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A feasibility study to develop and test a cognitive behavioral stress management mobile health application for HIV-related fatigue

Julie Barroso, PhD, ANP, RN, FAAN¹, Mohan Madiseti, MSc.¹, Martina Mueller, PhD^{1,2}

¹College of Nursing, Medical University of South Carolina, Charleston, SC, USA

²Dept. of Public Health Sciences, Medical University of South Carolina, Charleston, SC, USA

Abstract

Context: Exacerbated by life stressors, fatigue is the most common symptom for people living with HIV.

Objective: To adapt, develop, and assess the feasibility of a CBSM mHealth (cognitive behavioral stress management mobile health) application (app) for HIV-related fatigue.

Methods: This study had two phases: app development with key informants (N=5) and a randomized controlled trial (N=30). Patients randomized to the intervention group completed 10 weekly CBSM modules; those in the control group received a generic healthy lifestyle app. Measures included HIV-related fatigue, depression, anxiety, stressful life events, CD4 count, HIV viral load, credibility and acceptability of the intervention, and barriers to treatment participation.

Results: We were able to recruit participants for this study, and they were able to complete the required measures. They found the intervention to be credible and acceptable, and reported few barriers to treatment participation. The direction of change in the primary outcome, a decrease in fatigue, is in the expected direction, and provides evidence of the promise of the intervention, which still needs to be tested in an adequately powered trial. For completers (randomized to the intervention group and completed at least 80% of the modules), there were significant changes (95% CI; lower scores indicate improvement) in fatigue intensity (from 64.2 to 59.7) and overall fatigue-related functioning (from 6.6 to 4.2).

Conclusion: We have proof of concept as to the feasibility, acceptability, and initial signals of efficacy for an mHealth intervention to help people with HIV-related fatigue better cope with stress and reduce their fatigue.

Keywords

HIV; fatigue; mHealth technology; cognitive behavioral stress management

Corresponding author: Julie Barroso, PhD, ANP, RN, FAAN, Professor and Associate Dean of the Faculty, Medical University of South Carolina College of Nursing, 99 Jonathan Lucas St., Charleston, SC 29425, barroso@musc.edu.

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Introduction

Fatigue remains one of the most problematic symptoms for HIV-infected people, with prevalence ranging from 33–88% in recent studies.^{1–4} Fatigue adversely impacts one's ability to carry out activities of daily living (ADLs) and impairs social, vocational, and mental functioning.⁵ A recent meta-analysis found that fatigue interferes with antiretroviral adherence;⁶ fatigue was also among several factors that predicted virologic failure independent of adherence measures.⁷ Stressful life events (SLE) are associated with and exacerbate symptoms of HIV-related fatigue.⁹ People living with HIV infection face persistent stress: dealing with a chronic illness, the stigma associated with that illness, pressure to adhere to medication schedules, and often living in poverty.⁸ SLE have been shown to increase viral replication, suppress immune response, and impede adherence to antiretroviral medications.⁸ Etiological pathways for fatigue appear to follow psychosocial rather than physiological routes, highlighting the need to address the often chaotic and taxing lives of seropositive people.¹⁰ As such, there is increased focus on effects and potential interventions for life challenges that are not necessarily directly linked to the pathology of HIV infection, but that have a powerful impact on the course of the disease.¹¹ Stressful life events and chronic stress have been found to prospectively predict increased fatigue and decreased treatment adherence among individuals with HIV infection,¹² leading to the conclusion that stress management treatment could decrease fatigue and enhance antiretroviral adherence.

Our previous work measured a wide array of physiological and psychosocial variables over a 3-year period and found that HIV-related fatigue intensity and functional impairment were predicted only by psychosocial factors; specifically, a higher frequency of stressful life events was positively related to both increased fatigue intensity and greater fatigue-related functional impairment.^{13–14} There is a lack of evidence implicating purely physiological factors as driving HIV-related fatigue.¹⁵ Indeed, there is little evidence that HIV-related fatigue is related to disease progression, CD4 count or HIV viral load. The strongest predictors of HIV-related fatigue are psychological factors such as depression and anxiety secondary to life stressors.^{13–14} We also found that fatigue was chronic and did not remit spontaneously, underscoring the importance of developing symptom management interventions for HIV-related fatigue.¹⁶ Such interventions should enhance skills for coping with current stressful life events and prior traumatic stressors, both of which relate to increased HIV-related fatigue.^{13–14}

One such treatment is Cognitive Behavioral Stress Management (CBSM) developed by Antoni et al. specifically for people with HIV infection;^{17–18} this intervention has been tested in multiple studies over 20+ years. The intervention provides stress-related education, relaxation skills, coping strategies, interpersonal skills, and problem-solving skills. CBSM appears effective in reducing negative stress reactions in people living with HIV infection; four meta-analyses/systematic reviews of the literature on the efficacy of cognitive-behavioral therapy (CBT), the category of psychosocial treatments within which CBSM lies, concluded that these approaches are effective with people living with HIV with respect to improving a number of mood states.^{19–22} Three studies found that stress management interventions improved fatigue in those with HIV infection.^{19, 21, 23}

We wanted to greatly expand the reach of this intervention by adapting the delivery mode of this evidence-based treatment to that of symptom self-management enhanced through mobile health (mHealth) technology. mHealth applications (app) help those who do not live near treatment facilities, are concerned about stigma when presenting at treatment facilities, and resolves logistical issues related to cost and transportation. The Pew Research Center found that minorities rely more heavily on their phones for internet access and are more likely than whites to use their phones to research health conditions.²⁴ Mobile interventions are a way to help reduce minority health disparities by enabling access to information that would not necessarily be readily available to them.²⁴

The primary aim of this study was to determine the feasibility and acceptability of implementing a low-cost, technologically enhanced intervention to enhance coping and manage stress, and thus better manage fatigue, in people with HIV infection. The study reported here also involved a randomized controlled trial (RCT) comparing a cognitive behavioral stress management app based on Antoni's intervention to a healthy lifestyle app.

Methods

Ethical consideration

The study was approved by the Medical University of South Carolina (MUSC) Institutional Review Board (IRB) and was conducted in compliance with Good Clinical Practices (GCP) of the International Conference of Harmonization (ICH). The study's [ClinicalTrials.gov](https://clinicaltrials.gov) registration is .

Two-stage process

We employed a two-stage process wherein we leveraged our technology and community engagement P20 sub-cores to: 1) adapt Antoni's evidence-based intervention (CBSM) to a self-management format to address fatigue symptoms with input from 5 key informants (development phase), and 2) pilot this intervention with 30 individuals in a randomized controlled trial (intervention phase).

Participants

Potential subjects were aged 18 and older, living with HIV, who could read/understand English and who reported chronic (at least 3 months' duration) and moderate to severe fatigue (fatigue intensity mean of > 5 on a 1–10 scale, with higher numbers signifying greater fatigue, on the HIV-Related Fatigue Scale). Individuals with co-morbid conditions marked by fatigue (e.g., renal disease, cancer, multiple sclerosis) were excluded, to ensure that the fatigue experienced by study participants was related to HIV. Pregnant women and women who were less than 1 year postpartum (via self-report) were excluded, as fatigue is a prominent feature of pregnancy and the postpartum period. Other exclusion criteria included current suicidality, psychoses or substance dependence as measured by the Mini-International Neuropsychiatric Interview (MINI). Participants were not required to have a smartphone as we could lend one to them for the duration of the study.

Recruitment

Initially, we used our Biomedical Informatics Center that was capable of querying our electronic medical records to identify patients with HIV-related ICD-10 diagnosis codes who had agreed to be contacted for research studies for which they may potentially be eligible. However, this was not a fruitful endeavor as potential participants were suspicious of a cold call from someone they did not know and who knew their HIV diagnosis; they also did not recall signing paperwork agreeing to be in research studies. We quickly abandoned this strategy in favor of the distribution of study recruitment flyers at local AIDS service organizations and at the offices of health care providers known to treat people living with HIV in the surrounding community.

Development phase—To develop the app, we called on our tech team, who reviewed Antoni's paper workbook and explained that I needed to use a PowerPoint template they developed for app mapping/creation to show them what content I wanted in the app. I knew the content well, having taught it in a group format; I included nearly all of the content from the workbook. I was careful to think through how any of the content needed to be altered since we were moving from a group intervention to an mHealth intervention; other than some group building exercises, the content remained the same. After transforming the 10 weeks into 10 modules on the PowerPoint template, I met again with the tech team to talk about feasibility and what certain sections would need. For example, for every module, there is a "learn" section that covered content such as defining stress, its effects on the body, coping strategies, anger management, and the use of social support; and a "relax" section, which included various stress management techniques such as mantra meditation, use of imagery, and deep breathing. For the relax section, we realize we would need to shoot videos for some of the modules to demonstrate stress reduction techniques such as progressive muscle relaxation. We decided to add an optional audio feature to the modules in case reading comprehension, lack of glasses, etc., made reading difficult. We also discussed aesthetics such as colors on the app, font size, and photos to break up the content. There was homework to be done between modules as well. We shot an introduction video that explained the purpose of the app and the science upon which it was based, and a "how to" video which would review how to move about in the app. Participants had to complete one module before the next one would open.

Once the first 3 modules were developed, we had our first focus group meeting with our 5 key informants. They were recruited via flyers from our local AIDS service organization. We took the first 5 (2 women, both African American; 3 men, 1 Caucasian and 2 African American) who met the study criteria and consented to participate in the development phase. The app was loaded onto their phones, and we demonstrated how to use it; they were asked to do a return demonstration. We asked them to complete the first 3 modules and said that we would convene our first focus group 3 weeks from that date (focus groups were held in the evening at the College of Nursing) to get their feedback. These key informants worked on 3 modules at a time, and returned approximately every 3 weeks to advise us about what it was like to be a participant in the study, as well as what they thought about different aspects of the app itself, such as readability, the number/type of figures and photos, the amount of

time it took to complete each module, and their level of engagement. Each of the 3 focus groups lasted about 1 hour. See Table 1 for a list of the questions asked at each focus group.

Over the course of 3 focus groups, the development phase participants told us they liked the app and found it easy to use. The problems they reported were mainly technical glitches, i.e., a module would not open, a video stopped while playing; the developer corrected those within the next week. Some of the larger design issues we left for future work; for example, they wanted to be able to change font size, they did not care for the voice used in the audio feature, and they felt that the next step once completing a module was not intuitive. There was no inadvertent disclosure of HIV status due to app use. They reported spending about an hour/week on the app to complete one module, and while they thought the modules were a little long, they were not burdensome; however, they would like an avatar that could pop in and tell them how much of the module was left to complete. They found the exercises to be very relaxing. Their biggest complaint was about how much typing they had to do; there were activity logs to complete which would, for example, help them realize when they were using maladaptive coping responses. Their responses could involve a lot of typing, which can be cumbersome on a phone. The group suggested giving people the option of using a notebook (just like the original workbook) in which to complete the logs, to avoid so much phone typing. They also wanted more pictures and diagrams to break up the large amount of word content. See Figure 1 for screen shots from the app.

Intervention phase—During the intervention phase, we recruited and enrolled 30 people living with HIV-related fatigue through local study advertising. When contacted by interested participants, the research assistant conducted a telephone screening, using the HIV-Related Fatigue Scale and the MINI to determine eligibility. Everyone who was screened received a \$40 gift card. An in-person baseline study visit was scheduled for eligible participants where written informed consent was obtained prior to study enrollment and the collection of baseline measures via pencil and paper. Participants were randomized 1:1 to either the intervention or control group by a computer-generated randomization scheme provided by the study biostatistician. The intervention group had the CBSM app downloaded to their smartphones, and the control group had the LifeSum app downloaded to their phones; it is a free healthy lifestyle app that includes no stress management content. We demonstrated how to use the app, and then asked for a return demonstration to be sure of participant understanding. Intervention participants were asked to complete one module per week; control participants were encouraged to engage with the LifeSum app once a week. We were able to track whether or not the intervention participants completed the modules via tracking built into the app. Study visits occurred at week 5, week 10, and at 3 months post study completion (intervention group only). The purpose of the study visits was to collect data and ensure that there were no issues with use of the app; a visit lasted 45 minutes-1 hour. Only the initial baseline and week 10 visits were conducted in-person (and data collected via paper and pencil); week 5 and 3 months post study visits were conducted remotely by telephone (the research assistant read the items and choices to the participants). The research assistant entered the data into the electronic study database during the call. To promote study retention, we provided an additional \$40 in compensation for completing each study visit.

Measures

Demographic measures included age, sex, race, ethnicity, education level, household income, HIV diagnosis date and medications, and comorbid illnesses. Feasibility and acceptability measures include qualitative data obtained from the participants in the development phase, and two measures for feasibility of the intervention. The *Credibility/Expectancy Questionnaire* measures treatment expectancy and rationale credibility and demonstrates high internal consistency and good test-retest reliability.²⁵ A higher score indicates more favorable beliefs about the intervention. The *Barriers to Treatment Participation Scale* was adapted from the original scale to be appropriate for our participants and intervention; this scale demonstrates high internal consistency and convergent validity. A lower score indicates fewer barriers to participation.²⁶

Participant outcome measures include fatigue, anxiety, depression, and stressful life events. The *HIV-Related Fatigue Scale (HRFS)*^{27–28} is a 56-item instrument which assesses fatigue severity, responsiveness to self-care, and fatigue-related impairment of functioning in HIV infection. Each subscale demonstrated high internal consistency in a large (n=128) longitudinal observation study of the natural course of HIV-related fatigue (Cronbach's α =0.93, 0.91 and 0.97 for the severity, responsiveness and functioning scales, respectively).^{14,28} In addition, we used the *Patient Reported Outcomes Measurement Information System (PROMIS) Fatigue - Short Form 6a*, a 6-item self-report measure of fatigue experienced during the past 7 days. Using a 5-point Likert scale, lower scores indicate less fatigue. The PROMIS Fatigue Short Form has high internal consistency (α =0.85) and been shown to be valid and reliable in samples of individuals with a variety of chronic health conditions^{29–30} and HIV.³¹ The *State Trait Anxiety Inventory (STAI)-State*³² is a self-report measure of state anxiety, consisting of 20 emotion descriptor items; respondents indicate how they are feeling right now by rating each item on a 4-point scale. Internal consistency of the STAI-State is high,³² (α =.92) and STAI has high correlations with other measures of anxiety (e.g., Taylor Manifest Anxiety Scale, r =.80). The *Beck Depression Inventory II* is a 21-item self-report scale and is among the most widely used instruments to measure depression; the BDI-II has high internal consistency (α =0.86–0.91).³³ The *Life Experiences Scale*, derived from the Life Experiences Scale developed by Saranson et al.,³⁴ is a 43-item self-report measure that allows respondents to indicate recent stressful life events. It was modified by Leserman to include only those events which were moderately to severely stressful for people living with HIV infection based on previous studies,^{34–35} and correlates with poor health-related functioning, immune decline, and HIV disease progression.³⁵ The mean score for number of stressful events in one sample of HIV-infected individuals was 3.15 ± 2.53 ;³⁵ another study reported a median of 3 stressful life events over a 9 month period in a large sample of HIV-infected individuals in the Deep South.³⁶ In addition, we collected CD4 count and HIV viral load information from the participants' medical records, with their signed consent; we obtained the values collected before starting the study (before baseline), at the end of the study (10 weeks after baseline), and 3 months after the study concluded. We kept the clinical value closest to these dates if there were more than one.

Data Collection and Statistical Analysis

All data were collected and entered into the Research Electronic Data Capture (REDCap) study database. Statistical analysis was performed using the statistical package SAS statistical software version 9.4 (Copyright © 2016 by SAS Institute Inc., Cary, NC, USA.). Descriptive statistics were calculated for demographic, medical, and study-related variables. Feasibility measures are reported as frequencies, means and ranges. Participant outcome measures were compared at all time points between the two treatment groups as well as within groups to investigate change from baseline and 95% confidence intervals were obtained. In addition, change from baseline was examined for all outcome measures for the subset of participants in the intervention group who completed at least 80% of the modules to explore the impact of the intervention among adherent participants.

Results

Study enrollment and feasibility –

In the RCT intervention phase of the project, the researchers screened 44 potentially eligible patients who contacted us regarding study participation; 32 were subsequently screened eligible and 12 were excluded (1 prescreen failure, 1 not interested, 1 lost contact, and 9 screen failures per the study inclusion/exclusion criteria). Of these 32 eligible participants, 30 later provided written informed consent and were allocated per the devised randomization scheme into one of the two study arms (control group n=15 and intervention group n=15); the researchers lost contact with 2 eligible participants prior to providing consent at their baseline study visit. A CONSORT diagram of participant flow through the study is provided in Figure 2.

Characteristics of enrolled patients –

Please see Table 2 for demographic data about the sample. There were 15 participants in each of the arms at baseline. The only statistically significant differences between the 2 groups were gender, education, and currently being in a program for substance use recovery; there were more men in the control group, and more of the control group had at least some college education. There were 3 people in the intervention group who were in a program for substance use recovery, compared to none in the control group. With regard to feasibility and acceptability, scores on the Credibility and Expectancy Evaluation Scale were high, indicating strong positive beliefs in the intervention (22.3 at baseline, 21.6 at week 10; range from 3–27), and the Barriers to Treatment Participation Scale scores were 1.64 at baseline and 1.62 at 3 months after the conclusion of the intervention. Lower scores on this scale (range 1–5; 24 items) indicate fewer barriers to treatment participation.

Outcomes —Table 3 compares the intervention and control group outcomes in an intent-to-treat analysis. The intervention group had a greater decrease in impact of fatigue on ADLs from baseline to 3 months after the end of the intervention when compared to the control group (mean difference 1.6 [95% CI 0.3–2.8]). The intervention group also had a greater decrease in depression from baseline to week 5 when compared to the control group (mean difference 9.7 [95% CI 1.1–18.4]).

Of greater interest to us, since this was a feasibility trial, were the results of those participants in the intervention group who completed 80% of the modules (completer analysis, n=10 of the 15 – Table 4). Scores of the effect of fatigue on overall functioning (lower scores means less impact of fatigue) decreased from baseline to week 5 (mean decrease 1.9 [95% CI 0.9–2.9]), week 10 (mean decrease 2.7 [95% CI 1.4–3.9]), and 3 months after the conclusion of the intervention (mean decrease 2.4 [95% CI 1.0–3.8]). Similar changes were seen for the subscales regarding the impact of fatigue on ADLs, socialization, and mental functioning. The PROMIS fatigue scale, which measures fatigue intensity (reported in prorated t scores), indicated a decrease in fatigue from baseline to week 5 (mean difference 4.3 [95% CI 0.7–8.0]), week 10 (mean difference 7.3 [95% CI 4.1–10.4]), and 3 months after the conclusion of the intervention (mean difference 4.5 [95% CI 0.3–8.7]). There was a decrease in depression scores from baseline to week 5 (mean difference 9.9 [95% CI 3.3–16.5]), and state anxiety scores from baseline to 3 months after the conclusion of the intervention (mean difference 9.9 [95% CI 0.6–19.2]). The Life Experiences Survey scores for number of stresses were high; the completers group had a score of 4.4 stresses at baseline, which decreased to 1.9 (95% CI –4.7– –0.3) at the 3-month post-intervention time point. There were no statistically significant changes in HIV viral load or CD4 count.

Discussion

Participant feedback in the development phase was very helpful in helping us work out most of the technical bugs. Some of the items respondents asked for (see above) would need to wait until we revised the app for a larger study, i.e., an avatar that pops in and tells you how much of the module remains to be read. However, the overall impression is that they liked using the app and were engaged with it during the study. This is reinforced by the positive views of the intervention that were captured in the Credibility and Expectancy Scale and the Barriers to Treatment Participation Scale. We believe that, based on our studies and those of others, learning techniques to cope with very stressful lives helps to decrease fatigue for those living with HIV.

Other conclusions of this pilot RCT are that we were able to recruit participants into a trial for this intervention, and they were able to complete the required measures. They found the intervention to be credible and acceptable, and reported few barriers to treatment participation. The direction of change in the primary outcome, a decrease in fatigue, is in the expected direction, and provides evidence of the promise of the intervention, which still needs to be tested in an adequately powered trial. Thus, we have proof of concept as to the feasibility, acceptability, and initial signals of efficacy of the CBSM app to reduce HIV-related fatigue.

This study built on our work and that of other researchers that pointed to an increase in stressful life events leading to subsequent increases in HIV-related fatigue. As research on this topic evolved, it became clear that physiologic variables were less likely to be drivers of fatigue, leading to the search for psychosocial interventions targeted at helping people living with HIV. This evolution also helped clinicians and researchers to consider the context of

people's lives, and that factors such as chronic stress played a major role in anxiety, depression, and fatigue, all of which impact quality of life.

Limitations to this study include potential sample and selection bias; participants lived primarily in one Southern city, but the sample was representative of people living with HIV in this state, and we accepted everyone who met study criteria and wanted to participate. However, the feasibility results do not necessarily generalize beyond our inclusion and exclusion criteria.³⁷ Data collection may have encouraged adherence to the study protocol. Other limitations include the small sample size. There are some significant differences between the intervention and control groups; since the participants were randomized, we cannot account for these differences. But we acknowledge this may have influenced the outcomes.

Conclusions

These data provide proof of concept for the potential of the CBSM app to decrease the intensity of fatigue and the effects of fatigue on overall functioning and each of its subscales (impact on ADLs, socialization, and mental functioning) in people living with HIV infection. The mechanism by which the CBSM app is achieving these effects is via a stress management intervention that provides education about stress and a toolbox for participants, with proven stress management techniques that can be practiced anywhere. The CBSM app was shown to be easy to use, feasible, and acceptable. Most importantly, it takes an intervention previously delivered in a group setting, and makes it available to those without transportation to get to a study site, those without money to park in a garage, and those who are too fatigued to leave their homes.

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Figure 1.
Screenshots of app.

Figure 2.
Participant CONSORT flow diagram

Table 1.

Questions asked of development phase focus group members

What was it like to use the app overall? Easy? Difficult? Were there any glitches?
Did anyone else ask you about the app? Did you have any inadvertent disclosure while using the app?
Did you have to go back to the instructions/introductory videos? How many times?
Did you use the audio feature? If yes, tell us what that was like.
About how many days/week did you spend on the app? How many hours/week?
The “Learn” section: <ul style="list-style-type: none"> • Were there words you did not understand? • Were there enough pictures? Too many? Should they be different? • Could you figure out how/when to scroll? • Was the content enough? Too little? Too much?
The “Relax” section: <ul style="list-style-type: none"> • Were you able to follow the exercises? • Did you try them yourself? • What are your thoughts on them? Did you feel more relaxed afterward?
The homework section: <ul style="list-style-type: none"> • Did you do the homework? If so, what did you think? Was it burdensome? • Did it help you learn more about yourself?
Is there anything else you would like to tell us about the app?

Table 2.

Comparison of baseline demographic and clinical characteristics between intervention and control groups

	Intervention (n=15)	Control (n=15)	Difference	95% confidence interval
Participant age in years, mean $\pm$ SD	51.1 $\pm$ 9.2	51.3 $\pm$ 10.6	0.3 $\pm$ 9.9	-7.2; 7.7
Participants - percent who are male	53.3% (8/15)	73.3% (11/15)	0.22	0.32; 0.68
Participant race			0.15	-0.22; 0.52
Black or African-American	73.3% (11/15)	60.0% (9/15)		
White	26.7% (4/15)	40.0% (6/15)		
Hispanic or Latino	13.3% (2/15)	6.7% (1/15)	-	
Educational level			-	
Less than high school	33.3% (5/15)	13.3% (2/15)		
High school graduate	13.3% (2/15)	0		
GED or equivalent	6.7% (1/15)	0		
Some college, no degree	33.3% (5/15)	60.0% (9/15)		
Associate degree	6.7% (1/15)	13.3% (2/15)		
Bachelor's degree	0	6.7% (1/15)		
Master's degree	6.7% (1/15)	6.7% (1/15)		
Educational level			-0.45	-0.77; -0.13
GED or less	53.3% (8/15)	13.3% (2/15)		
At least some college	46.7% (7/15)	86.7% (13/15)		
Marital status			-	
Never married	53.3% (8/15)	53.3% (8/15)		
Married	6.7% (1/15)	6.7% (1/15)		
Separated, divorced or widowed	40.0% (6/15)	40.0% (6/15)		
Employment status			-	
Working now	33.3% (5/15)	33.3% (5/15)		
Disabled	53.3% (8/15)	66.7% (10/15)		
Retired or other	13.3% (2/15)	0		
Hours worked/week	12.3 $\pm$ 16.9	11.3 $\pm$ 17.4	-1.0 $\pm$ 17.2	-13.8; 11.8
Income (dollars/month)	1092 $\pm$ 963	1142 $\pm$ 665	49 $\pm$ 828	-570; 668
Time since contracting HIV (years)	22.1 $\pm$ 9.1	18.2 $\pm$ 10.9	-3.9 $\pm$ 10.0	-11.4; 3.6
Ever used street drugs? (Yes)	60.0% (9/15)	80.0% (12/15)	0.24	-0.14; 0.61
Ever injected street drugs? (Yes)	6.7% (1/15)	13.3% (2/15)	-	
Currently using street drugs	6.7% (1/15)	13.3% (2/15)	0.19	-0.38; 0.75
Ever had problem with alcohol? (Yes)	20.0% (3/15)	13.3% (2/15)	-0.12	-0.59; 0.35
Currently in recovery program for substance use? (Yes)	20.0% (3/15)	0	-0.56	-0.74; -0.37
Current medications (Yes)				
Antidepressants	33.3% (5/15)	40.0% (6/15)	0.07	-0.30; 0.44
Other mental health	13.3% (2/15)	13.3% (2/15)	0	-0.53; 0.53

	Intervention (n=15)	Control (n=15)	Difference	95% confidence interval
Taking ARV medications for HIV (Yes)	93.3% (14/15)	100% (15/15)	-	
Time with fatigue (years)	12.9 ± 11.6	6.8 ± 4.0	-6.1 ± 8.7	-12.6; 0.4

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Table 3.

Intent-to-treat comparison of outcome measures between treatment groups by time point (due to small sample size; mean $\pm$ standard deviation tests were not adjusted for multiple comparison)

	Intervention (n=15)	Control (n=15)	Difference	95% confidence interval
HRFS fatigue intensity				
Baseline	7.0 $\pm$ 1.2	7.5 $\pm$ 1.1	0.5 $\pm$ 1.1	-0.4; 1.3
Week 5	5.9 $\pm$ 1.9	6.5 $\pm$ 1.6	0.5 $\pm$ 1.8	-0.9; 1.9
Week 10	5.7 $\pm$ 1.4	5.9 $\pm$ 1.7	0.2 $\pm$ 1.6	-1.0; 1.5
3 months after week 10	5.6 $\pm$ 2.1	-	-	-
HRFS overall fatigue-related functioning				
Baseline	6.7 $\pm$ 1.2	6.9 $\pm$ 1.4	0.1 $\pm$ 1.3	-0.8; 1.1
Week 5	4.5 $\pm$ 2.0	5.7 $\pm$ 2.1	1.2 $\pm$ 2.1	-0.4; 2.8
Week 10	4.0 $\pm$ 1.4	5.3 $\pm$ 1.9	1.3 $\pm$ 1.7	-0.03; 2.6
3 months after week 10	4.0 $\pm$ 2.2	-	-	-
HRFS impact on activities of daily living				
Baseline	6.7 $\pm$ 1.3	6.9 $\pm$ 1.2	0.2 $\pm$ 1.2	-0.7; 1.1
Week 5	4.4 $\pm$ 2.1	5.5 $\pm$ 2.1	1.1 $\pm$ 2.1	-0.5; 2.7
Week 10	3.7 $\pm$ 1.2	5.3 $\pm$ 1.9	1.6 $\pm$ 1.6	0.3; 2.8
3 months after week 10	3.9 $\pm$ 2.1	-	-	-
HRFS impact on socialization				
Baseline	6.7 $\pm$ 1.3	7.2 $\pm$ 1.7	0.4 $\pm$ 1.5	-0.7; 1.4
Week 5	4.6 $\pm$ 2.3	5.7 $\pm$ 2.3	1.1 $\pm$ 2.3	-0.8; 2.9
Week 10	4.5 $\pm$ 2.0	5.6 $\pm$ 2.3	1.1 $\pm$ 2.1	-0.6; 2.8
3 months after week 10	4.0 $\pm$ 2.2	-	-	-
HRFS impact on mental functioning				
Baseline	6.8 $\pm$ 1.5	6.4 $\pm$ 2.3	-0.4 $\pm$ 1.9	-1.8; 0.9
Week 5	4.5 $\pm$ 2.0	6.2 $\pm$ 2.8	1.7 $\pm$ 2.4	-0.2; 3.7
Week 10	4.6 $\pm$ 1.9	5.2 $\pm$ 2.4	0.6 $\pm$ 2.2	-1.1; 2.4
3 months after week 10	4.5 $\pm$ 2.8	-	-	-
PROMIS fatigue scale - short form (prorated t-score)				
Baseline	63.0 $\pm$ 5.4	63.8 $\pm$ 5.3	0.8 $\pm$ 5.3	-3.2; 4.7
Week 5	57.6 $\pm$ 9.8	59.1 $\pm$ 5.3	1.5 $\pm$ 7.8	-4.6; 7.7
Week 10	57.5 $\pm$ 6.9	59.8 $\pm$ 6.5	2.3 $\pm$ 6.7	-3.0; 7.6
3 months after week 10	57.3 $\pm$ 10.4	-	-	-
Self-efficacy for managing fatigue - single item (1–10 scale)				
Baseline	7.5 $\pm$ 2.6	6.1 $\pm$ 2.5	-1.5 $\pm$ 2.5	-3.4; 0.4
Week 5	6.0 $\pm$ 2.4	5.8 $\pm$ 2.3	-0.2 $\pm$ 2.3	-2.0; 1.6
Week 10	6.9 $\pm$ 1.9	5.5 $\pm$ 2.6	-1.4 $\pm$ 2.3	-3.2; 0.4
3 months after week 10	6.2 $\pm$ 2.6	-	-	-
BDI-II Score				

	Intervention (n=15)	Control (n=15)	Difference	95% confidence interval
Baseline	20.9 ± 11.8	23.1 ± 11.2	2.3 ± 11.5	-6.4; 10.9
Week 5	12.3 ± 7.8	22.1 ± 13.1	9.7 ± 10.9	1.1; 18.4
Week 10	15.7 ± 8.3	20.0 ± 12.0	4.3 ± 10.4	-3.9; 12.6
3 months after week 10	14.9 ± 9.2	-	-	-
STAI-State				
Baseline	46.9 ± 13.4	48.5 ± 14.9	1.6 ± 14.1	-9.0; 12.1
Week 5	41.2 ± 12.5	46.9 ± 9.1	5.7 ± 10.9	-2.9; 14.3
Week 10	42.9 ± 9.7	43.0 ± 14.6	0.1 ± 12.5	-9.8; 10.0
3 months after week 10	40.6 ± 9.8	-	-	-
STAI-Trait				
Baseline	44.1 ± 12.2	50.1 ± 13.1	6.1 ± 12.7	-3.4; 15.5
Week 5	39.9 ± 12.4	46.5 ± 10.0	6.6 ± 11.2	-2.3; 15.5
Week 10	44.0 ± 9.7	44.1 ± 12.5	0.1 ± 11.2	-8.7; 9.0
3 months after week 10	42.4 ± 10.4	-	-	-
Credibility & Expectancy Evaluation Scale				
Baseline	22.7 ± 3.5	21.7 ± 4.1	-1.0 ± 3.8	-3.9; 1.9
Week 10	20.6 ± 4.1	19.4 ± 6.4	-1.3 ± 5.4	-5.6; 3.0
Barriers to Treatment Participation Scale				
Week 10	1.67 ± 0.38	1.68 ± 0.40	0.01 ± 0.4	-0.3; 0.3
3 months after week 10	1.57 ± 0.33	-	-	-
HIV viral load (excluding one participant with baseline value of 312000 and one with baseline value of 580)				
Baseline	15.0 ± 21.7	7.1 ± 9.9	-7.9 ± 15.8	-21.5; 5.8
Week 10	13.3 ± 16.6	13.3 ± 15.6	0.0 ± 16.0	-14.8; 14.8
3 months after week 10	4.3 ± 11.3	-	-	-
CD4 count				
Baseline	551.7 ± 288.2	744.8 ± 497.4	193.1 ± 402.1	-139.8; 526.1
Week 10	595.5 ± 310.9	753.3 ± 489.1	157.8 ± 409.8	-189.2; 504.7
3 months after week 10	567.2 ± 303.2	-	-	-
LIFE EXPERIENCES SURVEY				
Number of stresses				
Baseline	3.3 ± 2.7	3.9 ± 1.7	0.6 ± 2.2	-1.1; 2.3
Week 10	3.0 ± 3.4	2.6 ± 1.8	-0.4 ± 2.7	-2.6; 1.7
3 months after week 10	1.7 ± 1.7	-	-	-
Level of stress rating				
Baseline	4.0 ± 0.7	3.6 ± 1.0	-0.5 ± 0.9	-1.2; 0.2
Week 10	3.6 ± 1.0	3.8 ± 0.7	0.1 ± 0.9	-0.6; 0.9
3 months after week 10	3.9 ± 1.1	-	-	-
Average stress level rating times number of stresses				
Baseline	15.2 ± 10.1	14.7 ± 8.1	-0.6 ± 9.1	-7.6; 6.5

	Intervention (n=15)	Control (n=15)	Difference	95% confidence interval
Week 10	14.3 ± 12.7	11.3 ± 6.7	-3.0 ± 9.9	-11.8; 5.8
3 months after week 10	10.1 ± 4.5	-	-	-
Number of severe stresses				
Baseline	1.3 ± 1.6	1.8 ± 1.4	0.5 ± 1.5	-0.6; 1.7
Week 10	1.2 ± 1.3	1.4 ± 1.3	0.2 ± 1.3	-0.9; 1.3
3 months after week 10	1.0 ± 1.0	-	-	-
Level of severe stress rating				
Baseline	4.3 ± 0.6	4.1 ± 0.7	-0.2 ± 0.7	-0.8; 0.5
Week 10	4.1 ± 0.8	3.8 ± 0.7	-0.3 ± 0.7	-1.1; 0.5
3 months after week 10	4.0 ± 1.1	-	-	-
Average severe stress level rating times number of severe stresses				
Baseline	9.6 ± 4.9	9.3 ± 5.7	-0.4 ± 5.4	-5.5; 4.8
Week 10	8.4 ± 3.6	7.8 ± 3.5	-0.7 ± 3.5	-4.5; 3.2
3 months after week 10	6.3 ± 3.3	-	-	-

HRFS = HIV-Related Fatigue Scale; BDI-II = Beck Depression Inventory II; STAI = State/Trait Anxiety Inventory

Table 4.

Completer's comparison of change from baseline for outcome measures within the intervention group for those who completed at least 80% of their modules

Intervention with 80% module completion (n=10)		Change from baseline to respective visit	95% CI for change from baseline to respective visit
HRFS fatigue intensity			
Baseline	6.8 ± 1.2		
Week 5	6.4 ± 1.5	0.3 ± 1.1	-0.5; 1.1
Week 10	5.8 ± 1.3	1.0 ± 1.7	0.2; 2.2
3 months after week 10	6.0 ± 1.8	0.8 ± 1.7	-0.4; 2.0
HRFS overall fatigue-related functioning			
Baseline	6.6 ± 1.0		
Week 5	4.8 ± 1.9	1.9 ± 1.3	0.9; 2.9
Week 10	4.0 ± 1.2	2.7 ± 1.8	1.4; 3.9
3 months after week 10	4.2 ± 2.2	2.4 ± 2.0	1.0; 3.8
HRFS impact on activities of daily living			
Baseline	6.7 ± 1.1		
Week 5	4.7 ± 2.0	2.1 ± 1.4	1.0; 3.1
Week 10	3.7 ± 1.1	3.1 ± 1.7	1.8; 4.3
3 months after week 10	4.1 ± 2.2	2.7 ± 1.9	1.3; 4.0
HRFS impact on socialization			
Baseline	6.5 ± 1.0		
Week 5	4.8 ± 2.3	1.7 ± 1.8	0.3; 3.0
Week 10	4.3 ± 1.9	2.2 ± 2.5	0.3; 4.0
3 months after week 10	4.3 ± 2.1	2.2 ± 2.4	0.5; 4.0
HRFS impact on mental functioning			
Baseline	6.6 ± 1.2		
Week 5	4.9 ± 1.8	1.7 ± 1.5	0.6; 2.8
Week 10	4.7 ± 1.4	1.9 ± 1.5	0.9; 3.0
3 months after week 10	4.7 ± 2.9	1.9 ± 2.3	0.3; 3.6
PROMIS fatigue scale - short form (prorated t-score)			
Baseline	64.2 ± 5.0		
Week 5	59.9 ± 7.5	4.3 ± 5.1	0.7; 8.0
Week 10	57.0 ± 6.4	7.3 ± 4.3	4.1; 10.4
3 months after week 10	59.7 ± 7.0	4.5 ± 5.9	0.3; 8.7
Self-efficacy for managing fatigue - single item (1–10 scale)			
Baseline	6.6 ± 2.6		
Week 5	5.8 ± 2.3	0.8 ± 2.3	-0.8; 2.4
Week 10	7.2 ± 2.1	-0.6 ± 2.2	-2.2; 1.0
3 months after week 10	6.0 ± 2.7	0.6 ± 3.9	-2.2; 3.4

Intervention with 80% module completion (n=10)		Change from baseline to respective visit	95% CI for change from baseline to respective visit
BDI-II score			
Baseline	24.2 ± 11.0		
Week 5	14.3 ± 7.5	9.9 ± 9.2	3.3; 16.5
Week 10	16.4 ± 7.7	7.8 ± 12.0	-0.8; 16.4
3 months after week 10	16.4 ± 8.1	7.8 ± 12.0	-0.8; 16.4
STAI-State			
Baseline	51.4 ± 10.2		
Week 5	43.9 ± 12.5	7.5 ± 15.9	-3.9; 18.9
Week 10	42.9 ± 9.9	8.5 ± 14.1	-1.6; 18.6
3 months after week 10	41.5 ± 9.9	9.9 ± 13.1	0.6; 19.2
STAI-Trait			
Baseline	49.1 ± 8.8		
Week 5	43.0 ± 11.4	6.1 ± 10.5	-1.4; 13.6
Week 10	43.6 ± 10.8	5.5 ± 10.0	-1.6; 12.6
3 months after week 10	44.3 ± 8.6	4.8 ± 10.1	-2.4; 12.0
Credibility & Expectancy Evaluation Scale			
Baseline	22.3 ± 3.8		
Week 10	21.6 ± 4.1	0.7 ± 3.2	-1.6; 3.0
Barriers to Treatment Participation Scale			
Week 10	1.64 ± 0.32		
3 months after week 10	1.62 ± 0.30	0.01 ± 0.1	-0.06; 0.08
HIV viral load (excluding one participant with baseline value of 312000 and one with baseline value of 580)			
Baseline	15.0 ± 21.7		
Week 10	13.3 ± 16.6	5.0 ± 12.2	-7.9; 17.9
3 months after week 10	4.3 ± 11.3	11.7 ± 18.3	-7.6; 30.9
CD4 count			
Baseline	525.5 ± 293.3		
Week 10	595.5 ± 310.9	-24.6 ± 58.0	-66.1; 16.9
3 months after week 10	567.2 ± 303.2	-41.7 ± 61.9	-86.0; 2.6
LIFE EXPERIENCES SURVEY			
Number of stresses			
Baseline	4.4 ± 2.6		
Week 10	3.7 ± 3.6	-0.7 ± 2.8	-2.7; 1.3
3 months after week 10	1.9 ± 1.7	-2.5 ± 3.1	-4.7; -0.3
Level of stress rating			
Baseline	4.2 ± 0.7		
Week 10	3.7 ± 1.0	-0.4 ± 1.1	-1.2; 0.4
3 months after week 10	3.9 ± 1.1	-0.1 ± 1.4	-1.4; 1.2
Average stress level rating times number of stresses			

Intervention with 80% module completion (n=10)		Change from baseline to respective visit	95% CI for change from baseline to respective visit
Baseline	17.6 ± 10.2		
Week 10	15.1 ± 13.2	-3.9 ± 10.7	-12.1; 4.3
3 months after week 10	10.1 ± 4.5	-6.9 ± 10.8	-16.9; 3.2
Number of severe stresses			
Baseline	1.8 ± 1.7		
Week 10	1.5 ± 1.4	-0.3 ± 2.0	-1.7; 1.1
3 months after week 10	1.1 ± 1.0	-0.7 ± 1.6	-1.9; 0.5
Level of severe stress rating			
Baseline	4.2 ± 0.6		
Week 10	4.1 ± 0.8	-0.2 ± 0.8	-1.1; 0.6
3 months after week 10	4.0 ± 1.1	0.1 ± 0.8	-0.9; 1.2
Average severe stress level rating times number of severe stresses			
Baseline	10.3 ± 4.9		
Week 10	8.4 ± 3.6	-1.7 ± 8.1	-10.2; 6.9
3 months after week 10	6.3 ± 3.3	-3.4 ± 6.7	-11.8; 5.0

HRFS = HIV-Related Fatigue Scale; BDI-II = Beck Depression Inventory II; STAI = State/Trait Anxiety Inventory