DEVELOPMENT AND IMPLEMENTATION OF AN HIV AND ANXIETY MANAGEMENT/REDUCTION PROGRAM (HAMRT)

A Dissertation

Presented to

The Faculty of the Department

Of Psychology

University of Houston

In Partial Fulfillment

Of the Requirements for the Degree of

Doctor of Philosophy

By

Charles P. Brandt II

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Abstract

The Human Immunodeficiency Virus (HIV) is a worldwide pandemic affecting over 35 million individuals worldwide. Though revolutions in antiretroviral medications can control the virus and enable infected individuals to live full lifespans with the disease, upwards of half of all persons living with HIV/AIDS (PLWHA) are not appropriately adherent to their medication. This underadherence leads to higher than expected rates of mortality, disease spread, and increasing the financial burden on the global healthcare system. Recent research has indicated that mental health disorders, particularly anxiety, predicts poor antiretroviral medication adherence.

Despite this knowledge, there have not yet been treatments developed specifically to increase medication adherence via the reduction of anxiety among PLWHA. The present study aimed to fill in this gap by developing and implementing a six-session CBT-based integrated treatment/management program for PLWHA with concurrent anxiety that impedes success of HIV management. The recruited sample included 42 PLWHA (M_{age} = 46.95, *SD* = 9.93, *range* = 21-61, 45.2% female) who were randomized to either an active treatment condition, or a waitlist control condition of equal length. Participants were assessed pre-randomization, at the mid-treatment time point (after three sessions for the active participants and three weeks for the control participants) and post-treatment (six sessions for active participants, six weeks for control participants). Active participants were then re-assessed at 1-, 3-, and 6-months post-treatment.

Attrition was high for the active condition (i.e., 73.2%). Results indicated notable effect sizes between the active and control conditions on most outcome variables including HIV medication adherence (Partial Eta Squared = .189), anxiety symptoms (Cohen's D = .64), anxiety sensitivity (Cohen's D = 1.5), Depressive symptoms (Cohen's D = .8), and multiple quality of life indices (range of Cohen's D = .43 – 1.73). These findings are discussed in terms

of the feasibility and utility of administering an anxiety-reduction therapy program specifically designed for PLWHA with HIV medication adherence difficulties.

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Development and Implementation of an HIV Anxiety Reduction/Management Program (HAMRT)

HIV and AIDS

The human immunodeficiency virus (HIV) is an infectious disease that is transmitted via exposure to contaminated bodily fluids (e.g., blood, semen). The virus replicates in the human white blood cells, rendering these cells useless. As a result, unimpeded spread of HIV in the human body will result in a weakened immune system, enabling cancers and other opportunistic infections to spread and eventually kill their human host. Acquired immunodeficiency syndrome (AIDS) is a progression of the HIV virus to the point that the human immune system is no longer able to fight off infection. Specifically, an AIDS diagnosis occurs when the infected person has a white blood cell count of <200 cells per mL of blood (1000 cells per mL being the average for a non-immunocompromised individual) or an individual is infected with an opportunistic infection (e.g. Kaposi sarcoma, thrush, pneumonia).

Course of HIV Infection

Advances in medical treatment of HIV has changed course of infection in the past 30 years. Without medication, an average healthy person could expect to live about 10 years post initial HIV infection, with some succumbing to illness much faster (US Department of Health and Human Services, 2014). With medication, PLWHA can expect to live full lifespans with good medication management. As such, when conceptualizing people with HIV/AIDS, one must consider their time of infection and associated secondary effects from HIV as well as toxicity of prescribed HIV medication.

Changes in the HIV+ Population

Although in the U.S. HIV/AIDS once affected primarily White gay and bisexual men (Kelly & Murphy, 1992), it is now increasingly common among heterosexual men and women, children, and people of color (Centers for Disease Control, 2013). In the U.S., the most recent

estimates from 50 states, the District of Columbia, and 6 U.S. dependent areas, with long-term, confidential name-based HIV reporting, speculates that there are 1.1 to 1.2 million individuals living with HIV/AIDS (CDC, 2014). In 20010, approximately 44,000 new cases of HIV/AIDS were reported in the U.S., with the largest proportion of cases being among men who have sex with men (MSM; 60%) followed by persons infected through high-risk heterosexual contact (29%; CDC, 2014). In addition, it is alarming that almost three-quarters (72%) of these new cases are among people of color, given that people of color make up less than 40% of the population in these reporting states and dependent areas (US CensusBureau, 2015).

HIV Treatment

Combined antiretroviral therapy - cART - has been available since the mid 1990's (Leone et al., 2011). cART is a "cocktail" of medications that keeps HIV from spreading in the body through three mechanisms: 1) cART blocks the HIV from entering new cells, 2) cART disables HIV from binding to the RNA within cells, and 3) cART stops the replication process of HIV that is already within cells (US Department of Health and Human Services, 2014). Appropriate use of this medication (i.e., daily adherence) keeps HIV from replicating, prolonging the individuals life. One caveat of cART is that it must be adhered to at a 95% rate to be optimally effective (Paterson et al., 2000) and suboptimal adherence can lead to viral drug resistance (Hirsch et al., 1998). Research has shown that optimal medication adherence leads to longer survival rates (Lohse et al., 2007) higher quality of life (O'Cleirigh, Skeer, Mayer, & Safren, 2009) higher CD4 T-cell counts (O'Cleirigh et al., 2009), and lower rates of disease transmission (Fang et al., 2004; Warszawski et al., 2008) among PLWHA.

Side Effects of cART

Initial versions of cART and its precursors (e.g. AZT) were accompanied by a range of harmful side effects including rash, peripheral neuropathy, anemia (Abdella, Wabe, & Yesuf, 2011), cognitive decline and neuropathy (e.g., Robertson et al., 2011; Starace et al., 2002), and

others such as wasting and lipodystrophy (Polsky, Kotler, & Steinhart, 2001). Over time, newer iterations of cART have become less toxic and the side-effects have become less severe, however, side effects for even the most recent HIV medications are present, with upwards of 50% of PLWHA reporting side effects on most regimen (for a review see Achenbach, Scarsi, & Murphy, 2010). Unfortunately, these side effects, in combination with other physical and psychological factors, have a profound impact on adherence to medication.

Adherence to cART

Although cART has enabled HIV+ individuals to live full lifespans after infection, sub-optimal adherence to this medication is problematic (Bonolo Pde et al., 2005; Charania et al., 2014). National research has indicated suboptimal medication adherence rates are upwards of 50% among PLWHA (e.g., Atkinson & Petrozzino, 2009; Howard et al., 2002; Paterson et al., 2000). This reduced cART utilization is problematic for three reasons. First, among PLWHA with poor cART utilization, rates of disease and death are markedly higher when compared to their adherent counterparts (Gange et al., 2002). Second, cART adherence lowers the infectiousness of PLWHA. With appropriate medication management, rates of HIV infection to non-infected sexual partners is extremely low (Anema et al., 2008), thus poor adherence may be related to increases in global and national HIV infection rates. Third, medication nonadherence applies an unnecessary strain to the global healthcare system, as indicated by the increase in total cost of medical care for under-adherent individuals compared to their adherent counterparts (Gebo et al., 2010). Anxiety has been implicated as a predictor of poor adherence among PLWHA, but has been understudied to this point.

Anxiety

In contemporary work, “anxiety states” are typically viewed as a multidimensional emotional process that can be conceptually understood according to a “three channel response system” (sometimes referred to as a “triple-response mode” or “three-response mode”) that

includes physiological, cognitive, and overt behaviors (Lang, 1994). Physiological responses associated with anxiety involve a variety of bodily systems, and lead to such changes as increased heart rate, sweating, muscle tension, and respiration. Cognitive responses include processes such as thoughts, beliefs, and memories. Because it is impossible to directly observe thoughts, and often difficult to assess physiological processes, an individual's self-report of these events is frequently necessary for assessment. Overt anxious behavior most often involves avoidance of situations and/or objects, or may include prematurely leaving an event (i.e., "escaping").

It should be noted that channels of "anxiety states" (i.e., physiological, cognitive, and motor behavior) often are *independent* of one another (Rachman & Lopatka, 1986). As an example, a woman who abruptly experiences heart palpitations and feelings of impending doom associated with panic while in a movie theater may not verbally report a panic attack. Yet, she may leave the immediate situation (i.e., "escape"), if possible, and may be more likely to avoid such situation in the future. In this case, anxious physiological and overt behavioral responses are evident, even though verbal reports of anxiety are not present. Thus, there is often *discordance* among these response channels, and just because a person does not say "I feel anxious" at any one time point does not necessarily mean that he or she is not having problems with anxiety. In a similar way, there often is response *desynchrony* (Rachman & Lopatka, 1986), whereby the relation between two behavior channels respond to treatment at dissimilar rates over time. Often, one channel is expected to change first, and the others improve more slowly, although the exact sequence may vary by type of anxiety and setting events (Lang, 1994).

Many qualitatively distinct states are categorized under the general label of "anxiety." That is, all anxiety states are characterized by the aforementioned three channels of behavior, yet they differ in regard to core parameters of response such as duration, magnitude, as well as type of environmental cues associated with the specific form of anxiety being studied. Anxiety is

most often conceptualized as a primarily cognitive-affective state characterized by cognitive shifts that focus attention on *approaching* threat and danger (Craske, 1999). Thus, it is best conceptualized as a state of “active mobilization and ongoing vigilance” and can be contrasted to that of worry, whereby the individual is in a state of “preparation and readiness.” The future-oriented nature of anxiety for approaching sources of threat typically means that individuals show less dramatic signs of change in physiological systems compared to fearful or panicked states, and greater levels of more elaborate cognitive-based responses (e.g., “This is a dangerous situation and I need to be vigilant in case I need to respond;" Lang, 1994). Anxiety also tends to be longer in duration (e.g., lasting for hours at times at the extreme) compared to fear or panic states, which last on the order of 10 minutes or less (Lang, 1994). In this sense, anxiety can be considered more of a mood state than a specific emotional episode (Lang, 1994).

Although there has been debate about the distinctions between fear and panic states, most scholars now theorize that these two states are more similar than different (Craske, 1999). Fear and panic states both involve active fight-flight-freeze responses and are characterized by a high degree of physiological activation (e.g., heart rate change), threat-oriented behavioral responses (e.g., escape), and low-level cognition (e.g., “I need to flee this situation now”). Thus, fear and panic states are oriented on *imminent* threat (cf. approaching or potential threat; Gray & McNaughton, 1996). Notwithstanding these similarities between fear and panic, one domain where they sometimes differ is in regard to the identification of the source of threat (Craske, 1999). Here, research suggests that when an individual experiences a fear state as “out of the blue” they typically refer to this experience as a “panic attack.” In contrast, when a source threat is identified, they are more apt to label the emotional state as “fear” (seeG. R. Norton, Cox, & Malan, 1992for a review). For the purposes of the present review, from this point forward, I use the terms panic and fear interchangeably.

When anxiety-related states interfere with life functioning, an anxiety disorder diagnosis is warranted (American PsychiatricAssociation, 2000). In the current study DSM-IV-TR criteria will be used, because at the time of program initiation, adequate diagnostic tools for DSM-V defined anxiety disorders have not been developed. Additionally because we wish to examine the fear reaching effects of *anxiety* instead of specific anxiety diagnoses, the minor differences in diagnostic criteria between DSM-IV-TR and DSM-V will not greatly affect the outcomes of this study. According to the DSM-IV-TR (APA, 2000), anxiety disorders include disorders that share features of excessive fear (emotional response to real or perceived threat) and anxiety (anticipation of future threat) that interfere with daily activities and are present for prolonged periods of time. Please see Table 1 for an outline of DSM-IV-TR anxiety disorders. Because of the similarities across anxiety disorders, the current study will aim to treat anxiety pathology, not disorder-specific anxiety. However, anxiety disorders were diagnosed and tracked to monitor participant progress in treatment.

Although there has historically been a focus on anxiety disorders (diagnostic categories), the National Institute of Mental Health's Research Domain Criteria (RDoC) recent initiative has indicated a change in focus to seek to identify biobehavioral dimensions that are common across several disorders, and then, relate those dimensions to specific biological processes (Insel et al., 2010; Sanislow et al., 2010). Therefore, there is an increased level of scientific attention focused on the processes underlying specific anxiety disorders and how generalizable they are to other psychopathological conditions. At present, there has been little effort to relate the study of anxiety to RDoC criteria among the HIV/AIDS population; an issue I will discuss in greater detail later in this dissertation. In the following, therefore, I have reviewed only studies that focus on anxiety disorders among PLWHA.

Co-Occurrence of Anxiety and HIV

Common Methodological Issues

Assessment of psychiatric diagnosis. Across studies reviewed, the assessment of psychiatric status varied considerably. To ease interpretation, whenever possible (i.e., if diagnostic method is reported), the diagnostic methodology employed will be included, as will the time course of the diagnosis (i.e., lifetime vs. past year vs. current diagnosis). However, investigators often did not provide information regarding training and reliability estimates for diagnostic procedures; rather than repeat this issue in the review, I opt to simply note it from the outset.

Comorbidity (or, multimorbidity). There is great variability across studies reviewed in the consideration of the role of comorbid substance use (e.g., alcohol), physical (e.g., heart disease), and psychological conditions (e.g., depression) when examining the anxiety-HIV/AIDS association. Given such co-occurring conditions can markedly affect interpretation of anxiety-HIV/AIDS relations (e.g., it may be unclear whether a given finding is due to non-anxiety mood states or conditions); care was taken to specifically delineate this methodological characteristic for each study reviewed. For instance, if problematic alcohol use also was examined in a given study, the relation between such problems and anxiety-HIV/AIDS phenomena will be detailed.

Anxiety Disorders among the HIV/AIDS Population

Existing studies examining prevalence of anxiety disorders among PLWHA were evaluated using two methodologies. First, each study was reviewed individually and important information (i.e., authors, study characteristics including sample size and sample population, inclusion of a control or comparison group, anxiety measurement technique utilized, and rates of anxiety disorders) was synthesized in a table format (please see Tables 2-4). Of note, anxiety disorders among PLWHA may vary as a result of the referenced population. For instance, different emotional responses may be elicited in developing countries where HIV infection is often a terminal diagnosis compared to developed countries where life-prolonging medication is more readily available. Additionally, it may be that anxiety among PLWHA is more or less

common than HIV among persons living with anxiety. As such, articles examining anxiety-HIV/AIDS comorbidity were grouped into three population sets: (1) the extent to which anxiety disorders are present among PLWHA in the U.S. and other developed countries (17 studies; see Table 2); (2) the extent to which anxiety disorders are present among PLWHA in developing countries or regions (11 studies; see Table 3); and (3) rates of HIV among anxiety-disordered persons (1 study; see Table 4). Second, in order to visually interpret prevalence of anxiety among PLWHA across these studies, box and whisker plots were constructed to indicate median prevalence rates, as well as first and third quartiles, and sample high and low prevalence values (see Figures 1-4). Here, each study was weighed equally regardless of sample size. When examining the prevalence of anxiety disorders across studies, a number of discernable patterns emerge as well as a number of limitations to the extant literature. The following observations are particularly important to this dissertation.

First, rates of anxiety disorders diagnoses were significantly higher when questionnaire-based assessments (median = 33.3%) as compared to a diagnostic interview (median = 22.85%; see Figure 1) were employed. This finding is not particularly surprising, as diagnostic interviews are generally more stringent than questionnaires, including assessment of symptom interference, as opposed to symptom profiles (Andrews, Hejdenberg, & Wilding, 2006). Nonetheless, the high rate of diagnoses per questionnaire provides broad-scale evidence of elevated anxiety symptom profiles among PLWHA. Second, when examining rates of anxiety disorder diagnoses among all studies utilizing diagnostic interview (i.e., developed and developing countries; *n* = 6-16; See Figure 2), prevalence rates for anxiety disorders are notably higher among PLWHA than the general population. For instance, the median value of anxiety disorders among PLWHA in the reviewed studies was 22.85%, which is notably higher than the general population (18%; Kessler et al., 2005). When examining specific anxiety disorders individually, similar trends emerge for panic disorder (10.26% among PLWHA, compared to 3%

for the general population), GAD (5.6% compared to 2.5%), and social anxiety disorder (9.1% compared to 6%). One disorder that does not follow this trend is specific phobia, where 3.85% of PLWHA meet criteria for this illness compared to approximately 8% in the general population. Although studies have found generally high rates of anxiety disorders among PLWHA (median prevalence rate across all studies = 27.9%; range 1% to 47.8%), control/comparison groups have rarely been employed in such work. Therefore, it is challenging to ascertain the nature of 'true' differences in base rates of anxiety disorders among PLWHA versus non HIV+ samples.

Third, rates of anxiety disorders as diagnosed using diagnostic interview are higher among developed countries (median = 28.5%) compared to developing countries (median = 22.85%; see Figure 3). Also of note, rates of panic disorder are also notably higher among PLWHA in developed countries (median = 9.5%) compared to developing countries (median = 1.7%). The indication that PLWHA in developed countries present with anxiety disorders at higher rates than those found in developing countries may be due to a number of factors. For instance, stigma and knowledge about mental health may impact diagnostic presentation, as some studies in developing countries reported prevalence rates as low as 1% for any anxiety disorder. Additionally, given that HIV is still a terminal illness in some parts of the world, depression, instead of anxiety, may be a more common emotional response. For instance, in Nebhinani and colleagues (2011) found rates of anxiety disorders to be approximately 1% among PLWHA in India, but rates of depressive disorders almost 50% in the same sample. Additional work is necessary to understand the impact of culture and related factors on mental health among PLWHA.

Fourth, when examining rate of anxiety disorders among specific drug-using PLWHA compared to PLWHA who were not specifically selected for their drug-use status, rates of any anxiety disorder were notably higher among non-drug users compared to drug users (See Figure 4). However, rates of panic disorder were higher among drug-users compared to non-

drug users. This finding is in line with existing literature indicating that drug users may have a higher sensitivity to physical sensations, and may use drugs to escape these sensations, or be unable to quit using drugs because of withdrawal effects (Cox, Norton, Swinson, & Endler, 1990). However, a small number of samples limit the utility of this work, and additional research is needed to more fully understand these relations.

Fifth, it is important to note that one limiting factor of the existing literature is that there is limited work examining rates of anxiety disorders across different population groups with high rates of HIV infection. In particular, men who have sex with men (MSM) comprise over half of all HIV infections nationally, as well as an increasing number of new infections annually (CDC, 2013). There may be reason to theorize that MSM may have higher rates of anxiety disorders, as sexual minorities are more vulnerable to emotion dysregulation, more sensitive to interpersonal rejection, and more apt to feel stigmatized (for a review, see Pachankis, Hatzenbuehler, Rendina, Safren, & Parsons, 2015). Future work examining rates of anxiety among this population specifically, as well as other groups indexing high rates of HIV infection (e.g., drug users, low SES women) more generally, is an important next step to more fully understand the etiology and impact that anxiety may have among PLWHA.

Sixth, it is yet not clear whether the strength of the observed associations between anxiety and HIV is attenuated when psychiatric comorbidity, particularly substance use disorders and other medical disorders, is controlled/adjusted. As predicted by syndemic models of health, because HIV and anxiety comorbidity may co-occur within a larger context of substance use and health behavior (e.g., O'Cleirigh et al., 2008), future work is needed to explore how such co-occurring processes (in combination) affect the observed relations. Given the frequent absence of assessment of other health behavior and substance use in the above reviewed studies, future research would increase our understanding of this issue by assessing and reporting rates of polysubstance use and how such use relates to HIV-anxiety comorbidity.

Finally, it is important to remember that across all reviewed work, none of the studies have employed an empirically-derived representative sample. Thus, it is not possible to rule out the role of systematic sampling biases across this body of work. For example, the vast majority of studies documenting HIV-anxiety co-occurrence have been conducted in samples seeking treatment for anxiety or anxiety-related issues. These sites may increase the probability of self-selection biases (e.g., more severe psychopathology, high degree of mental health knowledge), and therefore, should not be considered uniformly applicable to the larger population. Alternatively, PLWHA engaged in care may represent a healthier sample that PLWHA not linked to care, or PLWHA unaware of their HIV status.

Effects of Anxiety on HIV Management

Given the documented HIV/AIDS-anxiety association, a next task is to explicate the extent to which these conditions may influence other important outcomes such as HIV disease management. In this context, it is important to remember that multiple bi-directional processes are potentially applicable across various stages of disorder development and disease stage. For example, HIV/AIDS may increase the risk for developing anxiety symptoms and disorders, while at the same time anxiety states may exacerbate the severity of HIV/AIDS and each instance may affect medical management of HIV differently. For the current proposal I focused on studies that specifically examined rates of anxiety disorders among PLWHA, and discussed the role of HIV/anxiety in HIV management. Please See Table 5 for information pertaining to these studies.

Cross-sectional work has generally supported an association between anxiety and HIV medication adherence problems. For example, Catz, Heckman, Kochman, and DiMarco (2001) examined 113 older HIV+ persons and found that participants adhering to their medication, as indexed by self-reported adherence in the past week, had lower levels of anxiety and somatization, as indexed by the Symptom Checklist-90 Revised (SCL-90-R; Derogatis, 1983). Van Servellen and colleagues (2002) also found that among 182 PLWHA, anxiety symptoms,

measured via the HADS, were related to self-rated HIV medication adherence which was confirmed via medical record review (van Servellen et al., 2002). In line with these studies, Mellins and colleagues (2002) reported that among 128 HIV+ women, psychiatric disorders (including anxiety disorders) diagnosed using the Clinical Diagnostic Questionnaire (CDQ; Aidala et al., 2004), were associated with worse HIV medication adherence measured by self-report from the Adult AIDS Clinical Trials Group (AACTG; Chesney et al., 2000). Unfortunately, anxiety disorders were not separated from the other psychiatric disorders, and therefore, it is unclear how specific the findings are to anxiety versus other clinical psychiatric conditions. Escobar and colleagues (2003) examined 283 PLWHA and found that patients who were not adherent to their HIV medications, as assessed by prescriptions filled in the past 6 months, were more likely to index high state and/or trait anxiety, as measured using the STAI. Another study (Schönnesson, Diamond, Ross, Williams, & Bratt, 2006) examined 193 HIV-infected Swedish persons and indicated that anxiety symptoms, measured by the anxiety subscale of the Brief Symptom Inventory, significantly predicted HIV medication nonadherence, measured by self-report and confirmed with patients' medical records. A large cross-sectional study measuring anxiety symptoms among French HIV-infected individuals similarly indicated that anxiety symptoms, as measured by the HADS, predicted self-reported cART nonadherence among HIV+ men, but not women, taking anxiolytics (Roux et al., 2009). Finally, Kosiba and colleagues (2014) examined rates of panic disorder among 131 HIV-positive adults in treatment for opioid use, indicating that panic disorder status, as indicated by the Miniature International Diagnostic Interview Schedule for Psychiatric Illness (MINI; Sheehan et al., 1998), significantly predicted HIV medication adherence, as measured using the ACTG-SDM.

There are also a number of prospective studies indicating that anxiety is related to HIV medication non-adherence. Tucker and colleagues (2003) prospectively examined 1,910 HIV+ persons from the HIV Cost and Services Utilization Study. They reported that the presence of

generalized anxiety disorder and panic disorder, measured by the World Health Organization composite international diagnostic interview short-form (CIDI-SF; Kessler, Andrews, Mroczek, Ustun, & Wittchen, 1998), were related to self-reported HIV medication non-adherence one year later. Another prospective study examined 96 injection drug using French PLWHA, and found self-reported anxiety symptoms predicted self-reported non-adherence to HIV medications at 6-, 12-, and 18-months post-initial interview (Carrieri et al., 2003). Campos and colleagues (2010) prospectively measured anxiety symptoms using the HADS and medication adherence via self-report, among 293 Brazilian PLWHA. Results of this study similarly indicated that symptoms of severe anxiety at the initiation of HIV medications were significant predictors of non-adherence.

A small number of studies suggest a modest association between anxiety and HIV medication adherence. For instance, Palmer and colleagues (2003) indicated that among 107 opioid-addicted PLWHA reporting at least one psychiatric diagnosis and at least one additional substance use disorder (as indicated by the SCID-I), anxiety disorders were not related to HIV medication non-adherence. Notably, this study utilized cross-sectional data and examined anxiety as an ancillary outcome. Moreover, by virtue of the study entry criteria, variability in anxiety states may have been truncated, limiting statistical power. In another cross-sectional study among 58 HIV+ homeless injection drug users, anxiety measured by the STAI approached, but did not reach statistical significance in predicting self-reported HIV medication non-adherence (Waldrop-Valverde & Valverde, 2005). Due to the small sample size, limited statistical power is an important caveat to this study. In another secondary and cross-sectional analysis, Nel and Kagee (2013) found that among 101 South African PLWHA symptoms of anxiety, as measured by the Beck Anxiety Inventory (Beck & Steer, 1993), did not significantly predict self-reported HIV medication adherence.

Together, of the 13 examining anxiety and HIV medication adherence, 10 suggested a direct relation between increased anxiety and HIV medication non-adherence. The three studies

not reporting such a relation appear underpowered and may also have had a truncated range of variability. Importantly, almost all studies have utilized self-report indices of medication adherence. Future work is needed that incorporates biologic indicators of adherence (e.g., blood draw to detect presence of medication; Desmond, Moodley, Conolly, Castel, & Coovadia, 2015) in addition to self-report indices. Nonetheless, given extant findings, future theory-driven tests of how anxiety is related to HIV medication adherence would indeed be useful. A number of candidate pathways exist. As one illustrative example, the misinterpretation of bodily sensations (i.e., "catastrophic thinking") may be related to poorer medication adherence. Antiretroviral medication regimens produce a number of adverse physiological side effects (e.g., rash, peripheral neuropathy, anemia). A distorted cognitive reaction to such medication-based sensations (e.g., " I cannot tolerate this distress any longer") may result in poorer medication adherence; that is, the individual may stop or decrease using their HIV medication because they are hypersensitive to its perceived or objective effects. This type of perspective could be explored in future work along with other theoretically-grounded mechanisms.

Existing Treatments for Anxiety among PLWHA

Given the high rate of anxiety disorders found among PLWHA and effects of anxiety on HIV medication adherence, the development of treatments specific to HIV and anxiety is an important area for development. To date, multiple treatment studies have been developed that are specific to PLWHA. Please see Table 6 for an outline of current HIV/Anxiety interventions, and see below for these interventions separated by therapeutic modality.

Psychodynamic Therapy

Psychodynamic therapy aims to reduce psychological distress by uncovering and addressing unconscious conflicts (e.g., Busch, Milrod, & Singer, 1999). For example, an HIV+ person may possess underlying conflicts with between their sexuality and “acceptable” sexuality, leading to the use of anxiety or depression as defense mechanisms (Weiss, 1997).

Other posited conflicts include pain, blame, and shame, among others (Weiss, 1997). A small corpus of work including of case studies, vignettes, and books discuss possible conflicts at work among PLWHA and indicate that exploration of these topics can result in reduced anxiety or depression symptoms (e.g., Barratt, 1996). One empirical study examined the effectiveness of a 20-session time-limited dynamic psychotherapy protocol among a sample of 79 gay HIV+ men (Pobuda, Crothers, Goldblum, Dilley, & Koopman, 2008). This study found that this short-term psychodynamic therapy resulted in significant improvement with regard to overall functioning including reductions in anxiety, depression, interpersonal difficulties, and challenges related to work and school. However, this study did not include a comparison control group, did not include long-term follow up data, and tested only a narrow sample of mostly Caucasian gay males. To date, no follow up studies have expanded upon this work.

Mindfulness-based Stress Reduction (MBSR)

MSBR integrates traditional Buddhist mindfulness processes and psychoeducation into a secular therapy aimed at increasing moment-to-moment awareness thereby lowering symptoms of mental health disorders (Kabat-Zinn, Lipworth, & Burney, 1985). Initially, MBSR was primarily aimed at helping individuals living with chronic pain and disease (Kabat-Zinn et al., 1985), though over time MSBR has been administered to individuals with a range of psychological and physical problems with positive results (see Grossman, Niemann, Schmidt, & Walach, 2004 for a review). To date, two randomized controlled trials of MBSR among PLWHA with have been conducted which broadly address anxiety. The first is a study of 76 PLWHA indicating that those receiving an MBSR program experienced a reduction of negative symptoms associated with HIV-medication as well as distress associated with those symptoms up to three months post intervention (Duncan et al., 2012). Results of this study showed non-significant negative trends in depression and affect. The second study included 117 HIV+ men and indicated that MBSR, when compared to treatment-as-usual, was related to lower avoidance and higher positive affect

post-intervention (Gayner et al., 2012). Results also indicated that across all groups increase in mindfulness was related to reduction in avoidance, higher positive affect, and improvements in depression. Though there are some positive effects of MSBR among PLWHA, these results are underwhelming and even contradictory. Additionally, long-term follow-up data were not provided, and samples included mostly Caucasian gay males.

Mindfulness-based Cognitive Therapy (MBCT)

MBCT is an umbrella term that encompasses treatments incorporating mindfulness and mindful meditation strategies into traditional CBT methods (Crane, 2009). Initially designed to help patients with treatment-resistant depression, MBCT has been shown to be effective at reducing rates of anxiety, mood, and substance use disorders across populations (e.g., Hoppes, 2006; McManus, Surawy, Muse, Vazquez-Montes, & Williams, 2012; Munshi, Eisendrath, & Delucchi, 2013). To date, there has been one study that examine MBCT among an HIV+ population. Gonzalez-Garcia et al. (2014) indicated that those receiving MBCT showed significant differences in quality of life, psychological stress, depressive symptoms, and anxiety symptoms when compared to a wait-list control group. Despite this work, further study is needed using larger samples and longer follow-ups to examine the effectiveness of MBCT over time.

Cognitive Therapy (CT)

Cognitive Therapy is based upon the cognitive model of psychopathology which posits that thoughts, feelings, and behaviors are all interconnected, and that individuals can overcome psychopathology by identifying and changing unhelpful or inaccurate thinking (Beck, 1976). Identification of unhelpful or unrealistic thought patterns may indeed be helpful for PLWHA, as this population has a host of vulnerabilities for pathology above and beyond the general population - including negative ruminative thought patterns regarding HIV infection (Gluhoski, 1996; McIntosh, Seay, Antoni, & Schneiderman, 2013). To date, utilizing CT one case study has been published (Gluhoski, 1997) underpinning the utility of CT among PLWHA. A more recent

cognitive-based coping intervention has also been shown to decrease negative affect, intrusive ideation, and anxiety among a sample of 90 hospitalized HIV-positive men (Côté & Pepler, 2002). In total, CT has shown utility in reducing anxiety, mood, and substance use disorders among PLWHA, but a small research base and other methodological limitations limit its generalizability and overall effectiveness. Though some exploratory evidence has indicated that CT may be affective at reducing depression among PLWHA, replication among larger and more diverse samples is needed.

Cognitive Behavioral Therapy (CBT)

To date CBT has been the most researched therapeutic option for reducing anxiety among PLWHA. CBT aims to identify automatic negative thoughts that affect behavior, and systematically change those thoughts and behaviors in order to reduce symptomology (Clark & Beck, 2010). A recent review of CBT interventions for mood and anxiety disorders among PLWHA (Spies, Asmal, & Seedat, 2013, See Table 6 for individual studies) indicated that well-performed CBT interventions elicit significant reductions in overall levels of anxiety and depression among this population when compared with control groups. Related studies have also indicated that CBT can reduce alcohol use, alcohol dependence symptoms (Esposito-Smythers et al., 2014), and use of other substances (Daughters, Magidson, Schuster, & Safren, 2010) compared to control groups. Though CBT has been the most widely used psychological treatment for PLWHA, a number of common limitations occur across existing studies. For instance, rates of treatment drop out for HIV+ individuals undergoing CBT are high; estimated around 50% (Poole et al., 2001). A treatment approach that is more easily attended by PLWHA will be important to reach more clients. Furthermore, there is little evidence of the long-term utility of CBT among this population, as there are very few studies with follow-up time points longer than 1-3 months after completion of treatment (Spies et al., 2013). It is difficult to gauge the long-term success of CBT among PLWHA without appropriate follow up information. Finally,

no existing CBT treatment for anxiety disorders specifically discusses the interpretation of bodily symptoms, nor do any include anxiety sensitivity reduction components. Such an omission is a weakness, as the interpretation of bodily sensations is an important maintenance factor for anxiety among PLWHA.

Limitations in Current Treatment Directions

Significant strides in helping PLWHA with problems adhering to HIV medication will likely be found in the ability to develop novel, targeted anxiety treatments (for a review see Campos et al., 2008). The lack of research aimed at examining and reducing rates of anxiety symptoms and disorders among PLWHA is surprising, as studies have consistently documented a clinically and statistically strong relation between HIV infection and anxiety (Kemppainen, MacKain, & Reyes, 2013; Morrison et al., 2002). Though there is work indicating that current psychological interventions can reduce rates of anxiety disorders among PLWHA, there are common limitations. First, there is a lack of follow-up data for these treatments, with most studies following patients for only one month after treatment completion, and many studies having no follow ups at all. This lack of information casts doubt on these programs' overall effectiveness. Second, high dropout rates indicate that these treatments are not suitable to enough individuals within this population (e.g., Johnson et al., 2008; Pecoraro et al., 2013). Third, these treatments generally do not help patients understand aversive physical symptoms that accompany HIV, an important process in living with such symptoms.

Existing clinical trials have proven that it is possible to decrease anxiety symptoms among PLWHA, but an array of limitations suggests that a more focused approach is necessary. This project aims to build on previous work to create and test a novel anxiety-reduction therapy program for PLWHA. In order to maximize the potential impact of this program, I will focus outcomes on two important areas: medication adherence and anxiety symptoms and impact.

Integrated Treatment for HIV and Anxiety: A Working Theoretical Model

Based on research explicating the bi-directional effect of HIV and anxiety, and current treatment options available, I have constructed a working, integrative conceptual model of anxiety and its' effect among PLWHA, as well as a next-step treatment option. At its' core, this model recognizes the impact of emotional and cognitive factors that impact anxiety and HIV, and the importance of addressing these issues prior to the implementation of exposure exercises, common for current anxiety treatments.

Anxiety and HIV

In the search for factors that influence cART adherence, research has indicated a strong link with mental health. Specifically, existing research has indicated that anxiety symptoms and disorders can affect medication adherence among PLWHA such that higher rates of anxiety predicts higher rates of missed medication doses (Antoni, 2003; Nilsson Schonnesson et al., 2006; van Servellen et al., 2002). This finding is alarming, given the high rates of anxiety and mood disorders evidenced by the HIV+ community (Bing et al., 2001; Kessler, Chiu, Demler, & Walters, 2005; Please additionally see Figure 1).

HIV and certain anxiety symptoms – such as panic attacks and worry, which are common across all anxiety disorders – have in common many bodily symptoms. The relationship between anxiety symptoms and physical health is important since research indicates that disease-specific bodily symptoms are experienced by 50-80% of HIV+ individuals (Aouizerat et al., 2010; Singer et al., 1993). One common and clinically significant pathway by which anxiety affects HIV may be the misinterpretation and catastorphization of bodily sensations (Carleton, Abrams, Kachur, & Asmundson, 2009). For example, antiretroviral medication regimens are complex and produce a number of physiological side effects including rash, peripheral neuropathy, anemia (Abdella et al., 2011). A distorted cognitive reaction to such medication-based sensations (e.g., " I cannot tolerate this distress any longer") has been shown

to result in poorer medication adherence (Aberg, 2009; Volberding & Deeks, 2010). That is, the individual may stop using their medication because they are hypersensitive to its effects.

Given that the symptoms of HIV and anxiety can present similarly, it is not surprising that individuals often mistake anxiety symptoms for a worsening of HIV symptoms (Gonzalez, Zvolensky, Solomon, & Miller, 2010). In addition to the psychological effects of these symptoms, higher rates of anxiety symptoms can facilitate disease progression. For example, anxiety can disrupt the hypothalamic pituitary adrenocortical (HPA) and sympathetic adrenal medullary (SAM) systems, elevating levels of norepinephrine and cortisol, which each have been independently linked to HIV disease progression (Ironson et al., 2014; Leserman et al., 2000). Additionally, higher levels of autonomic nervous system activity resulting from anxiety have been associated with poor response to cART therapy (Cole et al., 2001). Evidence indicates that these processes work cyclically to produce poor mental and physical health outcomes, as HIV-related symptoms increase anxiety symptoms (Gonzalez et al., 2010), which in turn, can increase HIV symptoms (Huggins, Bonn-Miller, Oser, Sorrell, & Trafton, 2012). It is, therefore, important to provide patients with the tools to distinguish between HIV and anxiety symptoms.

There is a vast literature indicating that mental health plays a significant role in health behaviors, including medication adherence, among PLWHA. PLWHA who suffer from anxiety disorders are more likely to exhibit poor HIV symptom control and management, compared to those without anxiety disorders (Antoni, 2003). Co-occurring anxiety is also associated with the perception of more severe HIV symptoms (Sewell et al., 2000), increased functional impairment, and higher levels of medical care (Leserman et al., 2005). Evidence has indicated that the primary way that anxiety and HIV serve to exacerbate one another is through common bodily sensations.

HIV and bodily symptoms

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HIV and anxiety sensitivity

Anxiety sensitivity is an individual difference factor reflecting the tendency to fear anxiety-related sensations (Reiss, Peterson, Gursky, & McNally, 1986), and represents a core transdiagnostic vulnerability factor for the etiology and maintenance of multiple anxiety disorders (e.g., panic and social anxiety) and other emotional disorders (e.g., depression and PTSD, Hayward, Killen, Kraemer, & Taylor, 2000; Maller & Reiss, 1992; Marshall, Miles, & Stewart, 2010; McNally, 2003; Schmidt, Lerew, & Jackson, 1999; Schmidt, Zvolensky, & Maner, 2006; Taylor, 2003). Given that PLWHA experience a range of aversive bodily sensations specific to the disease including headache, nausea, and fatigue (O'Connell-Edwards, Jones, Forehand, & Larkin, 2008); a tendency to fear such symptoms may be particularly impacting to this group. Overall, PLWHA who fear aversive bodily sensations caused by HIV but common with anxiety are more likely to be misinterpret to these sensations and view them as harmful or dangerous (e.g., Gonzalez, Zvolensky, Grover, & Parent, 2012; Gonzalez, Zvolensky, Parent, Grover, & Hickey, 2012). Because of the distress caused by the overlap of physical sensations and fear of such sensations, PLWHA with a concurrent anxiety disorder evidence lower levels of medication adherence than their less-anxious counterparts (Nilsson Schonnesson et al., 2006; van Servellen et al., 2002).

Overall, current treatments specific to HIV and anxiety have been limited in overall scope and effectiveness, and additionally hampered by a lack of focus on the impact of internal bodily sensations. The current study aims to improve upon these limitations by developing a novel therapy program that integrates issues relevant to both anxiety and depression symptoms and disorders.

Integrated Treatment for HIV and Anxiety: Treatment Development and Rational

Treatment Strategy

The HIV anxiety management-reduction treatment (HAMRT) utilized traditional CBT methods, as this therapeutic modality has shown the best utility for individuals suffering from anxiety. HAMRT also utilized a transdiagnostic approach, meaning underlying causes of anxiety were addressed instead of specific disorders. As such, this transdiagnostic anxiety treatment used CBT techniques to identify and eliminate reliance on processes that maintain anxiety and HIV symptoms. HIV education included HIV medication and symptom management techniques for improving disease control that were integrated within the protocol to teach patients skills to achieve their HIV control-related goals while simultaneously working to reduce their anxiety and other negative mood states (e.g. depression). Components of psychoeducation and the association of HIV-anxiety relations were integrated to facilitate better recognition and insight on how HIV and anxiety can be confused and can exacerbate each other. HAMRT was administered over 6 sessions and each session lasted approximately 50 minutes.

The Utility of Transdiagnostic CBT for the treatment of anxiety disorders

Norton and Hope (2005) published the first controlled trial of the efficacy of a transdiagnostic protocol and found that outcomes on clinician-rated severity (d = 1.42), caseness (d = 1.79), and idiographic fear-avoidance hierarchies (d = 1.42) were superior for patients receiving treatment compared to waitlist controls. Subsequent analyses showed that the treatment group improved more than waitlisted patients on self-reported comorbid depressive symptoms. Norton (2009) also has found no evidence for a session-by-diagnosis interaction for any principal or comorbid disorder, suggesting that patients benefited to a similar degree regardless of their DSM-IV anxiety diagnoses. Others have reported similar efficacy data from other distinct transdiagnostic anxiety protocols (Barlow, Allen, & Choate, 2004; Schmidt et al., 2012).

Transdiagnostic approaches offer several advantages compared to diagnosis-specific cognitive behavioral treatments (Craske & Barlow, 2008). First, transdiagnostic anxiety

treatments do not focus exclusively on a set of diagnosis-specific symptoms. Given that comorbidity among anxiety diagnoses is normative (Kessler et al., 2005; Watson, Swan, & Nathan, 2011), transdiagnostic approaches address the entire spectrum of an individual's fears within a single model, rather than sequentially treating disorders. Second, transdiagnostic treatments for anxiety are seen as more community-friendly and broadly disseminable than diagnosis-specific treatments, as it would require practitioners to only train with, and utilize, a single treatment protocol in order to effectively work with the most common set of psychiatric disorders (Norton & Philipp, 2008). Finally, transdiagnostic anxiety treatments are apt to be more efficient and cost-effective than diagnosis-specific treatments.

Cognitive Behavioral Anxiety Reduction Component

In HAMRT, based on Dr. Peter Norton's transdiagnostic treatment and used with permission from him, sessions are active and practice-oriented (Norton & Hope, 2005). Homework non-compliance is addressed in session as a barrier to recovery.

Treatment Rationale.

In the integrated treatment, the importance of targeting anxiety psychopathology and HIV simultaneously was continuously emphasized. For instance, patients were provided with a cognitive-behavioral model describing the maintenance of both anxiety disorders and HIV independently as well their co-occurrence and interplay. Further, the rationale and procedures for each intervention module (psychoeducation, transdiagnostic anxiety treatment) were described in detail.

Psychoeducation

Patients received psychoeducation regarding the nature of anxiety and its disorders. After a review of the treatment rationale, the concept of a fear-avoidance hierarchy was discussed, and each participant developed a hierarchy with assistance from the therapists. In this treatment, psychoeducation regarding the relation of anxiety to HIV management was

provided and HIV-situations were included and emphasized in the fear hierarchy. *Cognitive Restructuring*. Automatic thoughts and cognitive restructuring were introduced with a thorough discussion of the importance of automatic thoughts in provoking anxious states. In time, patients were also taught the concept of thinking errors. The process of asking and answering disputing questions and developing rational responses was developed based on thought challenging. Homework included monitoring and disputing these thoughts. In this treatment, this component included an explicit focus on identification of cognitions related to HIV in and of itself as well as thoughts related to both HIV and anxiety. *Exposure and Response Prevention*. In-session graduated exposure and response prevention were introduced, negotiated, and planned. All exposures were preceded by cognitive restructuring of likely automatic thoughts.

HIV and Psychoeducation Component

Psychoeducation regarding HIV and medication management is associated with benefits across multiple HIV outcomes (Goujard et al., 2003). Basic information, including effects of medication, effects of medication adherence, effects of medication nonadherence, and possible side effects was provided and discussed with each patient.

Additional Treatment Guidelines

Similar to depression-HIV work conducted by others (e.g., Daughters et al., 2010), HAMRT was conducted in a Motivational Interviewing (MI) spirit. That is, MI techniques were used during CBT sessions to increase motivation to change anxious thoughts, as well as HIV management behaviors. Core principles of MI include identifying the discrepancy between current HIV control and goals for HIV control, and exploring ambivalence about changes needed to meet those goals. Motivation to change HIV management behaviors and insight into how anxiety and HIV may influence one another were developed over the course of treatment. MI techniques were used to explore ambivalence toward behavior change as well as confidence in

making changes. This approach has been employed in HIV-depression treatments and other chronic illness interventions.

Summary and Study Aims

Overall, there are few treatments developed that address anxiety among PLWHA, and those that have been developed do not adequately address the unique challenges faced by the HIV+ population. Accordingly, the primary aim of the present study was to implement a recently-developed anxiety-reduction treatment specific for PLWHA with the goal of increasing cART adherence via reducing overall anxiety. I hypothesized that a treatment developed using transdiagnostic CBT principals while simultaneously addressing the physical effects of HIV and anxiety will significantly reduce anxiety and significantly increase cART adherence compared to waitlist controls. Specifically, the following hypotheses were tested:

One

I hypothesized that I can implement an integrated HIV anxiety-reduction treatment program specifically for PLWHA.

Two

I hypothesized that clients completing the aforementioned treatment program will increase HIV medication adherence post-treatment completion as well as at 1-, 3-, and 6-month follow up sessions. I additionally hypothesized that those completing the protocol will evidence better HIV medication adherence than wait-list control participants. I expect these effects to be evident above and beyond age, race, gender, and markers of disease severity (e.g. CD4 cell count, viral load, time living with HIV).

Three

I hypothesized that clients completing the treatment program will additionally report decreased rates of mental health problems including: anxiety and depression at the end of treatment, and that those completing treatment will show significantly greater decreases than

waitlist controls. I expect these effects to be evident above and beyond age, race, gender, and markers of disease severity (e.g. CD4 cell count, viral load, time living with HIV).

Method and Approach

Participants

Adults living with HIV/AIDS were recruited via a variety of mechanisms. Methods included: flyers at local community health clinics (e.g., Legacy Community Health Services, Thomas Street Health Center), and local doctors' offices (e.g., Dr. Hunter Hammill), newspaper advertisements (e.g., Houston Greensheet), webpage announcements (e.g., Craigslist.com), public speaking engagements (e.g., Ryan White Foundation Houston, Houston AIDS Foundation) and via word-of-mouth. Inclusion criteria for the current study included: (1) HIV+, (2) between age 18-65, (3) capable of providing informed consent, (4) reporting high trait anxiety, indexed by a STAI-T score (> 39) reflecting clinically-relevant anxiety symptoms (Addolorato et al., 1999), and (5) having demonstrated poor cART medication adherence, defined by missing more than one dose in the last two weeks (e.g. 95% adherence; Lima et al., 2009). Participants were excluded from the current study based on evidence of: (1) interfering untreated/unstable psychiatric conditions (i.e., bipolar or psychotic disorders), (2) participation in cognitive behavioral therapy for anxiety disorders in the past year, (3) insufficient command of the English language, and (4) the inability to give informed, voluntary, written consent to participate. Please see Table 7 for inclusion and exclusion criteria

Participant Triage

The CONSORT diagram for the current study is presented in Figure 5. A total of 264 participants called the laboratory and were screened for potential inclusion in the study, of which, four were excluded due to not meeting the abovementioned inclusion/exclusion criteria, and 11 were not eligible or able to be contacted to confirm an appointment date. The remaining participants were then scheduled for an in-person assessment to further screen for

inclusionary/exclusionary criteria. Of the 249 participants scheduled for an in-person assessment, 152 came to the laboratory. One of these individuals was excluded because they had participated before, or another was not interested due to lack of transportation compensation. Of the 150 assessed in-person, 108 were excluded. The most common reasons for ineligibility were: self-reporting optimal HIV medication adherence and self-reporting low levels of baseline anxiety. Three participants were pilot participants and thus were not randomized and not included in these analyses. Other reasons for exclusion are detailed in Figure 2. Of the 42 remaining participants, five were excluded due to evidence of random responding or inability to contact and schedule another study appointment. Thus, 37 participants were randomized into this study.

Thus, 42 participants (M_{age} = 46.95, *SD* = 9.93, *range* = 21-61, 45.2% female) were included in the analyses. Participants were randomly assigned to an active or wait-list control condition, although contact was lost with 5 (11.2%) eligible participants before they were randomized. As a result, 19 participants in the active condition (51.4%) and 18 in the control condition (48.6%). The sample overall comprised primarily of PLWHA who identified race as Black/African-American (45.2%), white (35.7%), Black/Hispanic (7.1%), Hispanic (9.5%), or other (2.4%). Participants report never being married (42.9%), divorced/separated (35.7%), married/co-habitating (16.7%), and widowed (4.8%). Regarding sexuality, 59.5% identified as heterosexual, 26.2% identified as homosexual, 14.3% identified as bisexual. Regarding educational attainment, 16.7% of participants reported not graduating high school, 21.4% reported high school diplomas (or equivalent), 40.5% reported some college, 9.5% reported receiving a 2-year degree, and 11.9% reported receiving a 4-year degree. However, occupational status was primarily reported as unemployed (76.2%); 14.3% of participants reported working full-time, and 9.5% reported working part-time. As such, most participants reported low annual incomes, with 52.4% making under $10,000 annually, 26.2% making

between $10,000-$20,000 annually, 11.9% making between $20,000-$30,000 annually, and 9.6% making more than $30,000 annually. Please See Table 8 for a breakdown of demographic data by experimental condition.

Regarding HIV characteristics, the average CD4 T-cell count for participants was 499.64 (although nine participants did not know their CD4 T-cell count), while 54.8% reported an undetectable viral load, 34.3% reporting detectable viral load, and 16.7% not knowing their viral load. On average, participants had been living with HIV for 19.2 years, and 50% were diagnosed with AIDS. Regarding psychological disorders among this sample, 91.5% of participants reported meeting criteria for any psychological disorder (average number of diagnoses = 2.93), 64.3% of participants met criteria for an anxiety disorder (average number of diagnoses = 1.10), 69% of participants met criteria for a mood disorder (average number of diagnoses = 1.05) and 40.5% of participants met criteria for a substance use disorder (average number of diagnoses = 0.62). Please See Tables 9 and 10 for a breakdown of this data by experimental condition.

Measures

Baseline Assessment

A standardized *phone-screening questionnaire* was used to collect standard demographic information (e.g., age, gender, race/ethnicity, level of education) and HIV-specific information (e.g., HIV infection, CD4 t-cell counts, viral loads). Mental competency and command of the English language were assessed via caller's understanding of screening questionnaire items. The following measures were administered in person at the baseline, mid-treatment, post-treatment, and follow-up sessions:

The AIDS Clinical Trials Group (ACTG) Adherence Questionnaire (Chesney et al., 2000). The ACTG-Adherence Questionnaire was used to measure adherence to antiretroviral medications via two methods. First, the participant is asked how many HIV medications they are

currently prescribed (including doses of each per day) and how many doses they had missed in the past day, three days, and two weeks. The percentage of missed doses to total prescribed doses was used to index adherence. Additionally, the ACTG contains a 14 item self-report measure where participants indicate, on a 4-point Likert-type scale (*1 = never, 4 = often*) reasons for missing medication. As previously recommended (Gay et al., 2011; Holzemer et al., 2006) nine of the 14 items on the original scale may be examined to index adherence (e.g., "simply forgot"; "felt sick or ill"), enabling a range of scores from 9 to 36. Previous work has classified individuals as adherent or non-adherent based on total ACTG scores (scores between 9-20 indicate adherence; scores between 21-36 indicate nonadherence). Using these questions, adherence was examined a continuous (scores ranging from 9-36) and dichotomous (adherence vs. nonadherence) variable. In the current study, internal consistency of the ACTG-Adherence Questionnaire was α = 0.75. See Appendix A for ACTG Adherence measure.

State-Trait Anxiety Inventory Anxiety Symptoms (STAI; Spielberger, Gorsuch, Lushene, Vagg, & Jacovs, 1983). The STAI is a 40-item self-report measure on which respondents indicate, on a four-point Likert-type scale (0 = *not at all; 4 = very much so*) the extent to which they have felt a number of anxiety-related sensations (e.g., "I am tense", "I am worried") at this moment (state anxiety) and as they generally feel (trait anxiety). This measure has been used extensively in previous research and has consistently demonstrated good psychometric properties (Spielberger et al., 1983). In the present investigation, only the 20-items pertaining to trait anxiety were used as a screening measure. Internal consistency of the STAI items in the current study was α = 0.88. See Appendix B for STAI measure.

MINI International Neuropsychiatric Interview (MINI; Sheehan et al., 1992). The MINI is a clinician administered semi-structured diagnostic assessment of Axis I psychopathology based on the DSM-IV-TR diagnostic guidelines. Highly trained post-baccalaureate research assistants conducted diagnostic assessments. All research assistants completed a 6-session training

conducted by the principal investigator and two additional doctoral level graduate students, shadowed administration of three assessment cases with a doctoral-level graduate student, completed two live-supervised assessments, and demonstrated diagnostic accuracy on three test cases, prior to being 'signed off' as MINI trained. In the current study, all diagnostic assessments were audio-recorded and 100% of cases were supervised by the study principal investigator for diagnostic accuracy. A random 10% of recordings were subjected to blinded inter-rater reliability review by a doctoral-level clinical psychology graduate student. No cases of diagnostic disagreement were noted (100% accuracy). The MINI was used to assess if any psychological exclusionary criteria were met (e.g., psychotic-spectrum, high suicidality). See Appendix C for MINI diagnostic summary page.

Anxiety Sensitivity Index-3 (ASI-3; Taylor et al., 2007). The ASI-3 is an 18-item psychometrically-sound self-report measure on which respondents indicate the extent to which they are concerned about possible negative consequences of anxiety-related symptoms (e.g., "It scares me when my heart beats rapidly"). Responses are rated on a 5-point Likert scale ranging from 0 (*very* little) to 4 (*very* much). The ASI-3 produces a total score as well as sub-scores indexing physical, cognitive, and social sensitivity to anxiety. Internal consistency of the ASI-3 items in the current study was $\alpha = .94$. See Appendix D for the ASI-3 measure.

World Health Organization Quality of Life (WHOQOL; WHO, 2002). The WHOQOL was used to assess global changes in quality of life. This measure has specific application, reliability, and predictive and construct validity in assessing quality of life in patients with HIV (Wu et al., 1997). The WHOQOL measures six domains of quality of life including: physical, psychological, independence, social relationships, environmental, and spiritual. Internal consistency of the WHOQOL domains in the current study ranged from $\alpha = .58$ - .77. See Appendix E for the WHOQOL measure.

Inventory of Depression and Anxiety Symptoms (IDAS; Watson et al., 2011) The IDAS is a 64-item self-report questionnaire that assesses dimensions of depression (e.g., "I felt depressed") and anxiety (e.g., "I felt a pain in my chest") using a 5-point Likert-type scale (1 = *not at all*, 5 = *extremely*). The IDAS was used to index changes in depressive symptoms over the course of treatment and follow-up. Internal consistency of the IDAS-general depression subscale was α = .90. See Appendix F for the IDAS measure.

Concurrent Treatment. Participation in any concurrent psychotherapeutic treatment was assessed at each major outcome assessment. At no time point did any participant report receiving outside CBT-based therapy services.

Biological Challenge Measures

Subjective Units of Distress Scale (SUDs; Wolpe, 1968). The SUDs rating scale is a self-reported measure of the extent to which a respondent is currently experiencing 'distress, discomfort, anxiety, or fear', rated from 0 (none) to 100 (extreme), which was completed immediately before and after the biological challenge task.

Procedure

A visual depiction of the study design is provided in Figure 6. Interested callers responding to study recruitment methods completed a *telephone assessment* with a trained research assistant. Potentially eligible participants were read a standardized script describing the research study, informed that the in-person assessment would last approximately 2-3 hours, and if they were deemed eligible via this in-person assessment, they would be randomized as a control or active participant in the study. Scheduled participants received two telephone reminder calls 72 and 24 hours prior to their scheduled visits to (a) bolster retention rates, and (b) provide any necessary clarification of protocol.

Upon arrival, participants provided written *informed consent*. A trained post-baccalaureate level research assistant explained the details of the study, potential benefits and

risks of participation, and the procedures the participant would undergo if he/she chose to participate. If the participant signed the informed consent form, he/she was notified that he/she could withdraw at any time. He/she was also notified that there were several tasks to be completed at many of the appointments.

First, the *Baseline Assessment* was completed to determine study eligibility. The assessment included a diagnostic assessment (per the MINI), the ACTG to index HIV medication adherence, and a series of self-report assessments (including the STAI, ASI-3, and IDAS). Eligible participants were then either randomized to an active or waitlist-control condition.

Phase I: HAMRT Treatment Development

As indicating during the dissertation proposal, HAMRT was developed and pilot-tested prior to the initiation of this dissertation (n = 3). There were no changes in the HAMRT protocol after the pilot procedures. Because the pilot participants were not randomized, they were not included in the final analyses.

HAMRT consisted of 6 individual therapy sessions administered weekly for 6 consecutive weeks. Individuals who missed or could not attend weekly sessions were allowed to attend treatment on an as-needed basis. Patients were discontinued if more than one month lapsed between any therapy appointments. HAMRT was delivered by myself as well as Daniel Paulus, another pre-doctoral graduate student under the supervision of Dr. Zvolensky. Below, please find a summary of each treatment session in HAMRT.

Session 1. This session serves as an opportunity for the therapist to discuss anxiety- and HIV-related issues with the client and build therapeutic rapport. Additionally, Session 1 incorporates overview of the HAMRT program and therapeutic rational, psychoeducation about anxiety and emotions, health benefits and side-effects of cART, and an overview of the CBT-based model for HIV and anxiety. The patient is asked to track their anxiety symptoms and their impact for homework before Session 2.

Session 2. This session focuses primarily on cognitive restructuring, termed “Changing My Thoughts” in the HAMRT client manual. During this session, homework is reviewed, as is the CBT model for HIV and anxiety. Then, the client is lead through a discussion of the form and function of unhelpful and negative automatic thoughts. Strategies to challenge and adapt negative automatic thoughts are discussed, and the client practices disputing negative thoughts with guidance from the therapist. Finally, a fear hierarchy is created, and homework is assigned, including reviewing the hierarchy and completing two cognitive restructuring exercises independently.

Session 3. During Session 3 cognitive restructuring is continued, and interoceptive exposure (IE) exercises (physical challenge tasks designed to elicit sensations similar to physical sensations associated with anxiety) are introduced. This session begins with a review of homework, including problem-solving regarding difficulties with cognitive restructuring exercises, and a review of the fear hierarchy. A minimum of three IE exercises are performed to show the client that physical symptoms associated with anxiety are normal, okay, to-be-expected, and will decrease with practice. Homework for this week includes a minimum of three at-home practice sessions of IE exercises. After Session 3 participants are re-assessed to index treatment progress

Session 4. Session 4 begins with a recap of the skills learned to date in treatment, and any lingering difficulties are discussed. After this, exposure exercises become the main focus of all remaining sessions; these sessions are called “Facing my Fears” in the client’s manual. During Session 4, the client and therapist pick a feared situation off of the fear hierarchy, agree to “face that fear”, perform a cognitive restructuring task about the exposure, and perform it in session. The client is asked his or her “SUDS” rating throughout the exposure to indicate that anxiety increases with initial exposure, and decreases over time. The client is assigned homework of performing his or her own exposure outside of therapy by the next Session.

Session 5. During Session 5 homework is discussed and another exposure exercises is selected to accomplish during session. For this exposure exercise, the client takes a more leading role in the selection of the exposure exercises. Participants are debriefed after the in-session exposure, and assigned another exposure for homework.

Session 6. During Session 6, homework is discussed and a final in-session exposure exercises is conducted. This exposure exercise was selected and lead by the client, and facilitated by the therapist. Afterwards, relapse prevention work included a discussion of the importance of continuing to face fear and anxiety, as well as signs of lapse and relapse and strategies for continuing progress. At this point, the patient was scheduled for their 1-mont post-treatment follow-up session.

Phase II - Randomized Controlled Trial (RCT).

Phase II Aims. The objectives for Phase 2 which is the focus of this dissertation project was to obtain (a) feasibility and acceptability data for the study procedures (e.g. acceptability and ease of delivery of HAMRT); (b) preliminary data for the efficacy of the refined HAMRT protocol; and (c) preliminary data for the proposed mechanisms by which the HAMRT protocol exerts its effects on HIV symptoms and medication adherence

Strategies to Minimize Attrition. In order to facilitate attendance to all treatment sessions and completion of homework assignments, a variety of strategies were used. In order to ensure attendance, patients were assigned to treatment condition within one week of initial application for treatment and receive an explanation of the study treatments, requirements, and follow-up procedures. Additionally, sessions were scheduled at a time that is convenient for all participants; and reminder calls were be made 72 and 24 hours before each session. During sessions, motivational interviewing (MI) strategies were used as the primary method of helping to ensure homework completion. As such, homework was framed as a means to accomplishing

the goals of therapy. Moreover, the importance of homework completion was verbally reiterated throughout sessions.

To reduce attrition at follow-up, participants were paid $10 in HEB gift cards for completing each follow-up assessment, and an extra $10 in HEB gift cards for completing all follow-up assessments (up to $80 in HEB gift cards in total compensation including $20 in HEB gift cards for intake session). We also used a two-pronged approach to remind participants of their scheduled (follow-up) appointments. First, we placed reminder calls to participants 72 and 24 hours prior to each scheduled follow-up session. During each follow-up session we systematically asked each participant for updated contact information (e.g., phone number, mailing address) adjusted our records accordingly. Study staff emphasized the patient's responsibility as a research participant, reiterate confidentiality, worked to develop good rapport with patients, and be trained on uniform procedures across conditions concerning late or missed appointments.

Active compared to Control Condition

Participants who completed the in-person intake interview and were eligible and interested in receiving treatment were randomized to an active or waitlist-control condition. Those randomized to the *Active condition* were immediately scheduled for Session 1 of HAMRT after their intake assessment. Participants were asked to complete assessments after Sessions 3 and 6, and were offered $10 in HEB gift cards for their participation. Participants completing the HAMRT program were then asked to return for 1-, 3-, and 6-month post-treatment follow up sessions, and offered $10 HEB gift cards for attending each session, and an extra $10 HEB gift card for completing all follow-up sessions.

Participants randomized to the *Control condition* were asked to return to the laboratory 3- and 6-weeks after their intake interview for assessment. After the 6-week assessment, all participants were offered HAMRT treatment. Please see Table 11 for an indication of

assessments collected at each appointment across conditions.

Data Analytic Plan

The effect of the HAMRT intervention was tested in comparison to a waitlist control in terms of medication adherence, anxiety symptoms, depressive symptoms, and quality of life. First, a repeated measures General Linear Model (GLM) was conducted to probe for significant differences between the active and control conditions from baseline to 6-week assessments. Second, because of the high attrition rate and potential resultant lack of statistical power, Effect Sizes (ES) were additionally employed to gauge the effects observed. For these analyses, the mean and standard deviation of the outcome variable at were entered into an effect size calculator producing Cohen's D and r values, as calculated as the difference in the means of the conditions divided by the average pooled variance of values (Cohen, 1988; Rosnow & Rosenthal, 1996).

Results

Sample

Forty-two PLWHA were eligible for the HAMRT program and 37 were randomly assigned to active (N = 19, 52.6% male; M_{age} = 45.68, *SD* = 11.56) and waitlist control (N = 18, 61.1% male, M_{age} = 49.83, *SD* = 7.05) conditions.

Baseline Differences

An ANOVA was used to test for differences between the conditions on demographic and outcome variables. In terms of demographic variables, there were no significant differences between conditions in terms of age (F[1, 35 = 1.71, $p > .05$), marital status (F[1, 35 = .06, $p > .05$), income level (F[1, 35] = .39, $p > .05$), highest education level (F[1, 35] = 2.36, $p > .05$), sexual orientation (F[1, 35] = 1.37, $p > .05$) or race (F[1, 35] = 2.12, $p > .05$) or current occupation status (F[1, 35] = 3.52, $p > .05$). There was also no difference in recruitment sites across conditions (F[1, 35] = .03, $p > .05$). In regard to HIV-relevant variables, there were no

differences between conditions in HIV vs. AIDS diagnosis (F[1, 33] = .03, $p > .05$), or CD4 T-cell count (F[1, 26] = .16, $p > .05$). In terms of the dependent variables, there were no significant differences across conditions in STAI scores (F[1, 35] = 3.87, $p > .05$), IDAS Depression (F[1, 35] = 1.19, $p > .05$), ASI3 total score (F[1, 35] = .17, $p > .05$), WHOQOL domains (range of *p's* = .19-.97), or adherence as measured by the ACTG "reasons for missing" items (F[1, 32] = .54, $p > .05$). However, there was a significant difference between conditions in regard to self-reported HIV medication adherence (F[1, 35] = 4.60, $p = .04$). Please see Table 12 for a breakdown of the condition comparison data.

Attrition

Notably, attrition rates were significantly different across conditions at week 3 (F[1, 36] = 18.06, $p < .001$) and at week 6 (F[1, 36] = 6.86, $p = .01$). Regarding the control condition, after randomization, 88.9% attended the 3-week follow-up and 66.7% attended the 6-week follow-up. In the active condition, however, 63.2% attended the first treatment session, 42.1% attended the second treatment session, 31.6% attended the third, fourth, and fifth treatment sessions, and only 26.3% attended the final treatment session. In terms of post-treatment follow-up for the participants randomized to the active condition, 60% attended the 1-month follow-up, 40% attended the 3-month follow-up, and 20% attended the 6-month follow- up. Because only one participant showed for the 6-month follow-up, and this participant did not complete the 1-, or 3-month assessments, further analyses were not conducted for this time point. Please see Table 13 for a breakdown of attrition across conditions.

Treatment Fidelity

All sessions were audiotaped and two independent graduate-level raters assessed therapist adherence to, and competence with, the HAMRT protocol. Therapist competence and therapy delivery were measured on four assessment scales: (1) *Fidelity to Theory* (e.g., did the intervention include "active ingredients" based on theory as measured by administration of

content (yes/no) and time spent on deliver); (2) *Treatment Implementation* (e.g., did the treatment providers actually implement the implementation as it was designed, as measured by administration (yes/no) of each item to be covered in treatment); (3) *Treatment Receipt* (e.g., did the participant receive the "active ingredients" as intended as measured by verbal review of patients' understanding of topics covered (yes/no); and (4) *Treatment Enactment* (e.g., did the participant put new skills into practice as measured by verbal report of skills use (yes/no) and homework completion (yes/no). Please see Appendix G for the scoring documents created to measure treatment fidelity for HAMRT.

Four individual therapy sessions (~10% of total therapy sessions delivered) were assessed using these criteria. Therapist adherence consistently displayed adequate Fidelity to Theory (100%), Treatment Implementation (96%), and Treatment Receipt (100%). Treatment enactment was adequate with participants using new skills during 50% of sessions, and completing homework 100% of checked sessions.

Effect Size Analyses

Repeated measures GLM was conducted to probe for differences between baseline and post-treatment outcomes, and effect size (ES) analyses were calculated at each time point (baseline assessment, 3-week assessment, 6-week assessment) for each outcome examined. Effect Sizes were calculated once for "intent to treat" participants; all eligible persons who completed any assessment regardless of dropout (control condition n = 18; active condition n = 19), and again for only "treatment completers" - those who completed each assessment for the control condition (n = 12) or completed every therapy session in the active condition (n = 5). This information is presented in table format as well as graphically for each outcome.

Self-Reported missed doses of HIV medication. First, a repeated measures GLM was conducted. Results indicated that time was trending as a significant factor in medication adherence ($F[1, 15] = 3.13$, $p = .097$), as was time by condition interaction ($F[1, 15]) = 3.50$, $p =$

.08). These analyses were underpowered (observed power = .42); however, the effect size was still large, with a Partial Eta Squared value of .819. Please see Table 14.

Changes in effect sizes between baseline assessment and post-treatment assessment were examining using Cohen's D. To calculate Cohen's D, the mean and standard deviation scores for self-reported reasons for missing medications across the two conditions were entered into an effect size calculator at post-treatment. Regarding the "intent to treat" group, a moderate effect size was found at baseline (Cohen's D = -.71; Pearson's r = -.33), whereas a large effect size was found for treatment completers at baseline (Cohen's D = -1.06; Pearson's r = -.47). At the post-treatment assessment, however, this effect size had reduced (Cohen's D = -.31, Pearson's r = -.16). Please see Figure 7 and Table 13.

Self-reported reasons for missing medications. Results indicated that neither time (F[1, 13] = 2.23, $p > .05$), nor the time by condition interaction (F[1, 13]) = 1.15, $p > .05$) significantly predicted reasons for missing medications. The effect size was small, with a Partial Eta Squared value of .082. Please see Table 14.

ES analyses indicated a small effect size (Cohen's D = -.21; Pearson's r = -.11), such that those in the control condition showed greater improvements in self-reported reasons for missing medications compared to those in the active condition. Cohen's U_3 indicated that 67% of the control condition would be above the mean of the active condition in terms of reporting less reasons for missing medications. Please See Figure 8 and Table 16 for rates of missing medications for intent-to-treat participants and treatment completers at each examined.

Anxiety. Results of the GLM indicated that time (F[1, 15] = 5.91, $p < .05$), and the time by condition interaction (F[1, 15]) = 7.36, $p < .05$) significantly predicted anxiety symptoms. These analyses were powered appropriately for the time by condition interaction (observed power = .72) and the effect size was large, with a Partial Eta Squared value of .329. Please see Table 14.

ES analyses indicated a medium effect size at post-treatment (Cohen's D = .64; Pearson's r = .30), such that those in the active condition showed greater reductions in anxiety compared to those in the control condition. Cohen's U_3 indicated that at post-treatment, 74% of the active condition was below the mean of the control condition in terms of anxiety symptoms. Please See Figure 9 and Table 17.

Anxiety Sensitivity. Results of the GLM indicated that time (F[1, 15] = 8.72, p = .01), and the time by condition interaction (F[1, 15]) = 20.27, p < .001) significantly predicted anxiety sensitivity. These analyses were powered appropriately for the time by condition interaction (observed power = .99) and the effect size was large, with a Partial Eta Squared value of .575 for the time by condition interaction. Please see Table 14.

ES analyses indicated a large effect size at post-treatment (Cohen's D = 1.50; Pearson's r = .60), such that those in the active condition showed greater reductions in anxiety sensitivity compared to those in the control condition. Cohen's U_3 indicated that 93% of the active condition was below the mean of the control condition in terms of anxiety sensitivity. Please See Figure 10 and Table 18.

Depression. Results of the GLM indicated that time (F[1, 15] = 32.09, p < .001), and the time by condition interaction (F[1, 15]) = 22.03, p < .001) significantly predicted depressive symptoms. These analyses were powered appropriately for the time by condition interaction (observed power = .99) and the effect size was large, with a Partial Eta Squared value of .611 for the time by condition interaction. Please see Table 14.

ES analyses indicated a medium effect size (Cohen's D = .80; Pearson's r = .37), such that those in the active condition showed greater reductions in depression compared to those in the control condition. Cohen's U_3 indicated that 79% of the active condition was below the mean of the control condition in terms of depressive symptoms. Please See Figure 11 and Table 19.

Quality of Life – Physical Domain. Results of the GLM indicated that time (F[1, 15] =

6.94, $p < .05$), and the time by condition interaction (F[1, 15]) = 5.47, $p < .05$) significantly predicted physical quality of life. These analyses were notably underpowered for the time by condition interaction (observed power = .59) and the effect size was large, with a Partial Eta Squared value of .267 for the time by condition interaction. Please see Table 14.

ES analyses indicated a large effect size (Cohen's D = 1.13; Pearson's r = .49) such that those in the active condition showed increases in physical quality of life compared to the control condition. Cohen's U_3 indicated that 87% of the active condition was above the mean of the control condition in terms of physical quality of life. Please See Figure 12 and Table 20.

Quality of Life – Psychological Domain. Results of the GLM indicated that time (F[1, 15] = 10.86, $p < .01$), and the time by condition interaction (F[1, 15]) = 8.89, $p < .01$) significantly predicted psychological quality of life. These analyses were appropriately powered for the time by condition interaction (observed power = .80) and the effect size was large, with a Partial Eta Squared value of .372 for the time by condition interaction. Please see Table 14.

ES analyses indicated a medium effect size (Cohen's D = .49; Pearson's r = .24) such that those in the active condition showed increases in psychological quality of life compared to those in the control condition. Cohen's U_3 indicated that 69% of the active condition was above the mean of the control condition in terms of psychological quality of life. Please See Figure 13 and Table 21.

Quality of Life – Independence Domain. Results of the GLM indicated that neither time (F[1, 15] = .35, $p > .05$), nor the time by condition interaction (F[1, 15]) = 1.83, $p > .05$) significantly predicted independent quality of life. These analyses were notably underpowered for the time by condition interaction (observed power = .24), and the effect size was small, with a Partial Eta Squared value of .108 for the time by condition interaction. Please see Table 14.

ES analyses indicated a large effect size (Cohen's D = 1.01; Pearson's r = .45), such that those in the active condition showed greater independence quality of life compared to those

in the control condition. Cohen's U_3 indicated that 84% of the active condition was above the mean of the control condition in terms of independence quality of life. Please see Figure 14 and Table 22.

Quality of Life – Social Domain. Results of the GLM indicated that time (F[1, 15] = .96, $p < .05$) was not significant, and the time by condition interaction (F[1, 15]) = 3.49, $p = .08$) was non-significantly trending with social quality of life. These analyses were underpowered for the time by condition interaction (observed power = .42), but the effect size was moderate, with a Partial Eta Squared value of .189 for the time by condition interaction. Please see Table 14.

ES analyses indicated a medium effect size (Cohen's D = .43; Pearson's r = .21), such that those in the active condition showed increases in social quality of life compared to those in the control condition. Cohen's U_3 indicated that 67% of the active condition was above the mean of the control condition in terms of social quality of life. Please See Figure 15 and Table 23.

Quality of Life – Environmental Domain. Results indicated that time (F[1, 15] = 5.43, $p < .05$), and the time by condition interaction (F[1, 15]) = 5.57, $p < .05$) significantly predicted environmental quality of life. These analyses were notably underpowered for the time by condition interaction (observed power = .60) and the effect size was large, with a Partial Eta Squared value of .271 for the time by condition interaction. Please see Table 14.

ES analyses indicated a large effect size (Cohen's D = -1.73; Pearson's r = .65), such that those in the active condition showed greater environmental quality of life compared to those in the control condition. Cohen's U_3 indicated that 96% of the active condition are above the mean of the control condition in terms of environmental quality of life. Please See Figure 16 and Table 24 for rates of environmental quality of life for intent-to-treat participants and treatment completers at each examined time point.

Quality of Life – Spiritual Domain. Results indicated that time (F[1, 15] = 10.87, $p < .01$), and the time by condition interaction (F[1, 15]) = 10.33, $p < .01$) significantly predicted physical

quality of life. These analyses were powered appropriately for the time by condition interaction (observed power = .85) and the effect size was large, with a Partial Eta Squared value of .40 for the time by condition interaction. Please see Table 14.

ES analyses indicated a large effect size (Cohen's D = -.85; Pearson's r = -.39), such that those in the active condition showed increased spiritual quality of life compared to those in the control condition. Cohen's U_3 indicated that 80% of the active condition was above the mean of the control condition in terms of spiritual quality of life. Please See Figure 17 and Table 25.

Post-Treatment Assessment

Of the five participants who completed treatment, three participants (60%) completed the 1-month post treatment and two participants (40%) completed the 3-month post treatment follow up. Because only one participant attended the 6-month follow-up (this participant did not attend the 1-, and 3-month follow up appointments), this data is not presented.

HIV medication adherence. At follow-up, HIV medication adherence remained relatively stable from end-of-treatment (24.29% of doses missed on average) to the 1-month follow up (28.57% of doses missed on average). Of note, one participant reported missing 71% of his medications in the past two weeks because online delivery of medications was late, causing them to miss 10 consecutive days of medications. At the three-month follow-up, participants reported missing on average 3.6% of daily medications. Please see Table 26 and Figure 18 for rates of medication adherence.

Reasons for missing HIV medications. At follow-up, reasons for missing HIV medications remained relatively stable from end-of-treatment (8.4) to the 1-month follow up (9.08). At the three-month follow-up, participants reported an increase in reasons for missing medications (9.5), but still less reasons than endorsed at baseline (11.75). Please see Table 26 and Figure 19 for rates of reasons for missing medications.

Anxiety Symptoms. Improvements in trait anxiety as measured using the STAI-trait index remained relatively stable from end-of-treatment (mean score 44.92) to the 1-month follow-up (mean score 43.25). At the 3-month follow up, anxiety scores had risen slightly (mean score = 47.50), but were lower from pre-treatment levels for the treatment-completers (mean score = 56.60). Please see Table 26 and Figure 20 for this information.

Anxiety Sensitivity. Improvements in anxiety sensitivity, as measured using the ASI-3, remained relatively stable from end-of-treatment (mean score 10.11) to the 1-month follow-up (mean score 13.67). At the 3-month follow up, anxiety sensitivity scores had risen (mean score = 23.50), but were still lower than pre-treatment levels for the treatment-completers (mean score = 32.80). Please see Table 26 and Figure 21 for this information.

Depression Symptoms. Improvements in depression, as measured using the IDAS general depression subscale, continued to improve from end-of-treatment (mean score 40.00) to the 1-month follow-up (mean score 18.30). At the 3-month follow up, depression symptom scores had risen (mean score = 51.50), but were lower than pre-treatment levels for the treatment-completers (mean score = 65.20). Please see Table 26 and Figure 22 for this information.

Quality of Life- Physical Domain. Improvements in physical quality of life remained relatively stable from end-of-treatment (mean score 14.60) to the 1-month follow-up (mean score 15.30). At the 3-month follow up, physical quality of life scores had decreased (mean score = 13.00), but were lower than pre-treatment levels for the treatment-completers (mean score = 10.40). Please see Table 26 and Figure 23 for this information.

Quality of Life- Psychological Domain. Improvements in psychological quality of life were relatively stable from end-of-treatment (mean score 12.80) to the 1-month follow-up (mean score 12.67). At the 3-month follow up, psychological quality of life scores had decreased (mean

score = 11.67), but were still improved from pre-treatment levels for the treatment-completers (mean score = 9.01). Please see Table 26 and Figure 24 for this information.

Quality of Life- Independence Domain. Improvements in independence quality of life were relatively stable from end-of-treatment (mean score 13.80) to the 1-month follow-up (mean score 14.89). At the 3-month follow up, independence quality of life scores (mean score = 11.83) had decreased below pre-treatment levels for the treatment-completers (mean score = 12.67). Please see Table 26 and Figure 25 for this information.

Quality of Life- Social Domain. Improvements in social quality of life continued to increase from end-of-treatment (mean score 10.40) to the 1-month follow-up (mean score 13.30). At the 3-month follow up, social quality of life scores (mean score = 11.83) had decreased, although remained above pre-treatment levels for the treatment-completers (mean score = 9.80). Please see Table 26 and Figure 26 for this information.

Quality of Life- Environmental Domain- Improvements in environmental quality of life remained relatively stable from end-of-treatment (mean score 15.57) to the 1-month follow-up (mean score 15.43). At the 3-month follow up, environmental quality of life scores (mean score = 13.75) had decreased, but remained improved from pre-treatment levels for the treatment-completers (mean score = 12.80). Please see Table 26 and Figure 27 for this information.

Quality of Life- Spiritual Domain. Improvements in spiritual quality of life remained relatively stable from end-of-treatment (mean score 16.00) to the 1-month follow-up (mean score 13.33). At the 3-month follow up, environmental quality of life scores (mean score = 12.00) had decreased, but remained improved from pre-treatment levels for the treatment-completers (mean score = 11.60). Please see Table 26 and Figure 28 for this information.

Discussion

The current study examined the effect of a six-session CBT-based transdiagnostic anxiety reduction therapy program (HAMRT) compared to a waitlist control condition on several

outcomes, including: HIV medication adherence, anxiety symptoms, anxiety sensitivity, depressive symptoms, and quality of life. Several key findings were observed.

Implementation of HAMRT was met with many challenges. Although rates of interest seemed to be high initially (i.e., 264 persons completing study phone screen), follow through by interested participants was low (i.e., only 152 persons attended the in-person baseline assessment). Additionally, the identification of eligible participants was difficult (e.g., 67 persons deemed ineligible because of adequate HIV medication adherence). Moreover, even when examining eligible and willing participants, attrition was high (i.e., 26.8% completed all treatment sessions). There may be several reasons for these challenges. First, participants were primarily recruited from community clinics, which primarily served low-SES persons. As a result, over three quarters of our sample was unemployed, and almost four fifths of our sample reported earning below $20,000 annually. It may be that socioeconomic stressors (e.g., lack of transportation) impacted attrition. Relatedly, it may be that lack of compensation in the active condition (i.e., participants were offered free therapy and were not compensated during therapy sessions 1, 2, 4, or 5) had a profound impact on attrition. Indeed, the largest attrition rates in the active condition were found between baseline and session 1 (when patients were informed that they would not be compensated for all therapy sessions) and between sessions 1 and 2, after patients had not been compensated following session 1. This finding is further supported by adherence in the control condition, where 66.7% of participants followed through with all study appointments, each of which offering compensations. Additionally, this sample was severe in terms of psychopathology, with 90.5% meeting criteria for a DSM-IV-TR diagnosed psychiatric disorder, including 40.5% meeting criteria for a substance abuse disorder. Psychiatric severity may have impacted attrition. Other factors that may have impacted HAMRT adherence include factors important to consider for PLWHA, including appointment burden (i.e., the burden of

adding therapy appointments into crowded medical appointment schedules) and social factors (e.g., fear of disclosure of HIV status to others).

Despite the challenges with the implementation of HAMRT, there were several important outcomes in terms of recruitment. First, our sample is largely representative of the national HIV population, including a large contingent of African-American gay and bisexual men and African American heterosexual women. Because these represent the populations most at-risk for HIV infection and poor HIV management today, it is important to reach and treat these individuals. Additionally, those who became engaged in treatment (e.g., those attending at least three therapy appointments) tended to stay engaged throughout treatment (83%). It may be that HAMRT was impactful for this sub-set of persons; future research should seek to understand reasons for treatment dropout and address these issues. Third, recruitment was bolstered by integration into medical doctor's offices, versus reliance on flyers and advertisements. Holistic integration of services (i.e., offering multiple health services at one site) may offer relief of appointment burden for PLWHA, and facilitate greater follow up.

Overall, treatment completers evidenced increases in most measured outcomes compared to the control condition. Despite high rates of attrition, significant differences were found between conditions in most instances, and generally medium to large effect sizes were observed, supporting the utility of HAMRT as a therapeutic mechanism. Below, these findings, their limitations, and potential future directions are discussed in regard to each outcome on an individual basis.

HIV Medication adherence

Despite random assignment of participants into the active and control condition, there were significant baseline differences in HIV medication adherence across the conditions (78.16% adherent in the control condition compared to 47.62% adherent in the active condition; $p = .04$). However, by the end of treatment, this gap had narrowed considerably (84.42%

adherent in the control condition compared to 75.71% adherent in the active condition). Results indicated a non-significant trend for improvements in the active condition compared to the control condition (p = .08), despite being underpowered (observed power = .42). However, a Partial Eta Squared effect size (.189) indicated that there was notable increase in HIV medication adherence in the active relative to the control condition. These gains were maintained post-treatment for those in the active condition.

Although those receiving HAMRT exhibited gains in HIV medication adherence, there is further room for improvement, as the goal of the program was to increase rates of HIV medication adherence to within "optimal" adherence rates (i.e., >95% adherence). There are many avenues for future research. For instance, the HAMRT program focused on anxiety, assuming that anxiety underpinned reasons for missing HIV medication adherence. It may be that for some individuals there are other factors that impact medication adherence (e.g., memory problems, stigma/shame from friends or family members, substance use). Future work would benefit from more thoroughly examining reasons for missing medications, and target therapy accordingly. Second, while the HAMRT program affected statistically significant rates of change in anxiety and depressive symptoms, other important mental health variables were not considered (e.g., substance use, shame, guilt). It may be that these related mental health factors play an additional role on HIV medication adherence, and should be studied accordingly.

Reasons for Missing Medications

Participants in the HAMRT condition did not report significantly less reasons for missed medications compared to those in the control condition at post-treatment. There may be a number or reasons for this lack of significant findings. First, despite a high level of internal consistency, reasons for missing medications did not correlate significantly with actual missed doses of medications (Pearson's correlation = -.10, $p > .05$). Additionally, 7% of patients reported "no reasons for missing medications" at baseline, despite also reporting missing

medications in the past two weeks. It may be that this measure was confusing for some participants, and not completed appropriately by those who had difficulty with the measure. However, treatment completers still did report fewer reasons for missing medications from pre-treatment (11.75) to post treatment (8.4). This reduction was not statistically significant when compared to the control condition.

Anxiety symptoms

Participants in the HAMRT condition reported significantly reduced anxiety levels compared to those in the control condition. These gains were also generally maintained at follow-up. Although participants receiving HAMRT did show significant reductions in anxiety symptoms, there are opportunities for future treatment development. For instance, while anxiety levels did significantly decrease, they remained above "clinical levels," as defined for inclusion in this study, even post treatment (average score = 44.92, clinical cutoff used for this study = 40). Because rates of anxiety symptoms were high among treatment completers (average score = 56.6), it may be that a more intense therapy dose is needed to further reduce symptoms, via longer sessions or a greater number of sessions. Additional work is needed to test the utility of anxiety-reduction treatments for PLWHA in a way that is easily disseminated and acceptable to patients.

Anxiety Sensitivity

HAMRT included one session aimed specifically at anxiety-sensitivity reduction; those completing HAMRT showed significant reductions in anxiety sensitivity between pre-treatment (average score = 32.8) and post-treatment (average score = 10.11) compared to the control condition. Although these gains had relapsed during follow up, they remained lower than pre-treatment levels. This finding has a number of possible implications. First, it is notable how high rates of anxiety sensitivity were among both treatment conditions, which indicates that this transdiagnostic variable may be important in understanding physical and psychological health

among this group. Second, HAMRT indicated that a brief intervention aimed at reducing rates of anxiety sensitivity was able to significantly decrease symptoms. Future work examining the impact of anxiety sensitivity reductions specifically may provide additional information regarding the importance of this variable among PLWHA.

Depressive Symptoms

Although not the focus of the HAMRT program, treatment completers showed significant reductions in depressive symptoms compared to waitlist control. These gains were generally maintained at the 1-month follow-up, but regressed by the 3-month follow-up. This finding is important, as anxiety and mood disorders are often comorbid, especially among PLWHA (e.g., Bing et al., 2001). Comorbidity was highly prevalent in the current sample, as 90.5% of participants met criteria for an anxiety disorder, and 69% of participants met criteria for a mood disorder, while 50% of participants met criteria for at least one comorbid mood and anxiety disorder diagnosis. This finding is also important by indicating the possible utility of transdiagnostic treatments among this population. Given the high rates of psychiatric problems among this population (participants averaged 2.93 psychiatric disorders at baseline), it is important to focus on underlying factors that cause and maintain these symptoms – instead of isolated symptom clusters (i.e., panic disorder, GAD) – thus affecting change on multiple symptoms. Future work may benefit by exploring if depressive symptoms may undergird other outcomes (e.g., medication adherence).

Quality of life

Overall, participants receiving HAMRT showed significant gains in quality of life compared to waitlist control in regard to physical, psychological, environmental, and spiritual quality of life. Notably, social quality of life evidenced a trend relation, but may have been underpowered. This finding is particularly important, as past research has noted that HIV has a notable negative effect on overall quality of life (Skevington & O'Connell, 2003). The HAMRT

program, while not specifically designed to increase quality of life per se, has clear implications on improvement of quality of life among PLWHA. Future work may do well to examine active therapeutic ingredients that predict quality of life among PLWHA.

Other noteworthy observations

Although HAMRT is a relatively short program (six 50-minute therapy sessions), participants showed significant improvement in many outcomes, and these treatment gains were maintained through 1-month follow up. Additionally, although participants evidenced regression by the 3-month follow-up, most outcomes were still improved compared to pre-treatment levels. These data are evidence of the clinical utility of the HAMRTprogram as it can affect meaningful change in a short time frame that can be generally maintained over time. However, there are two competing avenues for future directions. First, it seems as if a more intensive therapy protocol (i.e., more time in therapy) may be additionally helpful for these individuals. However, given the high rates of dropout, more intensive therapy may not be feasible for most patients. Alternative strategies may need to be developed and tested to increase treatment attendance and progress including pre-treatment motivational interviewing strategies and more acceptance-based approaches.

Limitations

Beyond the developmental nature of this study (i.e., treatment development), there are several limitations in this investigation that warrant comment. First, our sample, while representative of PLWHA in terms of race and ethnicity, was small in overall size and also skewed towards lower-income and less educated participants. It therefore may not be generalizable to the entire HIV+ community. Additionally, this sample may experience more HIV-related stressors due to their environment (Leserman et al., 2005) that may impact attrition rates as well as treatment outcomes. Other SES-relevant factors, such as access to medical care and medications, social support, and potential trauma history may have impacted findings.

Second, while random assignment into experimental and waitlist control were utilized, those in the control condition were more likely to be employed than those in the active condition. This pre-existing difference may have confounded findings, including in attrition rates, rates of baseline distress, and global improvement. However, based on lack of condition differences on other pre-randomization measures, consistent pattern of manipulation effects across outcome measures, and large effect sizes, the impact of this pre-condition difference may be negligible.

Third, despite targeted efforts to recruit PLWHA with poor medication adherence, many persons reported relatively high levels of medication adherence at baseline (e.g., 92%, 90%). It may be that there was not enough variability in some of these participants, thereby limiting the potential to find significant improvements due to condition.

Fourth, while anxiety sensitivity is often considered an *amplifier* of negative affective states (Zvolensky, Farris, Guillot, & Leventhal, 2014), it may also be conceptualized as an underlying explanatory factor that *accounts for* the link between anxiety and medication adherence among PLWHA. Thus, it would be warranted to model anxiety sensitivity as a statistical mediator of the effect of anxiety on HIV medication adherence. Here, the anxiety reduction effects in HAMRT would be expected to impact HIV medication adherence indirectly via the effect of anxiety sensitivity reduction.

Fifth, self-report was utilized to index all outcome variables, including medication adherence. Although self-report is often problematic in the assessment of psychological factors. It may be most impactful regarding the report of HIV medication adherence, as there are a number of social factors influencing persons to over-report adherence (Zimmerman, Morisky, Harison, & Mark, 2014). Conversely, there are a number of factors that may influence persons to under-report adherence (e.g., fear, stigma, shame; Bennett, Traub, Mace, Juarascio, & O'Hayer, 2016). Future work may do well to assess adherence via biologic methods (e.g., blood draws), and assess other outcomes (e.g., anxiety) via observable methods.

Finally, due to the preliminary nature of the current study, we did not adjust for the number of tests run. Thus, there is the potential for alpha inflation. Yet, given the observed effect sizes for many of the dependent variables, this concern appears relatively modest.

Integrative Summary and Implications

The current study extends existing work examining the effects of anxiety among PLWHA by developing and implementing a transdiagnostic CBT-based anxiety-reduction therapy program (HAMRT) designed to increase HIV medication adherence and improve psychological distress. Findings indicate that implementation of such a program is difficult and attrition is problematic, but that treatment completers significantly improve in regard to anxiety symptoms, depressive symptoms, anxiety sensitivity, and multiple indices of quality of life compared to waitlist control. Results also evidence a trend relation for medication adherence, despite low statistical power. Results indicate that treatment gains are generally maintained at 1-month post-treatment, with regression at 3-month post-treatment, although not to pre-treatment levels. These data provide evidence for the impact of anxiety among PLWHA in regards to physical and psychological health, and indicate the utility of targeting these symptoms therapeutically via transdiagnostic mechanisms.

Additionally, the HARMT program incorporated an anxiety-sensitivity reduction component which was successful in reducing anxiety sensitivity among treatment completers. This is the first empirical test aimed at reducing anxiety sensitivity among PLWHA, and was proven here to be feasible in a therapeutic setting. Next steps for this line of work include examination of the effects of anxiety sensitivity reduction among PLWHA in terms of HIV medication adherence and additional psychological outcomes (e.g., anxiety symptoms, depressive symptoms, substance use).

Although this study evidenced important findings, there are many avenues for future research. First, future studies may benefit by examining the causes of missed HIV medications,

and target intervention accordingly. Second, developing strategies aimed at increasing adherence to psychological intervention for PLWHA is an important next step in delivering useful interventions. Third, the HAMRT program indicates that transdiagnostic treatment is feasible and effective in impacting targeted symptoms. The HAMRT program also indicated that targeting one specific transdiagnostic factor (anxiety sensitivity) is feasible and effective. Next steps may include targeting other transdiagnostic factors (e.g., emotion dysregulation, distress tolerance) to examine their overall effects.

Overall, the present findings indicate the initial utility of transdiagnostic anxiety-reduction therapy in increasing HIV medication adherence, decreasing psychological symptoms, and increasing quality of life among PLWHA. When considered in the larger context of HIV/anxiety relations, the present findings are an important next-step indicating the need for a specific targeted focus on anxiety reduction among this population. The current intervention, while efficacious overall, opens the door for adaptation of future treatment strategies, including further assessment and targeting of HIV medication adherence, addressing attrition issues, and targeting transdiagnostic mechanisms of change.

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Table 1. DSM-IV-TR Anxiety Disorders

Disorder	Distinguishing Symptoms	Time Qualifier
Specific Phobia	• Marked fear or anxiety about a specific object or situation	None
Social Anxiety Disorder	• Marked fear or anxiety about one or more social situations in which the individual is exposed to possible scrutiny by others • Fear of negative evaluation	None
Panic Disorder	• Recurrent unexpected panic attacks • At least one panic attack followed by worry of future attacks or changes in behavior to avoid future attacks • Can occur with or without agoraphobia (see below)	1 month
Agoraphobia (qualifier for panic)	• Marked fear or anxiety about situations in which one may have a panic attack (e.g. being in open spaces, being outside of the home alone) • Avoidance of such situations because escape may not be available	1 month
Generalized Anxiety Disorder	• Excessive anxiety and worry about a number of events or activities • Difficulty controlling worry	6 months
Obsessive Compulsive Disorder	• Presence of Obsessions: recurrent and persistent thoughts or images that are distressing • Presence of Compulsions: Repetitive behaviors aimed at preventing or reducing distress (e.g. hand washing)	None
Posttraumatic Stress Disorder	• Re-experiencing of a traumatic event causing daily interference	-Acute<3 months -Chronic> 3 months

Table 2. Rates of Anxiety Disorders in Developed Countries (ordered chronologically)

Authors	Study Characteristics	Control Group	Measurement of Anxiety disorders	Rates of Anxiety Disorders
Sewell et al., 2000	*n* = 183 homosexual HIV+ men who reported nonintravenous drug use	84 seronegative nonintravenous drug using homosexual men; national comorbidity study as additional control group	Structured Clinical Interview for the DSM-IV Axis I (SCID-I[4])	19% of HIV+ participants met criteria for any anxiety disorder, compared to 18% in seronegative control group and 19% in the national comorbidity survey. There were no significant differences in rates of agoraphobia w/o panic, OCD, panic disorder, social phobia, or simple phobia.
Orlando et al., 2002	*n* = 2864 selected from the HIV Cost and Services Utilization Study (HCSUS[1]) who were reached for reassessment	None	Composite International Diagnostic Interview - Short Form (CIDI-SF[2])	At baseline assessment 47.9% of participants met criteria for any psychological disorder, 15.8% met criteria for GAD and 10.5% met criteria for panic disorder
Tucker, Burnam, Sherbourne, Fuan-Yue Kung, & Gifford, 2003	*n* = 1910 participants selected from the HIV Cost and Services Utilization Study (HCSUS[1]) indicating medication adherence	None	Composite International Diagnostic Interview (CIDI[3]) for GAD and panic disorder	3% of the total sample met criteria for GAD, and 13% for panic disorder
Mellins, Kang, Cheng-Shuin Leu, Havens, & Chesney, 2003	*n* = 128 HIV+ females; 58% African American	None	Clinical Diagnostic Questionnaire (CDQ[5])	50% of participants met criteria for a current psychiatric disorder

Palmer, Salcedo, Miller, Winiarski, & Arno, 2003	*n* = 107; 47% male, 63% Hispanic	None	SCID-I[4]	12% met criteria for panic disorder with and without agoraphobia; 0% met criteria for GAD
Ingersol, 2004	*n* = 120; 61.7% male, 83.3% African American, 47.5% disabled	None	CIDI-SF[2]	44.4% met criteria for any anxiety disorder, 26.1% for simple phobia, 14.8% for social phobia, 11.3% for panic attacks, and 9.6% for agoraphobia
Lambert, Keegan, & Petrak, 2005	*n* = 82 HIV+ females; 75% African American, 63% unemployed	None	Hospital Anxiety and Depression Scale (HADS[6])	44% experienced moderate to severe anxiety, indicative of an anxiety disorder
Whetten et al., 2006	*n* = 141; 55.7% male, 79.3% African American, 63.1% temporarily/permanently disabled	None	SCID-I[4]	29.8% of participants met criteria for PTSD, 9.22% met criteria for panic disorder
Pence, Miller, Whetten, Eron, & Gaynes, 2006	*n* = 1125; 66.7% male, 62.6% African American	None	Substance Abuse and Mental Illness Symptom Screener (SAMISS[7])	20.3% of participants met criteria for any anxiety disorder, 5.4% for panic disorder,
Nurutdinova et al., 2012	*n* = 9,003; Review of medical records for ICD-9-CM diagnostic codes	None	Psychiatric Disorder Diagnoses through VA healthcare system	18% of HIV+ veterans met criteria for an anxiety disorder
Reif et al., 2012	*n* = 40; 65% male, 80% African American, 62% over age 40	None	Brief Symptom Inventory (BSI[8]) and Short Form-12 mental health index (SF-12[9])	scores indicated 33% had a "probably anxiety disorder"
Lopes et al., 2013	*n* = 34,653 individuals taken from the National Epidemiologic Survey on Alcohol and Related Conditions, including 149 PLWHA	Non-HIV infected persons assessed during this survey	Alcohol Use Disorder and Associated Disabilities Interview Schedule – DSM-IV Version (AUDADIS-IV; Grant et al., 2001	HIV+ men were four times as likely to meet criteria for an anxiety disorder compared to HIV- men (OR = 4.02; 33.43% met criteria for any anxiety disorder), while HIV+ women were only marginally more likely to meet criteria for an anxiety disorder compared to HIV- women (OR = 1.17; 23.74% met criteria for any anxiety disorder).

Parhami, Fong, Siani, Carlotti, & Khanlou, 2013	*n* = review of 7834 medical records from HIV+ persons in California; mean age = 43.57, 88% male, 37% white	None	Diagnoses taken from medical records through AIDS Healthcare Foundation	16% of sample met criteria for an anxiety disorder
Glemaud et al., 2014	*n* = 96 HIV+ Haitian females, mean age = 74.6	None	Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME-MD[10])	42.7% of participants reported significant anxiety, and 2.1% reported panic-like symptoms
Robertson et al., 2014	*n* = 2863 PLWHA, 61.7% male, mean age = 42.9	None	HADS[6]	33.3% of sample met criteria for a "possible anxiety disorder"
Kosiba, Gonzalez, O'Cleirigh, & Safren, 2014	*n* = 131 PLWHA in treatment for opioid use	None	MINI International Neuropsychiatric Interview (MINI[15])	Among PLWHA 15.5% met criteria for GAD and 15.1% met criteria for PD. Among controls 4.3% met criteria for GAD, 6.5% met criteria for PD. All *p's* < .001
O'Cleirigh, Magidson, Mayer, & Safren, 2014, 2014	*n* = 503 HIV infected gay/bisexual men	None	Medical Record Review	22.3% of participants met criteria for social phobia, 9.5% met criteria for panic disorder, and 7.8% met criteria for GAD

[1]HIV Cost and Services Utilization Study (HCSUS; Bozzetter et al., 1998); [2]Composite International Diagnostic Interview - Short Form (CIDI-SF; WHO, 1998); [3]Composite International Diagnostic Interview (CIDI; Kessler et al., 1998); [4]Structured Clinical Interview for the DSM-IV Axis I (SCID-I; First, Gibbon, Spitzer, & Williams, 1996); [5]Clinical Diagnostic Questionnaire (CDQ; Aidella, 2000); [6]Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983); [7]Substance Abuse and Mental Illness Symptom Screener (SAMISS; Pence et al., 1999); [8]Brief Symptom Inventory (BSI, Derogatis, & Melisaratos,1983); [9]Short Form-12 mental health index (SF-12, Hurst, Ruta, & Kind, 1998); [10]Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME-MD; Spitzer, Kroenke, & Williams, 1999); [11]Alcohol Use Disorder and Associated Disabilities Interview Schedule – DSM-IV Version (AUDADIS-IV; Grant et al., 2001); [12]Composite International Diagnostic Interview (CIDI; World Health Organization, 1998); [15]MINI International Neuropsychiatric Interview (MINI; Sheehan et al., 1998)

Table 3. Rates of Anxiety Disorders in Developing Countries (ordered chronologically)

Authors	Study Characteristics	Control Group	Measurement of Anxiety disorders	Rates of Anxiety Disorders
Petrushkin, Boardman, & Ovuga 2005	*n* = 46 Ugandans, 52.2% female, mean age = 36.6	None	MINI International Neuropsychiatric Interview (MINI[1])	32.6% met criteria for panic disorder, 23.9% met criteria for panic with agoraphobia, 10.9% for social anxiety disorder, and 4.3% for OCD
Olley, Seedat, Nei, & Stein, 2004	*n* = 149 HIV+ individuals living in South Africa; 70% female, mean age = 30	None	MINI[1]	14.8% of participants met criteria for PTSD, and 6.7% met criteria for GAD
Adewuya et al., 2007	*n* = 88 HIV+ individuals living in Nigeria newly diagnosed with HIV (first seropositive test < 1 month prior)	87 seronegative controls matched on age, sex, and socioeconomic status	MINI[1]	34.1% of HIV+ participants met criteria for any anxiety disorder, compared to 12.5% of controls (Odds Ratio = 3.57; CI = 1.65-7.72)
Spies et al., 2009	*n* = 429 HIV+ individuals living in South Africa; 67% Xhosa speaking, 25% Afrikaans speaking, 8% English speaking	None	K-10[2] and MINI[1]	15.3% met criteria for panic disorder, 18.4% agoraphobia, 12.3% social phobia, 21.5% PTSD, and 18.4% GAD
Marwick & Kaaya, 2010	*n* = 220 HIV+ persons living in Tanzania, 74% female, mean age = 41	None	Clinical Interview Schedule- Revised (CIS-R[3])	12.7% of participants met criteria for mixed anxiety and depression, 3.2% for a specific phobia, 1.8% for panic disorder, and .9% for OCD
Campos, Guimaraes, & Remien, 2010	*n* = 293 HIV+ individuals living in Brazil; 65.9% male, 52.9% under age 35	None	HADS[4]	35.8% of participants met criteria for moderate and severe anxiety, indicating an anxiety disorder

Sivasubramanian et al., 2011	*n* = 150 HIV+ Men who have sex with men in Mumbai, India	None	MINI[1]	24% met criteria for any anxiety disorder
Nebhinani, Mattoo, & Wanchu, 2011	*n* = 100 HIV+ individuals living in India; 59% male, mean age = 33.6	40 patients with rheumatoid arthritis	Structured Clinical Interview for the DSM-IV Clinician Version (SCID-CV[5])	1% of participants with HIV met criteria for panic disorder; 2.5% of participants with RA met criteria for panic disorder
Hasanah, Zaliha, & Mihiran, 2011	*n* = 271 PLWHA in Malaysia, 57.6% male, 60.1% between ages 30-39	None	HADS[4]	29% of the sample met criteria for a "probable anxiety disorder"
Olagunju, Adeyemi, Ogbolu, & Campbell, 2012	*n* = 300 HIV+ individuals living with HIV in Lagos, Nigeria; 38.7% male, mean age = 36.95	None	Schedule for Clinical Assessment in Neuropsychiatry (SCAN[6])	21.7% of the sample met criteria for an anxiety disorder, including 4% for social anxiety disorder, 1.7% for panic disorder, and 6.2% for "anxiety disorder unspecified"
Breuer et al., 2014	*n* = 366 HIV+ individuals living in South Africa; 71% female, mean age = 32.7	None	Substance and Mental Illness Symptom Screener (SAMISS[7]) and Mini International Neuropsychiatric Interview (MINI[1])	3% of the sample met criteria for an anxiety disorder

[1]MINI International Neuropsychiatric Interview (MINI; Sheehan et al., 1998); [2]K-10, Kessler et al., 2002; [3]Clinical Interview Schedule- Revised (CIS-R; Lewis, Pelosi, Araya, Dunn, 1992); [4]Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983); [5]Structured Clinical Interview for the DSM-IV Clinician Version (SCID-CV; First et al., 1997); [6]Schedule for Clinical Assessment in Neuropsychiatry (SCAN; World Health Organization, 1999); [7]Substance and Mental Illness Symptom Screener (SAMISS; Pence et al., 1999)

Table 4. Rates of HIV Among Anxiety-Disordered Populations

Authors	Study Characteristics	Control Group	Measurement of Anxiety disorders	Rates of Anxiety Disorders
Stoskopf, Kim, & Glover, 2001	*n* = 378,710 individuals, 1,775 HIV+ individuals	None	Data from a range of Hospitals in South Carolina was taken, ICD-9[1] diagnostic codes were used	People with mental illness were 1.44 times as likely to have HIV/AIDS than persons without a mental illness ($p < .001$)

[1]International Classification of Diseases-9; (ICD-9, US Department of Health and Human Services, 1980)

Table 5. Anxiety and its Disorders in Relation to Medication Adherence

Authors	Study Characteristics	Clinical Process	Outcome Measured	Design	Main Finding
Catz, Heckman, Kochman, & DiMarco, 2001	*n* = 113 PLWHA, age 47-69	Anxiety and somatization via the Symptom Checklist 90-Revised (SCL-90-R[6])	Self-reported past-week HIV medication adherence	Cross-sectional	Patients reporting adhering to their medication had significantly lower levels of anxiety (r^2 = .06) and somatization (r^2 = .10)
Van Servellen, Chang, Garcia, & Lombardi, 2002	*n* = 182, 56.93% male, 42.7% Hispanic, average age 38.15	Hospital Anxiety and Depression Scale (HADS[7])	Self-reported HIV medication adherence, confirmed with medical record review	Cross-sectional	HADS Anxiety scores significantly predicted self-reported HIV medication nonadherence (r^2 = .05)
Mellins et al., 2002	*n* = 128, 58% African American, mean age = 38	Clinical Diagnostic Questionnaire (CDQ[8])	self-report taken from the Adult AIDS Clinical Trials Group (AACTG[9])	Cross-sectional	Presence of any psychiatric disorder (*OR* = 8.76) predicted missed HIV medication
Escobar et al., 2003	*n* = 283, 68.6% male, mean age = 36	State-Trait Anxiety Inventory (STAI[10])	Percentage of prescriptions filled in the past 4-6 months	Cross-sectional	Medication nonadherent patients were more likely to score >75% on the STAI state or trait anxiety scales (*OR* = 3.49) compared to medication adherent patients
Palmer et al., 2003	*n* = 107 opioid-addicted PLWHA, 47% male, 63% Hispanic	Structured Clinical Interview for the DSM-IV Axis I (SCID-I[13])	AACTG[9] measurement of past 3 day adherence	Cross-sectional	Anxiety disorders were not significantly related to missed HIV medication (ESU)

Tucker et al., 2003	*n* = 1,910, 78% male, 32% African American	Composite International Diagnostic Interview - Short Form (CIDI-SF[12])	Self-reported HIV medication adherence	Prospective	GAD (*OR* = 2.4) and Panic Disorder (*OR* = 2.0) significantly predicted nonadherence to HIV medication one year later
Carrieri et al., 2003	*n* = 96 drug-injecting HIV infected persons, 68.8% men	Self-reported symptoms of anxiety	Self-report of adherence in the past week	Prospective	Anxiety-related somatic symptoms significantly predicted HIV medication non adherence in the past week (*OR* = 2.7) six months later
Waldrop-Valverde & Valverde, 2005	*n* = 58 HIV+ injection drug users, 25.9% homeless, 24.1% female	STAI[10]	Self-reported one-day adherence	Cross-sectional	Anxiety was not significantly related to past-day adherence (ESU)
Schonnesson, Williams, Ross, Bratt, & Keel, 2006	*n* = 193 PLWHA in Sweden, 100% Caucasian, 75% male, mean age = 43	The Brief Symptom Inventory (BSI[11])	Self-report confirmed with medical record review	Cross-sectional	Anxiety symptoms predicted sub-optimal HIV medication adherence (*OR* = 6.25)
Roux et al., 2009	4,963 PLWHA in France	HADS[7]	Self-reported adherence and virology data	Cross-sectional	Anxiety symptoms were associated with nonadherence to cART in men (*OR* = 1.5) but not women (ESU).
Campos et al., 2010	*n* =293 Brazilian PLWHA, 65.9% male	HADS[7]	Semi-structured clinical interview measuring past 3 day adherence	Prospective	Severe symptoms of anxiety predicted HIV medication non-adherence (*RH* [Relative Hazard] = 2.28

Nel & Kagee, 2013	*n* = 107 HIV infected persons in South Africa, 82.2% female	Beck Anxiety Inventory (BAI[14])	Self-report scale for medication adherence[15]	Cross-sectional	No significant relation was found between anxiety and medication adherence (*OR* = 1.425)
Kosiba, Gonzalez, O'Cleirigh, & Safren, 2014	*n* = 131 PLWHA in treatment for opioid use	MINI International Neuropsychiatric Interview (MINI[15])	Medication-Event-Monitoring System (MEMS; AAR-DEX)	Cross-Sectional	Presence of panic disorder significantly predicted medication adherence (r^2 = .05)

[1]MINI International Neuropsychiatric Interview (MINI; Sheehan et al., 1998); [2]Hamilton Rating Scale for Anxiety (HAM-A; Hamilton, 1959); [3] Symptom Checklist 90 (SCL-90; Derogatis, 1983); [4]General Health Questionnaire 28 (GHQ-18; Mulder, Antoni, Duivenvoorden, Kaufmann, & Goodkin, 1995); [5]International Classification of Diseases-9; (ICD-9, US Department of Health and Human Services, 1980); [6]Symptom Checklist 90-Revised (SCL-90-R; Derogatis, 1983); [7]Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983); [8] Clinical Diagnostic Questionnaire (CDQ; Aidella, 2000); [9]Adult AIDS Clinical Trials Group (AACTG; Chesney et al., 2000); [10]State-Trait Anxiety Inventory (STAI, Spielberger, Gorsuch, & Lushene, 1970); [11]The Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983); [12]Composite International Diagnostic Interview - Short Form (CIDI-SF; WHO, 1998); [13]Structured Clinical Interview for the DSM-IV Axis I (SCID-I; First, Gibbon, Spitzer, & Williams, 1996); [14]Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988); [15]Self-report scale for medication adherence (Simoni et al., 2006); [16]Global Appraisal of Individual Needs (GAIN-I Version 5; Dennis, 1998); [17]NM-Assist (NIDA, 2009); [18]Inventory of Depression and Anxiety Symptoms (IDAS; Watson et al., 2007); [19]Alcohol Use Disorders Identification Test (AUDIT; Saunders, Aasland, Bbor, & Grant, 1993); [20]Time Line Follow Back (TLFB; Sobell & Sobell, 1993); [21]Mini Social Phobia Inventory (MINI SPIN; Connor, Kobak, Churchill, Katzelnick, & Davidson, 2001); [22]Patient Health Questionnaire (PHQ, Spitzer, Kroenke, & Williams, 1999); [23]Depression Anxiety and Stress Scale (DASS; Lovibond & Lovibond, 1995); [24]World Health Organization Quality of Life Questionnaire Brief version (WHOQOL-BREF; Skevington, Sartoris, & Amir, 2004); [25]SF-36 (Brazier, Roberts, & Deverill, 2002); [26]EQ-5D (Gusi, Olivares, & Rajendram, 2010); [27]Functional Assessment of Chronic Illness Therapy (FACIT; Peterman, Cella, Mo, & McCain, 1997); [28]ACTG-SF-21 (Wu et al., 1997); [22]Brief Symptom Rating Scale (BSRS-5; Lung & Lee, 2008); [30]MINI International Neuropsychiatric Interview (MINI; Sheehan et al., 1998); [31]Hong Kong List Learning Test (HKLLT; Chan & Kwok, 1999); [32]Patients Assessment of Own Functioning Inventory (PAOF-Memory; Chelune, Heaton, & Lehman, 1986); [33]Profile of Mood States (POMS; McNair, Lorr, & Droppleman, 1981); [34]Prospective and Retrospective Memory Questionnaire (PRMQ; Crawford et al., 2003); [35]Successful Cognitive Ageing (SCA; Antinori et al., 2007); [36]Wechsler Adult Intelligence Scale (WAIS-R; Wechsler, 2002).

Table 6. Existing HIV/Anxiety Interventions

Authors	Therapeutic Style	Outcome	Limitations
Pobuda et al., 2008	20 sessions of Psychodynamic Therapy	Improvement in overall functioning, including symptom distress	79 HIV+ Gay, primarily white men; no follow-up data; no direct measure of anxiety; no control group
Duncan et al., 2012	Eight session Mindfulness-based Stress Reduction (MSBR) versus Wait-List control (WLC); intended outcome: reducing cART symptoms and distress	MSBR group showed significant reduction in negative symptoms associated with HART and overall distress	Small heterogeneous sample; no significant findings regarding depression or affect; no direct measure of anxiety
Gayner et al., 2012	MSBR vs. treatment as usual (TAU) group; intended outcome: management of affective symptoms and improved quality of life	MSBR group showed significant reduction in avoidance, and higher positive affect post intervention compared to TAU group	Exclusively gay male sample; no direct measurement of anxiety or depression; upwards of 50% of sample was engaged in concurrent treatment during this study
Gonzalez-Garcia et al., 2014	Mindfulness-based Cognitive Therapy (MBCT) vs. WLC; intended outcome: quality of life, emotional status, and CD4 cell count	MBCT group showed significantly reduced anxiety and depression, and significantly increased quality of life and CD4 cell counts	Small sample size (n = 40), no direct therapeutic focus on anxiety
Gluhoski, 1997	Cognitive Therapy (CT)	Participant depression decreased post-treatment	Case study; no direct measurement of anxiety
Côté & Pepler, 2002	Two nursing interventions on either cognitive coping skills or expression of emotions	Both interventions reduced negative affect, but did not increase positive affect	Small sample size; no follow-up; very brief intervention
Antoni et al., 2000	10 session Cognitive Behavioral Stress Management (CBSM) vs. WLC; intended outcome: anxiety, norepinephrine output, and CD4 T cell count	CBSM participants showed significantly lower anxiety and mood scores than controls, including lower norephinephrine and higher CD4 T cells	small, homogeneous sample of gay/bisexual men; Intervention focus primarily on relaxation and stress management

Berger et al., 2008	12-session CBSM Treatment vs. waitlist control; intended outcome: Disease markers (e.g. CD4 cell count) and psychosocial parameters (e.g. anxiety)	CBT participants showed reduced anxiety symptomology at baseline and 12-month follow up compared to WLC group	Small heterogeneous sample; therapeutic focus on relaxation, not anxiety or disease/anxiety interrelations
Carrico et al., 2009	15 session CBT Treatment vs. waitlist control; intended outcome: psychosocial adjustment	No intervention-related reduction in anxiety or depression compared to WLC	only one measure of anxiety (State-Trait Anxiety Index); focus of treatment on adjustment rather than anxiety
Inouye, Flannelly, & Flannelly, 2001	14 bi-weekly CBT sessions vs. WLC; intended outcome: self-management and coping skills	CBT participants showed significantly lower anxiety, depression, and overall mood compared to controls	small sample size; no anxiety-specific sessions in therapy strategy
Molassiotis et al., 2002	12 2-hour CBT sessions vs. peer support counseling (PSC); intended outcome: decreasing psychological distress and increasing quality of life	Both CBT and PSC reduced anxiety, depression, and overall mood	small, heterogeneous sample; no anxiety-specific component to treatment

Table 7. Inclusionary and Exclusionary Criteria

Criteria	Inclusionary	Exclusionary
HIV+	X	
Between the ages of 18-65	X	
Capable of providing informed consent	X	
High trait anxiety, indexed by STAI-T > 39	X	
Poor cART medication adherence	X	
Interfering/unstable psychiatric conditions		X
Participation in CBT for anxiety disorders in the past year		X
Insufficient command of the English language		X
Inability to provide informed, written consent		X

Table 8. Participant Demographics

	Total (n = 42)	Active (n = 19)	Control (n = 18)	Not Randomized (n = 5)
Sex				
Male	54.80%	52.60%	61.10%	40.00%
Female	45.20%	47.40%	38.90%	60.00%
Sexuality				
heterosexual	59.50%	47.40%	66.70%	80.00%
homosexual	26.20%	31.60%	22.20%	20.00%
bisexual	14.30%	21.10%	11.10%	0.00%
Age				
	M = 46.95 (SD = 9.93)	*M* = 45.68 (*SD* = 11.56)	*M* = 49.83 (*SD* = 7.05)	*M* = 41.40 (*SD* = 10.74)
Race				
Black	45.20%	42.10%	44.40%	60.00%
White	35.70%	47.40%	22.20%	40.00%
Hispanic	9.50%	0.00%	22.20%	0.00%
Black/Hispanic	7.10%	5.30%	11.10%	0.00%
Other (Native American)	2.40%	5.30%	0.00%	0.00%
Education				
Did not graduate HS	16.70%	10.50%	22.20%	20%
High school equivalent	21.40%	10.50%	33.30%	40%
Some College	40.50%	52.60%	27.80%	40%
2-year degree	9.50%	10.50%	5.60%	20%
4-year degree	11.90%	15.80%	11.10%	0%
Marital Status				
Never Married	42.90%	47.40%	44.40%	20.00%
Divorced/Separated	35.70%	36.80%	33.30%	40.00%
Married/co-habitating	16.70%	15.80%	11.10%	40.00%
widowed	4.80%	0%	11.10%	0.00%
Employment				
Full-time	14.30%	15.80%	5.60%	40.00%
Part-time	9.50%	15.80%	0.00%	20.00%
Unemployed	76.20%	68.40%	94.40%	40.00%
Annual Income				
$0-$10,000	52.40%	52.60%	55.60%	40.00%
$10,001-$20,000	26.20%	15.80%	38.90%	20.00%
$20,001-$30,000	11.90%	15.80%	0.00%	40.00%
$30,001+	9.60%	15.80%	5.60%	0.00%

Table 9. HIV Characteristics

	Total (n = 42)	Active (n = 19)	Control (n = 18)	Not Randomized (n = 5)
CD4 T-cell	499.64 (333.58)	518.13 (392.09)	465.23 (279.28)	533.6 (334.05)
viral load % undetectable	54.80%	52.60%	60.00%	80%
Years HIV+	19.2 (8.23)	14.97 (9.34)	22.68 (5.83)	18.05 (7.68)
AIDS Diagnosed	50% (Yes)	47.4% (Yes)	47.1% (Yes)	80% (Yes)

Table 10. Psychiatric Characteristics

	Total (n = 42)	Active (n = 19)	Control (n = 18)	Not Randomized (n = 5)
Any Psychological Disorder				
	90.5% (Yes)	100% (Yes)	77.8% (Yes)	20% (Yes)
Average # Dx	2.93	3.21	2.42	3.4
Anxiety Disorders				
	64.3% (Yes)	63.2% (Yes)	66.7% (Yes)	60% (Yes)
Average # Dx	1.1	1.32	0.84	1
Mood Disorders				
	69% (Yes)	73.7% (Yes)	61.1% (Yes)	80% (Yes)
Average # Dx	1.05	0.89	1	1.8
Substance Use Disorder				
	40.5% (Yes)	47.4% (Yes)	33.3% (Yes)	40% (Yes)
Average # Dx	0.62	0.74	0.42	0.8

Table 11. Assessment Timeline

Measures	Baseline	Week 3*	Week 6*	Week 12	Week 24	Week 36
Anxiety Symptoms: STAI	X	X	X	X	X	X
Psychiatric Diagnoses: SCID MINI	X			X	X	X
Medication Adherence	X	X	X	X	X	X
Reasons for Missing Meds: ACTG	X	X	X	X	X	X
Quality of Life: WHOQOL	X	X	X	X	X	X
Depression Symptom: IDAS	X	X	X	X	X	X
Anxiety Sensitivity: ASI-3	X	X	X	X	X	X

* Week 3 and Week 6 represent mid-and post-treatment assessments administered after Session 3 (approximately 3 weeks after baseline) and Session 6 (approximately six weeks after baseline) for participants in the active condition. Control condition participants were also assessed 3-weeks and 6-weeks post intake assessment.

Table 12. Differences Across Conditions

Variable	F statistic	p-value
Demographic Information		
Age	1.71	NS
Marital status	0.06	NS
Income Level	0.39	NS
Education	2.36	NS
Sexuality	1.37	NS
Race	2.12	NS
Occupation	3.52	NS
Recruitment Site	2.08	NS
HIV-Specific Variables		
HIV/AIDS Diagnosis	0.03	NS
CD4 T-Cell Count	0.16	NS
Outcome Variables		
STAI Trait	3.87	NS
Self-Report Med Ad.	4.6	0.04
Reasons for Missing	0.54	NS
ASI3	0.17	NS
IDAS Depression	1.19	NS
WHOQOL (all subscale	.00-1.76	NS

Table 13. Attrition Across Conditions

	Active	Control	F Statistic	p-value
Week 1	63.2%			
Week 2	42.1%			
Week 3	31.6%	88.9%	18.06	<.001
Week 4	31.6%			
Week 5	31.6%			
Week 6	26.3%	66.7%	6.86	0.01

Table 14. Repeated Measures GLM for Medication Adherence

	F	Sig	Partial Eta Squared	Observed Power
HIV Medication Adherence				
Time	3.13	0.1	0.173	0.38
Time*Condition	3.5	0.08	0.189	0.42
Reasons for Missing Medications				
Time	2.23	NS	0.146	0.28
Time*Condition	1.15	NS	0.082	0.17
Anxiety Symptoms				
Time	5.91	0.03	0.282	0.62
Time*Condition	7.36	0.02	0.329	0.72
Anxiety Sensitivity				
Time	8.72	0.1	0.368	0.79
Time*Condition	20.27	<.001	0.575	0.99
Depressive Symptoms				
Time	32.09	<.001	0.7	0.999
Time*Condition	22.03	<.001	0.61	0.99
Physical Quality of Life				
Time	6.94	0.2	0.316	0.69
Time*Condition	5.47	0.3	0.267	0.59
Psychological Quality of Life				
Time	10.86	<.01	0.42	0.87
Time*Condition	8.89	<.01	0.372	0.8
Independence Quality of Life				
Time	0.35	NS	0.023	0.09
Time*Condition	1.83	NS	0.108	0.24
Social Quality of Life				
Time	0.96	NS	0.06	0.15
Time*Condition	3.49	0.08	0.189	0.42
Environmental Quality of Life				
Time	5.43	0.03	0.266	0.59
Time*Condition	5.57	0.03	0.271	0.6
Spiritual Quality of Life				
Time	10.87	<.01	0.4	0.87
Time*Condition	10.33	<.01	0.408	0.85

Table 15. Self-Reported HIV Medication Adherence

Intent to Treat			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	19.4	15.85	15.58
Active	42.3	21.83	24.29
Cohen's D	-0.71	-0.25	-0.31
Pearson's r	-0.33	-0.12	-0.15

Treatment Completers			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	21.84	19.53	15.58
Active	52.38	23.33	24.29
Cohen's D	-1.06	-0.14	-0.31
Pearson's r	-0.47	-0.07	-0.15

Table 16. Reasons for Missing Medications

Intent to Treat			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	8.32	8.63	7.3
Active	7.44	11.5	8.4
Cohen's D	0.17	-0.47	-0.21
Pearson's r	0.08	-0.23	-0.11

Treatment Completers			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	8.48	8.99	7.3
Active	11.75	12.2	8.4
Cohen's D	-0.66	-0.49	-0.21
Pearson's r	-0.31	-0.24	-0.11

Table 17. Anxiety Symptoms

Intent to Treat			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	49.32	48.31	51.75
Active	54.4	50.33	44.92
Cohen's D	-0.65	-0.08	0.64
Pearson's r	-0.31	-0.04	0.3

Treatment Completers			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	51.11	49.52	51.75
Active	56.6	49.4	44.9
Cohen's D	-0.66	-0.01	0.64
Pearson's r	-0.31	-0.01	0.3

Table 18. Anxiety Sensitivity

Intent to Treat			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	26.12	29.56	30.73
Active	28.51	17.5	10.11
Cohen's D	-0.13	0.69	1.5
Pearson's r	-0.07	0.33	0.6

Treatment Completers			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	26.02	34.28	30.73
Active	32.8	17.8	10.11
Cohen's D	-0.42	0.92	1.5
Pearson's r	-0.2	0.42	0.6

Table 19. Depression

Intent to Treat			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	53.81	48.93	51.27
Active	58.79	52	40
Cohen's D	-0.36	-0.22	0.8
Pearson's r	-0.18	-0.11	0.37

Treatment Completers			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	53.42	50.83	51.27
Active	65.2	48.8	40
Cohen's D	-0.92	0.15	0.8
Pearson's r	-0.42	0.07	0.37

Table 20. Physical Quality of Life

Intent to Treat			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	11.5	12.27	11.33
Active	10.41	12.17	14.6
Cohen's D	-0.35	-0.03	1.13
Pearson's r	-0.17	-0.01	0.49

Treatment Completers			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	11.08	11.92	11.33
Active	10.4	13.4	14.6
Cohen's D	-0.19	0.43	1.13
Pearson's r	-0.1	0.21	0.49

Table 21. Psychological Quality of Life

Intent to Treat			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	11.13	11.07	11.3
Active	10.1	11	12.8
Cohen's D	-0.43	-0.02	0.49
Pearson's r	-0.21	-0.01	0.24

Treatment Completers			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	11.11	10.61	11.3
Active	9.01	10.53	12.8
Cohen's D	-0.8	-0.03	0.49
Pearson's r	-0.37	-0.01	0.24

Table 22. Independence Quality of Life

Intent to Treat			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	11.56	11.49	10.11
Active	11.51	12.5	13.8
Cohen's D	-0.02	0.39	1.01
Pearson's r	-0.01	0.19	0.45

Treatment Completers			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	10.56	11.33	10.11
Active	12.67	13	13.8
Cohen's D	0.79	0.62	1.01
Pearson's r	0.37	0.3	0.45

Table 23. Social Quality of Life

Intent to Treat			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	10.98	10.27	9.42
Active	10.88	11.5	10.4
Cohen's D	-0.03	0.52	0.43
Pearson's r	-0.02	0.25	0.21

Treatment Completers			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	11.33	10.42	9.42
Active	9.8	10.8	10.4
Cohen's D	-0.6	-0.12	0.43
Pearson's r	-0.29	-0.06	0.21

Table 24. Environmental Quality of Life

Intent to Treat			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	12.35	12.29	12.04
Active	11.81	13.83	15.67
Cohen's D	-0.2	0.78	1.73
Pearson's r	-0.1	0.36	0.65

Treatment Completers			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	12.06	12.4	12.04
Active	12.8	13.4	15.57
Cohen's D	0.35	0.5	1.73
Pearson's r	0.17	0.24	0.65

Table 25. Spiritual Quality of Life

Intent to Treat			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	13.96	14.73	13.53
Active	13.18	13.33	16
Cohen's D	-0.24	-0.42	0.85
Pearson's r	-0.12	-0.2	0.39

Treatment Completers			
	Pre-Treatment	**Mid-Treatment**	**Post-Treatment**
Control	13.47	13.92	13.53
Active	11.6	14.2	16
Cohen's D	-0.5	0.09	0.85
Pearson's r	-0.24	0.05	0.39

Table 26. Rates of Outcome variables through Follow-Up

Variable	Baseline (n = 5)	Week 3 (n = 5)	Week 6 (n = 5)	1M FU (n = 3)	3M FU (n = 2)
HIV Medication Adherence (% Missed)	52.38	23.22	24.29	28.57	3.57
Reasons for Missing Medications	11.75	12.2	8.4	9.08	9.5
Anxiety	56.6	49.4	44.9	43.25	47.5
Anxiety Sensitivity	32.8	17.8	10.11	13.67	23.5
Depression	65.2	48.8	40	41.67	51.5
Physical QOL	10.4	13.4	14.6	15.33	13
Psychological QOL	9.01	10.53	12.8	12.67	11.67
Independence QOL	12.67	13	13.8	14.89	11.83
Social QOL	9.8	10.8	10.4	13.33	11.83
Environmental QOL	12.8	13.4	15.57	15.43	13.57
Spiritual QOL	11.6	14.2	16	13.33	12

Figure 1. Rates of Anxiety Disorders as Diagnosed by Questionnaire Compared to Interview

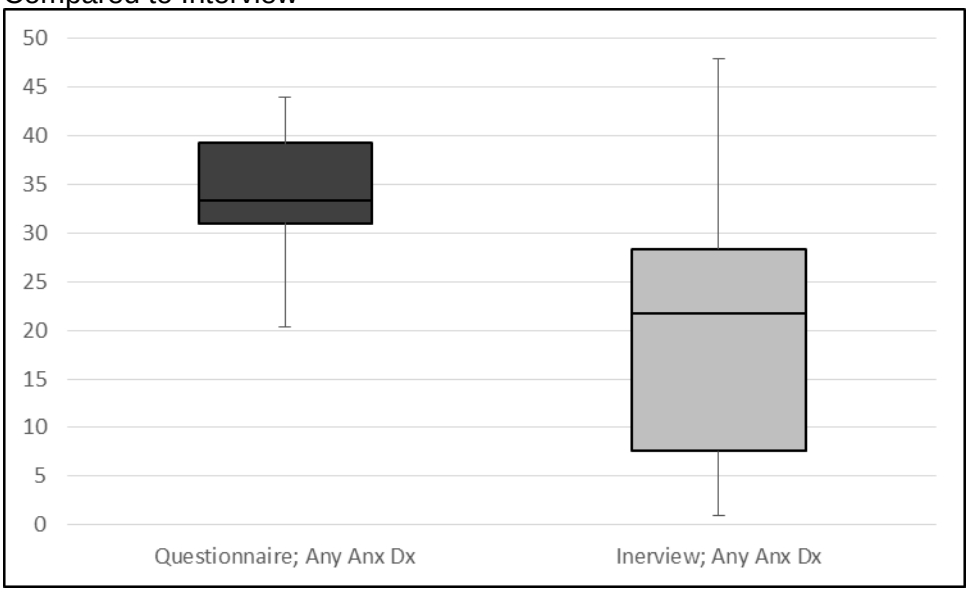


Figure 2. Rates of Anxiety disorders among PLWHA using diagnostic interview

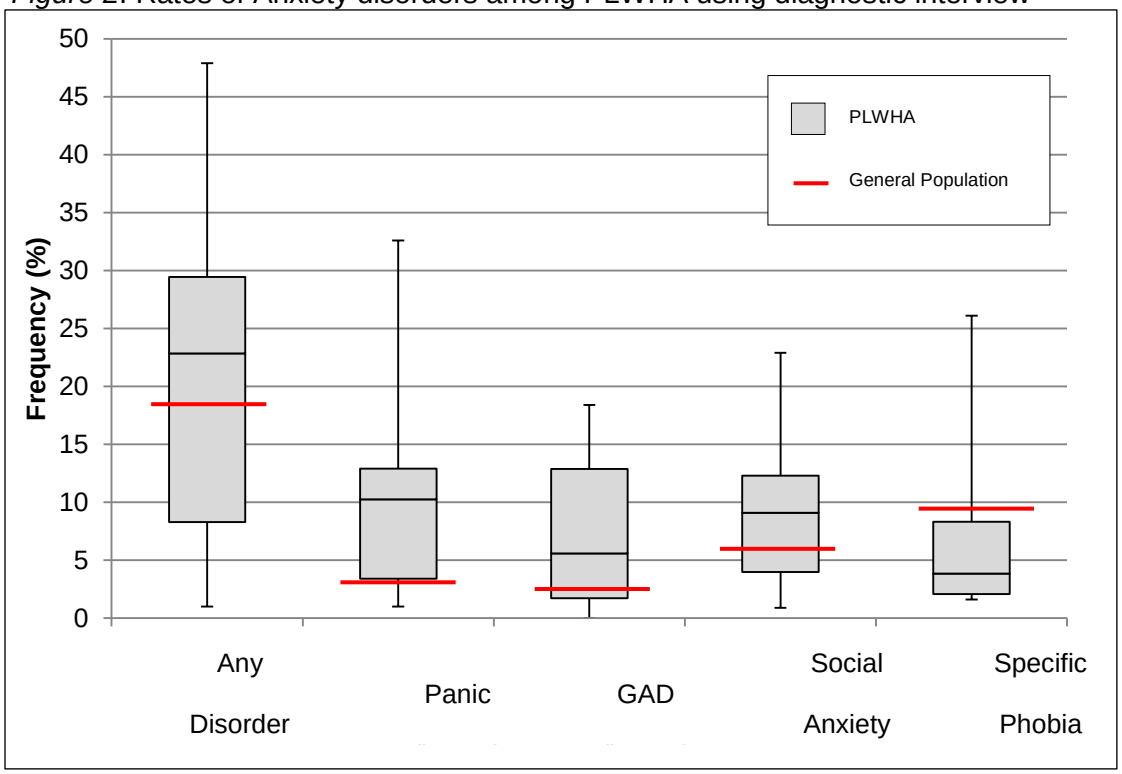


Figure 3. Rates of Anxiety Disorders in Developed compared to Developing Countries

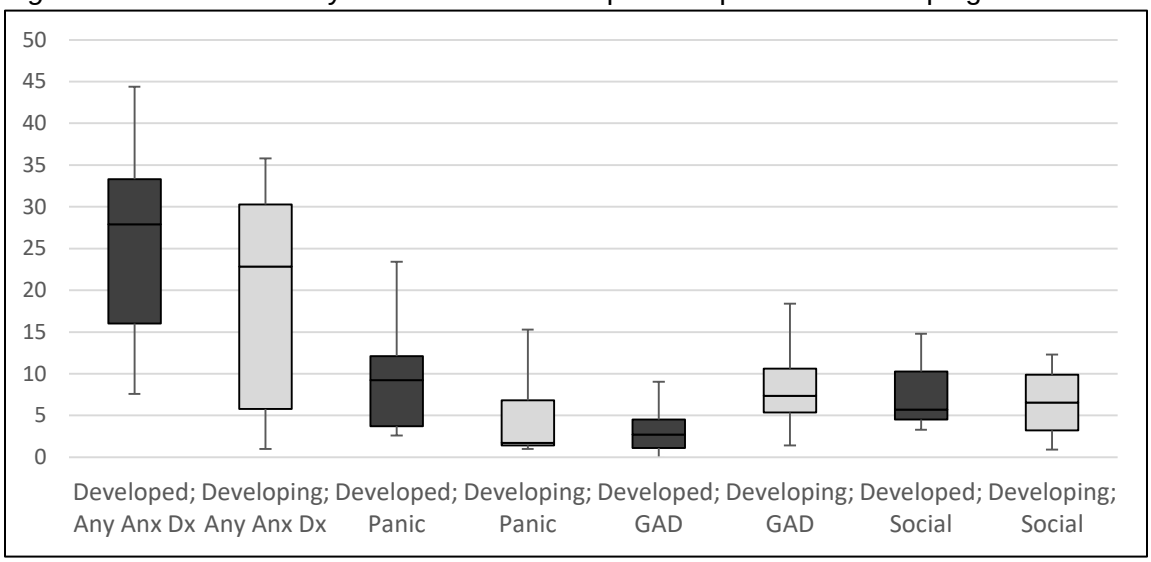


Figure 4. Rates of Anxiety Disorders in Drug-Using compared to Non-Drug Using Groups

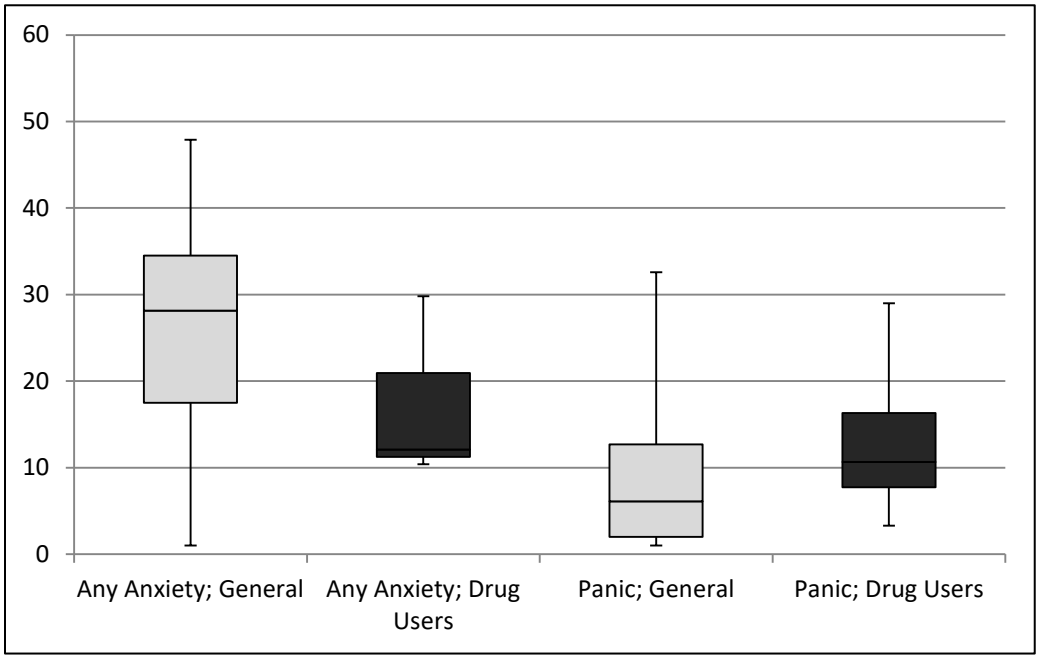


Figure 5. CONSORT Diagram

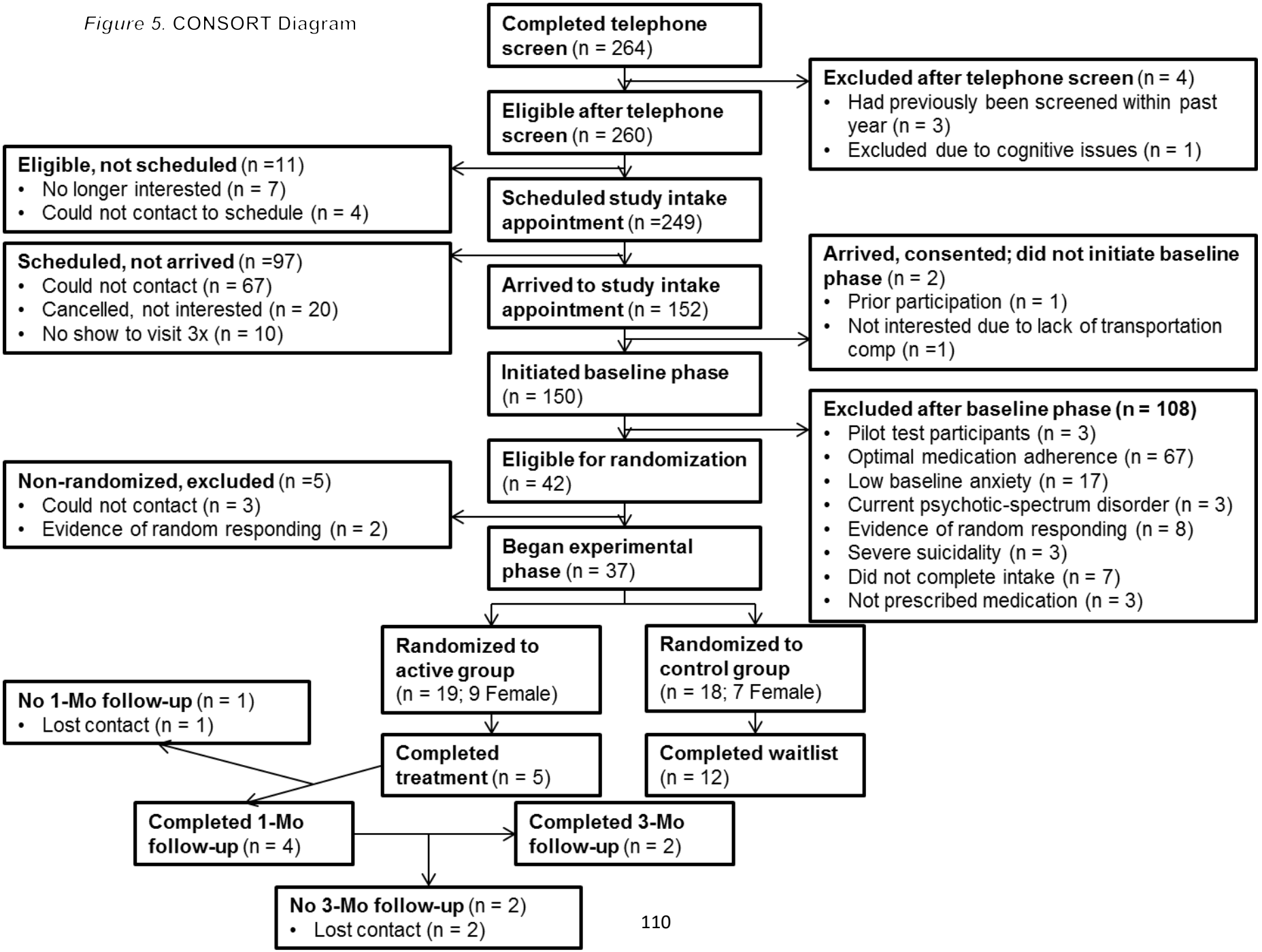


Figure 6. Study Procedures

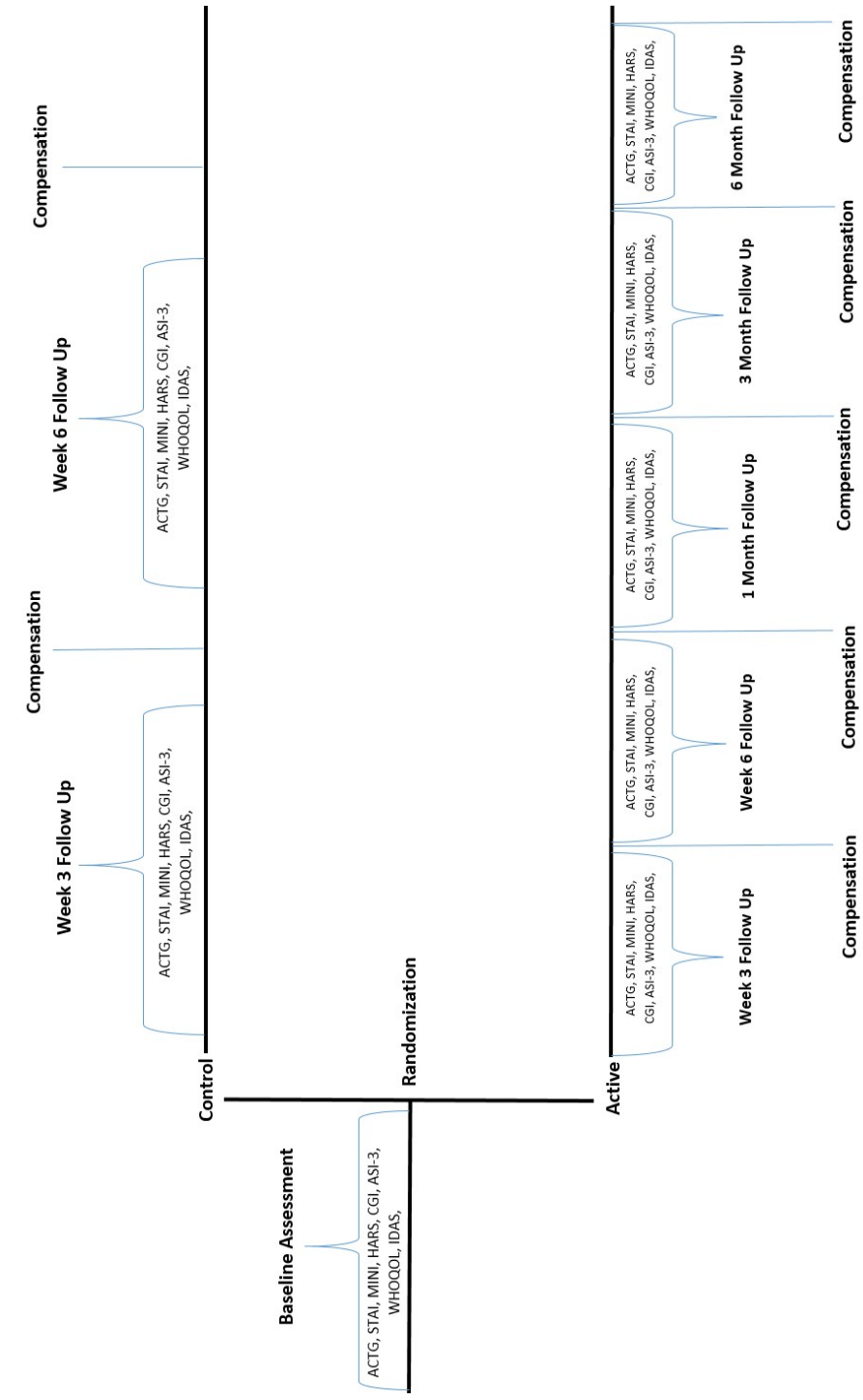


Figure 7. Self-Reported Medication Adherence

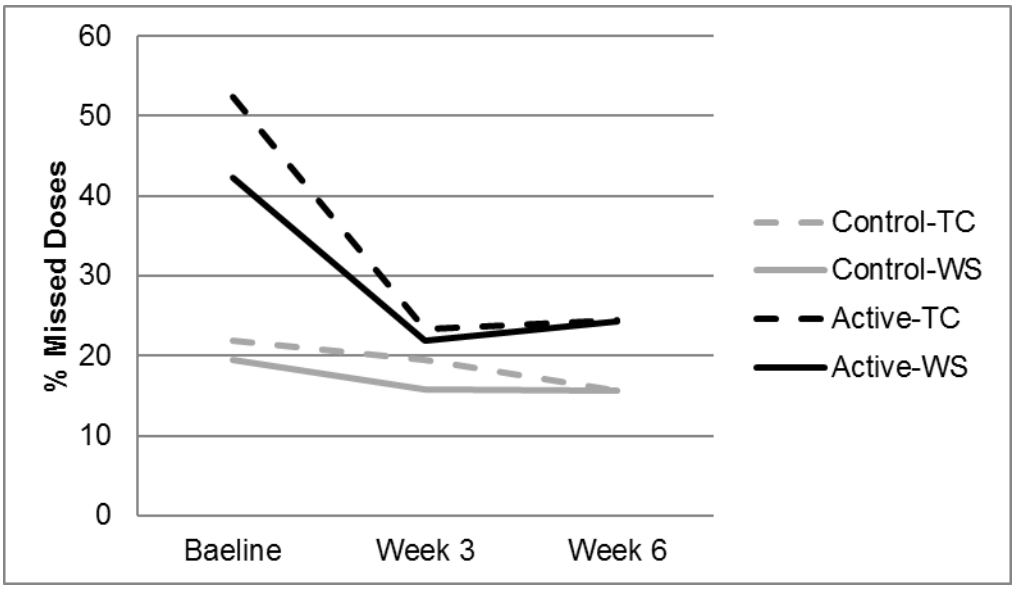


Figure 8. Reasons for Missing Medications

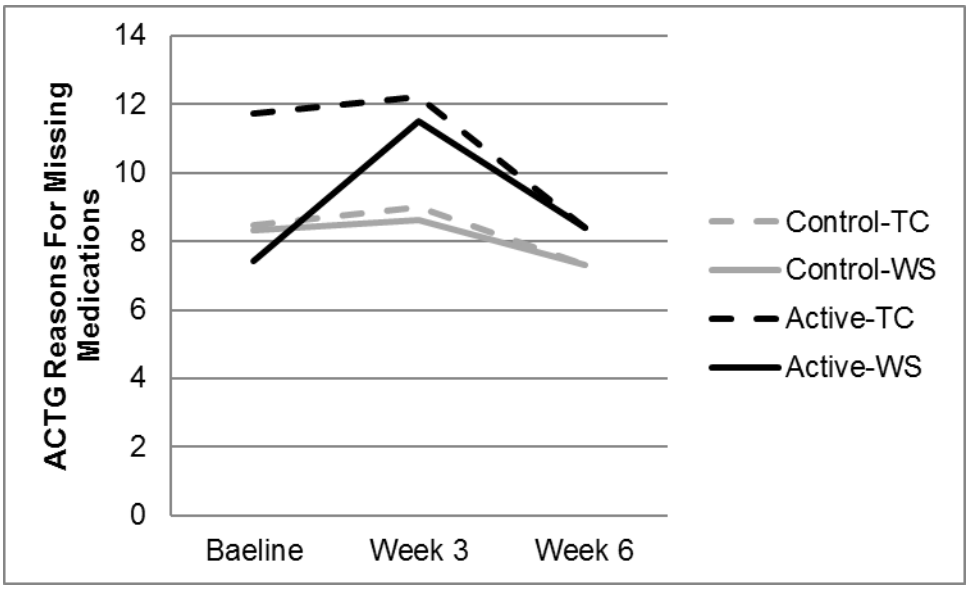


Figure 9. Anxiety Symptoms

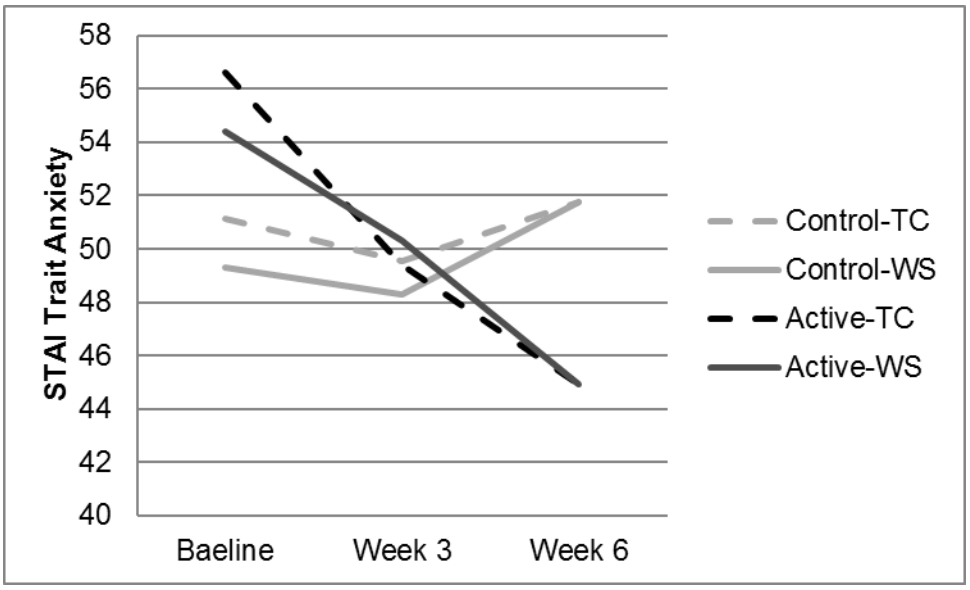


Figure 10. Anxiety Sensitivity

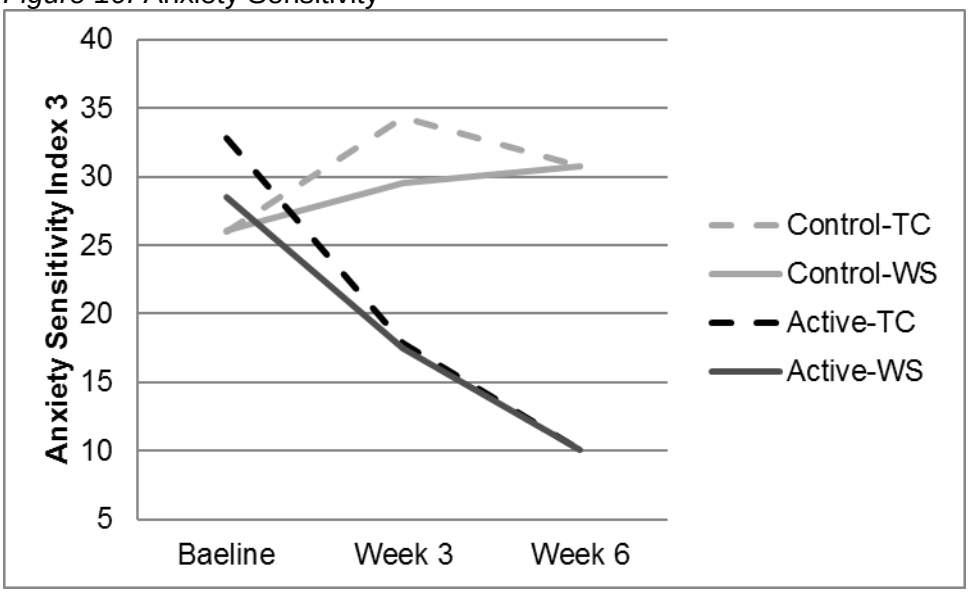


Figure 11. Depression

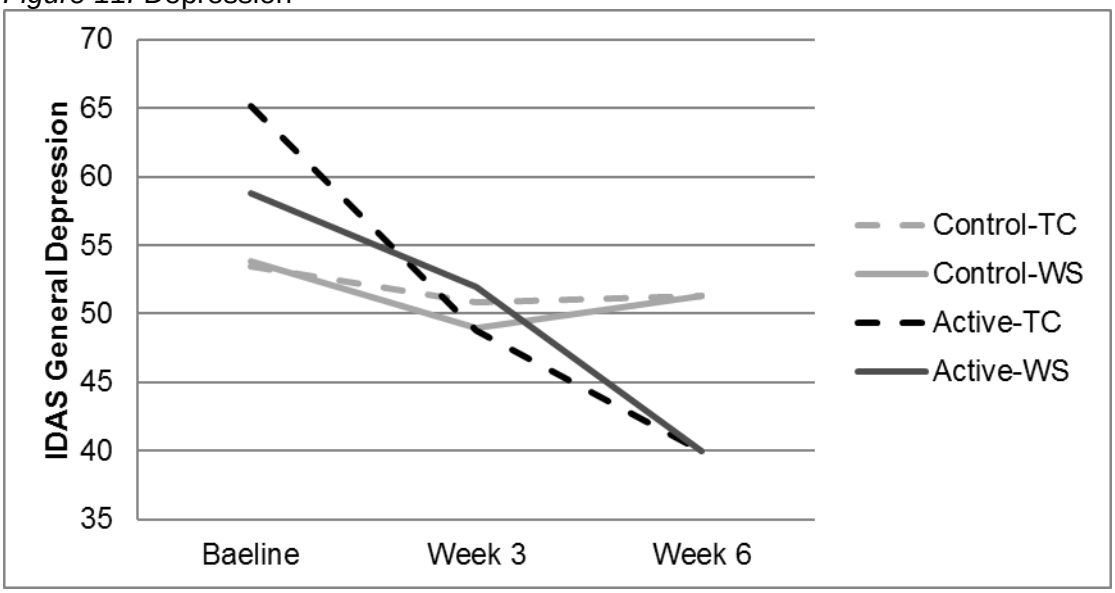


Figure 12. Physical Quality of Life

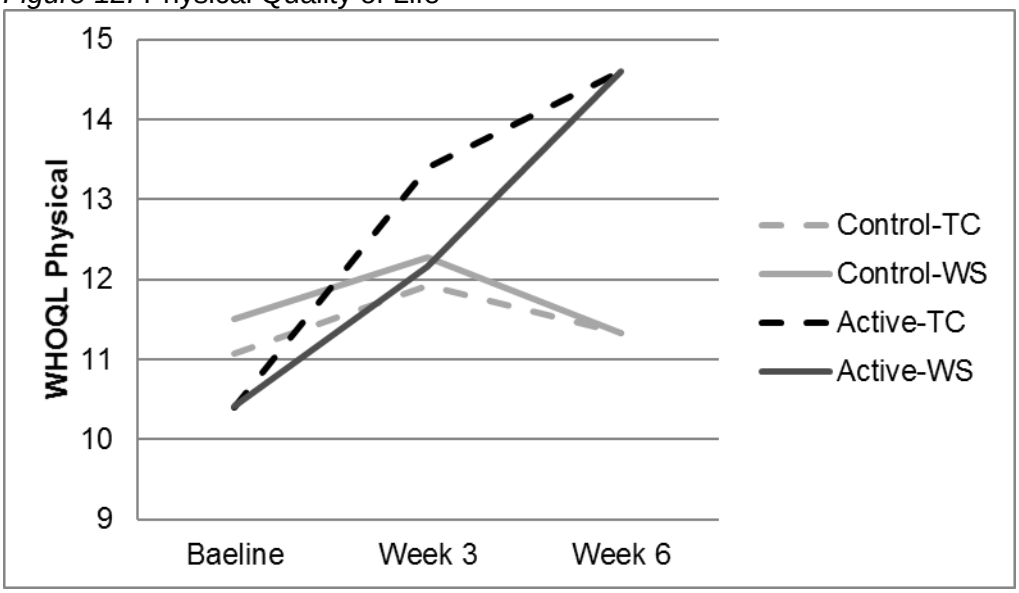


Figure 13. Psychological Quality of Life

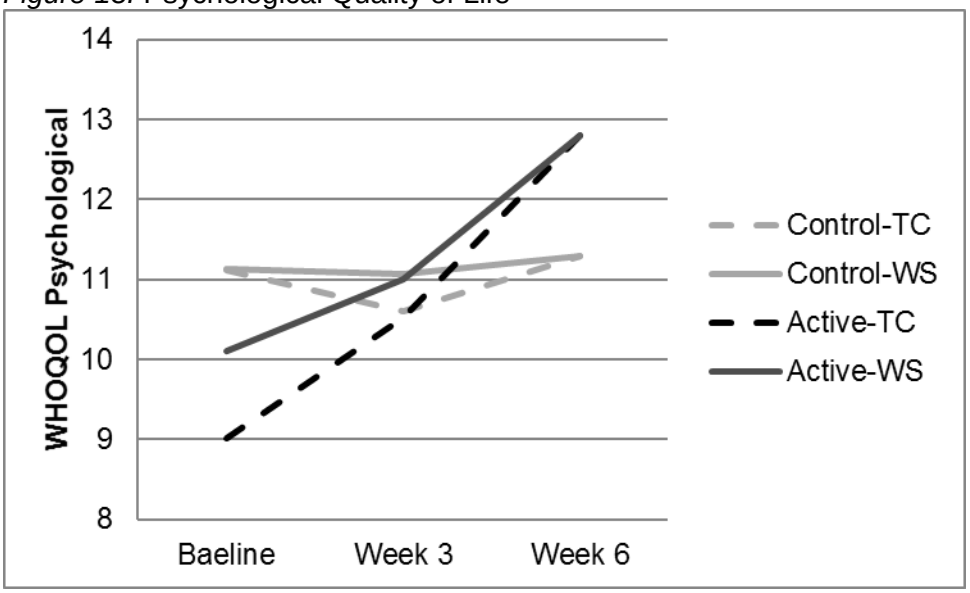


Figure 14. Independence Quality of Life

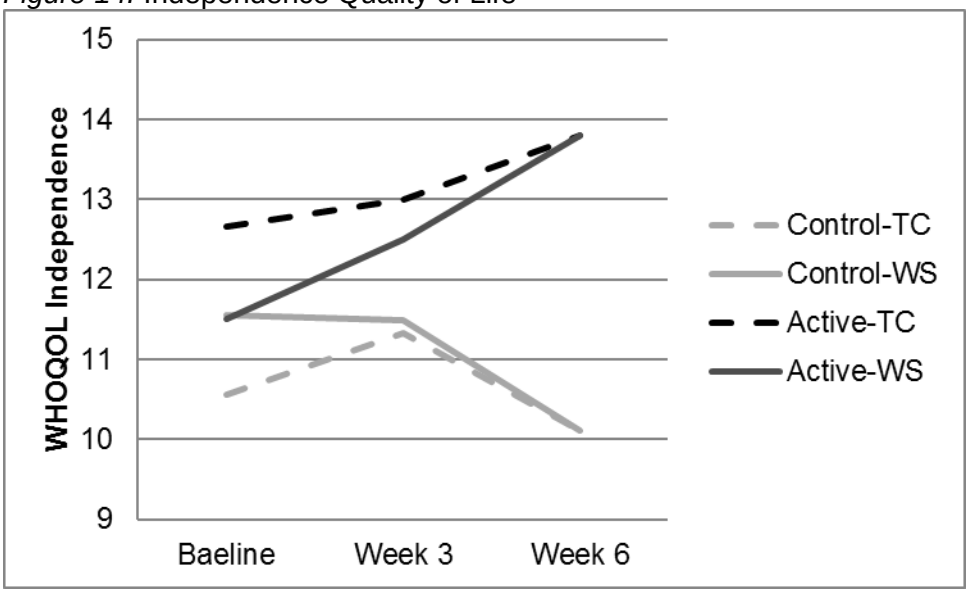


Figure 15. Social Quality of Life

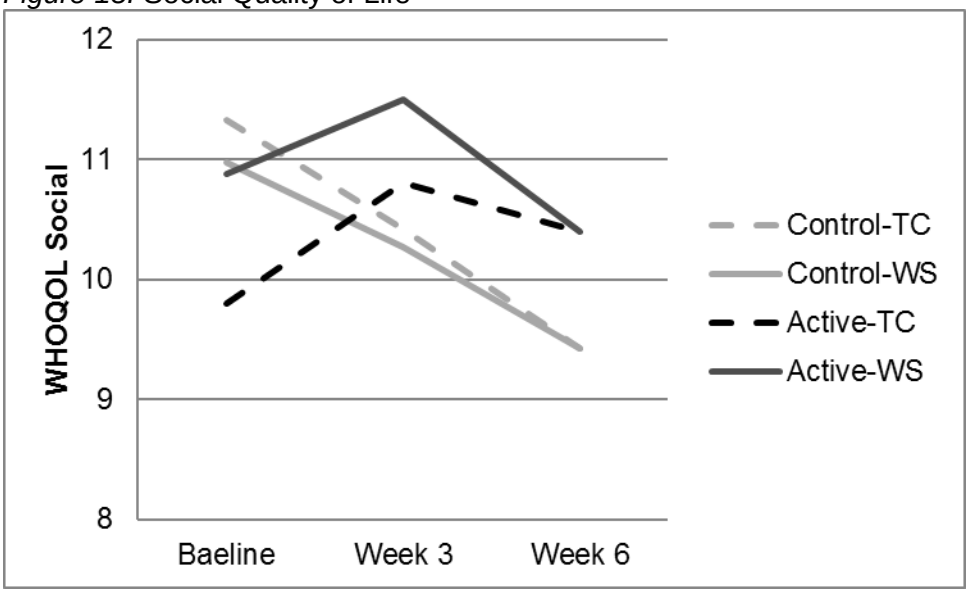


Figure 16. Environmental Quality of Life

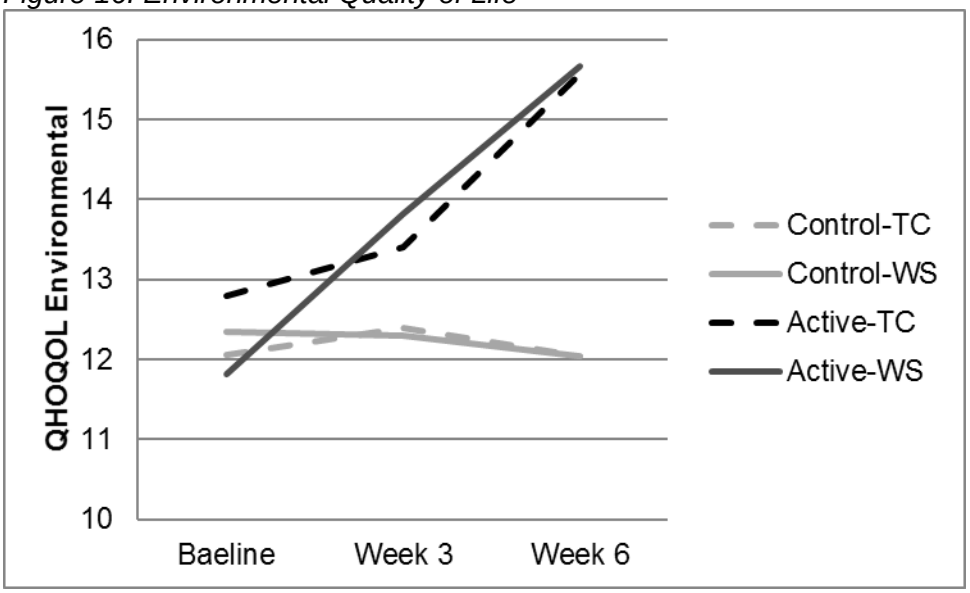


Figure 17. Spiritual Quality of Life

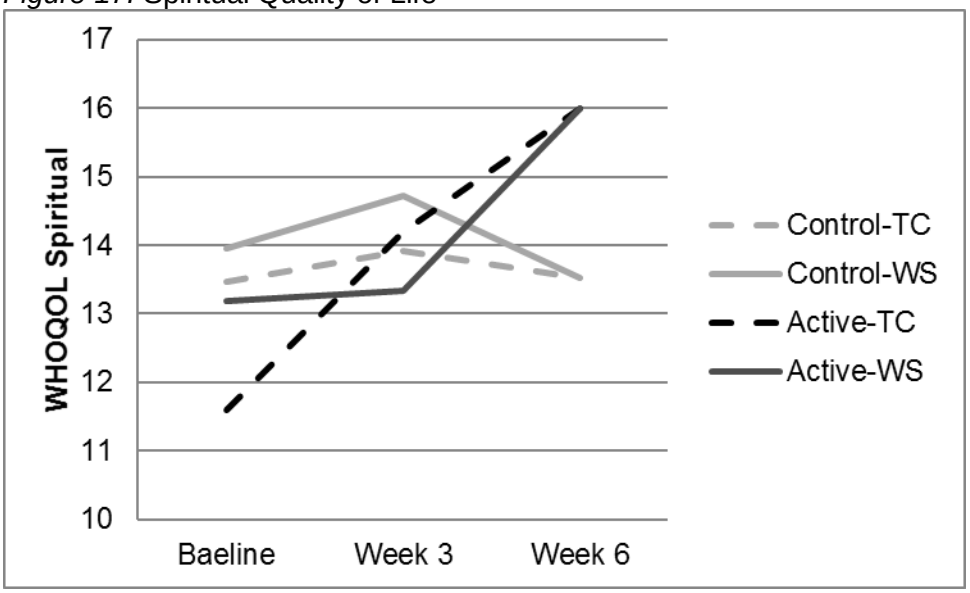


Figure 18. Medication Adherence Through Follow-Up

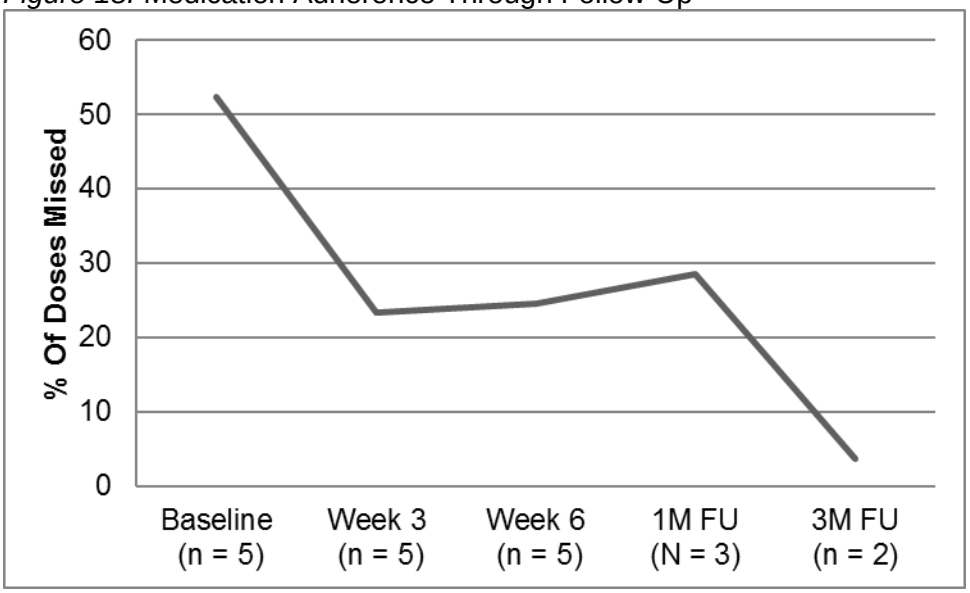


Figure 19. Reasons For Missing Medications Through Follow-Up

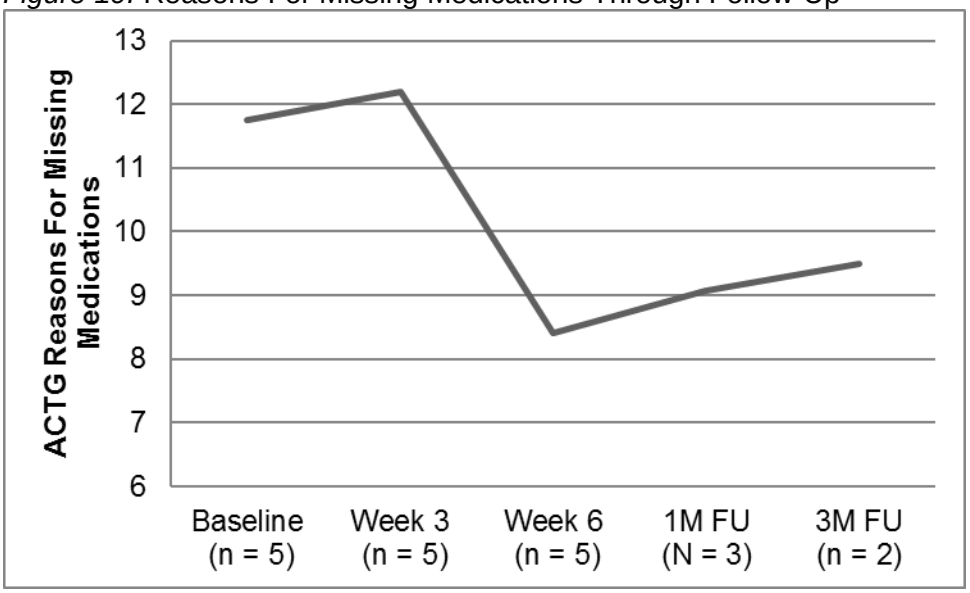


Figure 20. Anxiety Symptoms through Follow-Up

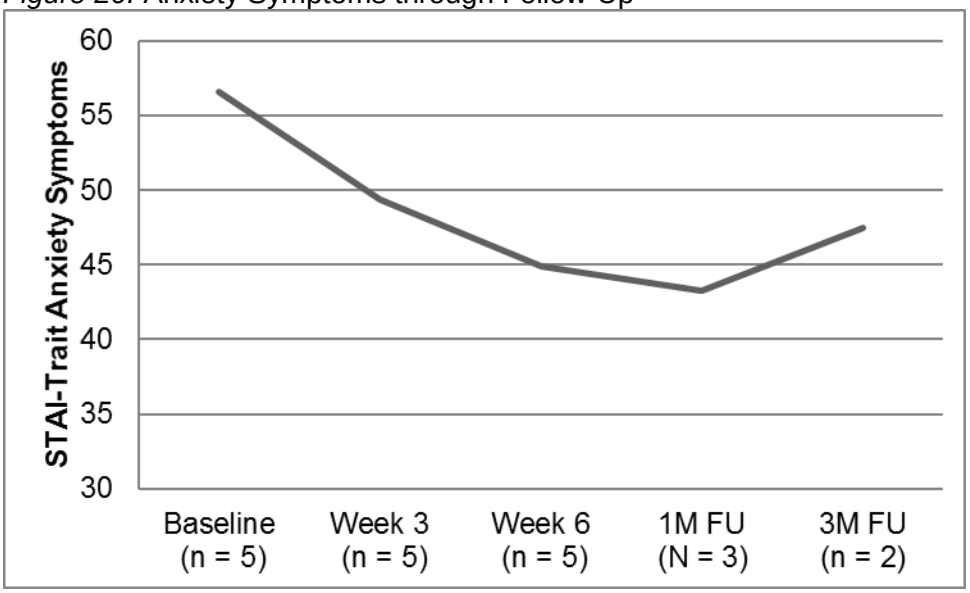


Figure 21. Anxiety Sensitivity through Follow-Up

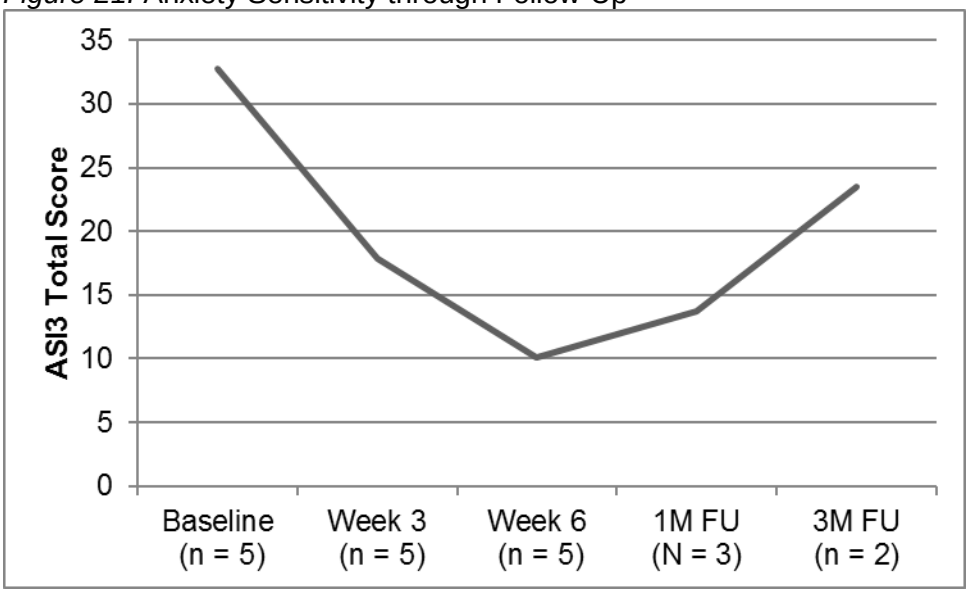


Figure 22. Depression Symptoms through Follow-Up

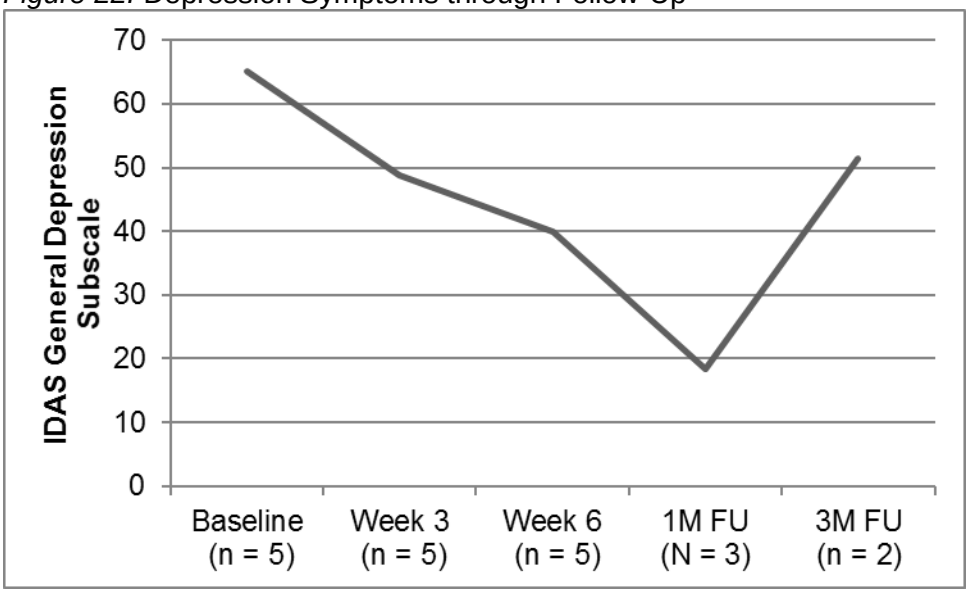


Figure 23. Physical Quality of Life through Follow-Up

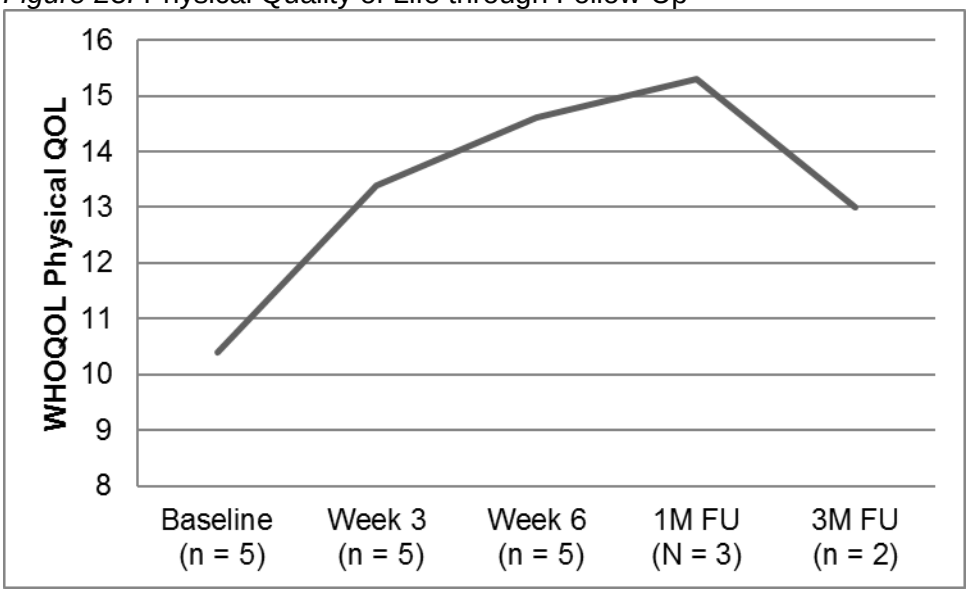


Figure 24. Psychological Quality of Life through Follow-Up

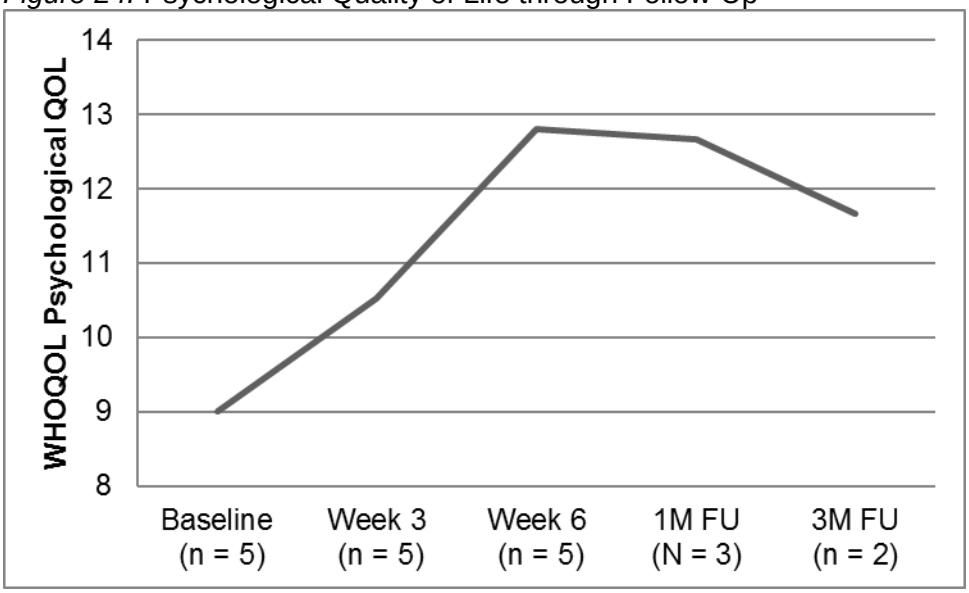


Figure 25. Independence Quality of Life Through Follow-Up

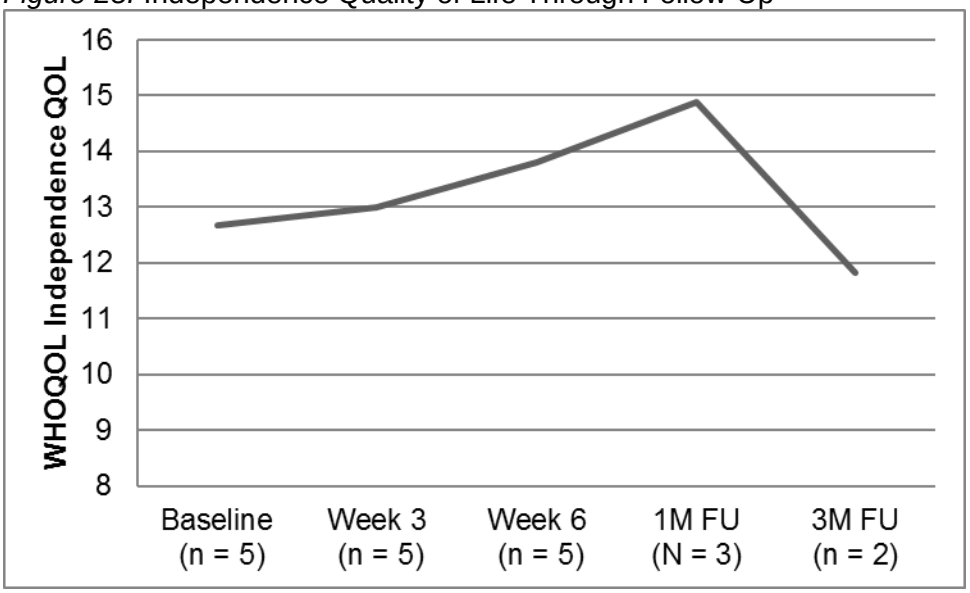


Figure 26. Social Quality of Life through Follow-Up

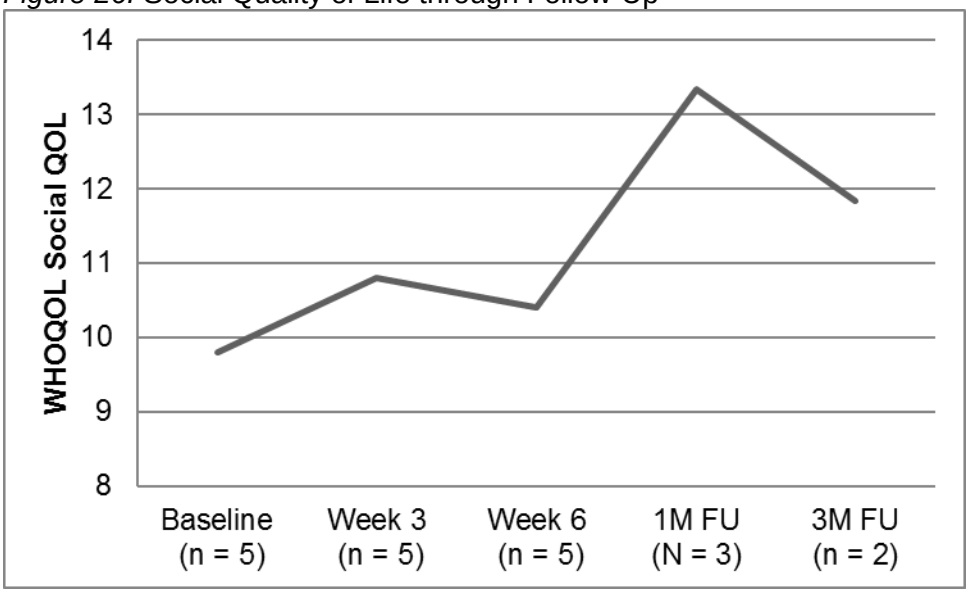


Figure 27. Environmental Quality of Life through Follow-Up

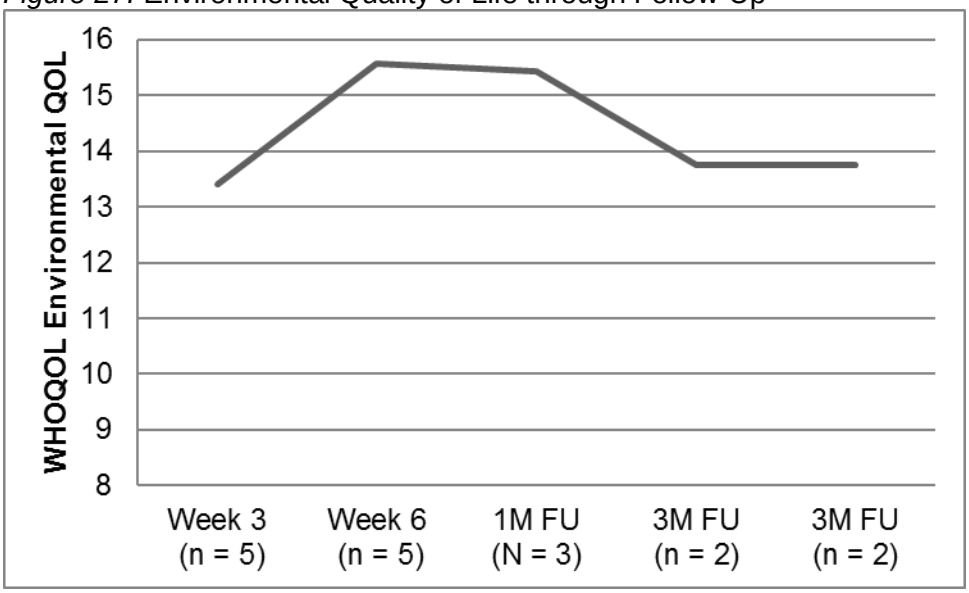
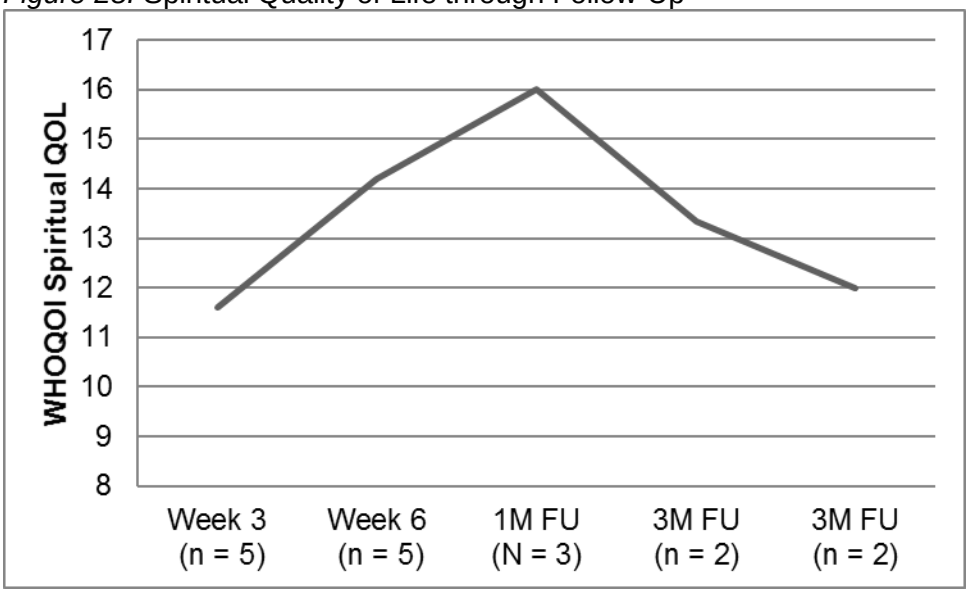


Figure 28. Spiritual Quality of Life through Follow-Up



Appendix A

1. Are you currently taking any anti-HIV medications? Yes ☐

No ☐

Most people with HIV have many pills to take at different times during the day. Many people find it hard to always remember their pills:

Some people get busy and forget to carry their pills with them

Some people find it hard to take their pills according to all the instructions, such as "with meals" or "on an empty stomach," or "every 8 hours", or "with plenty of fluids".

Some people decide to skip pills to avoid side effects or to just not be taking pills that day

We need to understand how people with HIV are really doing with their pills. Please tell us what you are *actually* doing. Don't worry about telling us that you don't take your pills. We need to know what is really happening, not what you think we want to hear.

The next section of the questionnaire asks about the medications that you may have missed taking over the last four days. Please complete the table below, using one line for each study medication you are taking, and using the abbreviations on this page. If you did not miss and doses, write a zero (0) in the box. Note that the table asks about DOSES, not PILLS.

IF YOU ONLY TOOK A PORTION OF A DOSE ON ONE OR MORE OF THESE DAYS, PLEASE REPORT THE DOSE(S) AS BEING MISSED.

		HOW MANY DOSES DID YOU MISS...			
Step 1 Abbreviation/Name or your drugs	Number of prescribed doses per day	Yesterday	Day Before Yesterday	3 Days Ago	Within the last 2 weeks (14 days)
	doses	doses	doses	doses	doses
____	doses	doses	doses	doses	doses
	doses	doses	doses	doses	doses
	doses	doses	doses	doses	doses
_____	doses	doses	doses	doses	doses
	doses	doses	doses	doses	doses
	doses	doses	doses	doses	doses

B. Are your currently in a clinical trial (a research study) of HIV medications? Yes

No

B.l. If so, is it a blinded study (where you don't know which study arm you are in)? Yes

No

Most medications need to be taken on a schedule such as "2 times a day" or "3 times a day" or "every 8 hours". How closely did you follow your specific schedule over the last four days?

Never	Some of the time	About Half the time	Most of the time	All of the time
(O)	(1)	(2)	(3)	(4)

Do any of your medications have special instructions such as "take with food" or "on an empty stomach" or "with plenty of fluids"?

Yes No

D.I. How often did you follow those special instructions **over the last four days**

Never	Some of the time	About Half the time	Most of the time	All of the time
(O)	(1)	(2)	(3)	(4)

E. Some people find that they forget to take their pills on the weekend days. Did you miss any of your medications last weekend- last Saturday or Sunday?

Yes No

People may miss taking their medications for various reasons. Here is a list of possible reasons why you may have missed taking any medications within the past month.

If you have NOT taken any medications within the past month, please check this box and skip to

Section D. In the past month, how often have you missed taking your medications because you:

Please circle one response for each question.

		Never	Rarely	Sometimes	Often
1.	Were away from home?	0	1	2	3
2.	Were busy with other things?	0	1	2	3
3.	Simply forgot?	0	1	2	3
4.	Had too many pills to take?	0	1	2	3
5.	Wanted to avoid side effects?	0	1	2	3
6.	Did not want others to notice you taking medication?	0	1	2	3
7.	Had a change in daily routine?	0	1	2	3
8.	Felt like the drug was toxiclharmful?	0	1	2	3
9.	Fell asleep/slept through dose time?	0	1	2	3
10.	Felt sick or ill?	0	1	2	3
11.	Felt depressed/overwhelmed?	0	1	2	3
12.	Had problem taking pills at specified times (with meals, on empty stomach, etc.)?	0	1	2	3
13.	Ran out of pills?	0	1	2	3
14.	Felt good?	0	1	2	3

When was the last time you missed taking any of your medications? Check one box.

- ☐ 5 Within past week
- ☐ 4 1-2 weeks
- ☐ 3 2-4 weeks
- ☐ 2 1-3 months
- ☐ 1 More than 3 months ago
- ☐ 0 Never

Appendix B

STAI

State Form

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment.* There are no right or wrong answers. Do not spend too much

time on any one statement but give the answer which seems to describe your

present feelings best.

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am currently worrying over possible misforuntes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

Trait Form

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally* feel.

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
21. I feel pleasant	1	2	3	4
22. I feel nervous and restless	1	2	3	4
23. I feel satisfied with myself	1	2	3	4
24. I wish I could be as happy as others seem to be	1	2	3	4
25. I feel like a failure	1	2	3	4
26. I feel rested	1	2	3	4
27. I am "calm, cool and collected"	1	2	3	4
28. I feel that difficulties are piling up so that I cannot overcome them	1	2	3	4
29. I worry too much over something that doesn't really matter	1	2	3	4
30. I am happy	1	2	3	4
31. I have disturbing thoughts	1	2	3	4
32. I lack self-confidence	1	2	3	4
33. I feel secure	1	2	3	4
34. I make decisions easily	1	2	3	4
35. I feel inadequate	1	2	3	4
36. I am content	1	2	3	4
37. Some unimportant thought runs through my mind and bothers me	1	2	3	4
38. I take disappointments so keenly that I can't put them out of my mind	1	2	3	4
39. I am a steady person	1	2	3	4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

M.I.N.I.

MINI INTERNATIONAL NEUROPSYCHIATRIC INTERVIEW

English Version 5.0.0 DSM-IV

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Hôpital de la Salpétrière - Paris

Patient Name:		***Patient Number:***	
Date of Birth:		***Time Interview Began:***	
Interviewer's Name:		***Time Interview Ended:***	
Date of Interview:		***Total Time:***	

	MODULES	TIME FRAME	CRITERIA	DSM-IV	ICD-10	MEETS CRITERIA
A	MAJOR DEPRESSIVE EPISODE	Current (2 weeks)	D	296.20-296.26 Single	F32.x	O
		Recurrent	D	296.30-296.36 Recurrent	F33.x	O
	MDE WITH MELANCHOLIC FEATURES Optional	Current (2 weeks)	D	296.20-296.26 Single 296.30-296.36 Recurrent	F32.x F33.x	O O
B	DYSTHYMIA	Current (Past 2 years)	D	300.4	F34.1	O
C	SUICIDALITY	Current (Past Month) Risk: D Low D Medium D High	D			O
D	MANIC EPISODE	Current Past	D D	296.00-296.06	F30.x-F31.9	O
	HYPOMANIC EPISODE	Current Past	D D	296.80-296.89	F31.8-F31.9/F34.0	O
E	PANIC DISORDER	Current (Past Month) Lifetime	D D	300.01/300.21	F40.01-F41.0	O
F	AGORAPHOBIA	Current	D	300.22	F40.00	O
G	SOCIAL PHOBIA (Social Anxiety Disorder)	Current (Past Month)	D	300.23	F40.1	O
H	OBSESSIVE-COMPULSIVE DISORDER	Current (Past Month)	D	300.3	F42.8	O
I	POSTTRAUMATIC STRESS DISORDER	Current (Past Month)	D	309.81	F43.1	O
J	ALCOHOL DEPENDENCE	Past 12 Months	D	303.9	F10.2x	O
	ALCOHOL ABUSE	Past 12 Months	D	305.00	F10.1	O
K	SUBSTANCE DEPENDENCE (Non-alcohol)	Past 12 Months	D	304.00-.90/305.20-.90	F11.1-F19.1	O
	SUBSTANCE ABUSE (Non-alcohol)	Past 12 Months	D	304.00-.90/305.20-.90	F11.1-F19.1	O
L	PSYCHOTIC DISORDERS	Lifetime Current	D D	295.10-295.90/297.1/ 297.3/293.81/293.82/ 293.89/298.8/298.9	F20.xx-F29	O
	MOOD DISORDER WITH PSYCHOTIC FEATURES	Lifetime Current	D D	296.24/296.34/296.44 296.24/296.34/296.44	F32.3/F33.3/ F30.2/F31.2/F31.5 F31.8/F31.9/F39	O
M	ANOREXIA NERVOSA	Current (Past 3 Months)	D	307.1	F50.0	O
N	BULIMIA NERVOSA	Current (Past 3 Months)	D	307.51	F50.2	O
	ANOREXIA NERVOSA, BINGE EATING/PURGING TYPE	Current	D	307.1	F50.0	O

GENERALIZED ANXIETY DISORDER F41.1	Current (Past 6 Months) 0	D	300.02
ANTISOCIAL PERSONALITY DISORDER F60.2	Lifetime 0	D	301.7

Optional

Which problem troubles you the most? Indicate your response by checking the appropriate check box(es).

Appendix D

ASI-3

Please circle the number that best corresponds to how much you agree with each item. If any items concern something that you have never experiences (e.g. fainting in public) answer on the basis of how you think you might feel *if you had* such an experience. Otherwise, answer all items on the basis of your own experience. Be careful to circle only one number for each item and please answer all items.

	Very little	**A little**	**Some**	**Much**	**Very much**
1. It is important for me not to appear nervous.	0	1	2	3	4
2. When I cannot keep my mind on a task, I worry that I might be going crazy.	0	1	2	3	4
3. It scares me when my heart beats rapidly.	0	1	2	3	4
4. When my stomach is upset, I worry that I might be seriously ill.	0	1	2	3	4
5. It scares me when I am unable to keep my mind on a task.	0	1	2	3	4
6. When I tremble in the presence of others, I fear what people might think of me.	0	1	2	3	4
7. When my chest feels tight, I get scared that I won't be able to breathe properly.	0	1	2	3	4
8. When I feel pain in my chest, I worry that I'm going to have a heart attack.	0	1	2	3	4
9. I worry that other people will notice my anxiety.	0	1	2	3	4
10. When I feel "spacey" or spaced out I worry that I may be mentally ill.	0	1	2	3	4
11. It scares me when I blush in front of people.	0	1	2	3	4
12. When I notice my heart skipping a beat, I worry that there is something seriously wrong with me.	0	1	2	3	4
13. When I begin to sweat in a social situation, I fear people will think negatively of me.	0	1	2	3	4
14. When my thoughts seem to speed up, I worry that I might be going crazy.	0	1	2	3	4
15. When my throat feels tight, I worry that I could choke to death.	0	1	2	3	4
16. When I have trouble thinking clearly, I worry that there is something wrong with me.	0	1	2	3	4
17. I think it would be horrible for me to faint in public.	0	1	2	3	4
18. When my mind goes blank, I worry there is something terribly wrong with me.	0	1	2	3	4

Appendix E

Instructions

This assessment asks how you feel about your quality of life, health, or other areas of your life. **Please answer all the questions.** If you are unsure about which response to give to a question, **please choose the one** that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last two weeks.** For example, thinking about the last two weeks, a question might ask:

	Do you get the kind of support from others that you need?	Not at all 1	Not much 2	Moderately 3	A great deal 4	Completely 5

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others as follows.

	Do you get the kind of support from others that you need?	Not at all 1	Not much 2	Moderately 3	A great deal 4	Completely 5

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks.

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

		Very poor	Poor	Neither poor nor good	Good	Very good
1(G1)	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2 (G4)	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4(F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5(F4.1)	How much do you enjoy life?	1	2	3	4	5
6(F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7(F5.3)	How well are you able to concentrate?	1	2	3	4	5
8 (F16.1)	How safe do you feel in your daily life?	1	2	3	4	5
9 (F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12 (F18.1)	Have you enough money to meet your needs?	1	2	3	4	5
13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how **good or satisfied** you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18(F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5
19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22(F14.4)	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23(F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24(F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3)	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to **how often** you have felt or experienced certain things in the last two weeks.

		Never	Seldom	Quite often	Very often	Always
26 (F8.1)	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1	2	3	4	5

THANK YOU FOR YOUR HELP

Appendix G

Type of Fidelity	*Steps Taken to Ensure Fidelity*	***How Was Fidelity Assessed?***
Fidelity to Theory *(did the intervention include the relevant "active ingredients" based on theory?)*	○ Review by experts ○ Ensure adequate "dose" of treatment is received ○ Ensure equivalent dose of treatment across conditions (if applicable)	○ Documentation of review, comments, suggestions ○ Statistics on number, frequency, length of contact ○ Show no difference in number, frequency, length, and type of content
Provider Training *(were the treatment providers capable of delivering the intervention as designed?)*	○ Initial training of interventionists ○ Test of provider skills ○ Ongoing supervision of interventionists ○ Periodic re-training to prevent "drift"	○ Training protocols and standardized materials ○ Results on post-training test ○ Forms used to document supervision ○ Schedule & protocols for re-training
Treatment Implementation *(did the treatment providers actually implement the intervention as it was designed?)*	○ Standardized intervention protocol ○ Provider monitoring (e.g., video, audio, in-person) ○ Participant rating of treatments' credibility ○ Minimize treatment contamination	○ Treatment manual or other standard delivery materials ○ Individual or aggregate results of monitoring ○ Survey of participants' perceptions of treatment ○ Methods used to prevent contamination (e.g., separate sites, patient exit interviews, checklist of *non*-allowed provider behaviors)
Treatment Receipt *(did the participant receive the relevant "active ingredients" as intended?)*	○ Check of participants' understanding ○ Measure of change in participants' knowledge ○ Review of homework completion ○ Self-report or diary to measure use of new skills	○ Results from participant measures {note: this section may be "N/A" if the participant is not expected to learn something from the intervention – e.g., in behavioral interventions with cognitively impaired patients}
Treatment Enactment *(did the participant put new skills or behaviors into practice? Were all necessary steps completed?)*	○ Success in implementing new behaviors ○ Level of skill in performing new behaviors (e.g., using an inhaler correctly)	○ Lab assessment of actual participant skills/behaviors ○ Self-report or home visit to assess actual skills/behaviors {note: this may be N/A in some but not all cases, when behavior is the outcome variable}

 Adapted from the report of the NIH Behavior Change Consortium workgroup on treatment fidelity: Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M. et al. (2004). Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology, 23,* 443-451.

Topic	Fidelity		Implementation	Receipt	Enactment	
	Reviewed (Y/N)	Length	Consistent with protocol (Y/N 85% adherence)	Understanding (Y/N)	HW (Y/N)	New skills used (Y/N)
Topic 1: Set Agenda and review homework						
Topic 2: Review CBT model for HIV and Anxiety						
Topic 3: Identifying Unhelpful Thoughts						
Topic 4: Automatic Thoughts and Thinking Errors						
Topic 5: Challenging & Adapting Unhelpful Thoughts						
Topic 6: Ranking My Fears						
Topic 7: Final comments, questions, reminders?						