ABSTRACT

Title of Document: PRELIMINARY TRIAL OF A BEHAVIORAL ACTIVATION-ENHANCED SMOKING CESSATION PROGRAM AMONG SUBSTANCE USERS WITH ELEVATED DEPRESSIVE SYMPOTMS IN RESIDENTIAL TREATMENT

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Individuals with elevated depressive symptoms and substance use disorders (SUDs) have particular difficulties quitting smoking and few treatments benefit these individuals. The current study compared five session BA-enhanced smoking cessation treatment + nicotine replacement therapy (BADAS) to smoking cessation treatment as usual (TAU; nicotine replacement therapy + *Clearing the Air* self-help manual). We hypothesized that participants in BADAS would be less likely to relapse, would have higher abstinence rates, would smoke fewer cigarettes, would exhibit decreases in depressive symptoms, and would have increases in environmental reward, as compared to TAU. Participants in residential treatment with elevated depressive symptoms and SUDs and were randomized to BADAS or to TAU. Participants in BADAS were significantly less likely to relapse during the first week post-quit;

abstinence and cigarette consumption rates did not differ significantly across treatments. All participants displayed reductions in depressive symptoms and increases in activation; treatment condition was not significant.

PRELIMINARY TRIAL OF A BEHAVIORAL ACTIVATION-ENHANCED SMOKING CESSATION PROGRAM AMONG SUBSTANCE USERS WITH ELEVATED DEPRESSIVE SYMPOTMS IN RESIDENTIAL TREATMENT

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Chapter 1: Introduction

Overview.

Tobacco use constitutes the leading, non-infectious cause of death and disease worldwide and half of the people who currently smoke will eventually die from smoking related causes (Center for Disease Control and Prevention, 2011; World Health Organization, 2007). In the United States, 20% of total deaths are related to smoking, accounting for 438,000 annual deaths, which is more than the number of deaths caused by motor vehicle injuries, suicides, HIV, drugs, alcohol, and murder combined (CDC, 2008; 2011). Tobacco use has an enormous financial cost, with health and economic losses related to smoking amounting to $193 billion annually (CDC, 2008). Currently, 70% of smokers are interested in quitting (CDC, 2008), but many smokers are nicotine dependent (CDC, 2011), making cessation particularly difficult. Among individuals who attempt to quit without treatment, only 4-7% are abstinent within one year, while cessation rates for combined counseling and pharmacotherapy range between 22-32.5% (Fiore et al., 2008). Cessation rates vary dramatically for individuals with psychological co-morbidities like depression (Niaura et al., 2001) and substance use disorders (Prochaska, Delucchi, & Hall, 2004) and are often lower than that observed in the general population.

Smokers with depressive episodes or elevated depressive symptoms are less likely to quit smoking (Lasser et al., 2000), are more likely to relapse (Kinnunen, Doherty, Militello, & Garvey, 1996; Niaura et al., 2001; Piper et al., 2010), have higher rates of nicotine dependence (Anda et al., 1990), and are more likely to experience depressive symptoms/episodes when attempting to quit (Glassman,

Covey, Stetner, & Rivelli, 2001; Killen, Fortmann, Schatzberg, Hayward, & Varady, 2003; Pomerleau, Marks, & Pomerleau, 2000) than individuals without depressive symptomatology. Even low-level depressive symptoms significantly reduce cessation rates (Berlin & Covey, 2006; Niaura et al., 2001; Swan, Ward, & Jack, 1996). Specific depressive symptoms like anhedonia (lack of/inability to experience pleasure) and low positive affect (PA) increase withdrawal symptoms and reduce the likelihood of continued abstinence, even when accounting for nicotine dependence, current depressive symptoms, and a history of depression (Leventhal, Ramsey, Brown, LaChance, & Kahler, 2008).

A critical behavior to consider among smokers with elevated depressive symptoms is substance abuse; 75-95% of individuals in substance use treatment smoke cigarettes (Budney et al., 1993; DiFranza & Guerrera, 1990; Kalman et al., 1998; 2005; Stark & Campbell, 1993) and depression and substance use disorders often co-occur (Cerdá, Sagdeo, & Galea, 2008; Grant et al., 2004; Kessler et al., 2005). Further, 25-61% of individuals in substance use treatment have experienced a depressive episode in their lifetime (Chen et al., 2011; Huang et al., 2006; Kessler et al., 2003; Regier, et al, 1990).

In terms of smoking, substance users are more likely than individuals in the general population to be nicotine dependent and to have difficulties when attempting to quit smoking (Fagerstrom & Aubin, 2009; Ginsburg et al. 1995; Hays et al., 1999; Novy, Hughes, & Callas, 2001; Prochaska et al., 2004). Moreover, smoking, not drug or alcohol use, is the largest contributor to mortality among substance users (Hurt el al., 1996). In fact, in a 24-year longitudinal study of substance abusers, the mortality

rate of those who smoked cigarettes was four times higher than the rate among those who did not smoke (Hser, McCarthy, & Anglin, 1994). Additionally, tobacco and substances have synergistic effects estimated to be up to 50 times higher than the effects of either individually, particularly when examining rates of specific types of cancers (Bien & Burge, 1990; Pelucchi, Gallus, & Garavello 2007; Zheng et al., 2004).

Taken together, the available research suggests that individuals with depressive symptoms and substance use disorders represent an important population to target in smoking cessation programs because of their combined mood and substance-related vulnerabilities. Importantly, individuals with these types of vulnerabilities are motivated to quit smoking, with 40-80% of individuals in substance use treatment reporting a desire to quit (Clarke et al., 2001; Richter et al., 2001). Despite the clear negative economic and health-related consequences of smoking among individuals with substance use disorders (SUDs) and depressive symptoms, few smoking treatments to date have been developed that specifically target individuals within these populations. Moreover, the majority of treatment research studies exclude these individuals. A thorough search of the literature did not uncover a single study specifically focusing on individuals in substance use treatment with elevated depressive symptoms who wished to quit smoking.

Recent work by Okoli and colleagues (2011) demonstrated that individuals with substance use disorders and mental illness show enhanced benefits when enrolled in more than eight weeks of cessation treatment. Further, there have been a handful of studies targeting smoking among individuals with comorbid substance use

disorders and mental health diagnoses. Unfortunately, existing treatments have generally shown minimal benefits within these samples. As such, the need for smoking cessation treatments targeting individuals with complex diagnostic profiles is apparent. Below, a review of smoking cessation treatments that are currently available, as well as the extent to which these treatments adequately address the issues of substance use and comorbid depressive symptoms, is undertaken. Then, a discussion of novel treatment strategies for targeting these combined vulnerabilities is introduced. Finally, a plan for testing a novel behavioral activation-enhanced smoking cessation treatment is proposed.

Standard Cessation Techniques Used with Individuals with Co-occurring Disorders

The guidelines for treating tobacco use and dependence (Fiore et al., 2008) recommend a variety of strategies to aid individuals in their smoking cessation attempts. Based on a review of the literature, Fiore and colleagues conclude that a combination of cognitive-behavioral and pharmacological treatments provides the greatest benefits. These recommended treatments, as well as some novel treatment strategies for specific populations, are reviewed below.

Pharmacological techniques. Nicotine Replacement Therapy (NRT; transdermal patches, gum, nasal sprays, inhalers, lozenges) is one of the primary tools used for smoking cessation because it helps reduce physiological withdrawal symptoms associated with abstinence. The patch has been shown to outperform placebo across 17 studies included in a meta-analysis and abstinence rates of individuals receiving the patch have been twice that of individuals receiving placebo (Fiore, Smith, Jorenby, & Baker, 1994). Furthermore, the patch has been

demonstrated to be the most effective form of NRT because it provides a constant dose of nicotine, is convenient and easy to use, and reliably reduces withdrawal symptoms (Hughes, 1993).

Among smokers with depressive symptoms or SUDs, however, the benefits of NRT may be less robust. Some researchers have not found NRT to benefit depressed smokers (Hall et al., 1996), while others have demonstrated attenuated cessation rates within depressed samples using the patch as compared to non-depressed samples using the patch (Kinnunen, Doherty, Militello, & Garvey, 1996; Kinnunen, Korhonen, & Garvey, 2008). Among individuals with alcohol use disorders (AUDs), similarly mixed patterns of results have been found. Leeman and colleagues (2007) reviewed six articles that used NRT among smokers with a history of AUDs. Four of the studies reviewed demonstrated equivalent cessation benefits among smokers with and without AUDs, while the remaining two studies showed smokers with AUDs to benefit less than their counterparts without AUDs. A meta-analysis examining smoking cessation among substance users demonstrated improved cessation outcomes when NRT was provided; however, cessation rates were still low, even among individuals who received concomitant therapy (Prochaska et al., 2004). Therefore, although NRT exerts some benefits among depressed smokers and smokers with SUDs, it is clear that other treatments must be utilized in conjunction with NRT to achieve higher rates of abstinence among this sub-population of smokers.

Bupropion has consistently been shown to benefit smoking cessation attempts; across 221 studies included in a review article, individuals who received bupropion were better able to quit smoking (Richmond & Zwar, 2003). Bupropion is

hypothesized to exert its benefits by blocking the reuptake of dopamine and norepinephrine, thereby alleviating symptoms of withdrawal during smoking cessation (George & O'Malley, 2004). Bupropion does not appear to exert its cessation benefits through a reduction of depressive symptoms (Hurt et al., 1997; Jorenby et al., 1999) and among highly nicotine dependent individuals, bupropion is associated with a strong rebound effect in depressive symptoms when discontinued post-cessation (Lerman et al., 2004). Among smokers with a history of an AUD, inconsistent results have been found. Specifically, smokers with and without a history of an AUD had similar cessation outcomes when using bupropion in three studies, while a fourth showed reduced benefits among smokers with an AUD (Leeman, Huffman, & O'Malley, 2007). Therefore, it is difficult to determine whether bupropion would benefit smoking cessation attempts within substance users with elevated depressive symptoms.

Researchers have also administered bupropion and NRT concurrently to determine whether the combination conferred additional benefits. In one study, bupropion, or a combination of NRT and bupropion were associated with significantly higher rates of continuous abstinence at one-year follow-ups (18.4% and 22.5%, respectively) compared to placebo and NRT (5.6% and 9.8%, respectively; Jorenby et al., 1999), whereas in another study the only treatment to produce significantly different abstinence rates at a six month follow-up was a patch + nicotine lozenges combination, (compared to other combinations that included bupropion; Piper et al., 2009). Importantly, when examining individuals with depression, the addition of bupropion to a standard treatment package (including CBT

for smoking and NRT) did not increase abstinence rates above and beyond that of the standard treatment package (Evins et al., 2008). Similarly, among alcoholics, bupropion added to a treatment that included NRT did not confer additional benefits (Grant, Kelley, Smith, Agrawal, Meyer, & Romberger, 2007). When examining carbon monoxide (CO) levels among substance dependent patients who quit smoking, (74% also had a co-occurring Axis I diagnosis) combination treatments that included standard psychoeducation, relapse prevention, NRT, and/or bupropion only resulted in 7.8% of participants having CO levels less than 9 ppm (parts per million; a quantity indicating abstinence) at the final session (Grant et al., 2007). This indicates that among our populations of interest- individuals with depressive symptoms and SUDs- combined pharmacological treatments might not produce particularly enhanced benefits.

Although pharmacotherapy benefits cessation attempts, the majority of individuals need additional strategies to aid in their cessation attempts. Particularly among individuals with depressive symptoms or substance use disorders, pharmacotherapy does not provide enough support to enable long-term abstinence. Therefore, psychological treatments are of particular importance within this population.

Cognitive behavioral techniques. The Guidelines for Treating Tobacco Use and Dependence recommend a variety of strategies to aid in cessation, including: self-monitoring, identifying coping strategies, eliciting social support, making lifestyle changes, identifying strategies for relapse prevention, and discussing effective and ineffective cessation strategies from prior quit attempts (Fiore et al., 2008), all which

can be categorized as cognitive-behavioral techniques. Although these strategies are effective among individuals without comorbid mental health diagnoses, outcomes are less favorable when they are applied in samples of smokers with SUDs or elevated depressive symptoms (e.g. Prochaska et al., 2004; Niaura et al., 2001), particularly in relation to maintaining abstinence. Smokers with elevated depressive symptoms who receive CBT are less likely to maintain abstinence than smokers without elevated depressive symptoms (Niaura et al., 2001) and lower rates of abstinence among smokers with SUDs who receive CBT have also been reported (Campbell, Wander, Stark, & Holbert, 1995; Story & Stark, 1991).

Important Considerations when Treating Smokers with Comorbid Conditions

Although smokers with SUDs and/or mental health diagnoses have difficulties maintaining abstinence, it is notable that about 40-80% of smokers in treatment for SUDs have expressed interest in smoking cessation (e.g. Clarke, Stein, McGarry, & Gogineni, 2001; Richter, Gibson, Ahluwalia, & Schmelzle, 2001). In one study examining individuals diagnosed with a psychiatric disorder (e.g. depression) in substance use treatment, a smoking cessation attempt was made by 54% of patients over the course of six months and 42% were abstinent for at least one day without formalized smoking cessation treatment (Unrod, Cook, Myers, & Brown, 2004). These studies reveal that individuals with complex diagnostic profiles are able to make a short-term cessation attempt without support and suggest that unique treatment strategies may help lengthen periods of abstinence.

Smokers with comorbid diagnoses not only have difficulties maintaining abstinence, but also drop out of cessation programs before completing treatment. In a

sample of patients dually diagnosed with an Axis I disorder and substance dependence, only 40% who enrolled in a standard smoking cessation program (which included weekly group therapy, NRT, and bupropion, if desired) attended the first four treatment sessions. Moreover, only 15% of enrolled patients attended at least eight treatment sessions and only 7.8% had CO levels less than 9 ppm at the end of treatment (Saxon et al., 2003). A review of smoking cessation programs targeting heroin users in methadone maintenance did not reveal significantly higher abstinence rates among individuals enrolled in smoking cessation programs compared to those who were not enrolled; overall abstinence at 6 month follow-ups ranged from 5-14% in the active treatment conditions (Okoli, Khara, Procyshyn, Johnson, Barr, & Greaves, 2010). Clearly, researchers working with individuals with multiple mental health diagnoses follow the treatment recommendations outlined by Fiore and colleagues (2008), but their clients do not evidence cessation rates comparable to those seen in less complex populations. Although considerable harm reduction and decreased rates of smoking in the short term have been demonstrated, low rates of session attendance and abstinence makes apparent the need for treatments that cater to this type of population, not only to help retain individuals in treatment, but also to provide meaningful benefits in the long-term.

Alternative Treatment Strategies for Smokers with Elevated Depressive Symptoms

A number of smoking cessation programs have been developed that aim to increase cessation rates above a beyond those found in standard cognitive behavioral treatment programs. Some of the treatments developed for smokers with elevated

depressive symptoms specifically focus on reducing depression, while others work within standard CBT frameworks, but add complimentary techniques.

Depressed smokers in a stage-based treatment evidenced more cessation attempts than did individuals in a no treatment control group (Hall et al., 2006). The stage-based intervention focused on changing clients' motivation to quit smoking and on targeting cessation treatment based on clients' motivation to quit. The treatment was successful, but this may have been less related to the motivational strategies used and more related to receiving treatment in general, particularly since previous research has demonstrated that individuals with psychiatric disorders are already motivated to quit smoking. Moreover, it is also impossible to determine whether the focus on clients' stages of change was relevant, since the study did not include a time-matched active control condition.

Cognitive behavioral therapy for mood management has been used among individuals who wish to quit smoking and who have had past episodes of major depression (Hall et al., 1996; 1998). Overall, the mood management treatment produced significantly higher abstinence rates than the standard treatment (ST; Hall, Muñoz, & Reus, 1994; Hall et al., 1998), particularly among individuals with recurrent depressive episodes (Haas et al., 2004). However, these results were confounded by contact time because individuals in the mood management treatment received 10 sessions while individuals in ST received five sessions. A later study equating for contact time between mood management and ST did not demonstrate different cessation outcomes (Hall et al., 1996). In a sample of Spanish speakers, however, self-administered mood management demonstrated better cessation

outcomes than did self-administered ST (Muñoz, Marín, Posner, & Pérez-Stable, 1997). Most recently, a treatment program that combined bupropion or NRT and cognitive-behavioral techniques for mood management improved abstinence rates among German smokers with elevated depressive symptoms and low levels of nicotine dependence (Batra et al., 2010), although changes in depressive symptoms were not analyzed. Unfortunately, this study also did not provide information on cutoff scores for inclusion in the depressive group, making difficult to fully understand the clinical profiles of the individuals the treatment benefitted. Interestingly, across all of these aforementioned studies, there were no differences across treatment conditions in reductions in depressive symptoms, making it difficult to determine why the mood management conditions occasionally conferred additional cessation benefits.

Interventions utilizing smoking cessation treatment with a cognitive behavioral therapy for depression (CBT-D) component have been tested among smokers with past major depressive episodes. When standard smoking cessation treatments have been compared to ST supplemented with CBT-D, better cessation outcomes have been demonstrated among heavy smokers and among smokers with a history of recurrent major depressive disorder (MDD) in ST + CBT-D than in ST (Brown et al., 2001). However, smokers with a history of MDD in ST + CBT-D had a significantly higher likelihood of developing a major depressive episode than individuals in ST during their quit attempts, which clearly is not ideal (Kahler et al., 2002). Further, when CBT-D has been added to standard smoking cessation

treatment, with or without bupropion, it has not conferred additional benefits to depressed smokers (Brown et al., 2007).

The literature has been unable to consistently demonstrate improved smoking outcomes when cessation programs have included elements focusing on depressive symptoms and negative mood (Hall et al., 1996; Kahler et al, 2002; Brown et al., 2007). This may suggest that a focus on increasing positive affect, rather than combating negative mood, might confer greater benefits. Recently, a promising new approach has been utilized that targets depressive symptoms via behavioral activation (BA). MacPherson and colleagues (2010) developed a behavioral activation-based approach utilizing, standard smoking cessation treatment (ST), behavioral activation (BA), and nicotine replacement therapy (NRT). Among community smokers with elevated depressive symptoms, this BA-based approach resulted in reductions in depressive symptoms and a greater odds of point prevalence abstinence across a six month follow-up among individuals receiving BA-enhanced smoking cessation (BA, ST, and NRT) compared to individuals receiving standard smoking cessation treatment (ST and NRT). Individuals receiving BA-enhanced treatment were 2.26 times more likely to be abstinent at the end of treatment than individuals in ST and at a 26-week follow-up, 16.7% of patients in the BA-enhanced cessation condition were abstinent, while 4.2% in the ST condition were abstinent. Further, there was an interaction between the treatment conditions and time, in that individuals in the BA-enhanced treatment had significantly greater decreases in depressive symptoms over time in comparison to individuals in the ST condition.

The successes of this BA-enhanced treatment, not only on cessation outcomes, but also in reducing depressive symptoms, suggests it is a promising new approach for smokers with unique diagnostic profiles. Since smoking cessation programs specifically developed for individuals with SUDs have not demonstrated improved long-term cessation outcomes across studies (Prochaska et al., 2004), new approaches, like BA are needed. Smokers with depressive symptoms and SUDs are among the most difficult to treat and the benefits of this BA-based approach may similarly enhance cessation among smokers with SUDs.

Smoking Cessation among Substance Users

Individuals with substance use disorders do want to quit smoking and previous research has demonstrated that they are able to quit without negatively impacting their substance use outcomes; however, long term abstinence is relatively rare within this population (Bobo et al., 1998; Burling, Burling, & Latini, 2001; Hurt et al., 1994). As mentioned, the meta-analysis of Prochaska and colleagues (2004) did not demonstrate significant long-term abstinence effects among substance users in smoking cessation treatment (only 3% quit overall); however, individuals enrolled in cessation treatments did have significantly higher abstinence rates immediately post-treatment (12% in the intervention group versus 3% in the comparison group). Interestingly, as with non-substance abusing populations, individuals who received NRT demonstrated significant increases in abstinence. Further research, with less than promising outcomes, focused on smoking cessation among methadone maintenance clients and found results similar to the Prochaska meta-analysis; overall there were not significantly higher abstinence rates among individuals who

participated in smoking cessation interventions examined within the review, compared to abstinence rates of individuals within control groups in the review (Okoli et al., 2010).

More recently, a multisite study focusing on individuals with SUDs in outpatient treatment demonstrated significant increases in abstinence among individuals receiving smoking cessation interventions, compared to individuals receiving TAU (Reid et al., 2008). Individuals in the smoking cessation program received NRT and nine sessions of cognitive behavioral smoking cessation group therapy, which included a mood management component. Although only 5-6% of individuals were abstinent at the 13 week follow-up visit, this was significantly better than the abstinence rates among individuals who did not receive treatment (0%). In terms of harm reduction, there were significant decreases in expired CO and cigarettes smoked in the active treatment condition, compared to the TAU condition. Interestingly, although abstinence rates remained constant among the active treatment group at the 26 week follow-up, individuals in the TAU group had increases in abstinence, with more than 5% of these individuals abstaining from cigarettes at that time. Therefore, at the 26 week follow-up smokers who did or did not participate in the cessation program had identical abstinence rates.

A smoking cessation study comparing concurrent versus delayed smoking cessation treatment for individuals with alcohol use disorders showed abstinence rates of 12.4 and 13.7%, respectively at 18 month follow-ups (Joseph, Willenbring, Nugent, & Nelson, 2004). Both the concurrent and delayed treatments included NRT and four one-hour individualized behavioral therapy sessions based on the

recommendations of Fiore and colleagues (2000). Individuals who received smoking cessation interventions while they were in treatment for their AUDs showed lower abstinence rates at six month and one year follow-ups; however the rates of abstinence across the two treatment conditions were equivalent at 18 month follow-ups. Furthermore, individuals in the concurrent treatment group were more likely to enroll in cessation programs than individuals in the delayed treatment group (78.5 versus 64.5%, respectively), which is important. Therefore, treating substance users with elevated depressive symptoms while they are in treatment for their SUDs is the best course of action as it increases the likelihood that individuals will enroll in cessation interventions.

Overall, smoking cessation programs aimed at individuals with SUDs have produced mixed outcomes. The critical meta-analysis in this area (Prochaska et al., 2004) demonstrated individuals who enrolled in smoking cessation programs to have higher rates of abstinence compared to individuals in control groups post-treatment; however significant benefits of enrollment in cessation programs dissipated at long-term follow-ups. Clearly, it is necessary to try alternative cessation strategies with individuals with SUDs, as previous treatments generally have not conferred significant benefits within this population. Based on the success of BA-enhanced smoking cessation programs among community smokers with elevated depressive symptoms (MacPherson et al., 2010) and the success of a BA-enhanced treatment among individuals with SUDs and elevated depressive symptoms (Daughters et al., 2008), it is logical to consider this treatment for smokers with SUDs who have elevated depressive symptoms. However, a review of the theoretical underpinnings

and research supporting BA as a treatment for depression is necessary before discussing the potential for BA-enhanced therapy among this population.

Background and Theoretical Underpinnings of Behavioral Activation

Behavioral Activation (BA) focuses on helping individuals to become involved in meaningful, enjoyable activities that resonate with their values across a variety of life areas. It is hypothesized that involvement in these activities exposes individuals to environments that are more rewarding and enables them to derive enjoyment from activities within these environments (Lejuez, Hopko, LePage, Hopko, & McNeil, 2001).

BA is based on the tenets of reinforcement theory, which argues that depression results from a loss of positive reinforcement (Ferster, 1973; Lewinsohn, 1974; Skinner, 1953) and from an increase in punishment for healthy behaviors in individuals' environments (Lewinsohn, Antonuccio, Breckenridge, & Teri, 1984). Early research using the Pleasant Events Scale, which monitored the frequency with which individuals engaged in pleasant activities and their associated mood, demonstrated a significant relationship between frequency of engagement in pleasant events and positive mood among depressed, non-depressed psychiatric and non-depressed controls (Lewinsohn & Graf, 1973; Lewinsohn & Libet, 1972). Depressed individuals, in particular, were less likely to engage in pleasant activities; when they occasionally did engage in pleasant activities, they were also less likely to experience positive mood than controls (Lewinsohn & Graf, 1973). Further, these individuals were less likely to seek interpersonal interactions, which may have limited their ability to receive social reinforcement (Hopko, Lejuez, Ruggiero, & Eifert, 2003).

Individuals may be less likely to engage in pleasant events for a variety of reasons and the loss of reinforcement they experience can be quantitative (e.g. less frequently visiting friends) or qualitative (e.g. certain enjoyable activities have been replaced with less enjoyable activities). In this context, researchers have developed BA treatments that enable clients to become involved in a greater frequency of activities that are pleasant and rewarding (Hopko et al., 2003; Jacobson et al., 1996; Lejuez, Hopko, & Hopko, 2001; Lejuez et al., 2001; Martell, Addis, & Jacobson, 2001). Utilization of these types of treatments have produced significant reductions in depressive symptoms, demonstrating benefits comparable to those seen with antidepressants and traditional CBT (Dimidjian et al., 2006).

Comparison of BA to other treatment techniques. Jacobson and colleagues (1996) compared BA as a stand-alone treatment to a full CBT treatment package. Results of this trial indicated that BA was the critical component across treatments; specifically the treatments were equally effective in treating depression at a six-month follow-up, indicating that the addition of cognitive components did not significantly benefit clients (Gortner, Gollan, Dobson, & Jacobson, 1998; Jacobson et al., 1996). In a separate study, Dimidjian and colleagues (2006) found cognitive therapy (CT) to be less effective than BA or antidepressants in treating depression among severely depressed individuals, in that individuals receiving BA or antidepressants had significantly lower Beck Depression Inventory and Hamilton Rating Scale for Depression scores than individuals in CT over the course of treatment. In a follow-up study assessing the long term effects of these therapies, CT, BA, and medication were equally effective in preventing recurrences of depression, establishing BA as an

important treatment strategy for depression (Dobson et al., 2008). A number of studies have demonstrated significant decreases in depressive symptoms among individuals participating in a BA treatment for depression (Hopko, Lejuez, LePage, Hopko, & McNeil, 2003; Lejuez, Hopko, LePage, Hopko, & McNeil, 2001). Finally, BA has been established as an evidence-based treatment for depression (Sturmey, 2009).

There have recently been three meta-analyses examining the efficacy of behavioral activation as a treatment for depression (Cuijpers, van Straten, & Warmerdam, 2007; Ekers, Richards, & Gilbody, 2008; Mazzucchelli, Kane, & Rees, 2009). Cujipers and colleagues (2007) focused on studies using activity scheduling (an important component of BA) and demonstrated large pre-post treatment effect sizes (.87). Moreover, when BA was compared to CT within these studies, outcomes were found to be equivalent. More recently, Ekers and colleagues (2008) compared behavioral treatments for depression to supportive counseling and brief psychotherapy and concluded that the behavioral treatments were superior to the other treatments. Similarly, the Mazzucchelli and colleagues (2009) meta-analysis demonstrated an effect size of .78 that favored BA in comparison to control conditions and for participants with a major depressive disorder diagnosis, the effect size was .74 in favor of BA.

A more recent study successfully targeted depressive symptoms in substance dependent clients using BA (Daughters et al., 2008), under a similar BA protocol used in the study conducted by MacPherson and colleagues (2010). Daughters and colleagues' BA treatment for substance users with elevated depressive symptoms

significantly reduced clients' depressive symptoms, and only 4.5% of clients in the BA treatment dropped out of residential substance use treatment compared to 22.7% in the treatment as usual condition. Therefore, the BA treatment not only reduced depressive symptoms, but also had the potential to improve substance use treatment outcomes. A more recent study compared the effects of BA to a contact-time matched control condition, supportive counseling (SC), among substance users with elevated depressive symptoms (Magidson et al., 2011). Within this study, BA did not result in differential changes in depressive symptoms between the two groups; however, individuals in the BA treatment were less likely to drop out of substance use treatment and more likely to experience enhanced activation than individuals in SC. Thus, BA appears to retain individuals in substance use treatment more so than supportive counseling, perhaps through increased activation.

Clearly, BA is a beneficial treatment for individuals with elevated depressive symptoms who have a substance use disorder, or who smoke cigarettes. BA may be successful because it does not require abstract reasoning skills and because it specifically focuses on increasing positive affect, rather than on decreasing negative affect. Indeed, Kahler and colleagues (2002) hypothesized that increases in depressive symptoms among patients enrolled in their CBT-D condition may have been related to participants' expectation that they would experience depressive symptoms when quitting smoking, as learned in the CBT-D intervention. Moreover, recently it has been argued that both the heterogeneity of depressive symptoms as well as a focus on depression as a broad category has limited the effects of mood-focused smoking cessation interventions (Leventhal et al., 2008). Leventhal and colleagues argue that

smoking cessation treatments should target low PA in particular, as a mechanism through which to improve cessation outcomes, rather than on decreasing negative affect, which has been unsuccessful in the past (e.g. Kahler et al., 2002). Further, they argue that behavioral activation may be especially useful for increasing positive affect (Leventhal et al., 2008) within these types of samples.

Behavioral Activation for Drug Abusing Smokers (BA-DAS)

There is a dearth of research focusing on the unique needs of substance abusing smokers with elevated depressive symptoms, who represent an important target for smoking cessation interventions. The outcomes of treatments targeting depressive symptoms within smokers, depressive symptoms within drug users, and smoking among drug users have been mixed, making the continued development and examination of treatments for these populations critical. BA may be an ideal treatment for substance abusing smokers with elevated depressive symptoms, based on its preliminary efficacy among smokers with elevated depressive symptoms (MacPherson et al., 2010) and among individuals in residential substance use treatment with elevated depressive symptoms (Daughters et al., 2008). BA has been shown to be as effective, if not more effective than, CBT; therefore its use in treating depressive symptoms in this population may have great utility (Dimidjian et al., 2006; Gortner, Gollan, Dobson, & Jacobson, 1998; Jacobson et al., 1996). Moreover, BA is unique because of its focus on increasing positive affect, rather than on decreasing negative affect, which may be of key importance in this type of population (Leventhal et al., 2008).

As previously mentioned, CBT can be difficult for some clients to comprehend; clients with low abstract reasoning skills do not show improvements in CBT in comparison to 12-step treatments (Maude-Griffin et al., 1998). Because BA relies heavily on changing individuals' activity patterns, rather than their cognitive patterns, it may be easier for individuals with lower level abstract reasoning skills to succeed in BA than in CBT. Furthermore, the simplicity of BA means it may be easier in the future for drug treatment center staff to implement it, as many staff members lack the background necessary to administer complex theory-based treatments like CBT (McCoy, Messiah, & Zhao, 2002). Indeed, few drug treatment centers actually integrate treatments for mental health diagnoses into their standard treatments, (Drake, Mueser, Brunette, & McHugo, 2004), often leaving clients who have multiple diagnoses with insufficient care.

Current Study

The current study compared a novel integrated behavioral activation smoking cessation intervention (BA-DAS) to treatment as usual (TAU) among smokers with elevated depressive symptoms in a residential substance use treatment center in Washington D.C. Treatment as usual included all of the standard substance abuse treatment groups at the center, transdermal nicotine replacement therapy, and the National Cancer Institute's *Clearing the Air* manual. TAU represented the treatment likely to be provided to individuals in residential substance use treatment who wished to quit smoking. BA-DAS included key elements of cognitive behavioral smoking cessation treatment, NRT, and critical elements of behavioral activation. BADAS was administered over five 60-90 minute individual treatment sessions. Across the

treatment conditions, individuals' self-reported smoking statuses, carbon monoxide output, depressive symptoms, positive affect, anhedonia, activation levels, and drug use were monitored before, during, and after treatment to determine whether BA-DAS significantly benefited smokers, as compared to TAU. As an accepted standard in smoking cessation research, a number of cessation outcomes were examined, including seven-day point-prevalence abstinence, time to relapse (smoking five cigarettes per day for three days in a row), and smoking reductions (Hughes et al., 2003; Shiffman et al., 2006). Multiple outcomes were examined, because different outcomes have implications for processes by which treatments work as well as specific behavioral targets of intervention (e.g. Shiffman et al., 2006). It was hypothesized that participants in BA-DAS would (1) show significantly higher point prevalence abstinence rates, lower cigarette consumption, and a longer time to relapse (2) evidence significant reductions in depressive symptoms, (3) exhibit significant increases in positive affect, and (4) become more active and derive more pleasure from being active. All outcomes were assessed over treatment and at two-week and one month follow-ups.

Aim 1: To compare smoking outcomes among substance users with elevated depressive symptoms as a function of treatment condition.

A1a: To examine time to relapse as a function of treatment condition.

Hypothesis 1a: Participants in TAU will more quickly relapse to smoking than participants in BADAS.

A1b: To examine seven day point prevalence abstinence as a function of treatment condition.

Hypothesis 1b: There will be higher abstinence rates among smokers in BADAS than among smokers in TAU.

A1c: To examine reductions in cigarette consumption as a function of treatment condition.

Hypothesis 1c: There will be greater overall reductions in cigarette consumption among smokers in BADAS than among smokers in TAU.

Aim 2. To examine changes in depressive symptoms over time as a function of treatment condition.

Hypothesis 2: Smokers in BADAS will evidence greater reductions in depressive symptoms over time than will individuals in TAU.

Aim 3: To examine changes in activity levels and rewards over time as a function of treatment condition.

Hypothesis 3. Individuals in BADAS will exhibit greater increases in activity levels and enjoyment derived from being active over time than will individuals in TAU.

Exploratory Aim: To examine treatment satisfaction and treatment compliance among participants in BADAS.

Chapter 2: Method

Participants

All participants were recruited from a residential substance use treatment center in Washington D.C. The majority of participants at the center were low-income, African Americans who were court-mandated to receive substance use treatment (see Table 1). The most common treatment contract length was 30 days, but participants could stay at the center for up to 180 days and the center provided transition services upon treatment completion (see Table 1). Participants were recruited during their first week of residential treatment after complete detoxification, which typically occurred in specialized facilities prior to entering the center. Treatment at the center included a variety of programs intended to help participants develop a substance-free lifestyle, based on Alcoholics Anonymous and Narcotics Anonymous techniques as well as on strategies focusing on the development of relapse prevention skills. Participants were involved in group therapy, work therapy, Bible study, educational programs, literacy education, and anger management programs, which lasted from 8am to 9pm Monday-Saturday. Sundays were spent in church at the treatment facility. Residents were only permitted to leave the center for treatment required activities (e.g. physician visits, to attend court hearings). The center regularly drug tested participants and positive drug screens were grounds for dismissal. Participants were provided five smoking breaks daily and all participants were required to go outside into the treatment center courtyard during these smoking

breaks. Participants were allowed to have two packages of cigarettes delivered to the treatment center by friends or family members once weekly.

All individuals at the treatment center received a standard intake assessment within their first week of arriving to the treatment center. Those who met preliminary inclusion criteria for our study were invited to complete a baseline assessment to determine full eligibility. Participants in our study were: (1) between the ages of 18-65; (2) had a BDI-II score of at least 7 during the intake assessment (in line with MacPherson et al., 2010); (3) were motivated to quit smoking (endorsed at least a 5 on a scale from 1-10 for motivation to quit during the intake assessment), (4) and regularly smoked (were smokers who reported smoking at least 5 cigarettes/day and having smoked for at least one year during the intake assessment). We excluded participants if they (1) endorsed psychotic symptoms (as assessed by the SCID-IV during the intake assessment), (2) had limited mental competency and/or the inability to give informed consent, (3) reported using tobacco products other than cigarettes during the baseline assessment (but not excluding mini cigars, like Black and Milds), (4) had physical concerns that prevented them from using the patch (further described below), (5) reported using other medications to quit smoking during the baseline assessment, (6) were reading below a 5^{th} grade reading level, or (7) reported initiating psychotropic medications within the prior three months during the intake assessment. We recruited participants to participate in our study within their first 7-10 days at the center.

Screening and Recruitment

Graduate students and research assistants supervised by Dr. Lejuez administered the SCID-IV (Spitzer, Gibbon, & Williams, 1995) to assess Axis I and II disorders as a part of the initial intake procedures for all participants at the treatment center. Participants reported basic demographic information, completed the Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996), and provided information about their daily smoking levels and motivation to quit smoking during their intake assessments. Based on this initial information, participants who were eligible, based on the aforementioned inclusion and exclusion criteria, were invited to complete further assessments administered by research assistants to determine whether they would be eligible to participate in the current study. These participants completed a brief medical history questionnaire focusing on contraindications for transdermal nicotine patch use (i.e., cardiovascular, neurological, renal, immunological problems, pregnancy/ breast feeding, significant medical/systemic illnesses). Women received additional questions regarding their plans to become pregnant within the following six months and their use of birth control. The study nurse followed up with participants who endorsed contraindications for patch use during this initial screener. As multiple research studies are conducted by our staff at this residential treatment center, participants who met inclusion criteria for more than one study were allocated to studies based on the study need. Of the 353 participants we screened, there were 48 who met our inclusion and exclusion criteria; 31 were invited to participate in our study and 17 were recruited to participate in other studies (see Figure 1).

Treatment Group Assignment and Basic Treatment Components

Participants were assigned to TAU or BADAS within four sequential cohorts. This type of assignment schedule minimized potential bleeding effects of the BA-DAS treatment into the TAU condition, as many participants often overlapped at the treatment center while they were quitting smoking. Participants 1-7 and 15-19 recruited into the study were assigned to the TAU condition, while participants 8-14 and 20-24 were assigned to the BA-DAS treatment condition.

Treatment for BADAS participants consisted of five 60-90 minutes sessions conducted over 2 ½ weeks, with the quit day scheduled to occur on the third session. Treatment included transdermal nicotine replacement therapy (NRT), standard cognitive behavioral smoking cessation treatment components, and behavioral activation. Treatment for TAU participants included transdermal NRT and NCI's *Clearing the Air* manual. By design, participants in TAU were assigned a quit day that occurred five to nine days after their baseline assessment session to most closely approximate the number of days between the baseline assessment session and session three for participants in the BADAS treatment condition.

Transdermal nicotine replacement therapy. All participants in BADAS and TAU received the Nicoderm CQ, 24-hour transdermal nicotine patch, with the initial dose calibrated to match the participants' average number of cigarettes smoked. For example, a participant who generally smoked 14 cigarettes per day started on the 14-mg patch, while a participant who generally smoked a pack-a-day (20 cigarettes) began on the 21-mg patch. In line with manufacturer's recommendations, participants who began on the 21-mg patch received the 21-mg dose for 4 weeks, followed by two

weeks of the 14-mg patch and two weeks of the 7-mg patch, while participants who started on the 14-mg patch received the 14-mg dose for 6 weeks, followed by two weeks of the 7-mg patch. Participants were provided with the safety information instructions provided with the patch. Prior to the third session (or four days after the baseline assessment for participants in TAU), participants were educated on the use of the patch and possible side effects were discussed. The importance of wearing the patch for the full two months was emphasized. Participants who continued smoking while receiving the patch, or who lapsed while using the patch, were instructed to discontinue use of the patch if their smoking level reached four cigarettes per day for four days. Participants who discontinued use of the patch because of a smoking lapse were encouraged to set a new quit day.

Cognitive behavioral techniques for smoking cessation. Participants in BADAS received components of standard smoking cessation techniques based on the most recent guidelines provided by the U.S. Department of Health and Human Services, Treating Tobacco Use and Dependence (Fiore et al., 2008). In the first two sessions, participants discussed previous quit attempts, the benefits of quitting, high risk situations, coping skills, and enlisting social support. During the third session, participants discussed the first day of their quit attempt, coping strategies they had used/intended to use, and high risk situations they thought they might encounter. The final two sessions focused on their quit experiences, patch use, withdrawal symptoms, strategies for avoiding smoking, and the perceived benefits of quitting. The treatment included a condensed form of these topics, as to allow time for the BA components of treatment. Since previous research has successfully used shortened forms of ST (e.g.

30 minute sessions; Fiore et al., 2008) this condensed ST format was able to cover necessary areas, while providing time for the BA components of therapy.

Behavioral activation for drug abusing smokers (BADAS). The BA-DAS treatment manual was developed using strategies tested among community smokers with elevated depressive symptoms (MacPherson et al., 2010) and strategies used among individuals with substance dependence and elevated depressive symptoms (Daughters et al., 2008). The BA-DAS manual was developed in an iterative fashion, with participant and therapist feedback that occurred during pilot sessions informing different iterations of the treatment manual. The BADAS manual used in this study included simplified behavioral monitoring forms, re-wording in several sections to ease comprehension, and better integration of standard smoking cessation techniques with BA techniques.

Behavioral activation strategies focused on helping participants form rewarding smoke-free lifestyles. Behavioral activation components (Lejuez et al., 2001; 2011) in BA-DAS included 1) daily completion of an activity and smoking log; 2) identification of important life areas (i.e. Relationships, Career/Education, Free Time, and Wellness) and values (things that are valued by an individual within these specific life areas); 3) selection of activities that enable participants to live their lives according to their values within these specific life areas; 4) formulation of a schedule with participants to determine when activities will be performed; and 5) assessment of completion of activities and modification of selected activities when necessary. Participants were encouraged to engage in these treatment components so they would become more involved in important and enjoyable activities during their quit attempt.

Therapists regularly ensured participants understood the connection between involvement in important/enjoyable activities, mood, and smoking behaviors.

Session 1: During the first session, therapists explained the components and rationale of the BA-DAS treatment. After discussing the standard smoking cessation treatment strategies (outlined above), therapists introduced the Daily Activity and Smoking Form, and instructed participants to record their activities (including the importance and enjoyment associated with these activities), mood, and cigarette consumption each day for the remainder of treatment. Then, the therapist discussed participants' normal daily activities, with a consideration of the importance and enjoyment of these activities. Therapists encouraged participants to reflect on how their involvement in important/enjoyable activities affected their mood and smoking behaviors. In this session, the therapist also elicited participants' opinions on the benefits of quitting smoking and information about their past quit attempts as a part of the standard CBT-based smoking cessation component.

Session 2: Participants reflected on the enjoyment and importance of activities they completed since the last session and were encouraged to note patterns between the importance/enjoyment of their activities, their mood, and their patterns of cigarette smoking. Participants discussed any difficulties encountered with daily activity monitoring. Therapists then introduced the concepts of life areas and important values within these areas. Participants identified their values within their life areas (i.e., Relationships, Career/Education, Free Time, and Wellness). They then brainstormed activities related to their values using the Life Areas, Values, and Activities (LAVA) form. Using their Daily Activity and Smoking Form for the

following week, participants selected activities from their LAVA form and scheduled them within specific time slots. The therapist encouraged participants to select important and enjoyable activities congruent with their values. Therapists suggested participants choose the easiest activities to complete first, increasing the likelihood of activity completion. Therapists emphasized that being active in enjoyable and important activities would better enable participants to remain abstinent from cigarettes. Standard treatment components were discussed at the end of the treatment session and included an introduction to the patch and information about high risk situations and eliciting social support for quitting. Participants were provided their first NRT patch by the therapist and were instructed to apply it the night prior to, or the morning of, their quit attempt.

Session 3: Participants' Daily Activity and Smoking Forms were reviewed. Difficulties participants had in completing scheduled activities were discussed. Then, participants scheduled activities from their LAVA form for the following week on their Daily Activities and Smoking Form. Participants were encouraged to continue engaging in activities they had already selected, as well as to add additional enjoyable/important activities from their LAVA form. Participants had the opportunity to discuss concerns about the patch and quitting smoking. Standard smoking cessation treatment components were further discussed, in particular the abstinence violation effect and high risk situations.

Sessions 4 and 5: During the fourth and fifth sessions, participants continued adding more activities to their Daily Activity and Smoking Form and discussed difficulties that arose when they attempted to complete new activities. Participants

also created contracts to be used with individuals within, as well as outside of, the treatment center. Participants selected activities from their LAVA forms for which they desired social support. They then selected individuals whom they believed could help them complete these activities. Standard smoking cessation techniques were integrated throughout these sessions.

Therapists

The therapists for this study included graduate students and senior research assistants who were extensively trained and supervised in BA and CBT-based smoking cessation techniques. These therapists shadowed experienced therapists conducting smoking cessation treatment sessions during the piloting stages of treatment development. They received supervision sessions with Dr. MacPherson throughout the duration of treatment administration. The therapist manual specifically outlined the components and steps of treatment for each session and treatment supervisors reviewed these areas as necessary during supervision. All therapy sessions were audiotaped and reviewed to ensure compliance with the treatment manual.

Measures

Several assessments were used to examine a variety of important variables, including: (1) basic demographics (age, gender, ethnicity, marital status, income level, employment status, and education level), (2) smoking information: smoking history, current cigarette consumption, type of cigarettes smoked (regular, menthol, black and milds, etc.), nicotine dependence, and smoking outcomes (Time Line Follow Back, Smoking History Questionnaire, Fagerstrom's Test for Nicotine

Dependence, Smoking: Self-Efficacy/Temptation Short Form, salivary cotinine, carbon monoxide analysis of breath samples), (3) motivation to quit smoking, (4) depressive symptoms and mood (Beck Depression Inventory, the Profile Of Mood States, Snaith-Hamilton Pleasure Scale, Environmental Reward Observation Scale), (5) activity levels (BADS), and (6) treatment adherence (homework completion checklist completed by the therapist). Participants enrolled in BA-DAS and TAU completed all assessments at the five time points.

Timeline follow back (TLFB; Sobell, Maisto, & Sobell, 1979; Sobell & Sobell, 1979; 1992; 1996). The TLFB is a reliable and valid self-report measure for examining individuals' use of cigarettes and drugs over time. It is the standard tool for retrospectively examining individuals' smoking rates, has demonstrated high test-retest reliability when analyzing drug use, and correlates with urinalysis results (Brown et al., 1998; Fals-Stewart, O'Farrell, & Freitas, 2000). During our baseline interview, participants provided information about the number of cigarettes they smoked daily for each of the prior 90 days. They also reported substances used during each of the prior 90 days, including number of alcoholic beverages consumed. Participants completed the TLFB at the third session, at the fifth session, and at a two week post-treatment follow-up session. During these additional assessment sessions, they reported on their cigarette, alcohol, and substance use since the prior assessment session. Participants' reports on the TLFB were compared to biochemical assessments of abstinence (carbon monoxide; CO output) and when there were discrepancies, we utilized CO results.

Time Line Follow Back data were used to determine all of our primary smoking-related outcomes. Data collected on the TLFB were used to calculate 7-day point-prevalence abstinence rates, which were defined as self-reported abstinence (verified with CO) for blocks of seven days assessed at four points post-quit (Hughes et al., 2003). Time 1 abstinence was defined as: not smoking from quit day through day 6 post-quit; time 2 abstinence was defined as: not smoking from day 7 post-quit through day 13 post-quit; time 3 abstinence was defined as: not smoking from day 14 post quit through day 20 post-quit; time 4 abstinence was defined as: not smoking from day 21 post-quit through day 27 post-quit. If participants smoked during a time period, they were coded as not abstinent. Time Line Follow Back data were also used to examine smoking reductions across the aforementioned four blocks of time. Thus, the total number of cigarettes smoked during time 1 (days 0-6 post quit), time 2 (days 7-13 post-quit), time 3 (days 14-20 post-quit), and time 4 (days 21-27 post-quit) were examined. Time Line Follow back data were used to examine time to relapse, which was defined as the number of days from quit date until the participant smoked five cigarettes per day for three days in a row post-quit (Shiffman et al., 2006).

Biochemical verification. Expired carbon monoxide (8ppm cutoff) via a Vitalograph Breathco carbon monoxide monitor for self-reported abstinence was used as a biochemical verification of self-reported abstinence. In cases of discrepancy where self-report indicated abstinence and biochemical measurement indicated smoking, the participant was coded as smoking.

Diagnoses, depressive symptoms, and mood states. Axis I and II diagnoses were determined using the SCID-IV (First, Spitzer, Gibbon, & Williams, 1995),

which was administered to participants by trained doctoral level students and senior research assistants within the first week of admission to the treatment center. The Beck Depression Inventory-II (BDI-II; Beck, Brown, & Steer, 1996), which is a well-validated measure assessing the existence and severity of depressive symptoms, was used to determine whether participants met the clinical cutoff to be included in the study. The BDI-II was administered at each assessment time point. The Profile of Mood States (POMS; McNair, Lorr, & Droppleman, 1971) has demonstrated psychometric properties and was used in the current study to examine week-to-week changes in mood.

Activity level and enjoyment. Participants' activity levels were assessed throughout treatment using a variety of tools. The Environmental Reward Observation Scale (EROS; Armento & Hopko, 2007) was used to gather general information about participants' engagement in and enjoyment of activities. The EROS is a 10 item measure with strong divergent and convergent reliability that was administered at each assessment point. The Behavioral Activation for Depression Scale (BADS) is a scale with demonstrated reliability and validity, which was used to assess participants' behavioral activation throughout treatment (Kanter, Rusch, Busch, & Sedivy, 2009). The four subscales (Activation, Avoidance/Rumination, Work/School Impairment, and Social Impairment) have adequate to strong internal consistency (α = .75 - .92), as does the Total score (α = .87). The Total score, as well as the Activation scores, were used in the current study.

Treatment satisfaction and compliance. A paper-based survey was created to determine participants' treatment satisfaction and compliance (see Appendix 1).

Participants rated the frequency with which they completed their daily activity and smoking forms, how helpful they found the various components of treatment, the clarity of the presentation of the materials, and their compliance with activity scheduling. They also described the components of treatment they found to be helpful/not helpful. The six participants recruited into the first BADAS cohort completed these treatment rating forms after each treatment session. This survey was not completed by the six participants in the second BADAS cohort for administrative reasons. The therapists also rated participants' treatment compliance after each treatment session (see Appendix 2). Therapists recorded participants' homework completion, the number of activities scheduled and completed, the number of life areas targeted by the activities, and clients' participation during the treatment sessions. Therapists completed this adherence form for eight of the 12 participants in BADAS.

Medical history. Participants were screened for nicotine replacement therapy, via the patch, using a medical screener questionnaire. If participants endorsed specific symptoms that contraindicated patch use, they were referred to the study nurse for further screening.

Data Analysis

Prior to data entry, the completed questionnaires and interview sheets were reviewed and checked for completeness or obvious errors. Data were double entered into SPSS (versions 16-18 over the course of the study) so potential inconsistencies or inaccuracies could be easily detected.

Missing data. There were missing data points due to participants dropping out of treatment or due to difficulties contacting participants for the one-month follow-up assessment (see Figure 1). On the quit day assessment, 100% of participants in BADAS completed the assessment, whereas 91.7% of participants in TAU completed the assessment. On the assessment occurring after the final treatment session, 100% of participants in BADAS completed the assessment, while 83.3% of participants in TAU completed the assessment. Finally, 75% of participants in BADAS completed the one-month follow-up assessment, whereas 41.7% of participants in TAU completed the one-month follow-up assessment. To determine whether there were differential follow-up rates in BADAS and TAU, a chi-square analysis was conducted examining the relationship between treatment group and participating in the follow-up assessment. The relationship was not significant ($p > .05$). Participants who did not complete the follow-up assessment had the greatest amount of missing data for the TLFB, since the one-month follow-up generally collected smoking data for the prior 2-3 weeks.

Administrator error resulted in missing data for some measures. In TAU, there were six missing data points for CO data for participants who self-reported abstinence on the TLFB, while in BADAS, there was one missing CO data point for a participant who self-reported abstinence. These data were missing because of equipment malfunction, or because the assessment administrator failed to collect CO data. There were also five participants with missing data for education and income; imputation was not used because of the small sample size, the limited number of demographic characteristics collected, and the categorical nature of the data.

There were occasional missing data points due to non-responses. When greater than 80% of data points were present for the self-report measures (e.g. BDI, BADS), totals scores were computed, with imputation for missing data points (average scores, based on other responses on the measure, were imputed). Of the assessments completed, imputation was only required in 3.7% of cases. There were no assessments where less than 80% of data points were complete.

Continuous independent variables were centered before conducting any analyses. Data collected on covariates were examined for non-normality and were log transformed to achieve normality. After transformation, the skew and kurtosis for the BDI-II was -.49 and -.21, respectively; for the BADS was -.50 and .24, respectively; and for the POMS Depression subscale was .40 and -1.11, respectively, indicating that the transformation reduced skewness and kurtosis.

Aim 1 analyses. Participants' time to relapse was computed using survival analysis, with treatment condition as the grouping factor (Niaura et al., 2001; Shiffman et al., 2006), which estimated the risk of relapse by examining time to relapse in relation to treatment group assignment. The hazard ratio (HR) was computed using Cox regression with treatment condition, BDI score, gender, and baseline cigarettes per days as covariates; all were entered simultaneously. The HR indicates the ratio of risk in BADAS as compared to TAU, where a higher HR indicates that individuals in BADAS are less likely to relapse than individuals in TAU. An examination of the survival distribution within the Kaplan-Meier survival analysis, using the Wilcoxon test was conducted, which indicates differences in group mean scores.

Repeated measures analyses were conducted using generalized estimating equations (GEE), which is an extension of the generalized linear model that assumes correlated observations, in this case within subjects over time, of independent and dependent variables (Hanley et al., 2003), to examine point prevalence abstinence rates. GEE was used because it can accommodate missing time points, can handle repeated measures within subject data, and because a working group formed by the Society for Research on Nicotine and Tobacco recommended using GEE when examining smoking outcomes (Hall et al., 2001). Participants who dropped out of treatment or who could not be contacted were coded as being not abstinent, per accepted standards in the smoking field. GEE was used to examine differences in the odds of being abstinent (measured as 7-day point prevalence abstinence) between individuals in BA-DAS and TAU in seven day increments for the 28 days post-quit. Time Line Follow Back (TLFB) data were used to determine 7-day point prevalence abstinence at each assessment point. Individuals were considered to be abstinent at a particular time point if they had not smoked in the prior 7 days. Here, expired CO was used as a biological indicator of abstinence to confirm smoking reported on the TLFB, with levels lower than 8 ppm coded as abstinent. Treatment type (BA-DAS and TAU) was used as the independent between groups variable in this analysis. Based on the literature (Cinciripini et al., 2003; MacPherson et al., 2010), depressive symptoms (BDI-II), average daily cigarette consumption prior to quitting, gender, and the linear effect of time were examined as covariates. For this analysis because the outcome measure was binary, we used a logit link function with a binomial distribution, and an independent correlation matrix.

GEE also was used to examine differences in cigarette consumption between BADAS and TAU. Daily cigarette consumption data obtained via the TLFB were combined into seven day blocks to determine average daily cigarette consumption over the four weeks of treatment and follow-ups. All available data were included in these analyses. Treatment type was the independent between groups variable and as above, the BDI-II, baseline cigarette consumption, gender, and the linear effect of time were examined as covariates. For this analysis, we used an identity link function, a normal distribution, and an independent correlation matrix.

Aim 2 analyses. GEE was used to examine changes in depressive symptoms (BDI-II; POMS Depression subscale) over the course of treatment and follow-ups. The treatment type (BADAS versus TAU) was used as the independent, between groups variable, and gender and the linear effect of time were included as covariates. For GEE analyses examining changes in BDI and POMS Depression scores, we used an identity link function, a normal distribution, and an independent correlation matrix.

Aim 3 analyses. GEE was used to examine changes in activity levels and environmental reward over treatment. Activity levels were examined with BADS scores as the dependent variable and treatment condition as the independent between groups variable. Rewards derived from participation in activities were analyzed with EROS scores as the dependent variable and treatment condition as the independent between groups variable. In both analyses, the linear effect of time was included as a covariate.

Chapter 3: Results

Aim 1 Analyses

Time to relapse. In comparing rates of early relapse (i.e., smoking five cigarettes per day for three days in a row) within TAU, 58.3% relapsed within the first seven days post-treatment, while within BADAS, 16.7% relapsed within the first seven days post-treatment ($\chi^2(1) = 4.44$, $p = .035$; see Figure 2). Those in TAU demonstrated a mean survival time of 14.75 days until relapse, which was less than those in BADAS, who demonstrated a mean survival time of 23.00 days until relapse ($\chi^2(1) = 3.59$, $p = .058$). At the final assessment point during the one-month follow-up, 66.7% of participants in BADAS had not relapsed to smoking, as compared to 41.7% of participants in TAU ($p = .219$). Using a cox regression analysis, the significance of the full model, including treatment condition, baseline BDI, gender, and baseline smoking was shown to be not significant $\chi^2(4) = 3.95$, $p = .410$. Within this model, treatment condition approached significance for predicting time to relapse ($\chi^2(1) = 3.37$, $p = .071$, HR = 4.0, see Figure 2).

Point-prevalence abstinence. Seven-day point prevalence abstinence rates were examined using GEE. None of the included covariates examined (BDI, gender, baseline smoking levels) were significantly related to point-prevalence abstinence rates (Table 2). Among participants in TAU, 33.4% were abstinent at the first assessment point (days 0-6), 25.0% were abstinent at the second assessment point (days 7-13), 16.7% were abstinent at the third assessment point (days 14-20), and 16.7% were abstinent at the fourth assessment (days 21-27). Among participants in

BADAS, 8.3% were abstinent at the first assessment point, 25.0% were abstinent at the second assessment point, 25.0% were abstinent at the third assessment point, and 16.7% were abstinent at the fourth assessment point. Seven day point prevalence abstinence rates did not differ as a function of treatment condition (β = 1.06, SE = 1.05, p = .313), as a function of time (β = 0.02, SE = 0.36, p = .947), or as an interaction between the two (β = -0.26, SE = 0.50, p = .606; see Table 2 and Figure 3). Thus, participants' abstinence rates did not increase over time.

Cigarette smoking rates. Among participants in TAU, the average weekly cigarette consumption during the first week post quit was 12.00 cigarettes (*SD* = 14.45), during the second week post-quit was 8.82 (*SD* = 12.48), during the third week was 10.00 (*SD* = 13.11), and during the fourth week was 11.97 (*SD* = 12.98). Among participants in BADAS, the average weekly cigarette consumption during the first week post-quit was 5.81 cigarettes (*SD* = 6.25), during the second week post-quit was 10.08 (*SD* = 21.36), during the third week post-quit was 11.13 (*SD* = 22.54), and during the fourth week post-quit was 12.88 (*SD* = 22.13). Participants' cigarette consumption did not differ as a function of treatment condition (β = 0.08, SE = 1.01 p = .937), time (β = 0.36, SE = 0.29 p = .215) or the interaction between treatment condition and time (β = 0.23, SE = 0.37 p = .533; see Figure 4 and Table 3). None of the included covariates examined (BDI, gender, baseline smoking levels) were significantly related to smoking rates post-quit (Table 3).

Aim 2 Analyses

Beck depression inventory. For TAU, the BDI scores at baseline, quit day, the final treatment session, and the one month follow-ups were: 11.00 (*SD* = 7.83), 8.36

(*SD* = 8.60), 5.70 (*SD* = 2.21), and 2.80 (*SD* = 2.39), respectively. For BADAS, the BDI scores at baseline, quit day, the final treatment session, and the one month follow-ups were: 13.55 (*SD* = 9.02), 12.58 (*SD* = 6.59), 9.36 (*SD* = 5.94), and 6.67 (*SD* = 8.47), respectively. Within the GEE analysis, there was a significant effect of time; participants' BDI scores decreased significantly over treatment and follow-ups (*B* = -0.15, *SE* = 0.03, $p < .001$; see Figure 5). However, within the GEE analyses BDI scores did not differ as a function of treatment condition (*B* = 0.17, *SE* = 0.12, *p* = .160), gender (*B* = 0.01, *SE* = 0.15, *p* = .943), or the interaction between treatment condition and time (*B* = 0.03, *SE* = 0.06, *p* = .542; see Table 4).

The profile of mood states. For TAU, the POMS Depression scores at baseline, quit day, the final treatment session, and the one month follow-ups were: 5.75 (*SD* = 5.69), 4.33 (*SD* = 6.00), 4.70 (*SD* = 7.73), and 1.40 (*SD* = 1.94), respectively. For BADAS, the POMS Depression scores at baseline, quit day, the final treatment session, and the one month follow-ups were: 8.55 (*SD* = 9.26), 6.92 (*SD* = 6.70), 3.64 (*SD* = 5.09), and 2.00 (*SD* = 1.87). The POMS depression scale score did not differ as a function of treatment condition (*B* = 0.89, *SE* = 1.92, *p* = .643), the interaction between treatment condition and time (*B* = -1.19, *SE* = 1.11, *p* = .284), or by gender (*B* = 0.92, *SE* = 2.05, *p* = .653; see Table 4). There was a significant effect of time, in that POMS depression scores decreased over time (*B* = -0.82, *SE* = 0.30, *p* = .007; see Figure 6).

Aim 3 Analyses.

The environmental reward observation scale. For TAU, the EROS scores at baseline, quit day, the final treatment session, and the one month follow-ups were:

25.00 (*SD* = 4.79), 26.33 (*SD* = 5.65), 27.60 (*SD* = 4.27) and 29.78 (*SD* = 3.98), respectively. For BADAS, the EROS scores at baseline, quit day, the final treatment session, and the one month follow-ups were: 23.73 (*SD* = 4.27), 25.00 (*SD* = 5.44), 28.27 (*SD* = 6.41), and 30.00 (*SD* = 5.64), respectively. EROS scores did not differ as a function treatment condition (*B* = -0.01, *SE* = 0.03, *p* = .748), or the interaction between treatment condition and time (*B* = 0.01, *SE* = 0.02, *p* = .475; see Table 5). There was a significant increase in environmental reward across treatment and follow-ups (*B* = 0.03, *SE* = 0.01, *p* < .001; see Figure 7).

The behavioral activation for depression scale. The BADS Total score and BADS Activation score did not differ as a function of treatment condition, time, the interaction between treatment condition and time, or as a function of any of the included covariates (see Table 5).

Treatment satisfaction and compliance. Participants reported on their treatment compliance and satisfaction at each treatment session. Participants rated how useful the specific skills learned were in terms of helping them quit smoking. On a categorical scale where a 1 indicated "not at all useful" and a 5 indicated "extremely useful", the average score participants rated the BADAS treatment to be was 4. Participants rated the extent to which skills learned in BADAS helped them to increase their positive mood; on a categorical scale where 1 indicated "not at all" and 5 indicated "a great deal" the average score of BADAS participants was 4.4. Finally, participants rated the extent to which skills learned in the BADAS program helped them to be more active on a categorical scale where 1 indicated "not at all" and 5

indicated “a great deal”. All participants reported that the program helped them a great deal; the average score reported across participants was five.

On the qualitative portion of the survey, participants were given the opportunity to describe the elements of treatment they found to be helpful, and the elements of treatment they would change. In describing elements they found to be helpful, participants wrote comments like “My worker- she was encouraging and helpful”; “The young lady that’s helping me”; “Helping me find activities”; “Being able to discuss stressful situations that may have caused me to smoke”; “Making a list to see how I view my emotions and what I want to do about each one”; and “Using the patches”. In describing elements of the treatment that they would change, participants wrote, “None”; “Keep up the good work”; “Keep doing what you’re doing”; “Less meetings and bringing snacks or gum to fight the urges to smoke”; “Keep things as they are”; and “None”.

The number of scheduled activities participants completed between each session was divided by the number of days between each session to determine the average number of activities completed daily by participants in BADAS. Overall, participants completed one scheduled activity every two days (or .594 activities daily). Six participants created one contract, while two participants created two contracts. On average, participants schedule activities targeted 2.44 life areas out of the four potential life areas described in the treatment manual.

Chapter 4: Discussion

This is the first study to our knowledge to compare a behavioral activation-enhanced smoking cessation treatment, to a basic smoking cessation treatment, in a residential substance use treatment center for participants with elevated depressive symptoms. This small-scale trial provides important information relevant for future larger-scale studies on the effects of BA-enhanced smoking cessation treatments. Smoking cessation outcomes will first be discussed below. Then, outcomes for mood and activations levels will be reviewed. Finally limitations of the study and future directions will be noted.

Smoking Outcomes

Participants in BADAS were significantly less likely to relapse to smoking within the first seven days post-quit. Moreover, their time to relapse approached significance, in that participants in BADAS on average relapsed on the 23rd day post-quit, as compared to participants in TAU, who on average relapsed on the 15th day post-quit. This suggests that the BADAS treatment benefitted participants during the time in which they were most vulnerable to relapse, that is within the first couple of weeks post-quit (Brown, et al., 2001 ; Cook, Gerkovich, O'Connell, & Potocky, 1995 ; Doherty, Kinnunen, Militello, & Garvey, 1995 ; Garvey, Bliss, Hitchcock, Heinold, & Rosner, 1992). Our findings suggest that participants in BADAS may require additional follow-up treatment sessions in order to avoid relapsing over time, particularly during the third and fourth weeks post-quit. During this time, participants with a 30-day treatment contract at the Center completed substance use treatment; the resulting living transition may be particularly challenging for some participants.

Follow-up therapy during this time would allow BADAS participants to revisit their values and the activities available to them in their new living situations. This support would likely increase activation, mood, and abstinence rates.

Although participants in BADAS were significantly less likely to relapse during their first week post-quit, they did not demonstrate significant group differences in terms of point prevalence abstinence rates or smoking reductions. There are a number of factors that may help to explain these findings. Abstinence and cigarette consumption metrics focus on different processes than measures of relapse. Relapse rates focus on whether a pattern consistent with returning to smoking has been established, whereas abstinence and cigarette consumption rates focus on whether, and how much, participants are smoking daily. In addition, there are a number of broader systemic factors that help explain the pattern of findings for measures of abstinence and cigarette consumption. These include our small sample size—which limited our power to detect differences between the two treatment conditions, the established difficulties associated with quitting smoking more generally within this population (e.g. Baca & Yahne , 2009; Prochaska et al., 2004), and broader environmental barriers that made it difficult for participants to successfully implement treatment techniques (Burling et al., 1997**;** Orleans & Hutchinson, 1993. These will be more fully discussed below.

First, substance users in general experience particular difficulties with quitting smoking. Even among substance users who receive NRT and concomitant therapy, cessation rates are still quite low (Prochaska et al., 2004). A review by Baca and Yahne (2009) examining smoking cessation rates of substance users reports cessation

rates ranging from 4.7% at a six-month follow-up to 23.4% at a one-week follow-up. Similarly, Okoli and colleagues (2010) found overall abstinence rates of substance users at six month follow-ups ranging from 5-14%. In a sample of patients dually diagnosed with an Axis I disorder and substance dependence, only 7.8% had CO levels less than 9 ppm at the end of an eight-session treatment (Saxon et al., 2003). The above findings mirror the abstinence rates observed within our sample. Overall, low cessation rates appear to be the norm, rather than the exception, among substance users.

Second, the low overall cessation rates among substance users make it particularly difficult to detect differential cessation outcomes *across* treatment conditions, as beneficial treatments may often have smaller effect sizes, which would necessitate large samples to detect significant effects. Following this, there are a number of studies that have not shown differential treatment outcomes across treatment conditions for smokers with substance use disorders. It is unclear whether the lack of significant findings across studies is due to small effect sizes, or whether the treatments compared actually do not differentially affect smoking outcomes. A study of substance users in an active smoking cessation treatment condition, compared to substance users in a TAU condition, demonstrated equivalent cessation outcomes at a 26-week follow-up (Reid et al., 2008). Similarly, a review of studies of former heroin users receiving methadone maintenance compared active smoking cessation treatments to control conditions, but did not find significantly different outcomes between the active treatments and control conditions (Okoli et al., 2010). These studies demonstrate the difficulties associated with finding significant

differences in smoking cessation rates across different conditions within this type of population.

Third, there are a number of environmental factors that can help to explain why substance users in particular may have difficulties quitting smoking. Burling and colleagues (1997) discuss environmental barriers to quitting among substance users, including higher rates of smoking among peers and family members of substance users than among non-users; the majority of substance users live with smokers (Orleans & Hutchinson, 1993) and the majority of substance users' peers in substance use treatment smoke (Prochaska et al., 2004). This makes this group particularly vulnerable, as they are regularly exposed to smoking cues that may compromise their ability to maintain abstinence. Moreover, substance use treatment providers often do not support cessation attempts (e.g. Prochaska et al., 2004). One example within the treatment center where our study was conducted concerned a policy implemented midway through the study that required participants to go outside during smoking breaks, even if they wished to stay inside to avoid smoking cues. Engaging in alternative activities, such as reading books or writing letters during breaks, often was challenging because of rules proscribing participants from carrying books or loose paper with them during the day. The difficulties for some participants in BADAS to select alternative rewarding activities during their cessation attempt may help explain their low point prevalence abstinence rates. Anecdotally, many participants reported that they were dissatisfied with the types of activities they were able to schedule because of the restrictions imposed by the treatment center.

Third, previous research has demonstrated that smokers with depression, as compared to nonpsychiatric smokers, choose smoking as a preferred activity more often and ascribe more benefits to smoking (Spring, Pingitore, & McChargue, 2003). Moreover, smokers with depression also find cigarettes to be more appealing than alternative rewards and believe that the benefits of smoking outweigh the costs, whereas nonpsychiatric smokers perceive the pros and cons to be equivalent (Spring et al., 2003). Thus, our participants may already have had difficulties finding other activities to be rewarding because of their elevated depressive symptoms, which were then compounded by their difficulties in scheduling potentially rewarding activities during their quit attempts. It will be important in future work to determine what treatment dose is necessary to counteract these effects, that is, how many activities participants need to schedule in order to improve their mood and thus decrease some of the reward potential of cigarettes. It will also be interesting to examine whether the duration of a rewarding activity (five minutes versus 30 minutes) is of particular importance, or whether the overall enjoyment and importance associated with an activity is what is most critical. Finally, it is also necessary to examine whether follow-up treatment sessions would decrease participants' likelihood of relapse, as it would encourage continued engagement in alternative rewarding activities post-treatment, which is where relapse rates increased for participants in BADAS. Overall, there are challenges with implementing this type of treatment within our setting; however, there are a number of factors that can be examined in future work that will help us understand how to enhance participants' abstinence rates.

Mood and Activation

Previous research has demonstrated that early relapse is associated with low positive mood and elevated depressive symptoms (e.g. Holt, Litt, & Cooney, 2012; Niaura et al., 2001; Zvolensky, Stewart, Vujanovic, Gavric, & Steeves, 2009). Further, depression has been shown to predict early relapse (smoking at one week post-quit), but not late relapse (smoking at six months post-quit) among individuals attempting to quit smoking (Japuntich et al., 2007). Thus, it was important to us to target depressive symptoms in BADAS. Similar to the findings of a number of prior smoking cessation studies, the addition of a treatment component aimed at improving participants mood during cessation did not differentially improve participants' mood, as compared to a treatment condition that did not target participants' mood (e.g. Hall et al., 1994, 1996, 1998; Kahler et al., 2001; Muñoz et al, 1997; Patten et al., 1998). Although there were no significant group differences in POMS depression or BDI scores, there were significant decreases in both scores across both treatment conditions over time. There are a number of factors that might help to explain why BADAS and TAU did not differentially impact participants' mood that will be discussed.

First, although participants reported on the treatment satisfaction and compliance surveys that BADAS helped them to become more active and helped to improve their mood, it is possible that they did not get a large enough treatment dose to impact their mood. Prior BA research has not determined the necessary BA treatment dose necessary to increase participants' moods. On average, participants in our sample completed one scheduled activity every two days; perhaps larger

improvements in participants' mood would have been observed if they had completed more activities throughout treatment. Additionally, it is possible that participants in BADAS had difficulties implementing BA treatment techniques while at the residential substance use treatment center because of the restrictive nature of the center. As participants had group activities scheduled daily from 9am-9pm, and as they were unable to leave the treatment center, it was difficult for many participants to schedule activities they saw to be important and enjoyable while at the center. Finally, many participants attempted to solely schedule their activities during their smoking breaks, rather than scheduling activities throughout the day while at the treatment center. Although therapists emphasized the importance of scheduling activities throughout the day, participants often wanted to schedule their activities to coincide with smoke breaks, so that they would have an alternative enjoyable activity to do during those times. In the future, it will be important to more strongly encourage participants to schedule activities during alternative times as well as during smoke breaks. Because of somewhat low level of activity scheduling in BADAS, it is possible that other factors may have had a larger impact on participants' moods during treatment.

It is possible that participants in our sample generally became more active and had enhanced moods over the course of drug treatment, as many were incarcerated or homeless prior to entering treatment. Further, participants' reductions in depressive symptoms may have been more strongly related to their continued abstinence from drugs and alcohol during substance use treatment (e.g. Liappas, Paparrigopoulos, Tzavellas, & Christodoulou, 2002; Satel et al., 1991). Finally, as the majority of

participants within this drug treatment center meet diagnostic criteria for substance dependence (e.g. Chen et al., 2011) it is likely that a large percentage were not engaged in alternative rewarding activities prior to entering treatment. Thus, the decreases in negative moods over the course of treatment may have been tied to participants' mood changes over treatment in both conditions because of the profound impact of entering residential treatment and becoming abstinent from drugs. These changes in environmental context, and adjustment to the new context, may have had a larger impact on participants' activation and mood scores that their smoking cessation treatment condition (e.g. Kosten et al., 2003; Rounsaville, Kosten, & Kleber, 1986). This suggests that it might be important to recruit participants after they have adjusted to the treatment center (during their third week of treatment, rather than during their first week of treatment) and to follow them for longer periods of time post-treatment in order to see significant benefits of the BADAS treatment on mood and activation outcomes. It is possible that our short follow-up period did not allow us to observe changes in mood that may have occurred post-treatment, which is similar to the findings of Magidson and colleagues (2011) and Daughters and colleagues (2008). Their research suggested that there might be halo effects for measures of mood in TAU that dissipate over longer term follow ups. In general, it is possible that our lack of significant findings for mood and activation may have been more related to our lack of power due to our very small sample size, or to the short follow-up period within the current study, rather than to an actual lack of differences.

In general, participants in our TAU condition demonstrated unexpected improvements across a number of domains. As compared to participants in the TAU

condition in Daughters and colleagues (2008) study of BA for depression for substance users, participants in our TAU condition did unexpectedly well, considering that our participants merely received NRT. For example, Daughters and colleagues (2008) TAU group demonstrated an increase on the EROS from about 24 at baseline to 25 post-treatment, as compared to TAU in the current study which demonstrated an increase in the EROS from about 25 at baseline to 30 at the final assessment. The increase in EROS scores in our TAU group was actually larger than the EROS increases in Daughters and colleagues (2008) BA group (about 23 at the baseline and 26 post-treatment). Similarly, participants in our TAU condition demonstrated a seven point decrease in their average BDI score from baseline to the final assessment session, as compared to the five point decrease in Daughters and colleagues (2008) TAU and the 10 point decrease in their BA group. When comparing BDI scores in our sample to the BDI scores of participants in MacPherson and colleagues' (2010) study of BA for smokers with elevated depressive symptoms (BATS), a similar pattern of findings emerges. For example, MacPherson and colleagues (2010) standard treatment participants experienced a four point decrease in their BDI scores from baseline to their one-week post-quit assessment, while participants in BATS experienced a six point decrease during that same time period, which is comparable to the decrease in our TAU condition (seven point decrease). It is unclear why our TAU condition experienced these increases in environmental reward and decreases in depressive symptoms during their quit attempt. It will be important to examine whether similar patterns of findings are observed in future

control groups within future smoking cessation studies in this population, or whether this pattern is unique to our particular sample.

Treatment Satisfaction

Participants in BADAS were generally very satisfied with the smoking cessation treatment they received; noting that the techniques taught, the therapist with whom they worked, and the NRT received, were helpful. Participant treatment satisfaction is important for a number of reasons. It has been suggested that individuals' treatment preferences are critical when considering treatment through collaborative models of care (Katz, 2001). Additionally, patient satisfaction predicts treatment outcomes and health-related behavioral decisions (Albrecht & Hoogstraten, 1998; Brody, Miller, Lerman, Smith, Caputo, 1989). Following this, it may be that participants in BADAS were generally compliant with the BA portion of treatment because they were satisfied with the treatment they were receiving. Participants completed most of their homework assignments, which is critical in treatments targeting elevated depressive symptoms (Addis & Jacobson, 2000). However, it is possible that the effects of treatment may have been diluted by the low number of activities scheduled by participants and the narrowness of the life areas targeted. It is possible that participants within our study may have placed too much of a focus on scheduling activities during smoke breaks at the treatment center, rather than scheduling pleasant activities throughout the day. This may have narrowed participants' focus on alternative activities that would have proven to be rewarding.

Limitations

There are a number of important limitations to consider when interpreting these findings. First, the small sample size resulted in insufficient power to detect anything but large group differences in smoking and mood outcomes. The sample size also impacted our ability to examine whether covariates like sex, age, or baseline depressive symptoms affected smoking or mood outcomes. Second, the control condition included in the current study was not contact-time controlled, which limits conclusions about the effects of BADAS. Third, CO data were missing for six assessment points in TAU and one assessment point in BADAS, which prevented us from biochemically verifying participants' abstinence rates at every assessment point. These missing data were due to administrator errors, particularly those that occurred in the first cohort of TAU participants that were recruited. This is a common problem in smoking cessation studies, particularly in cases where follow-up assessments are conducted by phone. Fourth, we lost contact with several participants after they were discharged from the substance use treatment center, which introduces error into our analyses examining smoking outcomes and participants' mood at the one-month follow-up assessment. Fifth, despite random assignment of participants to BADAS and TAU, there were more women in BADAS than in TAU and there were some differences in terms of educational backgrounds and incomes between the two groups; these factors were all controlled for in all analyses. Sixth, the sample was homogenous in terms of race; future research is needed to determine whether these findings apply to participants who are not African American. Seventh, it is possible that a treatment like behavioral activation might benefit all smokers, rather than just

those with elevated BDI scores; perhaps excluding participants with low BDI scores narrowed our potential recruitment pool. Finally, the EROS has been recently supplanted by the RPI (Carvalho et al., 2011), which is a stronger measure of environmental reward.

Future Directions

Future work examining the efficacy of BA-enhanced smoking cessation treatments among substance users in residential treatment would benefit from a number of changes. A larger sample size would increase power and would enable the detection of small, but meaningful effects. As noted by Prochaska and colleagues (2004), even small effects are important in smoking cessation work because of their large impacts on morbidity and mortality. A larger sample size would also enable us to determine whether this treatment differentially impacted smokers with particularly elevated depressive symptoms, or whether it differentially impacted depressive symptoms over time. Related to this, a longer follow-up period would enable us to determine whether the effects of either treatment condition persisted for a longer period of time. Similarly, it would be beneficial to have follow-up treatment sessions so that therapists could help participants in BADAS to continue scheduling activities after leaving the treatment center. In order to determine whether BADAS differentially impacted both smoking cessation and mood, it would be necessary to compare it to a contact-time controlled cessation condition, which will be important in future work. Although the current study did not observe differences in cessation rates and mood, future work is necessary in this area, as there are relatively few treatments that benefit this particular population, and as many of the nonsignificant

effects may have been due to the small sample size and poor follow-up rates. Finally, one area that may be of particular importance is staff buy-in, as a number of participants reported struggling with the constraints imposed by the treatment center in utilizing strategies discussed in our cessation treatment sessions.

In conclusion, although a number of the outcomes examined in this study were not significantly different, there are a number of factors that argue for the potential benefits of BADAS as a smoking cessation treatment for substance users with elevated depressive symptoms. First, participants in BADAS endorsed high levels of treatment satisfaction. In general, they did not suggest any modifications to the treatment. Second, participants were willing to schedule and engage in activities, even though doing so was often difficult at the treatment center. On average, they completed a scheduled activity every other day throughout treatment. Third, participants in BADAS were significantly less likely to relapse during their first week post-quit, which is the time in which they are most vulnerable to relapse. Overall, further examination of this treatment is necessary, as it could prove to be of particular benefit to individuals in substance use treatment with elevated depressive symptoms.

Table 1.

Comparisons on Baseline Demographic, Smoking History, and Affective Variables across Treatment Conditions. One way ANOVAs were used for continuous variables, chi-square analyses were used for categorical variables. Not all percentages add to 100 because of missing data.

	TAU N=12			**BADAS N=12**			
	M	**SD**	**%**	**M**	**SD**	**%**	***p***
Demographics							
% Female			16.7			41.7	.19
% African American			100			100	N/A
% Court-mandated			72.7			36.4	.10
Average Age	40.17	7.72		39.18	10.25		.80
Average treatment length (in days)	34.16	17.61		34.50	17.53		.96
Education							
Middle school graduate			-			8.3	.028
Some high school			33.3			8.3	
High school graduate/GED			41.7			16.7	
Some college			-			41.7	
Average household income							
$0-9,999			33.3			25	.015
$10,000-19,999			-			16.7	
$20,000-29,999			41.7			-	
$30,000+			-			33.3	
Smoking History Variables							
Number of year smoking	20.42	7.73		18.27	10.95		.59
FTND	5.42	2.47		5.18	2.36		.82
Average cigarettes per day	12.47	6.77		13.85	13.28		.75
Baseline Affective Variables							
BDI-II	11.00	7.83		13.55	9.02		.48
POMS depression	5.75	5.66		8.55	9.26		.39
EROS	25.00	4.79		23.73	4.27		.51

Table 2.

Generalized Estimating Equations Predicting Seven Day Point Prevalence Abstinence.

	OR	**95% CI**	***p***
Main Effects			
Treatment Condition	1.92	[0.24, 15.56]	.540
Time	1.03	[0.55, 1.93]	.921
BDI	1.10	[0.99, 1.22]	.091
Gender	0.19	[0.03, 1.43]	.107
Baseline Smoking	1.04	[0.93, 1.16]	.524
Interaction			
Time x Treatment	0.67	[0.26, 1.69]	.393

Table 3.

Generalized Estimating Equations Predicting Average Daily Cigarette Consumption across Treatment

	OR	**95% CI**	***p***
Main Effects			
Time	1.43	[0.81, 2.54]	.215
Treatment Condition	1.08	[0.15, 7.76]	.937
Gender	.216	[0.24, 1.92]	.169
BDI	3.41	[0.64, 1.06]	.151
Baseline Smoking	0.99	[0.93, 1.05]	.640
Interaction			
Treatment x Time	1.26	[0.67, 2.62]	.533

Table 4.
Generalized Estimating Equations Predicting Depressive Symptoms Scores

	OR	**95% CI**	***p***
BDI Score Predictors			
Treatment Condition	1.21	[0.96, 1.53]	.102
Time	.807	[0.76, 0.86]	.001
Treatment x Time	1.073	[0.95, 1.21]	.242
Gender	.983	[0.74, 1.30]	.906
POMS Depression Predictors			
Treatment Condition	2.44	[0.06, 10.56]	.643
Time	.187	[0.06, 0.55]	.002
Treatment x Time	.306	[0.04, 2.67]	.284
Gender	2.51	[0.05, 13.87]	.653

Table 5.

Generalized Estimating Equations Predicting Activation and Environmental Reward.

	OR	**95% CI**	***p***
EROS Score Predictors			
Treatment Condition	.990	[0.93, 1.05]	.748
Time	1.03	[1.02, 1.05]	.001
Treatment x Time	1.01	[0.98, 1.04]	.475
Gender	1.00	[0.92, 1.09]	.999
BADS Total Score Predictors			
Treatment Condition	1.04	[0.97, 1.11]	.319
Time	1.04	[1.02, 1.06]	.001
Treatment x Time	1.02	[0.98, 1.07]	.326
Gender	.998	[0.93, 1.08]	.959

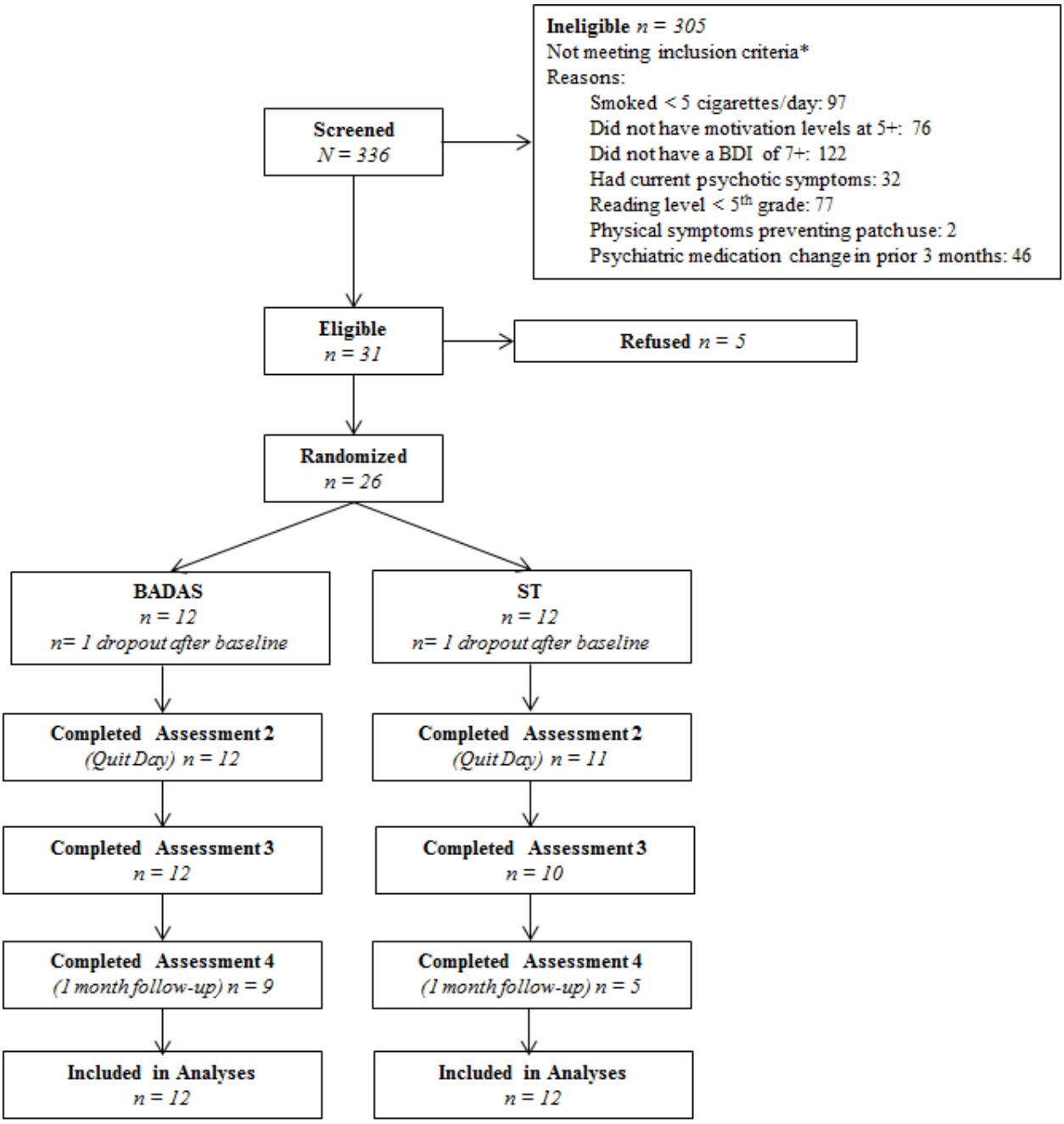

Figure 1.

Recruitment and Retention Consort Diagram. Participants were screened based on a number of criteria outlined in the Method section.

* N's here do not sum to 305 because some participants had multiple characteristics that excluded them from the current study. Only individuals who smoked at least one cigarettes per day were screened for the study.

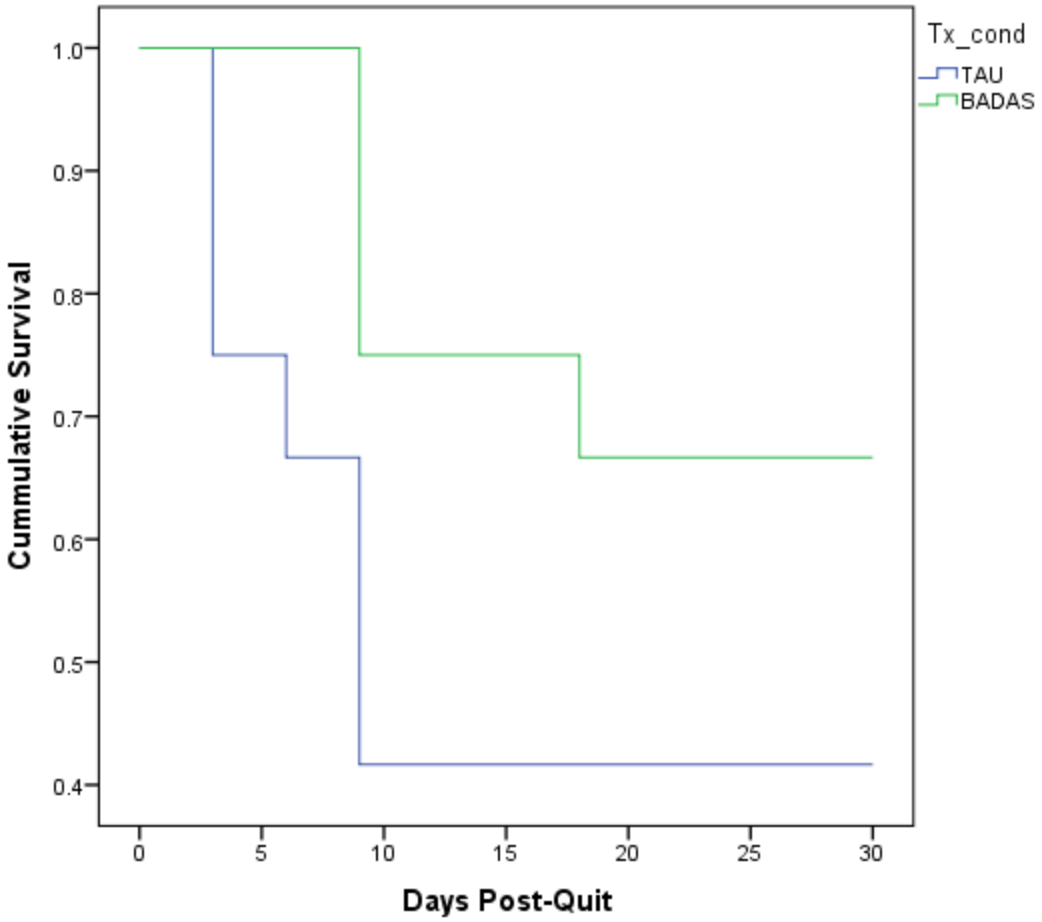

Figure 2.

Time to Relapse. Relapse is defined as smoking five cigarettes per day for three days in a row. Relapse is coded as the first day in which this pattern of smoking began.

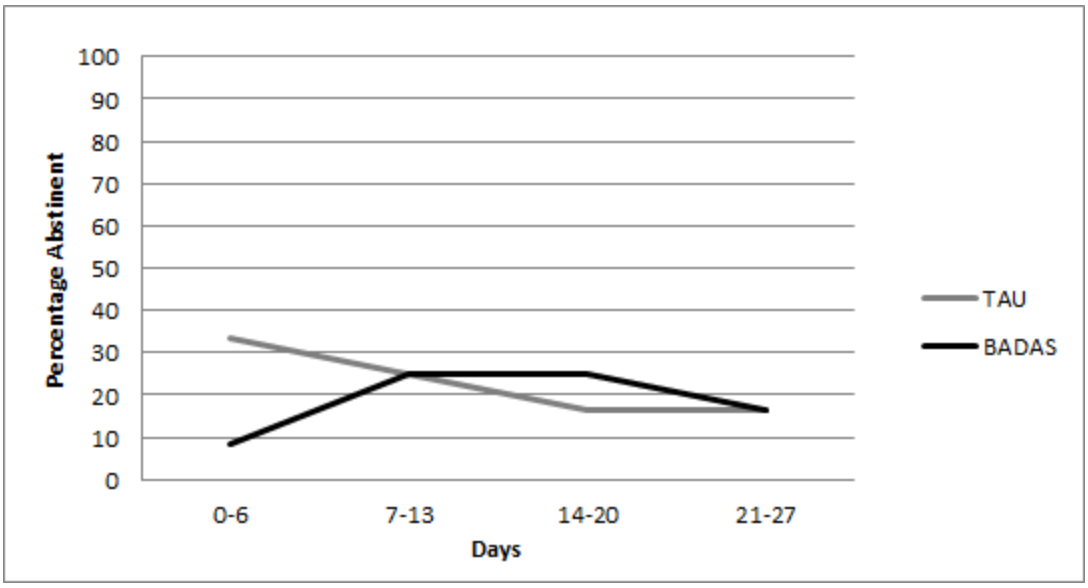

Figure 3.
Conservative Seven Day Point-Prevalence Abstinence. Data from all participants are included in this graph. Each time point represents a seven-day time period. Subjects who did not smoke during a seven day time period are coded as abstinent. Missing data values were coded as "not abstinent" in this graph.

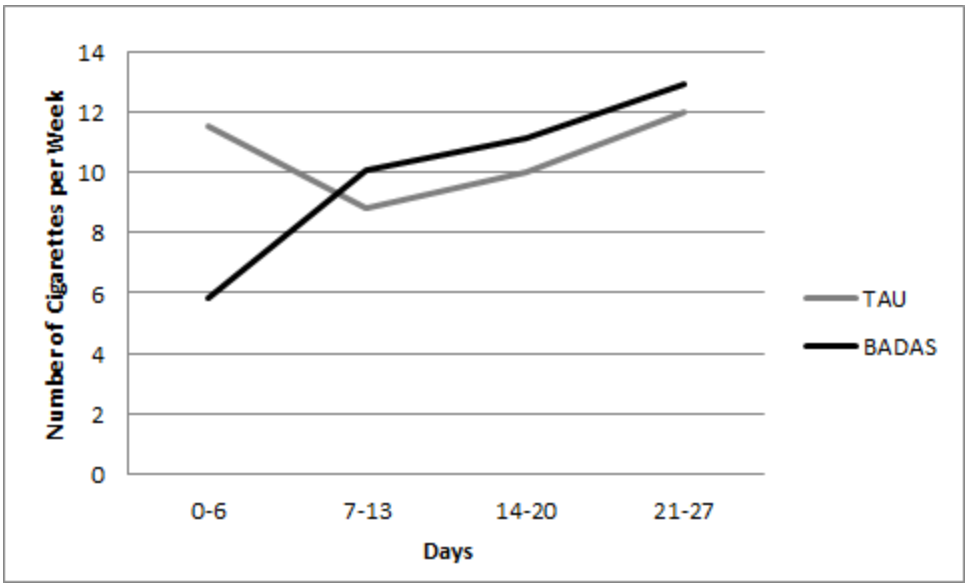

Figure 4.
Cigarette Consumption over Treatment and Follow-ups. The number of cigarettes participants smoked post-quit are graphed as a function of time. Each time point represents the average weekly cigarette consumption during the seven-day block, by treatment condition. Data at each time point includes all available data for that time point.

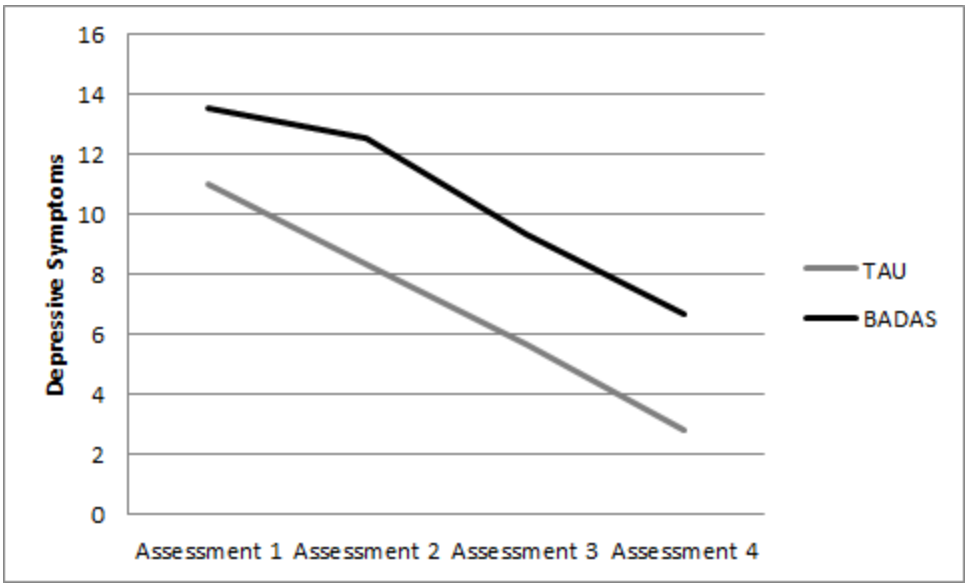

Figure 5.

BDI Scores as a Function of Treatment Condition and Time. Assessments occurred at baseline, quit day, final treatment session day (the equivalent for TAU), and at a two week follow-up. Each time point represents the average score of all data collected at that time point.

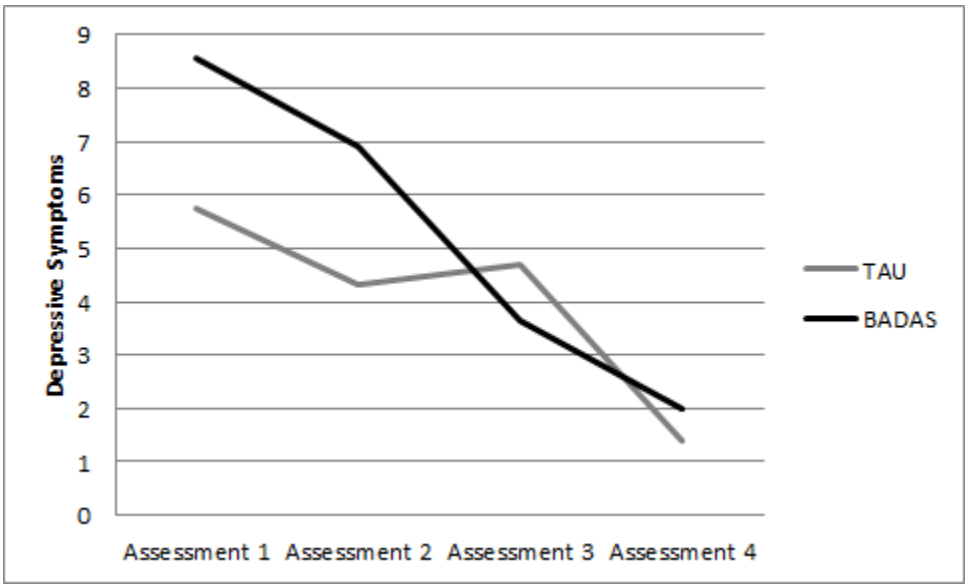

Figure 6.
POMS Depression Scores as a Function of Treatment Condition and Time. Assessments occurred at baseline, quit day, final treatment session day (the equivalent for TAU), and at a two week follow-up. Each time point represents the average score of all data collected at that time point.

Figure 7.
Environmental Rewards as a Function of Treatment Condition and Time. Assessments occurred at baseline, quit day, final treatment session day (the equivalent for TAU), and at a two week follow-up. Each time point represents the average score of all data collected at that time point.

Appendix 1.

UMD LET'S Quit Program Survey 1

Instructions: Please answer each of the following questions as it relates to your experience in our quit smoking program.

1. I was able to complete the Daily Activity and Smoking Forms.

1	2	3	4	5
No, never		Some of the time		Yes, all of the time

2. When I could <u>not</u> complete the Daily Activity and Smoking Forms it was because (circle all that apply):

a) I forgot
b) It was too much work
c) I did not want to
d) It was difficult to understand what to do
e) I didn't have time to do it
f) Other:
_____

3. I found rating the "importance" and "enjoyment" of my activities to be helpful.

1	2	3	4	5
No, not at all helpful		Somewhat helpful		Yes, very helpful

If you responded "1" or "2", what about it was <u>not</u> helpful? _____
_____
_____

4. It was helpful to track the number of cigarettes I smoked each day.

1	2	3	4	5
No, not at all helpful		Somewhat helpful		Yes, very helpful

If you responded "1" or "2", what about it was <u>not</u> helpful? _____
_____
_____

5. I found the presentation in my manual of "values" and "life areas" to be clear.

1	2	3	4	5
No, not at all clear		Somewhat clear		Yes, very clear

If you responded "1" or "2", what about it was not clear and how can we make it clearer?

_____
_____
_____

6. I found the presentation in my manual of "activities" to be clear.

1	2	3	4	5
No, not at all clear		Somewhat clear		Yes, very clear

If you responded "1" or "2", what about it was not clear and how can we make it clearer?

_____
_____
_____

7. What has been the most helpful part of being in the LET'S Quit Program so far?

_____
_____
_____

8. What suggestions do you have for any changes for the LET'S Quit Program or the treatment manual so far?

_____
_____
_____

UMD LET'S Quit Program Survey 2

Instructions: Please answer each of the following questions as it relates to your experience in our quit smoking program.

1. I was able to complete the Daily Activity and Smoking Forms.

1	2	3	4	5
No, never		Some of the time		Yes, all of the time

2. When I could <u>not</u> complete the Daily Activity and Smoking Forms it was because (circle all that apply):

a) I forgot
b) It was too much work
c) I did not want to
d) It was difficult to understand what to do
e) I didn't have time to do it
f) Other:

_____

3. I found the presentation in my manual of "values" and "life areas" to be clear.

1	2	3	4	5
No, not at all clear		Somewhat clear		Yes, very clear

If you responded "1" or "2", what about it was not clear and how can we make it clearer?

_____
_____
_____

4. I was able to schedule a variety of activities for the upcoming week.

1	2	3	4	5
No, not able		Somewhat able		Yes, very able

If you responded "1" or "2", what about it was difficult and prevented your from scheduling activities and how can we make it easier?

_____
_____
_____

5. What has been the most helpful part of being in the LET'S Quit Program so far?

_____
_____
_____

8. What suggestions do you have for any changes for the LET'S Quit Program or the treatment manual so far?

_____
_____

UMD LET'S Quit Program Survey 3

Instructions: Please answer each of the following questions as it relates to your experience in our quit smoking program.

1. I was able to complete the Daily Activity and Smoking Forms.

1	2	3	4	5
No, never		Some of the time		Yes, all of the time

2. When I could <u>not</u> complete the Daily Activity and Smoking Forms it was because (circle all that apply):

a) I forgot
b) It was too much work
c) I did not want to
d) It was difficult to understand what to do
e) I didn't have time to do it
f) Other:

_____

3. I found the presentation in my manual of "values" and "life areas" to be clear.

1	2	3	4	5
No, not at all clear		Somewhat clear		Yes, very clear

If you responded "1" or "2", what about it was not clear and how can we make it clearer?

_____
_____
_____

4. I was able to schedule a variety of activities for the upcoming week.

1	2	3	4	5
No, not able		Somewhat able		Yes, very able

If you responded "1" or "2", what about it was difficult and prevented you from scheduling activities and how can we make it easier?

_____
_____

_____

5. It was difficult for me to complete my scheduled activities

1	2	3	4	5
It was not difficult		It was somewhat difficult		It was very difficult

If you responded "1" or "2", what about it was difficult? _____
_____
_____

6. I found the presentation in my manual of "Contracts" to be clear.

1	2	3	4	5
No, not at all clear		Somewhat clear		Yes, very clear

If you responded "1" or "2", what about it was not clear and how can we make it clearer?

_____
_____
_____

7. What has been the most helpful part of being in the LET'S Quit Program so far?

_____
_____
_____

8. What suggestions do you have for any changes for the LET'S Quit Program or the treatment manuals so far?

_____
_____
_____

UMD LET'S Quit Program Survey 4

Instructions: Please answer these questions about your experience in our quit smoking program.

1. I was able to complete the Daily Activity and Smoking Forms.

1	2	3	4	5
No, never		Some of the time		Yes, all of the time

2. When I could <u>not</u> complete the Daily Activity and Smoking Forms it was because (circle all that apply):

g) I forgot
h) It was too much work
i) I did not want to
j) It was difficult to understand what to do
k) I didn't have time to do it
l) Other:
_____

3. I found the presentation in my manual of "values" and "life areas" to be clear.

1	2	3	4	5
No, not at all clear		Somewhat clear		Yes, very clear

If you responded "1" or "2", what about it was not clear and how can we make it clearer?

_____
_____
_____

4. I was able to schedule a variety of activities for the upcoming week.

1	2	3	4	5
No, not able		Somewhat able		Yes, very able

If you responded "1" or "2", what about it was difficult and prevented your from scheduling activities and how can we make it easier?

_____
_____
_____

5. It was difficult for me to complete my scheduled activities from last session

1 2 3 4 5
It was not difficult It was somewhat difficult It was very difficult

If you responded "1" or "2", what about it was difficult? _____
_____
_____

6. I created a Contract with someone at Harbor Light Yes No

If you did not create a contract, what got in your way of doing it?
_____
_____
_____

7. What was the most helpful part of being in the LET'S Quit Program?
_____
_____
_____

8. What suggestions do you have for any changes for the LET'S Quit Program or the treatment manual?
_____
_____
_____

How useful were the specific skills learned in the program in helping you quit smoking?

1. Not at all useful
2. Slightly useful
3. Moderately useful
4. Very useful
5. Extremely useful

To what extent did the skills you learned in the program help you <u>increase positive</u> moods?

1. Not at all
2. A slight amount
3. A moderate amount
4. A good deal
5. A great deal

To what extent did you experience negative moods while quitting smoking?

1. Not at all

2. A slight amount
3. A moderate amount
4. A good deal
5. A great deal

How much did negative moods jeopardize your success at quitting smoking and staying quit?

1. Not at all
2. A slight amount
3. A moderate amount
4. A good deal
5. A great deal

To what extent did the skills you learned in the program help you <u>be more active</u> while at Harbor Light?

1. Not at all
2. A slight amount
3. A moderate amount
4. A good deal
5. A great deal

Appendix 2.

Homework Completion Form-BA-DAS

Name:
Date of first session:
Date of last session:
Total # of Sessions Attended:
Total # of Sessions Missed:

Session 1, Date:

Please rate the client's participation on a scale from **1 to 5**:

Session 2, Date:

Please rate the client's participation on a scale from **1 to 5**:

Total # of Days Possible for Recording	
Total # of Days Completed for Recording Daily Activities	
Total # of Days Completed for Recording Enjoyment/Importance Ratings	
Total # of Days Cigarettes Smoked Recorded	
Total # of Days Mood Recorded	

Session 3, Date:

Please rate the client's participation on a scale from **1 to 5**:

Total # of Days Possible for Recording	
Total # of Days Completed for Recording Daily Activities	
Total # of Days Completed for Recording Enjoyment/Importance Ratings	
Total # of Days Cigarettes Smoked Recorded	
Total # of Days Mood Recorded	

Session 4, Date:

Please rate the client's participation on a scale from **1 to 5**:

Total # of Days Possible for Recording	
Total # of Days Completed for Recording Daily Activities	
Total # of Added Activities	
Total # of Added Activities Completed	
Total # of Life Areas Targeted in Activities	

Session 5, Date:

Please rate the client's participation on a scale from **1 to 5**:

Total # of Days Possible for Recording	
Total # of Days Completed for Recording Daily Activities	
Total # of Added Activities	
Total # of Added Activities Completed	
Total # of Life Areas Targeted in Activities	
Total # of Contracts Completed	

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