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# Feasibility of telephone-based cognitive behavioral therapy targeting major depression among urban dwelling African-Americans with co-occurring HIV

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## **Abstract**

Given the burden of depression among those with HIV, and the impact of HIV on urban minority communities there is an urgent need to assess innovative treatment interventions that not only treat depression but do so in a way that allows for increased access to mental health care. This single site, uncontrolled, pilot study sought to determine the feasibility and depression outcomes of an 11 session telephone based cognitive behavioral therapy intervention delivered over 14 weeks targeting low income, urban dwelling, HIV infected African-Americans with major depression. The diagnosis of major depression was made using the Mini International Neuropsychiatric Interview. The primary outcome was the HAM-D and the secondary outcome was the Quick Inventory of Depression Symptomatology -Self Report (QIDS-SR). Feasibility and satisfaction were also assessed. Assessments occurred at baseline, midpoint and at study conclusion (14 weeks). Fifteen people were screened for the study. Six HIV infected, low-income, African American individuals (5 Female, 1 Male) were eligible and participated in the study. All patients finished the study. On average, participants completed 9 sessions. The sessions lasted for an average of 48 minutes (SD=11.5). Compared to mean HAM-D score at baseline (HAM-D=22.8 (SD = 3.1), the mean HAM-D score was significantly reduced at study conclusion (HAM-D= 9.8 (SD =7.4);(t (5) =4.6, p=.006);(Cohen d=1.9)). Compared to the mean OIDS-SR score at baseline (QIDS-SR=15.5 (SD =4.2) the mean QIDS score was significantly reduced at study conclusion (QIDS=7.0 (SD =5.4); (t(5) = 3.2, p=.02); (Cohen d=1.3)). The mean satisfaction scores across all participants at post treatment was 5.7 (SD=.3) with of a maximum score of 6. Telephone based CBT can be delivered to low-income, urban dwelling ethnic minority HIV infected people resulting in significant reductions in depression symptoms with high satisfaction. The efficacy of this intervention will be assessed in a planned randomized control trial.

# **Background**

Depressive disorders are highly prevalent among those infected with HIV (Bing et al., 2001). Individuals with HIV and depressive disorders, compared to those with HIV alone, have worse adherence to taking antiretroviral medication, increased HIV related morbidity (Fairfield, Libman, Davis, & Eisenberg, 1999; Gordillo, del Amo, Soriano, & Gonzalez-Lahoz, 1999; Leserman et al., 1999; McDaniel, Fowlie, Summerville, Farber, & Cohen-Cole, 1995) and among women a higher mortality (Cook et al., 2002; Ickovics et al., 2001). Although mental health interventions may lead to improved depressive and HIV related outcomes among whites (Himelhoch & Medoff, 2005b; Himelhoch, Medoff, & Oyeniyi,

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2007), studies in the United States suggest that HIV infected ethnic minorities may have more difficulty accessing mental health care (Himelhoch, Josephs, Chander, Korthuis, & Gebo, 2009) and ethnic minorities with depression may be less likely to access, receive treatment (Williams et al., 2007) and benefit from standard mental health services compared to whites (Voss Horrell, 2008). A systematic review and metanalysis found that antidepressants are efficacious targeting depression among those with HIV (Himelhoch & Medoff, 2005a). However, antidepressant treatment may be associated with high drop out rates (Himelhoch et al., 2005a) and may not be acceptable to all patients. Alternatively, psychotherapeutic interventions may be particularly well suited to address the psychosocial and interpersonal difficulties as well as the distress associated with HIV. A systematic review of 8 randomized control trials that used group therapy techniques to decrease psychological distress and improve coping among HIV infected people found a pooled effect size of 0.38 (95% Confidence Interval [CI]: [0.23–0.53]) representing a moderate effect (Himelhoch et al., 2007). These studies though were not designed to address treatment for major depression.

Recently, telephone based cognitive behavioral therapy (CBT) has emerged as a feasible, acceptable and efficacious treatment for major depression and has been studied in several medically ill patient populations in the United States (Mohr et al., 2000; Mohr et al., 2005; Simon, Ludman, Tutty, Operskalski, & Von Korff, 2004). Advantages of telephone based psychotherapy include the use of flexible scheduling, use of patient preferred locations (e.g. home) which may help alleviate concerns about stigma (e.g. attending a mental health clinic), as well as ease of utilization (e.g. no transportation required to get to clinic) (Mohr et al., 2006). These advantages may be particularly important for low income HIV infected people living in urban environments who may have difficulties with transportation, financial problems, multiple and conflicting medical appointments, and concerns about stigma (Heckman et al., 1998). To our knowledge no telephone based CBT interventions have been evaluated targeting major depression among people with HIV. However, a pilot study of a 6 session telephone based interpersonal psychotherapy (IPT) intervention targeting major depression among rural, white, primarily male HIV infected individuals (IPT) (Ransom et al., 2008) found no difference in outcome between the IPT and the control condition. The lack of efficacy may be due to several factors including limited dose of treatment and confounding due to receipt of concomitant mental health interventions.

Given the burden of depression among those with HIV and the impact of HIV on urban minority communities, there is an urgent need to assess innovative treatment interventions that not only treat depression but do so in a way that allows for increased access to mental health care. This pilot, uncontrolled study evaluated the feasibility (i.e., the number of calls made by the therapist to contact, arrange and conduct a therapy session; the number of sessions completed by the participant and the length of time spent on the phone per therapy session) as well as the change in depressive symptoms associated with a telephone delivered cognitive behavioral psychotherapy intervention targeting major depression among a sample of HIV infected, low-income, urban dwelling African-American individuals.

#### **Methods**

## Study Design

This single site, uncontrolled, pilot study used a within subject pre-post design to determine the feasibility, satisfaction, and depression outcomes of a telephone based cognitive behavioral therapy intervention targeting major depression among HIV infected clients attending an urban HIV clinic affiliated with a University Medical Center. The pilot implementation study was not designed to test a specific hypothesis per se, but rather to

inform the implementation and feasibility of a Rounsaville Stage 1B randomized clinical trial (Rounsaville, Carroll, & Onken, 2001).

#### **Study Sample and Consent**

As part of routine clinical care, clients attending the HIV clinic were screened for depression using the Patient Health Questionnaire (PHQ-9) (Spitzer, Kroenke K., & Williams J.B., 1999). Clients who endorsed anhedonia and/or depressed mood without endorsing suicidal symptoms and scored a 12 or higher on the PHQ-9 were referred to meet with a research assistant to discuss the study and consent procedures. Inclusion criteria included being an adult, English speaker who had access to a working telephone, was able to read at a 6th grade reading level determined by the Wide Range Achievement Test- Fourth Edition (WRAT-4) (Wilkinson & Robertson, 2006) and met criteria for Major Depressive Episode based on the Mini International Neuropsychiatric Interview (MINI) (Sheehan et al., 1998). Exclusion criteria included receiving concurrent psychotherapy, life expectancy less than 6 months as determined by their HIV clinician, having HIV related dementia as determined by the HIV dementia scale (Power, Selnes, Grim, & McArthur, 1995), initiating antidepressant treatment targeting depression or having an antidepressant medication dose change within 3 months of the consent process, and/or having current drug or alcohol dependence. The MINI was also used to rule out anyone with serious psychiatric pathology (e.g., schizophrenia, bipolar affective disorder) for whom participation in the study might be considered dangerous or unethical. Clients who were ineligible for the study were referred to mental health clinicians at the HIV clinic for follow-up. Clients were recruited from April 2009 through June 2009. The study was approved by the University of Maryland Institutional Review Board and all participants provided informed consent.

**Intervention Development**—The telephone cognitive behavioral therapy intervention used in this study was initially adapted from a previously studied manualized telephone cognitive behavioral therapy developed by Mohr called Telephone Cognitive Behavioral Therapy (Mohr et al., 2005) as well as a manualized face-to-face cognitive behavioral therapy for adolescents developed by Clarke called Steady. Using the Stage Model of Behavioral Therapies Research (Rounsaville, Carroll, & Onken, 2001) we modified the these manualized interventions to tailor the intervention to the needs of HIV infected, depressed individuals who may be more physically ill, more likely to be non-Caucasian, more likely to have a lower socioeconomic status, more likely to live in an urban environment and more likely to have a lower literacy level then depressed individuals who previously received these interventions. This adaptation and modification process resulted in an 11 session manualized cognitive behavioral therapy telephone intervention targeting depression called Connect. The intervention included one initial evaluation session, five sessions of behavioral activation and five sessions of cognitive restructuring delivered over a 14 weeks period. The intervention included a patient workbook and a linked therapist manual. As part of the adaptation process, the workbook and manual were iteratively reviewed by a purposive sample of 6 HIV infected patients with a history of depression (workbook only) and a purposive sample of 3 therapists experienced in delivery of CBT interventions targeting depression among those infected with HIV (workbook and manual) in order to determine acceptability, readability and cultural appropriateness of the intervention. Based on the results of these studies the workbook and manual were modified, updated and sent to an expert panel for final review. The expert panel reviewed the updated workbook and manual and concluded that the workbook and manual were in accordance with the principles of CBT and was appropriately modified to be delivered to urban, minority, HIV infected individuals with depression.

**Therapist Training**—The adapted intervention was delivered by two therapists (one therapist had a masters degree in social work and one therapist had a PhD in psychology) experienced in delivering cognitive-behavioral interventions. In order to be certified, each therapist received 12 hours of didactic training and subsequently completed one supervised case using the adapted telephone based psychotherapy intervention. In order to receive final certification, the therapist demonstrated high fidelity to the adapted intervention and score a mean score of 4 or greater on the Cognitive Therapy Adherence and Competence Scale (CTACS) (Barber, Liese, & Abrams, 2003), which was used to rate audiotaped sessions over the course of the telephone case mentioned above.

#### **Study Procedures**

After providing informed consent, participants were given a study workbook and a calendar and were given the name and telephone number of their therapist. The therapist contacted the participant to set up the first session. Participants were reminded to choose a private and confidential location (e.g., in a private room in a location of their choice behind a closed door) when participating in a therapy phone call. Each subsequent telephone based CBT session was scheduled in advance and lasted anywhere from 27–70 minutes. All therapy sessions were audiotaped. In the case of a psychiatric emergency participants would be directed by their therapist to an urgent care facility and the study psychiatrist would be contacted to facilitate the participant's access to care. Participants requiring this level of care would no longer be eligible to participate in the study and would be referred to the study psychiatrist for referral for further care. None of the study participants required this level of care.

#### **Schedule of Assessment and Outcome Measures**

Research assessments were conducted at baseline, at midpoint (week 7) and at the conclusion of the intervention (week 14). Participants were paid \$10.00 for their first assessment, \$40.00 for their midpoint assessment and \$50.00 for their final assessment. The research assessment assessed the following process and outcome measures.

To assess the primary outcome of depression, the Hamilton Depression Rating Scale (HAMD) (HAMILTON, 1960) and the Quick Inventory of Depressive Symptomology (QIDS-SR) (Rush et al., 2003) were used. The HAM-D is a semistructured interview that rates symptoms of depression. It consists of 17 variables that are scored on a five-point or a three-point scale. Total scores range from 0 to 52 with scores 0 to 6 indicating a normal mood and scores  $\geq$  24 indicating severe depression. The HAMD has good interrater reliability with an interclass correlation of 0.89 (Williams et al., 2008). Internal consistency reliability measured by coefficient alpha is 0.78 (Williams et al., 2008).

The QIDS-SR is a brief, 16-item, self-report measure of depression severity. For each item, responders are asked to rate themselves in the past seven days on a scale of 0 to 3. Total scores range from 0 to 27 and reflect the nine DSM-IV diagnostic criteria for Major Depressive Disorder. The QIDS-SR has high internal consistency measured with a Cronbach's alpha of 0.86 (Rush, et al., 2003).

To assess feasibility of the intervention we tracked the following: a) the number of calls made by the therapist to contact, arrange and conduct a therapy session; b) the number of sessions completed by the participant and c) the length of time spent on the phone per therapy session.

To assess the therapeutic process between the participant and therapist we used the Working Alliance Inventory (WAI) (Horvath & Greenberg, 1989). The WAI is a self-report

assessment that measures the quality of alliance between a patient and their therapist as it affects the success of the intervention. The WAI was completed individually with each participant and with each Therapist. The WAI Client version consists of 36 variables. The WAI Therapist version consists of 12 variables. Both versions of the WAI are scored on a seven-point scale where higher numbers indicated greater agreement. Both the WAI client version and therapist version have good reliability. Cronbach's alpha are 0.93 and 0.87 respectively (Horvath et al., 1989).

To assess the fidelity to the CBT model, two sessions were randomly selected and rated using the Cognitive Therapy Adherence and Competence Scale (CTACS) (Barber et al., 2003). The CTACS, consisting of 21 items rated on a 0-6 scale, is the most widely used measure of therapist fidelity to CBT. The CTACS has been shown to possess high internal validity for both competence ( $\alpha=.93$ ) and task completion measures ( $\alpha=.92$ ). A rating of 4 or greater is considered consistent with the adhering to the CBT model of psychotherapy (Barber et al., 2003).

To assess satisfaction we used the Satisfaction Index- Mental Health (SIMH)(Nabati, Shea, McBride, Gavin, & Bauer, 1998). The SIMH is a 12-item, self-report instrument developed to measure patient satisfaction with mental health care (Nabati, et al., 1998). The SIMH has high internal consistency reliability (Cronbach's alpha = 0.90), test- retest reliability (r = 0.79, p = 0.05), and sensitivity to change (Nabati, et al., 1998).

## **Analysis**

Univariate distributions included percentages for bivariate and categorical variables and means and medians for continuous variables. Repeated measure ANOVA was used to evaluate within-subject differences over time. A test for sphericity using the Mauchly's Test was found to be non-significant. To be conservative we used the Greenhouse-Geiser correction when presenting our results. Comparison of baseline and post-intervention means for the main outcome variables was made using paired sample t-tests. Statistical analysis was completed using SPSS for Windows version 15.0. All reported p-values are two sided.

## Results

## **Participants**

Fifteen participants participated in the screening and eligibility part of the study. Nine were deemed ineligible for the following reasons. Two did not meet criteria for MDD. One had bipolar disorder and one had a psychotic disorder not otherwise specified. Two had a history of recent suicidal ideation. Each were evaluated by on-site mental health staff, found not to be in imminent danger to self and were referred for further outpatient mental health treatment. Two had cognitive difficulties as determined by the HIV Dementia Scale, and one had a current substance use disorder. Six participants signed informed consent and received the telephone based CBT intervention. The participants (n=6) ranged in age from 35 to 66 (M = 44). Five reported their race to be African American and one reported their race to be half African-American and half white. Five were female. The majority (n=4) had completed high school, were unemployed (n=5) and earned less then \$10,000 per year (n=4). Most (n=5) were diagnosed with HIV in the mid to late 90s and were being prescribed HAART (n=5). For those on HAART, CD4 counts at the start of the study ranged from 123–655 (M = 463).

## Feasibility and Fidelity

All 6 patients completed treatment and all assessments. Four out of 6 patients were able to complete all 11 sessions and the remaining two missed sessions intermittently. The mean

number of sessions completed was 9. On average each session lasted 48 minutes ((SD=11.5) (range 22–70 minutes)). To arrange and conduct each session it took an average of 3 calls (SD= 2.2 per session). Review of a random sample of therapy sessions revealed high fidelity (mean=4.7, (SD=.8)).

## Depression

There was a significant reduction in the HAM-D, from a mean of 22.8 (SD =3.1) at baseline to 9.8 (SD=7.4) at post-treatment (F (1.5, 7.7) =16.6, p=0.002). A paired sample t-test revealed a significant difference between subjects' baseline and post-treatment follow-up (t (5) =4.6, p=.006). The effect size was 1.9 representing a large effect. Similarly, there was a significant reduction in the QIDS score, from a mean of 15.5 (SD =4.2) at baseline to 7.0, (SD =5.4) at post-treatment (F (1.4, 6.8)=7.7, p=0.02). A paired sample t-test revealed a significant difference between subjects' baseline and post-treatment follow-up (t (5) = 3.2, p=.02). The effect size was 1.2 representing a large effect.

#### Satisfaction and Alliance

The mean of the mean satisfaction scores across all participants at midpoint was 5.2 (SD=.3) out of a maximum possible score of 6, and was 5.7 (SD=.3) at post treatment follow-up. Both the patients and the therapist reported high levels of client and counselor alliance. The mean of the WAI Client scores across all participants at both the midpoint and post treatment follow-up was 6.7 (SD=.2) out of a maximum possible score of 7. The mean of the WAI Counselor scores across all participants was 5.36 (SD= 1.1) at midpoint and 5.0 (SD=1.1) at post treatment follow-up.

## Discussion

The results of this uncontrolled pilot study suggest that a telephone based CBT intervention targeting major depression can be feasibly delivered to a low-income, urban dwelling ethnic minority sample of HIV infected people with high fidelity resulting in significant reductions in depression symptoms with corresponding high satisfaction. With respect to feasibility, most participants completed all 11 sessions. Each session required on average 3 phone calls to contact the participant and conduct each session. The sessions were delivered with high fidelity and with high therapist patient alliance.

Few studies have evaluated the efficacy of CBT targeting depression specifically among African-Americans (Voss Horrell, 2008). One randomized control trial found that among depressed, low income, African-American and Hispanic women, CBT was as likely to lead to reductions in depression compared to whites (Miranda et al., 2003). Of note the authors reported that participant engagement in the study was demanding and that intensive outreach often by telephone was required in order to gain participant trust. They also noted that flexible scheduling paid transportation and reimbursement for child care expenses were important facilitators of retention in the intervention. The reported benefits of these facilitators dovetails well with the previously noted advantages of telephone based psychotherapy (Mohr et al., 2006). An exploratory post-hoc analysis of a randomized control trial evaluating the efficacy of CBT and interpersonal psychotherapy (IPT) among HIV infected people with depression found that African-Americans randomized to CBT were significantly more likely to have elevated depression scores at the conclusion of the treatment compared to whites., (Markowitz, Spielman, Sullivan, & Fishman, 2000). However, the exploratory analysis was only based on a sample of 4 African-American participants randomized to receive CBT. Although 3 of the 4 dropped out of treatment, the one participant who completed the therapy actually improved.

As noted above, telephone based cognitive behavioral therapy (CBT) has emerged as a feasible, acceptable and efficacious treatment for depression (Mohr et al., 2000; Mohr et al., 2005; Simon et al., 2004). Our study results are consistent with these findings and preliminarily extend the findings to a low income, African-American patient population. Although telephone support groups have been evaluated among those with HIV residing in rural areas with limited efficacy (Heckman & Carlson, 2006), to our knowledge only one telephone based intervention targeting major depression among HIV infected people has been reported (Ransom et al., 2008). That study evaluated the preliminary efficacy of a 6 session telephone based interpersonal psychotherapy (IPT) intervention targeting depression among rural, white, HIV infected individuals (the majority of whom were male). At study completion there was no difference in outcome between the IPT and the control condition and both continued to have significant depression symptoms. The lack of efficacy may be due to several factors including limited dose of treatment and confounding due to receipt of concomitant mental health interventions.

There are several limitations to this study which should be mentioned. First, the absence of a control arm limits our ability to make inferences regarding the efficacy of the intervention. While the reductions in depression are similar to those seen in trials of psychotherapy or pharmacotherapy, the possibility that these improvements were due to factors other than the treatment cannot be ruled out. Second, due to the small sample size and specific characteristics of the sample, this study is limited in its ability to generalize to the larger HIV positive, depressed, nonurban population. Furthermore, the patients were screened for stability on medications, co-occurring substance abuse issues, and other co-occurring psychological conditions which may otherwise be found in HIV clinics. Finally, this is a small sample, and small samples are likely to include biases that affect both internal and external validity. Nonetheless, meaningful information can be interpreted. The participants successfully completed the intervention and reported satisfaction with the therapy. The participants began the intervention with severe depression and their depression scores were significantly reduced at the final assessment. Thus, while it is premature to conclude that the telephone based CBT should be used in the delivery of clinical services, these results suggest that telephone based CBT should be evaluated in a larger RCT.

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