informatics*. Under review.
- 6) Cho H, Porras T, Baik D, Beauchemin M, Schnall R. Understanding the Predisposing, Enabling, and Reinforcing Factors Influencing the Use of a Mobile-Based HIV Management App: A Real-World Usability Evaluation. *International Journal of Medical Informatics*. Under Review.

Peer Reviewed Posters:

- 1) Cho H, Milian L, Schnall R. Card Sorting of Symptom Self-Management Strategies to Inform the Development of a mHealth App in underserved Persons Living with HIV (2016). AMIA 2016 Annual Symposium.
- 2) Cho H, Milian L, Schnall R. Use of Card Sorting for Incorporating Symptom Self-Management Strategies into a mHealth App for underserved Persons Living with HIV (2016). IEEE Wireless Health 2016 Conference.
- 3) Cho H, Rojas H, Fulmer C, Schnall R. Usability Evaluation of a Prototype mHealth App for Symptom Self-Management in Underserved Persons Living with HIV (2017). AMIA 2017 Annual Symposium.
- 4) Schnall R, Cho H, Mangone A, Pichon A, Jia H. Mobile Health Technology for Improving Symptom Management in Low-Income Persons Living with HIV. Accepted for presentation at the 10th Annual Conference on the Science of Dissemination and Implementation, December 2017.