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# Decreased Depression Up to One Year Following CBSM+ Intervention in Depressed Women with AIDS: The Smart/EST Women's Project

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# **Abstract**

This prospective multisite Phase III clinical trial (Miami, New York, New Jersey) investigated the long-term (one year) effects of a 10-week group cognitive-behavioral stress management/expressive supportive therapy (CBSM+) intervention on disadvantaged minority women living with AIDS. The CBSM+ intervention consisted of 10-weekly group session of stress management, cognitive-behavioral skill training, relaxation techniques and expressive-supportive therapeutic strategies. The primary study outcome was self-reported depression scores as measured by the BDI. The CBSM+ Group intervention significantly decreased depression scores on the BDI for women following the intervention and maintained the decreased level at one-year follow-up.

## **Keywords**

AIDS; CBSM+; depression; women

Minority women have sustained the largest increase in rates of newly acquired immune deficiency syndrome (AIDS) cases in the USA (Centers for Disease Control and Prevention, 2002). Although recent guidelines from the National Institutes of Health (NIH) mandate the inclusion of women in clinical trials, minority women remain one of the least studied populations (Weijer, 1999). Minority women with AIDS have many other life stressors including single parenthood (Marcenko & Samost, 1999), unstable income and limited access to health care (Gonzalez-Calvo, Jackson, Hansford, & Woodman, 1998). Of particular relevance to the objectives of this study, depression has been found to be related to disease progression and mortality in women with HIV (Ickovics et al., 2001).

Numerous studies have documented the prevalence of distress among HIV/AIDS infected individuals (Chandra, Ravi, Desai, & Subbakrishna, 2001; Fukunishi et al., 1997) and have linked this distress to stressful life events (Crystal & Kersting, 1998), health status (Grassi et al., 1999), illness-related stressors, including social stigmatization (Kadushin, 1996) and cognitive deficits (Claypoole et al., 1998), loss of employment and autonomy (Hoffman, 1991) and faster disease progression (Cruess et al., 2003; Leserman, 2003).

Cognitive-behavioral interventions have been found to be successful in reducing distress associated with human immunodeficiency virus (HIV) disease (Church, 1998; Kelly et al., 1993). Investigators from our research team have tested the utility of a targeted cognitive-behavioral stress management (CBSM) intervention in reducing distress in gay men with clinically significant results (Antoni et al., 1991; Lutgendorf et al., 1997), as well as predicting clinical outcomes (Ironson et al., 1994) for those with better attendance. However, this intervention has not been tested with a population of women with case-defined AIDS. The present study was designed to extend previous research by examining the efficacy of the standard CBSM intervention, with an added expressive-supportive therapy component, in decreasing levels of depression among women living with AIDS.

#### Method

## **Participants**

Participants were recruited from the three major epicenters for women living with HIV/AIDS: Miami-Dade County, New York City and the New Jersey metropolitan area. Recruits were drawn primarily from hospitals, community health centers/agencies and via participant referrals. Of the 628 candidates recruited, 28 percent did not meet eligibility requirements for the following reasons: 44 percent had significant cognitive impairment, 10 percent were substance dependent, 22 percent met the diagnostic criteria for major depression, 8 percent for psychosis and 16 percent did not meet the diagnostic criteria for case defined AIDS or failed to appear for scheduled screening appointments. A total of 451 women were randomized into the study. Participants were not selected on the basis of a specific psychological or social characteristic or disorder. Therefore, to evaluate the effects of the intervention on any given characteristic, one would have to conduct subgroup analyses on those persons who possessed the characteristic in question. Thus, to assess the effect of the intervention on depression, the sample of participants in the two comparison conditions was restricted to those who were considered depressed (scores > 10 on the BDI) at baseline. The mean BDI at entry into the study was  $16.3 \pm 5.1$  for the 154 depressed women, and  $4.4 \pm 2.9$  for the 297 non-depressed women (not included in the sample reported on in this article). Of the 154 depressed women, 74 were in the CBSM+ Group intervention, and 80 were in the Individual low intensity comparison condition.

Participants were an average of  $38 \pm 7$  years of age with 12 years of education. The majority of women (67%) were African American, 16 percent were Hispanic, 12 percent were Caucasian and 5 percent were of other ethnic backgrounds. Most women (80%) were unemployed and receiving government assistance.

**Inclusion criteria**—We attempted to minimize the 'inclusion/exclusion' criteria to ensure that our sample of women was truly representative of the population under study. All women met the revised CDC classification for case defined AIDS (i.e. CD4+ cell count below 200/ mm² and/or one opportunistic infection; Centers for Disease Control, 1992), were 18 years or older, fluent in English and had at least a sixth grade education.

**Exclusion criteria**—Women were excluded with psychiatric, neuropsychiatric or medical conditions which would interfere with their or others' participation in the intervention. The

presence of psychosis and/or substance dependence resulted in 'temporary exclusion' pending confirmation of entry into treatment. Drugalcohol dependent and psychiatric symptoms were assessed by the Structured Clinical Interview for the DSM-III-R, adapted for use with non-patient participants with HIV (SCID-NP-HIV; Spitzer, Williams, Gibbon, & First, 1988). Women with significant cognitive impairment were excluded as assessed by the Mini Mental Status Exam (Folstein, Folstein, & McHugh, 1975: scores  $\leq$  26 below the mean of HIV-positive individuals) and the HIV Dementia Scale (Power, Selnes, Grim, & McArthur, 1995: scores < 10).

#### **Procedure**

The ethical concerns attendant on a 'no treatment' control group for women with a serious, life-defining illness, resulted in the selection of a 'low intensity' comparison condition rather than a true control group. Under these circumstances, the women in this condition were offered the same information provided in the 'high intensity' intervention condition, albeit delivered via videotape in an individual format, rather than the professionally facilitated group format characterized by intensive face-to-face interaction and high levels of social support. It was expected that participants in both conditions would receive some benefit from the interventions, but that the high intensity format would provide more striking and longer lasting benefits.

Group intervention condition—The CBSM+ Group intervention condition consisted of 10-weekly 120-minute sessions (90-minute stress management and 30-minute relaxation component). The intervention included didactic components explaining the physiological effects of stress, stress management strategies, cognitive-behavioral interpretation of stress and emotions, identification of cognitive distortions and automatic thoughts, rational thought replacement, coping skills training, assertiveness training, anger management and identification of social supports, combined with group processing of personal issues as conceptualized within the CBSM framework (Antoni et al., 2000; Ironson et al., 2000). Participants were asked to practice relaxation and CBSM techniques between sessions. The expressive-supportive therapy (EST) component of the intervention (Diamond, Gore-Felton, Gale, Classen, & Spiegel, 1997; Spiegal & Spira, 1991) was designed to address participant needs for: (1) mutual support and reduced isolation; (2) improved family and social support; (3) greater openness and emotional expressiveness; (4) integration of changed self and body image; (5) normalization of experiences; (6) improved doctor—patient relationships; (7) detoxification of death and dying issues.

Group leaders were licensed doctoral level psychologists and post-doctoral fellows who completed a 10-session training program that was based on a detailed therapist training manual, and audio taped practice of relaxation and stress management techniques that was supervised by two of the co-authors (MA and EB). Fidelity to the intervention protocol was optimized by weekly face-to-face supervision and/or review of audio taped intervention sessions by these two supervisors as well as through peer supervision.

**Low intensity comparison condition**—The comparison condition consisted of 10-weekly individual 120-minute sessions (45-minute informational/educational videotape component supplemented by a 75-minute entertainment video tape). The information videotapes related to stress management/relaxation training and coping with HIV/AIDS and were supplemented by entertainment tapes to minimize dropout and equalize session length with the group condition.

Although the study may be described as intervention (experimental) vs comparison (control), both conditions were provided similar information. The primary difference between the two

conditions was that only the experimental condition received group-based emotional support, individualized coping skill training and feedback concerning thoughts, attitudes and behavior.

**Beck Depression Inventory (BDI)**—The BDI (Beck, Ward, Mendelson, & Erbaugh, 1961) is a 21-item inventory used to assess depression, including somatic and cognitive subscales. The BDI has a split-half Spearman-Brown correlation of.93, a demonstrated internal consistency of.81 for nonpsychiatric patients, a high concurrent validity with the Hamilton Rating Scale for Depression (.73 to.80 for nonpsychiatric patients) and slightly lower correlations with clinical ratings (.55 to.73; Beck, Steer, & Garbin, 1988). A score greater than 10 on the BDI was used to define individuals as depressed (Kendall, Hollon, Beck, Hammen, & Ingram, 1987).

**Statistical analyses**—An 'Intent-to-Treat' (ITT) strategy for analysis is often preferred to a completer only analysis since the results of the ITT analysis are more representative of the clinical population (Mazumdar, Liu, Houck, & Reynolds, 1999). Consequently, each individual does not need to have been measured for the same number of time points, or even at the same time points. This model assumes that data available for each individual adequately represent the subject's deviation from the estimated group trend line over the time frame of the study (Gibbons et al., 1993).

Our ITT strategy did not involve the actual replacement of any missing data into the dataset. Statistical analyses were conducted using the Statistical Analytic System (SAS) version 8.2 (SAS Institute, Inc., 2002). Repeated measures analysis of variance with *Time* (baseline, post-intervention, six-months and one-year) as the within-subjects factor and *Condition* (CBSM+ Group intervention, Individual low intensity comparison) as the between-subjects factor was utilized using linear mixed models and a random subject effect (Laird & Ware, 1982) with SAS PROC MIXED. These methods allow error terms to be modeled in ways to provide handling of missing observations (Verbeke & Molenberghs, 2000). Because our a priori hypotheses stated that although both conditions would show a decrease in depression over time, the CBSM+ Group intervention would show significantly larger deceases in depression; these hypotheses were evaluated using one-tailed tests of significance at the alpha levels of p < .05.

Prior to statistical analyses, differences at baseline between subjects with missing BDI scores at any time point and subjects with BDI scores at all time points were tested using One-Way ANOVA and non-parametric Chi-Square test for baseline BDI scores, including subscales, and all relevant demographic information. In addition, to check for differential dropout between conditions, the above analyses were repeated between the CBSM+ Group Intervention and the Individual low intensity comparison conditions. No differences were observed on any of these analyses for any variables (p > .1). Effect sizes were calculated for the BDI Total score as described by Cohen (1988) separately for the CBSM+ Group intervention and Individual low intensity comparison conditions from baseline to post-intervention, and baseline to one-year follow-up.

# Results

Means and standard deviations for the BDI Total score, as well as, the Somatic and Cognitive subscales for the sample of 154 depressed women are presented in Table 1. At baseline, no differences were observed between women randomized to the CBSM+ Group intervention and the Individual low intensity comparison condition for: BDI Total [F(1,154) = .85, p > .1]; Somatic [F(1,154) = .84, p > .1]; and Cognitive subscales [F(1,154) = .23, p > .1]. A RANOVA (using PROC MIXED) revealed a significant Condition by Time interaction for BDI Total [F(3,290) = 2.3, p < .05] and the Somatic subscale [F(3,290) = 2.1, p < .05]. Within Condition simple effects ANOVA demonstrated a significant decrease in the CBSM+ Group intervention

for BDI Total [F(3,130) = 22.5, p < .001]; Somatic [F(3,130) = 22.3, p < .001]; and Cognitive subscales [F(3,130) = 12.9, p < .001]; as well as, a significant decrease in the Individual low intensity comparison condition for BDI Total [F(3,160) = 7.7, p < .001]; Somatic [F(3,160) = 7.2, p < .001]; and Cognitive subscales [F(3,160) = 4.5, p < .001]. The effect size for the CBSM + Group intervention from baseline to post-intervention for BDI Total was .66; and for the Individual low intensity comparison condition was .36. Additionally, the effect size for the CBSM+ Group intervention from baseline to one year for the BDI Total was 1.5, and for the Individual low intensity comparison condition .99. In the CBSM+ Group intervention condition a Pearson correlation revealed a significant dose-response between number of intervention sessions attended and reductions in BDI Total scores from baseline to post-intervention (r = -.24, p < .05), and from baseline to one year (r = -.30, p < .05).

## **Discussion**

The present study is consistent with previous findings, primarily in gay men, demonstrating the effectiveness of CBSM interventions in reducing distress and depression (Antoni et al., 1991; Church, 1998; Kelly et al., 1993; Lutgendorf et al., 1997). These results suggest that an appropriately modified CBSM+ Group intervention can decrease depression for women with AIDS, and maintain these improvements over one year. The modifications included techniques to complement the more didactic components of the cognitive behavioral therapies of the CBSM intervention, thereby resulting in a more engaging intervention for disadvantaged ethnically diverse women. For instance, a number of the examples used within the modules reflect a cultural emphasis on familial relationships rather than on work situations or relationships with friends. In addition, there are specific instances where spirituality is addressed. For example, the coping module incorporates 'The Serenity Prayer' to demonstrate the importance of applying the appropriate coping responses (emotion-focused vs problemfocused) to stressors. The expressive/supportive component is designed to help women who are feeling depressed, helpless and hopeless, allowing the women to express their feelings and to learn successful styles of adaptive coping used by other women in the group (Diamond et al., 1997; Spiegal & Spira, 1991). The expanded CBSM+ Group intervention is tailored to address issues of discloser, loss of personal control, domestic violence, financial difficulties, housing, social isolation and depression; all salient issues for women living with AIDS. Finally, child care and refreshments were provided, and transportation costs were reimbursed.

Ironson and colleagues (1994) have shown that attendance/frequency of practicing elements of the CBSM Group intervention are related to improved outcomes. In this study there was a dose-response effect for women in the CBSM+ Group intervention condition, where women who attended seven or more sessions showed larger decreases in BDI scores than those women who attended less than seven sessions, both at post-CBSM+ and one year later. Examination of the trend lines for BDI Total scores suggests that the reduction in depression seen in the CBSM+ Group condition was most profound during the 10-week intervention period relative to the Individual comparison condition. During this period women in the CBSM+ Group intervention reduced their BDI Total scores by an average of 4.5, while women in the Individual condition showed only a 1.6 average reduction in BDI scores over the same period. Although women in both conditions showed similar reductions in depression from post-intervention to one-year follow-up, the women in the Group intervention achieved an average BDI score of 7.4 (which is below the cut-off for depression), whereas, women in the Individual condition continued to be categorized as mildly depressed with an average Total BDI score of 10.2. Note however, that these continued decreases in depression scores from post-intervention to one year were not due to a differential dropout of the more depressed women, as evidenced by no difference at study entry in BDI scores between women who remained in the study and women who dropped out in either the CBSM+ Group Intervention or the Individual comparison conditions.

The prevalence of depression in our study sample is not surprising since it has been repeatedly shown that depressive symptoms tend to increase in the later stages of HIV disease (Hoover, Saah, Bacellar, Detes, & Phair, 1992; Maj et al., 1994; Rosenberger, Bornstein, & Nasrallah, 1993). Increased distress may accompany the difficult emotional experiences arising from decreased physical and cognitive functioning associated with late stage illness. Lyketsos et al. (1996) reported significant elevations in depressive symptomatology beginning 1.5 years before AIDS diagnosis and continuing after the diagnosis of AIDS. The magnitude of these changes ranged from 30 to 40 percent above baseline depression levels. Among women, the progression of HIV to AIDS may be associated with increasing relationship concerns; identifying care takers for surviving family members including children and aging parents, providing for children with dwindling financial resources following the loss of employment, reducing the threat of viral transmission to sexual partners while maintaining romantic harmony and coping with increasing HIV-related fatigue, sleeplessness and nausea. Factors that may contribute to the increase in mood disturbance include fear of death, abandonment, the threat of becoming dependent on others (Mulder & Antoni, 1994).

The CBSM+ Group intervention is composed of several components that may have played a role in reducing depression. Generally, coping strategies categorized as active-behavioral (planning, seeking social support) or active-cognitive (finding meaning in an illness, reframing) are associated with more positive affect and higher self-esteem (Ironson et al., 1994; Spiegel, Bloom, & Yalom, 1981; Yalom & Greaves, 1977). Individual differences in the application of coping strategies for dealing with psychosocial stressors may be among the most significant predictors of depression and clinical disease progression (Felton, Revenson, & Hinrichsen, 1984; Ironson et al., 1994). In studies of HIV-infected individuals, it has also been demonstrated that stress is associated with increased depression (Folkman, Chesney, Pollack, & Coates, 1993). Effects could also have been attributed to the fact that CBSM is designed to alter cognitive appraisals which result in distress by the use of positive reframing and acceptance, thereby reducing depression (Lutgendorf et al., 1998). Depression has been associated with decreased CD4 cell counts over time (Burack et al., 1993; Patterson et al., 1995) progression to AIDS (Leserman et al., 2002) and increased risk of mortality (Ickovics et al., 2001; Mayne, Vittinghoff, Chesney, Barrett, & Coates, 1996; Patterson et al., 1996). Future work should be directed to elucidating the mechanisms of these effects by 'dismantling' the CBSM+ intervention and examining each component (i.e. coping strategies, relaxation techniques, positive reframing, expressive supportive therapy, etc.). In addition, while we have provided preliminary evidence that CBSM+ can be helpful in a community setting, the CBSM + intervention should be translated from investigative research to become a routine part of the standard of care and every effort made to improve accessibility for women with HIV/AIDS in their local community health care centers. Since depression has been linked to HIV disease progression (Cruess et al., 2003; Leserman et al., 2003), a CBSM+ Group intervention offers the promise not only of remitting depression, but could have clinical implications for HIV disease course as well (Ickovics et al., 2001).

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**Table 1**Means and standard deviations for the BDI, including subscales, in moderately depressed women living with AIDS (BDI scores greater than 10) at all 4 time points for both conditions

Measure <sup>a</sup>	Baseline Mean ± SD	Post-CBSM <sup>+</sup> Mean ± SD	Six months Mean ± SD	Twelve months Mean ± SD
CBSM + Group condition				
	(n = 74)	(n = 55)	(n = 44)	(n = 34)
BDI—Total	$16.8 \pm 5.8$	$12.3 \pm 7.8$	$9.7 \pm 7.1$	(n = 34) 7.4 $\pm 6.0^{+**}$
BDI—Cognitive	$5.7 \pm 3.6$	$4.4 \pm 4.1$	$3.0 \pm 3.3$	2.1 +2.6
BDI—Somatic	$11.1 \pm 3.6$	$7.9 \pm 4.5$	$6.7 \pm 4.9$	5.3 ±4.1 <sup>+</sup> **
Low intensity comparison	condition			
•	(n = 80)	(n = 71)	(n = 47)	$(n = 45)_{**}$
BDI—Total	$16.3 \pm 4.6$	$14.7 \pm 10.3$	$12.8 \pm 9.9$	$10.2 \pm 9.0$
BDI—Cognitive	$5.5 \pm 3.2$	$4.9 \pm 5.3$	$4.5 \pm 5.1$	3.2 +3.7**
BDI—Somatic	$10.8 \pm 3.4$	$9.8 \pm 6.1$	$8.3 \pm 5.8$	7.0 ±6.0 **

 $<sup>^+</sup>$ significant interaction effect between Condition and Time, p < .05

<sup>\*\*</sup> significant simple effect for Time (all 4 time points), p < .001

<sup>&</sup>lt;sup>a</sup> abbreviations: BDI = Beck Depression Inventory (total score, cognitive and somatic subscales)