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# Pilot randomized trial of collaborative behavioral treatment for chronic pain and depression in persons living with HIV/AIDS

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## Abstract

In this pilot study, we assessed feasibility and acceptability of a behavior therapy intervention for pain and depressive symptoms in persons living with HIV/AIDS (PLWH). We randomly assigned 23 participants to HIV-PASS (HIV-Pain and Sadness Study) or a health education control arm for 3 months. On average, participants attended more than 5 sessions (of 7 possible) in both arms. Qualitative data suggest HIV-PASS participants understood key messages and made concrete behavioral changes. HIV-PASS was associated with effects in the expected direction for three of four outcomes, including the primary outcome (pain-related interference with functioning). Findings suggest that HIV-PASS is promising.

### Keywords

HIV/AIDS; chronic pain; depression; behavioral medicine

## INTRODUCTION

Even in the era of Highly Active Antiretroviral Treatment (HAART), 34–48% of persons living with HIV/AIDS (PLWH) report having experienced pain in the prior week, with reports of chronic pain in various parts of the body (1). In PLWH with pain, rates of depression are particularly high (1). As shown in non-HIV populations, chronic pain patients with comorbid depression have a poorer response to pain treatment (2).

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Existing pharmacological treatments for pain in PLWH do not seem to adequately mitigate suffering in all PLWH (1). Further complicating pharmacologic pain management, many PLWH have a history of substance abuse and misuse of prescribed opioid analgesics. Thus, there is a clear need for non-pharmacological options for pain that may be used as adjunctive or stand-alone treatments.

A recent Cochrane review (3) reported that cognitive behavior therapy (CBT) has a positive impact on pain-related disability and mood across different types of pain conditions. There are three clinical trials of CBT for chronic pain in PLWH, including one randomized trial (4) and two single-arm trials (5, 6). Although results were somewhat encouraging, all three studies were limited by notably low intervention adherence. In the RCT, treatment non-completers reported more depressive symptoms than treatment completers (4). However, none of these trials specifically targeted depressive symptoms.

CBT is also effective for major depression (7), although CBT protocols targeting depression differ in some important ways from those targeting pain. Most CBT protocols targeting depression never address physical pain, and do not include specific pain management strategies such as time-based pacing (i.e., the pre-planned use of scheduled rest periods during physically demanding activities).

There are several ways in which CBT for chronic pain could be modified to increase adherence and boost efficacy in PLWH with chronic pain. First, given CBT is useful for depression as well, a CBT protocol should explicitly and simultaneously target both chronic pain and co-occurring depressive symptoms. Second, placing a CBT intervention in an HIV care setting, and collaborating with the primary care provider (PCP), could reduce appointment burden and allow for increased buy-in from patients as well as ensure that the PCP and the behavioral health specialist (BHS) present the same message about the need to actively engage in self-management strategies, including physical activity. With the advent of the Medical Home model, close collaboration between PCPs and BHSs has become a reality in some settings. Yet, only one of the previous studies of CBT for chronic pain in PLWH occurred in a primary care setting (6). Third, telephone sessions might increase convenience for patients and intervention adherence. Fourth, sending written notes home to patients following a treatment session may enhance the patient's sense of engagement, and serve as a written reminder of topics discussed.

For the purposes of simultaneously targeting pain and depressive symptoms in PLWH, we chose a version of CBT, behavioral activation, in which the focus is on patients identifying meaningful long-term life goals, and then setting short-term goals consistent with these long-term goals. The underlying theory is that both pain and depressive symptoms are a cause of, and are exacerbated by, lack of engagement in (i.e, avoidance of) important physical, social, and role activities (8). Avoidance and withdrawal are often related to fear of increased physical (or emotional) pain. Behavioral activation directly targets avoidance by promoting the opposite: engagement in valued life activities.

Based on our team's collective clinical experiences with PLWH as well as the rationale described above, we modified our own existing manualized behavioral activation protocol

for primary care to be targeted toward patients with HIV, depressive symptoms, and chronic pain. After piloting the manual with 6 individuals, and making some modifications, we conducted this study. The primary goal of this study was to assess feasibility and acceptability of HIV-PASS (HIV-Pain and Sadness Study) in a pilot randomized clinical trial in which participants were assigned to HIV-PASS or a health education (HE) control arm. To that end, we assessed: 1) attendance at intervention sessions; 2) satisfaction with treatment; 3) ability to retain participants for follow-up assessments; and 4) qualitative feedback from participants. We also include data on key outcomes (pain-related interference with psychosocial and physical functioning, depressive symptom severity, pain severity, and engagement in meaningful activities); however, this pilot study is underpowered to detect differences between groups on these outcomes. The purpose of this study was to use all available information to determine whether further testing of HIV-PASS is warranted.

## METHODS

### Setting

This study occurred in two primary care practices June 2013 – August 2014. The first was a federally qualified community health center (FQHC) that included three internal medicine physicians with expertise in primary care for PLWH. The second was a specialty academic, hospital-based, outpatient HIV clinic with 22 physicians. All physicians agreed to participate with their patients.

### Participants

Inclusion criteria were: 1) chronic pain (duration ≥ six months); 2) pain interference with functioning (Brief Pain Inventory Interference Scale (9) ≥ 5); 3) pain severity ≥ 4 on a 0–10 Numeric Rating Scale indicating “worst pain in the last week”; 4) at least one trial of PCP-recommended medication intended to treat the pain; 5) elevated depressive symptoms (i.e., a Quick Inventory of Depression Symptomatology (QIDS) score of ≥ 9); 6) stable dose of an antidepressant, if using, for the previous 1 month; 7) age 18 or older; 8) HIV+; and 9) English speaking. Exclusion criteria were: 1) currently attending CBT (for any reason) or a multidisciplinary pain management program; 2) expected surgery in the next 6 months; 3) current mania or psychotic symptoms; 4) daily or near-daily alcohol use in the past month; binge drinking (≥ 4 drinks per day) in the past month; 5) use of cocaine, crack, or methamphetamine ≥ 12 days in the past month; 6) suicidality requiring immediate attention; 7) pregnancy.

### Procedures

Participants were recruited by two methods: screening PLWH who came in for a primary care visit; and asking HIV PCPs to identify patients potentially eligible and having research staff contact these patients to inform them about the study. After completing a brief screening interview (via telephone or in person), interested and potentially eligible participants were scheduled for an in-person interview. Informed consent was obtained from all individual participants included in the study. Following informed consent, the research assistant completed assessment of inclusion criteria to determine study eligibility. Participants then completed the baseline assessment.

Once a participant was determined to be eligible and enrolled in the study, the participant immediately met with both the BHS and PCP for her/his initial study intervention visit. BHSs used a computer-generated scheme to randomize participants to intervention arm. The BHS informed the patient of the arm to which he/she was randomized (HIV-PASS or HE) before the joint PCP visit. Participants were not told that one arm was considered "active" while the other was considered to be a control arm. Both arms were presented as adjunctive interventions that the participant might find helpful. This study was approved by the Butler Hospital IRB.

## Study interventions

Both interventions were administered using a detailed manualized protocol and patient workbook. Interventionists (i.e., BHSs) were post-doctoral fellows in clinical psychology or licensed clinical psychologists who provided both HIV-PASS and HE. Interventionists had weekly supervision. Both interventions included: an initial joint meeting with the patient, PCP, and BHS (session 1), immediately followed by a meeting of just the patient and BHS (session 2); and then 5 BHS telephone calls with the patient over the next 3 months, each lasting 30–50 minutes. Although sessions occurred every 2 weeks on average, we allowed flexibility in scheduling to reflect clinical practice. To further enhance acceptability to patients, telephone sessions could be scheduled for early evening.

In HIV-PASS, BHSs first discussed the medical treatment strategy for the patient's depressive symptoms and chronic pain in the joint meeting with the PCP. The BHS asked for the PCP's perspective on physical activity as well. In this brief visit, the BHS placed emphasis on open communication between the patient, PCP, and BHS. Subsequently, in the next two visits with the patient only, the BHS elicited a history of HIV, pain, and depressive symptoms, and then provided education about the nature of chronic pain, depression, and their interaction; the maintaining role of avoidance; and how engaging in important and meaningful activities could help to reverse a negative cycle of pain, depression, and avoidance. The BHS emphasized three key messages: 1) Pain and discomfort (e.g., physical pain, sad feelings) are not harmful in and of themselves; 2) Avoidance is a natural response to emotional and physical pain; and 3) the patient will need to find a balance between behaviors consistent with achieving long-term meaningful life goals (that might elicit some pain in the short-term) and minimizing short-term discomfort.

Beginning in session 3 and continuing to the end of treatment, BHSs and patients focused on behavioral activation. BHSs helped patients to identify meaningful long-term life goals that were consistent with their values. These often related to relationships with family members, work or other meaningful activities, and health. Then BHSs helped patients set manageable short-term goals that were in line with their long-term goals; BHSs often encouraged the patient to engage in physical activity as a way to work towards a longer-term goal of improved physical health or self-care. Each session, the BHS and patient reviewed previous goals and set new ones. If the patient did not meet certain goals, and the patient continued to believe the goal to be important, then the BHS would engage in problem-solving with the patient to increase the likelihood of goal attainment in the future.

The BHS taught two additional skills. In session 4, the BHS introduced time-based pacing. This is a skill commonly taught in CBT for pain that involves planning rest periods while engaging in physical or other activities so that one does not push oneself to the point of exhaustion or extreme pain that results in the inability to function for a time. In session 5, the BHS introduced the concept of disease self-management and being an activated, informed patient. This included discussions of medication adherence, communication with PCP, and making healthcare decisions. In the two final sessions, the BHS emphasized the patient's accomplishments and helped the patient to plan for how to maintain and extend gains made in the previous 3 months.

BHSs sent clinical notes detailing each HIV-PASS session to the PCP and to the patient (with the patient's permission). BHSs wrote treatment notes designed to be informative for these two sets of readers, and included specific recommendations for how the PCP might provide support for goals identified in HIV-PASS, as well as any specific topics the patient stated he/she would like to discuss with the PCP. The BHS reviewed the previous treatment note with the patient at the beginning of each session.

Health education (HE) served as the control condition. First, there was an initial fifteen-minute joint meeting with the BHS and PCP. During this meeting, all three parties discussed and chose most relevant health education topics for this particular participant. They chose from a menu of topics, including: a second session on nutrition (all participants received one session on nutrition); colds and the flu; preventing cancer; diabetes; protecting your heart; getting a good night's sleep; complementary and alternative medicine; caffeine; and physical activity. Subsequently, patients had an in-person session with the BHS focused on nutrition. For the 5 telephone sessions, topics discussed were those chosen from the menu of topics. Sessions were interactive but didactic in nature; BHSs refrained from helping patients to set personalized goals or from providing specific advice about depressive symptoms or pain.

## Assessments

The intervention period lasted for 3 months; assessments occurred at baseline, month 1, month 2, month 3 (endpoint), and month 4 (one month follow-up).

Feasibility and acceptability outcomes included average number of sessions attended by participants, patient satisfaction at intervention endpoint (month 3), and responses to qualitative interviews with participants. After treatment ended, we administered the Client Satisfaction Questionnaire (CSQ-8) (10), an 8-item scale that yields a total score ranging from 8–32, with 32 indicating highest satisfaction. A research staff member not affiliated with the other assessments or interventions conducted qualitative interviews with HIV-PASS participants after the 4-month assessment using a structured interview guide. Interviews included questions about overall impressions, what was and was not helpful, opinions about various specific aspects of HIV-PASS, and suggestions for improvement.

We assessed relevant patient outcomes. We used the Brief Pain Inventory—Interference scale (BPI-I) (9) to capture pain-related interference with physical (walking, general activity, and work) and psychosocial (relations with others, enjoyment of life, mood) functioning. BPI-I scores range from 0 to 10, with higher scores representing more interference. The

BPI-I is intended to be the primary outcome in subsequent, larger scale trials. We assessed depressive symptoms using the Quick Inventory of Depression Symptoms--Clinician Rating (QIDS), a commonly-used clinical interview that yields a depression severity score between 0 and 27 (11). We assessed average pain in the past week using a numerical rating scale, where 0 = no pain and 10 = pain as bad as one can imagine. Finally, we assessed activities engagement using the relevant subscale of the Chronic Pain Acceptance Questionnaire (CPAQ) (12). A sample item is: "I lead a full life even though I have chronic pain." Items were rated on a scale of 0 (never true) to 6 (always true). Scores range from 0 to 66, with higher scores indicating more engagement.

### Data Analysis

We present descriptive statistics to characterize the sample. Because sample sizes are small and distributions often non-normal, we used nonparametric Wilcoxon rank-sum test and Fisher's exact test for between group comparisons on continuous and categorical variables, respectively.

To analyze data from qualitative interviews, two investigators independently read transcriptions of interviews and selected all quotes relating to three topics: positive/helpful aspects of HIV-PASS, including evidence participants understood key principles; negative/unhelpful aspects of HIV-PASS or evidence that patients did not understand key principles; and ways in which participation in HIV-PASS did or did not change their everyday lives. They then created a master list of relevant quotes using consensus, summarized themes (in italics below), and chose quotes to illustrate themes. They specifically looked for (and we report below) any negative comments about HIV-PASS.

We estimated intervention effects as the between-group difference in change scores between baseline and 4-month assessment. We present Cohen's d (13) with 95% confidence intervals (CIs). CIs are often large; this is not surprising due to the pilot nature of the study. Therefore, Cohen's d values should be interpreted with caution and only within the relevant confidence intervals. Effect sizes of 0.2 may be considered small, 0.5 medium, and 0.8 large (13). We used a change score analysis in this study because it 1) examines within subject change, 2) controls for time-invariant between-group differences, and 3) unlike more complex analytical models, is not based on statistical assumptions that may not be reasonable with small sample sizes.

## RESULTS

### Participant Characteristics

We screened 129 participants from both sites for study participation. Of these, 81 did not meet inclusion criteria. Most common reasons for exclusion were: low pain severity (n = 48) or not depressed (n = 11). Twenty-five refused participation (either before or after being screened). Therefore, we recruited 23 participants, 12 from the FQHC, and 11 from the HIV clinic. See Table I for demographics. The only significant baseline difference between groups was percent taking an antidepressant medication. Post-hoc, we examined whether antidepressant use could be considered "time invariant" throughout the trial. Of the 19

participants for whom we had 3 month data, 16 did not change antidepressant use, and 2 participants dropped and 1 participant added an antidepressant medication (all 3 were assigned to HIV-PASS).

### Acceptability and feasibility

Participants attended an average of 5.75 (SD = 1.8; range=3 – 7) sessions in the HIV-PASS arm and 5.27 (SD = 2.2; range =2 – 7) sessions in the HE arm. This was not significantly different between groups (t = 0.57, df = 21, p = .572). Patient satisfaction scores (CSQ-8) at study endpoint were significantly higher (Wilcoxon rank-sum z = −2.31, p = .021) for the HIV-PASS group than the HE group; means were 29.4 (± 3.1) vs. 23.6 (± 5.8), respectively. We had good retention for follow-up assessments, collecting data from 21, 18, 19, and 19 participants at months 1, 2, 3, and 4, respectively.

Of the 11 participants assigned to HIV-PASS, we were able to conduct qualitative follow-up interviews with 7. Four participants responded in ways that suggested *they very clearly used and appreciated goal setting*. One person summed up the experience of goal-setting: “I didn’t like it…I was out of my comfort zone but I’m glad I did it.” (For the other 3, it was unclear to what extent the engaged in goal-setting or believed it to be important.) When asked, participants cited *specific ways in which they increased engagement in meaningful activities*, including physical activity, going back to work, going to church, and improving interpersonal relationships. Most participants also *appreciated the joint meeting with their PCP and/ or believed that they had improved communication with their PCP*, although one person who gave HIV-PASS generally high ratings (i.e. “I enjoyed doing it”) was concerned that parts of some clinical notes shared with her PCP were not completely accurate. (For us, this reflects the importance of sharing notes with patients – it gives patients the chance to comment on the notes and clear up misunderstandings with the BHS.) Participants also discussed *other key aspects of HIV-PASS*: i.e., learning about pacing, and acceptance of pain: “can’t take away pain. Can do a little more to get around it.” *Difficulties with HIV-PASS* included scheduling meetings for a participant who went back to work, and dislike of “paperwork” (although we believe this refers to primarily the research assessments rather than the workbook). Another participant stated that she got “great feedback about managing pain” from her BHS, but continued to have trouble with anxiety.

### Treatment effects over 4 months

We present differences between groups, along with effect sizes and 95% confidence intervals in Table I. Effect sizes were in the expected direction for pain interference (BPI), depressive symptoms (QIDS), and activities engagement (CPAQ), and 95% confidence intervals for these variables all included a at least a medium effect favoring HIV-PASS. The effect size for change in average pain score was not in the expected direction (i.e., favored HE). We found one statistically significant difference between HIV-PASS and HE, with HIV-PASS showing greater decreases in depressive symptoms over 4 months. We also examined outcomes at 3 months (not shown), and found no statistically significant differences between groups on change scores. As one might expect, relative to baseline, means were generally decreased for both groups at months 1, 2, 3, and 4, for the BPI, average pain, and QIDS, and

generally increased for the CPAQ, although the pattern of change was variable from month to month.

## DISCUSSION

The primary aim of this pilot trial was to assess feasibility and acceptability of HIV-PASS. This aim was particularly important given that CBT for pain has been efficacious in other patient groups (3) yet in PLWH has shown poor intervention adherence. We specifically designed HIV-PASS to increase acceptability. We observed good intervention attendance; HIV-PASS met our adherence goal with participants attending, on average, more than 5 of 7 sessions. This number of sessions is sufficient to receive all the HIV-PASS content; sessions 6 and 7 serve to repeat previous content and reinforce gains. Although patient satisfaction scores were higher in HIV-PASS than in HE, both arms yielded acceptable satisfaction scores. Our qualitative data showed that many participants understood and used key skills (behavioral goal-setting in everyday life, pacing) taught in HIV-PASS, and appreciated the goal of improved communication with one's PCP, and the participation of the PCP in the initial session. Thus, we conclude that HIV-PASS is a feasible and acceptable intervention.

With regard to specific clinical outcomes, we found that, relative to the control group, HIV-PASS participants showed significantly larger decreases in depressive symptoms compared to the HE group at 4 months. This is best viewed as encouraging but in no way definitive. There were no statistically significant differences between groups on change scores at month 3. Further, although use of antidepressants did not change throughout the trial for most participants (i.e, was time-invariant), antidepressant use did change for 3 participants and we were not able to control for group differences in antidepressant medication use at baseline. In a larger trial, investigators might choose to stratify randomization based on antidepressant (and opioid pain medication) use. Although it may not be possible to control antidepressant (and pain medication) use during the trial, it is important to track and consider ways to statistically control for such use in analyses. Further, in larger studies, more robust multilevel models that include all available data points could be used.

Although not statistically significant, we did find effects in the expected direction on the primary outcome -- pain-related interference with psychosocial and physical functioning – as well as on activities engagement. Pain severity decreased in both groups over time; however, pain severity did not decrease *as much* in HIV-PASS as in HE. If the lesser improvement in the HIV-PASS group was not a spurious result (given the small study size), what could explain it? It is possible that increased engagement in meaningful activities resulted in improved mood (as well as decreasing the perception that pain interferes with psychosocial functioning). At the same time, increased activity--especially increased physical activity -- may somewhat limit decreases in short-term pain scores, although we would hope that improved fitness would decrease pain in the longer term. This points to the importance of a longer-term follow-up period in the next study as well as a careful examination of the association between the four outcome variables of interest over time.

This study had several limitations. First, we did not have "major depression" as an inclusion criterion – rather, we included people with elevated depressive symptoms. Although this

may have made the sample more heterogeneous, it also reflects clinical practice, where physicians seldom use structured interviews to ascertain criteria for major depression. Second, we excluded patients with high levels of cocaine or alcohol use; HIV-PASS did not target substance abuse, although substance use was discussed, as required, during sessions. Third, we were able to conduct exit interviews with only 7 of the 11 HIV-PASS participants, and it is possible that the persons we did not reach were less satisfied with HIV-PASS. Finally, the pilot nature of this study means that it was not powered to detect potentially clinically meaningful changes on outcomes, and the sample size was insufficient to impute missing data or use multilevel modeling.

However, we believe our trial does provide sufficient evidence of feasibility and acceptability to merit an adequately powered clinical trial of HIV-PASS with more rigorous methodology, including blind outcome assessors and longer-term follow-up. We would continue to conduct most sessions by phone, as it seems acceptable to patients, and gives participants more flexibility. HIV patients with chronic pain and depressive symptoms need novel, disseminable behavioral interventions based in primary care settings that can improve quality of life.

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## REFERENCES

1. Uebelacker LA, Weisberg RB, Herman DS, Bailey GL, Pinkston-Camp MM, Stein MD. Chronic Pain in HIV-Infected Patients: Relationship to Depression, Substance Use, and Mental Health and Pain Treatment. Pain Med. 2015; 16(10):1870–1881. [PubMed: 26119642]
2. Barnes D, Smith D, Gatchel RJ, Mayer TG. Psychosocioeconomic predictors of treatment success/failure in chronic low-back pain patients. Spine. 1989 Apr; 14(4):427–430. [PubMed: 2524113]
3. Williams AC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database Syst Rev. 2012; 11:CD007407. [PubMed: 23152245]
4. Evans S, Fishman B, Spielman L, Haley A. Randomized trial of cognitive behavior therapy versus supportive psychotherapy for HIV-related peripheral neuropathic pain. Psychosomatics. 2003 Jan-Feb;44(1):44–50. [PubMed: 12515837]
5. Cucciare MA, Sorrell JT, Trafton JA. Predicting response to cognitive-behavioral therapy in a sample of HIV-positive patients with chronic pain. J Behav Med. 2009 Aug; 32(4):340–348. [PubMed: 19234779]
6. Trafton JA, Sorrell JT, Holodniy M, et al. Outcomes associated with a cognitive-behavioral chronic pain management program implemented in three public HIV primary care clinics. J Behav Health Serv Res. 2012 Apr; 39(2):158–173. [PubMed: 21947662]
7. Butler AC, Chapman JE, Forman EM, Beck AT. The empirical status of cognitive-behavioral therapy: a review of meta-analyses. Clin Psychol Rev. 2006 Jan; 26(1):17–31. [PubMed: 16199119]

8. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. Pain. 2000 Apr; 85(3):317–332. [PubMed: 10781906]

9. Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. Ann Acad Med Singapore. 1994 Mar; 23(2):129–138. [PubMed: 8080219]

10. Nguyen TD, Attkisson CC, Stegner BL. Assessment of patient satisfaction: development and refinement of a service evaluation questionnaire. Eval Program Plann. 1983; 6(299-313)

11. Rush AJ, Trivedi MH, Ibrahim HM, et al. The 16-item Quick Inventory of Depressive Symptomatology (QIDS) Clinician Rating (QIDS-C) and Self-Report (QIDS-SR): a psychometric evaluation in patients with chronic major depression. Biol Psychiatry. 2003; 54:573–583. [PubMed: 12946886]

12. Vowles KE, McCracken LM, McLeod C, Eccleston C. The Chronic Pain Acceptance Questionnaire: confirmatory factor analysis and identification of patient subgroups. Pain. 2008 Nov 30; 140(2):284–291. [PubMed: 18824301]

13. Cohen, J. Statistical power analysis for the behavioral sciences. 2nd. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.

**Table I**

Demographic and clinical characteristics at baseline and at 4 months

| | Descriptive Statistics | | Comparison between groups at baseline | | Comparison between groups in change from baseline to Month 4 | | |
|---|---|---|---|---|---|---|---|
| | HIV-PASS | HE | Wilcoxen rank-sum (or Fisher's exact test)[a] | p – value | d (95%CI) [g] | z[h] | p-value |
| **Baseline Demographics and Clinical Characteristics (HIV-PASS n = 11; HE n = 12)** | | | | | | | |
| Years of age – Mean (SD) | 52.0 (± 7.2) | 49.7 (± 9.4) | −0.43 | .646 | | | |
| Male -- n (%) | 7 (63.6%) | 6 (50.0%) | | .680 | | | |
| Race/Ethnicity | | | | | | | |
| Caucasian -- n (%) | 4 (36.7%) | 8 (66.7%) | | .446 | | | |
| African-American -- n (%) | 2 (18.2%) | 1 (8.3%) | | | | | |
| Hispanic -- n (%) | 2 (18.2%) | 2 (16.7%) | | | | | |
| Other -- n (%) | 3 (27.3%) | 1 (8.3%) | | | | | |
| Employed part or full time -- n (%) | 2 (18.2%) | 1 (8.3%) | | .590 | | | |
| Years with HIV – mean (SD) | 14.6 (± 8.1) | 17.8 (± 7.9) | 0.74 | .460 | | | |
| Method of HIV transmission | | | | | | | |
| Intravenous drug use -- n (%) | 7 (63.6%) | 4 (33.3%) | | .547 | | | |
| Men who have sex with men (MSM)-- n (%) | 2 (18.2%) | 5 (41.7%) | | | | | |
| Heterosexual -- n (%) | 1 (9.1%) | 2 (16.7%) | | | | | |
| Unknown -- n (%) | 1 (9.1%) | 1 (8.3%) | | | | | |
| Completely adherent to antiretroviral treatment– n (%)[b] | 10 (90.9%) | 9 (81.8%) | | 1.00 | | | |
| Taking chronic opioids [c] -- n (%) | 6 (54.6%) | 7 (58.3%) | | 1.00 | | | |
| Taking pain medications [d] -- n (%) | 11 (100.0%) | 8 (66.7%) | | .093 | | | |
| Taking an antidepressant -- n (%) | 9 (81.8%) | 6 (50.0%) | | .193 | | | |
| Daily/ near daily marijuana use – n (%) | 3 (27.3%) | 4 (33.3%) | | 1.00 | | | |
| **Outcome Variables** | | | | | | | |
| Baseline pain interference- Mean (SD) [e] | 7.3 (±1.6) | 6.6 (± 2.0) | −0.83 | .404 | | | |
| Month 4 pain interference – Mean (SD)[e] | 5.5 (± 1.9) | 4.8 (± 2.7) | | | −0.39 (−1.36; 0.58) | 0.57 | .566 |

| | Descriptive Statistics | | Comparison between groups at baseline | | Comparison between groups in change from baseline to Month 4 | | |
|---|---|---|---|---|---|---|---|
| | HIV-PASS | HE | Wilcoxen rank-sum (or Fisher's exact test)[a] | p – value | d (95%CI) [g] | z[h] | p-value |
| Baseline QIDS total – Mean (SD) [e] | 14.1 (± 3.4) | 14.1 (± 3.5) | 0.03 | .975 | | | |
| Month 4 QIDS total – Mean (SD) [e] | 7.1 (± 3.5) | 11.1 (± 4.6) | | | −1.28 (−2.25; −0.31) | 2.29 | .023 |
| Baseline pain severity – Mean (SD) [e] | 6.9 (±1.6) | 6.6 (±1.8) | −0.35 | .728 | | | |
| Month 4 pain severity – Mean (SD) [e] | 5.8 (± 1.3) | 4.6 (±1.3) | | | 0.67 (−0.30; 1.64) | −0.97 | .332 |
| Baseline activities engagement – Mean (SD) [f] | 39.7 (± 6.9) | 35.5 (±12.7) | −0.87 | .385 | | | |
| Month 4 activities engagement – Mean (SD) [f] | 47.8 (± 7.3) | 39.9 (± 9.4) | | | 0.87 (−0.43; 2.17) | −1.22 | .224 |

[a] We used the nonparametric Wilcoxon rank-sum test and Fisher's exact test for between group comparisons on continuous and categorical baseline characteristics, respectively. There is no test statistic associated with Fisher's exact test.

[b] One subject in the HE arm reported no use of HIV medications at baseline assessment and was not included in this comparison.

[c] Includes daily use of suboxone, methadone, or other opioids.

[d] Includes both opioid and non-opioid medications used to control pain.

[e] These instruments were administered to all 23 participants at baseline and 20 (9 in HIV-PASs and 11 in HE) participants at follow-up, leaving change scores available for 20 participants.

[f] This instrument was administered to 15 participants (7 in HIV-PASS and 8 in HE) at baseline and 17 (8 in HIV-PASs and 9 in HE) participants at follow-up, leaving change scores available for only 12 participants.

[g] Cohen's standardized difference in mean change scores and 95% confidence interval estimate.

[h] z-values from nonparametric Wilcoxon rank-sum test for differences in rank-ordered distributions.