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Mobile Health Technology for Improving Symptom Management in Low Income Persons Living with HIV

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Abstract

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

Resumen

Personas viviendo con el VIH (PLWH) están viviendo más tiempo pero están siendo afectadas por síntomas adversos asociados a la enfermedad y su tratamiento. Este estudio examino el impacto de una aplicación (app) móvil de salud (mHealth) compuesta de estrategias de autocuidado basadas en la evidencia de los síntomas experimentados de PLWH. Realizamos una prueba de factibilidad de 12 semanas con 80 PLWH que fueron aleatorizadas (1:1) a una aplicación móvil de salud, "mobile Video Information Provider" (mVIP), con estrategias de autocuidado para mejorar 13 síntomas comúnmente experimentados en PLWH, o a una aplicación de control. Los participantes del grupo de intervención mostraron una mejoría significativamente mayor que el grupo de control en 5 síntomas: ansiedad (p = 0.001), depresión (p = 0.001), neuropatía (p = 0.002), fiebre/escalofríos/sudor (p = 0.037), y pérdida de peso/pérdida de masa (p = 0.020). Los participantes en el grupo de intervención mostraron una mayor mejoría en la adherencia a sus medicamentos antirretrovirales (p = 0.017) en comparación al grupo de control. En esta prueba de 12 semanas, mVIP fue asociada con un mejoramiento en la carga de síntomas y un aumento en la adherencia a medicamentos en PLWH.

Introduction

HIV has evolved from a fatal diagnosis into a chronic illness largely due to the success of HIV medications [1]. In view of the change in the course of the disease, persons living HIV (PLWH) are living longer but experiencing more adverse symptoms associated with the disease and its treatment [2]. 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 [3]. Patients' symptom experiences and symptom management success are strongly related to HIV disease progression and adverse clinical profiles [4, 5].

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Symptom management in PLWH has been shown to decrease symptom severity [6], improve quality of life [7], reduce disability, increase medication adherence, and promote health [8]. Self-management involves helping patients set achievable goals and learn techniques of problem-solving relevant to their condition [9]. The ability to self-manage adverse symptoms of HIV illness has been shown to improve patient-centered outcomes and quality of life [10]. In response to this need, a team of researchers at the UCSF School of Nursing developed a paper-based symptom management manual with self-care strategies for 21 common HIV/AIDS symptoms. The manual was found to be efficacious in a 775-person randomized controlled trial (RCT) over 3 months at 12 sites [11].

Despite the success of the findings in the trial, uptake of these self-care strategies has been low. To facilitate dissemination of evidence-based strategies for symptom self-management, we developed a mobile application (app), mobile Video Information Provider (mVIP), which delivers these self-care strategies to PLWH based on their symptom reporting. Mobile technology is a platform that is well-suited for the implementation and dissemination of evidence-based strategies for HIV symptom management. This project is unique in that mobile health (mHealth) technology is typically developed without incorporating patient-centered outcomes research. There are currently hundreds of apps for PLWH, yet these apps have not been conceptualized using evidence-based research and/or patient-centered design [12], and as a result are expected to be off the marketplace in a few years. For instance, of the 55 apps for PLWH which were reported in Muessig's 2013 review [13], only 18 are still available on the app marketplace. 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 the dissemination of evidence-based information. In addition, incorporation of the evidence-based information has the potential to substantially improve the rigor of these technologies [14].

Use of mobile technology can improve communication, access, and information/resource delivery to racial and ethnic minority groups [15, 16]. mHealth technology has the potential to bridge a divide in healthcare delivery among these underserved groups [17]. Ownership of a mobile device is equally as common among Blacks and Whites (94%) and highest among Hispanics (98%) [18]. While mobile internet use in the US has been on the rise across all groups, Blacks and Hispanics are more likely to use a smartphone for internet use (94% for both groups) compared to Whites (85%) [19, 20]. The use of mobile technologies at nearly equal rates across racial and ethnic groups supports the use of these tools for bridging some of the current disparities in healthcare access and health outcomes.

Despite the rapid proliferation and widespread uptake of mHealth apps, there is a dearth of mHealth technology interventions focusing on PLWH's self-management, and thus little is known about the impact of using mobile apps for managing PLWH's symptom experience. To address these gaps, this study examined the impact of using mobile technology for the dissemination and implementation of evidence-based self-care strategies and the effect of this mHealth app on patient-reported outcomes. We hypothesized that consumers who received evidence-based self-care strategies through a mobile app would have a decrease in their symptom burden compared with patients who did not have access to self-care strategies.

Methods

We compared symptom burden in PLWH when using a mobile app with self-care strategies for symptom management versus a mobile app without self-care strategies between December 2016 and June 2017. 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 [21, 22], 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 [23]. 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.

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.

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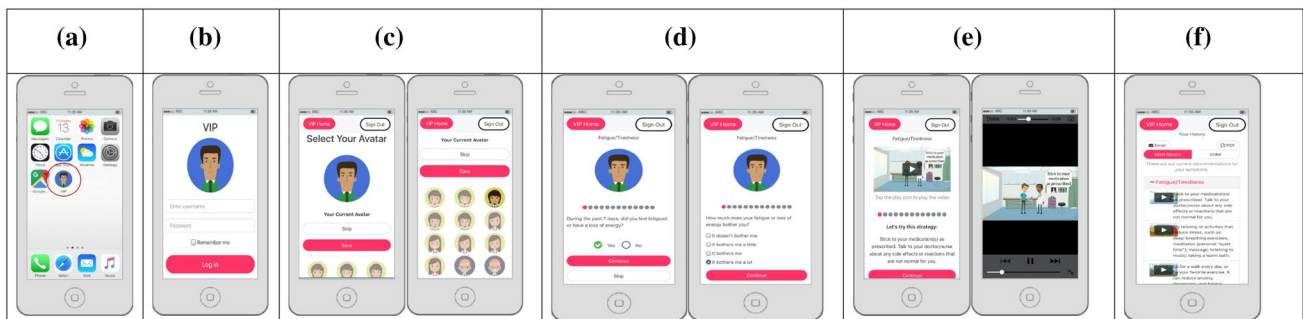
Fig. 2 **a** mVIP shortcut, **b** Log-in, **c** Avatar selection, **d** Symptom assessment, **e** Animated video, **f** Summary of strategies

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) [24]. 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.

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); [25] 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 smartphones. 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 and Measures

Study participants completed a baseline survey comprised of demographic questions, PROMIS-29 [26], RAND 36-item health survey [27, 28], engagement with healthcare provider [29], antiretroviral therapy (ART) medication adherence using the Visual Analogue Scale (VAS) [30] and CASE Adherence Index [29], number of medical visits, and usability through the Health-ITUES [31]. 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.

Data Analysis

The study analysis followed an intention-to-treat approach. Intervention and control characteristics collected at baseline were summarized with descriptive statistics (mean ± SD or frequency). To assess the effect of the intervention on symptom burden during the follow-up period, we used a linear mixed model to analyze repeated measured data, and the models controlled for age, sex, race, education, and CD4 count.
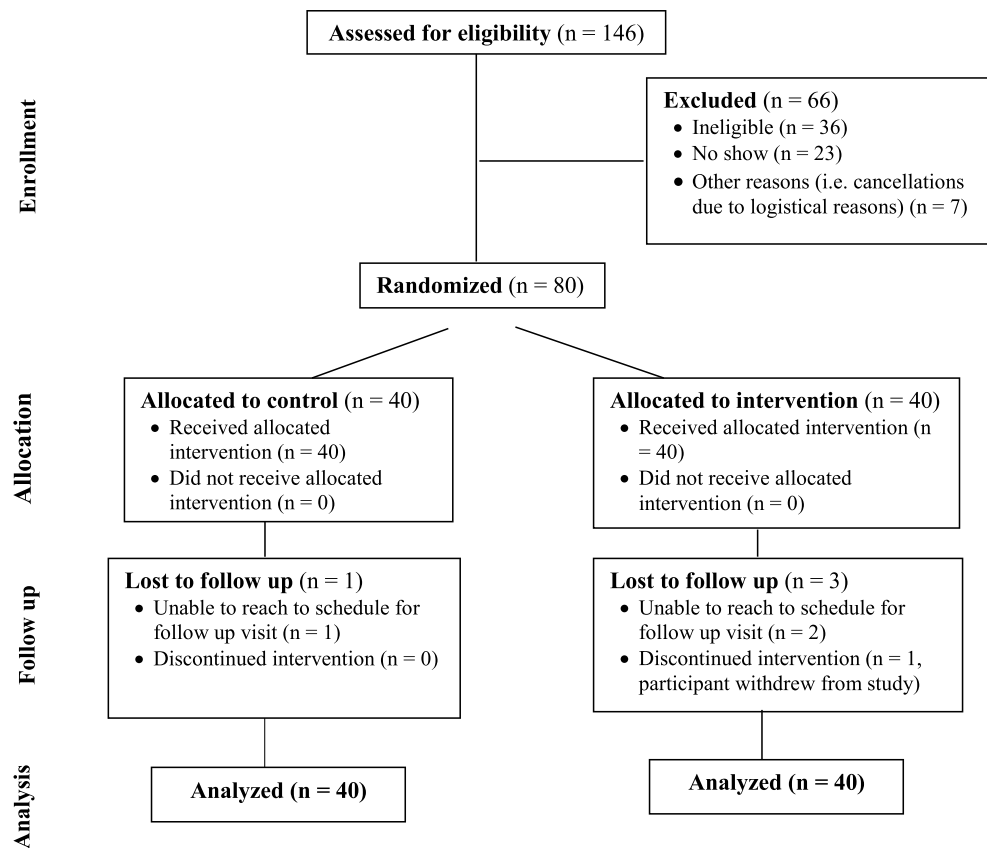
For all secondary outcome measures, which were collected at baseline and 12-week follow-up, we used the same linear mixed model or a generalized linear mixed model. We used a linear mixed model for continuous outcomes (e.g. PROMIS score); generalized linear mixed model (Poisson or Negative binomial model) for count outcomes (e.g. number of ER visits); and the generalized linear mixed models (logistic model) for binary outcomes (e.g. CASE Adherence Index).

Results

Figure 3 summarizes enrollment. 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.

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

Fig. 3 Enrollment summary diagram

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                          │ Assessed for eligibility (n = 146)│
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                                        │        │ Excluded (n = 66)                   │
                                        ├────────│ • Ineligible (n = 36)               │
                                        │        │ • No show (n = 23)                  │
                                        │        │ • Other reasons (i.e. cancellations │
                                        │        │   due to logistical reasons) (n = 7)│
                                        │        └────────────────────────────────────┘
                          ┌─────────────────────┐
                          │ Randomized (n = 80)  │
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Allocated to control (n = 40) • Received allocated intervention (n = 40) • Did not receive allocated intervention (n = 0)	**Allocated to intervention** (n = 40) • Received allocated intervention (n = 40) • Did not receive allocated intervention (n = 0)
Lost to follow up (n = 1) • Unable to reach to schedule for follow up visit (n = 1) • Discontinued intervention (n = 0)	**Lost to follow up** (n = 3) • Unable to reach to schedule for follow up visit (n = 2) • Discontinued intervention (n = 1, participant withdrew from study)
Analyzed (n = 40)	**Analyzed (n = 40)**

Enrollment / Allocation / Follow up / Analysis (vertical labels)

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 2 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 3 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.

Secondary Outcomes

Table 4 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 [32] and the RAND-36 Item Health Survey [27] 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 effect 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 [30] and the CASE Adherence Index [29]. 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 [29] in our intervention group as compared to

Table 1 Baseline demographics

Variable	Overall N = 80	Intervention N = 40	Control N = 40
Age mean (SD)	50.4 (10.4)	50.0 (11.7)	50.8 (9.0)
Sex, male	38 (47.5%)	15 (37.5%)	23 (57.5%)
Race			
White, non-hispanic	8 (10.0%)	4 (10.0%)	4 (10.0%)
Black, non-hispanic	55 (68.8%)	29 (72.5%)	26 (65.0%)
Hispanic	17 (21.3%)	7 (17.5%)	10 (25.0%)
Education			
Less than high school	14 (17.5%)	9 (22.5%)	5 (12.5%)
High school	25 (31.3%)	11 (27.5%)	14 (35.0%)
Some college or associates degree	28 (35.0%)	15 (37.5%)	13 (32.5%)
Bachelors or advanced degree	13 (16.3%)	5 (12.5%)	8 (20.0%)
Annual income			
Less than $10,000/year	39 (48.8%)	22 (55.0%)	17 (42.5%)
$10,000–$19,999/year	19 (23.8%)	9 (22.5%)	10 (25.0%)
$20,000–$59,999/year	11 (13.8%)	3 (7.5%)	8 (20.0%)
Don't know or prefer not to answer	11 (13.8%)	6 (15.0%)	5 (12.5%)
Employment			
Working (full, part, off-books)	15 (19.7%)	7 (18.4%)	8 (21.1%)
Unemployed (looking, not looking)	26 (34.2%)	15 (39.5%)	11 (29.0%)
Retired	4 (5.3%)	3 (7.9%)	1 (2.6%)
Student	4 (5.3%)	2 (5.3%)	2 (5.3%)
Disabled	27 (35.5%)	11 (29.0%)	16 (42.1%)
ART use			
None	4 (5.0%)	3 (7.5%)	1 (2.5%)
2 + pills per day	34 (42.5%)	15 (37.5%)	19 (47.5%)
1 pill per day	41 (51.3%)	21 (52.5%)	20 (50%)
Prefer not to answer	1 (1.3%)	1 (2.5%)	–
Virologically suppressed	68 (85.0%)	34 (85.0%)	34 (85.0%)
Ever diagnosed with AIDS	41 (51.3%)	17 (42.5%)	24 (60.0%)
CD4 count greater than 500	42 (53.2%)	22 (55.0%)	20 (51.3%)
Possible alcohol use disorder	25 (31.3%)	15 (37.5%)	10 (25.0%)
Substance use weekly or more often	24 (30.0%)	15 (37.5%)	9 (22.5%)

our control group participants, but this difference was not detected when measuring adherence with the VAS.

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.

Discussion

Multiple studies have addressed the potential benefits of mobile phone apps for patients with chronic illnesses [33, 34]. 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.

Table 2 Frequency of symptoms at baseline

Variable	Overall N = 80	Intervention N = 40	Control N = 40	Significance (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

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

Table 3 Difference in symptom score between the intervention and control groups

	Score change from baseline to week 12				Difference between groups		
	Intervention		Control				
	Score	Standard error	Score	Standard error	Estimate	Standard error	Significance (p value)
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
Nausea or vomiting	− 0.122	0.066	− 0.185	0.077	0.063	0.101	0.534
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
Weight loss or wasting	− 0.254	0.070	− 0.004	0.081	− 0.250	0.107	0.020

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 [29], 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 [35]. ART adherence and symptom management

Table 4 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

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 [36], 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 [37]. 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 [30] 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 [38]. 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 healthcare services over a longer study period may provide important information on healthcare use and costs to our healthcare 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 [39, 40].

Importantly, this app was designed employing earlier evidence from patient-centered outcomes research studies [41], 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 [42]. 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.

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.

Key elements of feasibility were successfully tested, including: acceptability, integration, demand, practicality, implementation, and limited efficacy testing [43]. 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 [44] 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.

Compliance with Ethical Standards

Conflict of interest All authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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

Research Involved in Animal Rights This article does not contain any studies with animals performed by any of the authors.

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