

ABSTRACT

Title of Dissertation: A BEHAVIORAL ACTIVATION APPROACH TO SMOKING CESSATION FOR DEPRESSED SMOKERS AT VETERANS AFFAIRS MEDICAL CENTERS.

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Depressed smokers experience greater difficulty in quitting, and patients who report improvement in depressive symptoms during smoking cessation treatment achieve higher rates of abstinence. Patients may benefit from a novel treatment approach that combines standard smoking cessation with behavioral activation treatment for depression (BA; Jacobson et al., 1996). Veterans Affairs (VA) Medical Center patients are a psychiatrically complex population with a smoking prevalence 10% higher than the general population. VA patients experience low cessation rates and may be underserved by standard treatments. The purpose of the present study was the development and initial investigation of a brief BA-based smoking intervention called the Life Enhancement Treatment for Smoking (LETS-Quit). A total of 21 VA patients with elevated (≥ 12) Beck Depression Inventory-II scores (BDI-II; Beck, Steer, & Brown, 1996) received 3-sessions of LETS-Quit or a control treatment and were followed for 30 days. A small sample size limited treatment evaluation and no benefit of LETS-Quit on smoking outcome was noted. However, findings suggested a strong effect of LETS-Quit on depressive symptoms. Treatment of depression during smoking cessation may greatly improve long-term success rates for this difficult to treat population. The feasibility and potential effectiveness of LETS-Quit in outpatient medical settings is discussed to guide further treatment evaluation.

A BEHAVIORAL ACTIVATION APPROACH TO SMOKING CESSATION
FOR DEPRESSED SMOKERS AT VETERANS AFFAIRS MEDICAL CENTERS

by

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Chapter 1: Background

Introduction

Many cigarette smokers have made the decision to quit due to overwhelming health, social, and financial consequences. Although many smokers have been able to quit successfully on their own, others struggle with cessation. It is estimated that approximately half of smokers who quit will relapse within the first two weeks (Brown, Herman, Ramsey, & Stout, 1998; Cook, Gerkovich, O'Connell, & Potocky, 1995; Doherty, Kinnunen, Militello, & Garvey, 1995; Garvey, Bliss, Hitchcock, Heinold, & Rosner, 1992; Shiffman, Hickcox, Paty, Gnys, Richards, & Kassel, 1997), and that 60-90% will relapse within 1 year (e.g., Krall, Garvey, & Garcia, 2002). In an effort to identify individuals most vulnerable to relapse, researchers have uncovered psychosocial predictors including age, education, health consciousness, average cigarette consumption, social support, and substance use (Krall et al., 2002). Psychiatric factors, such as depression, also appear strongly associated with smoking.

The literature suggests that the odds of being a smoker, given a history of depression, range between 1.4 and 3.0 (e.g., Benjet, Wagner, Borge, & Mendina-Mora, 2004; Breslau, Kilbey, & Andreski, 1991; Glassman et al., 1990; Hall, Munoz, Reus, & Sees, 1993; Hughes, Hatsukami, Mitchell, & Dahlgren, 1986; Johnson & Breslau, 2006; Kendler et al., 1993; Wu & Anthony, 1999). The question of whether depression negatively impacts quitting has clear implications for treatment. Early reports in the literature suggested that lifetime history of depression could be used to predict smoking relapse following a quit attempt (e.g., Glassman et al., 1988). However, inconsistent findings (e.g., see Hitsman, Borrelli, McChargue, Spring, & Niaura, 2003) have directed

attention to the importance of depressive symptoms at baseline and the pattern of mood change during the course of quitting (Burgess et al., 2002; Catley, Harris, Okuyemi, Mayo, Pankey, & Ahluwalia, 2005).

Veterans Affairs (VA) medical centers represent the largest integrated health care system in the country. While current VA smoking cessation programs vary in structure, they typically involve nicotine replacement, pharmacotherapy, and behavioral counseling. Kennedy and colleagues (2004) found overall 1-year abstinence rates were only as high as 13%, and a multi-site study designed to increase smoking intervention in primary care clinics found that only 12.3% of smokers identified at baseline reported achieving cessation at 1-year follow-up (Joseph, Arikian, et al., 2004). Additionally, standard VA interventions do not specifically target depression, and mood management has shown promise in helping depressed smokers quit (Hall et al., 1994). A considerable need exists for improved VA smoking interventions, particularly for patients with depression. Behavioral Activation (BA) has shown to be efficacious in the treatment of depression (Jacobson et al., 1996) and may be useful in combination with nicotine replacement and standard cessation techniques to treat this challenging population. The following literature review discusses current smoking interventions, treatment at VA medical centers, cognitive-behavioral and pharmacological smoking treatments for depressed smokers, and BA treatment for depression.

Smoking Cessation

Nicotine Replacement Therapy. The rationale of nicotine replacement therapy (NRT; transdermal patches, gum, lozenges, and nasal sprays or inhalers) is to prevent

withdrawal symptoms that make a cessation attempt uncomfortable and precipitate relapse. The level of nicotine is tapered gradually over weeks of treatment to decrease physiological dependence on nicotine while the smoker adapts to a non-smoking lifestyle. Nicotine gum and transdermal nicotine patches are among the most common nicotine replacement therapies used today. Research comparing the efficacy of different forms of NRT has generally shown that combination therapy (e.g., patch plus inhaler) has no long-term benefit over single NRT (Croghan et al., 2003; Bohadana, Nilsson, Rasmussen, Mayo, 2000).

Nicotine gum has been reported to increase success rates by 10-15% for low-dependence smokers and up to 20-30% for smokers with higher levels of nicotine dependence (Hughes, 1993). Scheduling gum use may provide more consistent relief from withdrawal symptoms rather than ad-lib use. Nicotine gum was found to be particularly effective for both depressed and non-depressed smokers compared to placebo gum when used in the context of brief behavioral counseling (Kinnunen, Doherty, Militello, Garvey, 1996).

Of all the nicotine replacement systems available, transdermal nicotine patches provide the most convenient application, consistent level of nicotine, and reliable reductions in craving and withdrawal symptoms (Hughes, 1993). In his analysis of 3 early studies of nicotine patches, Hughes determined a 2.5 factor increase in success rate relative to placebo patches. He also found that abstinence rates were more consistent with the patch, relative to nicotine gum, across smokers with low and high levels of dependence. Fiore, Smith, Jorenby, and Baker (1994) conducted a meta-analysis of 17 clinical trials studying the efficacy of nicotine patches. Abstinence rates greatly favored

use of nicotine patches over placebo, but there seemed to be no advantage in extending treatment with the patch beyond 8 weeks. When intensive behavioral counseling was paired with the patch, the likelihood of quitting nearly doubled. However, this effect was modest after 6 months and use of the patch was beneficial even with minimal counseling. Participants assigned to the patch achieved a 27% abstinence rate at the end of treatment overall, compared to a 13% abstinence rate for placebo. Twenty-two percent of patch users were abstinent at 6-months compared to only 9% for placebo.

NRT is a highly effective aid for smoking cessation that will likely remain a first-line approach. Because smoking involves making behavioral changes, NRT may be best delivered within the context of cognitive-behavioral programs that help patients avoid relapse through targeting behaviors associated with smoking while the physical addiction to nicotine is faded with NRT (Richmond, Harris, de Almeida Neto, 1994; Richmond, Kehoe, de Almeida Neto, 1997).

Pharmacotherapy Based Cessation. Bupropion is a dopaminergic and noradrenergic reuptake inhibitor thought to decrease withdrawal and cravings by acting on neural reward pathways (Balfour, 2001). Because bupropion is well tolerated with few side-effects, it is considered a first-line pharmacotherapy intervention for smoking cessation (Fiore et al., 2000b; Ingersoll & Cohen, 2005), and has demonstrated effectiveness in medical practice (e.g., Swan et al., 2003). Two early double-blind, placebo controlled trials of immediate-release bupropion demonstrated favorable results (Ferry & Burchette, 1994) and the medication was approved for use in smoking cessation by the Food and Drug Administration (FDA) in 1997. Two studies have demonstrated efficacy of bupropion sustained-release (SR) in double-blind, placebo-controlled trials.

In the first of these studies (Hurt et al., 1997), community participants received treatment with placebo, or 100 mg, 150 mg, or 300 mg daily bupropion SR, beginning one week before an established quit-date. Participants returned for weekly assessment during a 7-week treatment period. Results indicated that the group receiving daily 300 mg bupropion SR attained the highest rate of continuous abstinence during the treatment phase (24.4%) compared to 100 mg bupropion SR and placebo (13.7% vs. 10.5%, respectively). Point-prevalence data at one-year follow-up showed that participants in the 300 mg and 150 mg groups both maintained significantly better abstinence rates when compared to placebo.

Jorenby and colleagues (1999) conducted a study with community volunteers to evaluate outcome of 150 mg bupropion SR, nicotine-patches, and combination therapy in comparison with placebo. At four-weeks all three treatment groups were superior to placebo. However, only the two groups that included bupropion SR ultimately demonstrated greater efficacy over placebo at 12-month follow-up with 30.3% maintaining abstinence in bupropion SR alone, 35.5% abstinence in the combined treatment, and 15.6% in the placebo group. Use of bupropion SR alone, or in conjunction with NRT, has shown to be efficacious at 12-month follow-up for smokers who initially failed to maintain abstinence using NRT alone (Jamerson et al., 2001). Bupropion 150 mg SR has been shown to benefit African-American smokers at the end of a 6-week treatment and at 6-month follow-up (Ahluwalia, Harris, Catley, Okuyemi, & Mayo, 2002).

Public Health Initiatives. In an effort to provide standard guidelines for cessation specialists and general practitioners, the Agency for Health Care Policy and Research

Smoking Cessation Clinical Practice Guideline was released (Fiore et al., 1996). Following this initiative, a committee of more than 30 members, sponsored by 7 governmental and non-profit agencies, was assembled to review the prior 1996 guideline in light of current, effective, and empirically validated treatments available for smoking cessation. These efforts resulted in the publication of a new practice guideline by the Department of Health and Human Services, titled “Treating Tobacco Use and Dependence: A Clinical Practice Guideline” (Fiore et al., 2000a; 2000b). This guideline is considered to be the current standard of care in smoking cessation.

According to the guideline, patient assessment in primary care settings begins with the 5 “A’s” (ask about use, advise users to quit, assess willingness to quit, assist the patient with a treatment plan, and arrange follow-up contact). For patients who are unwilling to quit at the current time, the guideline recommends a brief motivational intervention aimed at helping the patient to identify the personal relevance of quitting, highlight the negative consequences of smoking and the rewards associated with quitting, and identify possible obstacles to quitting.

Patients who are ready to make a quit attempt should receive a combination of counseling or behavioral therapy and pharmacotherapy. According to the authors of the guideline, a strong dose-response relationship exists, indicating that more intensive treatment is associated with the best possible outcome. Therefore, the guideline recommends more than 30 minutes of total contact time between provider and patient. Effective counseling includes the following elements: identify triggers for smoking, teach coping or problem-solving skills (e.g., stress reduction), educate about withdrawal symptoms and addiction, provide supportive counseling, and help in establishing social

support at home and a smoke-free environment. First-line pharmacotherapy recommended in the guideline includes NRT or bupropion SR. Patients who are unable to use these medications for medical reasons may be candidates for second-line medications, such as clonidine or nortriptyline. Long-term use of pharmacotherapy (e.g., more than 6 months) appears to be safe when needed and can be combined with NRT.

Because smoking is a chronic addiction, consistent relapse prevention is needed after the patient has quit. The guideline recommends that practitioners reinforce the patient's decision at every encounter, review the benefits of quitting, and assist with any problems the patient experiences (e.g., lack of support, depressed mood, or weight gain). These simple efforts at relapse prevention are especially important in the first few weeks of quitting when relapse rates are highest (e.g., Cook et al., 1995).

Other treatment services are available to smokers in the community as well. For instance, toll-free quit lines are available in most states and the Department of Health and Human Services provides a national phone line service (Schroeder, 2005). Some smokers may prefer the convenience and anonymity of phone line services (e.g., Zhu et al., 2002). Online material based on the current guideline (Fiore et al., 2000a) also exists for smokers (e.g., www.treatobacco.net) and corresponding web-based training programs are available for health care professionals (Pederson & Blumenthal, 2005).

Smoking Treatments for Veterans

The VA medical system provides care to approximately 4.1 million individuals and veterans have a higher rate of tobacco use compared to the general population (33% vs. 23%; Jonk et al., 2005). In the mid 1990s, the VA system set as its goal that in 2000,

“100% of Veterans Health Administration (VHA) facilities have intensive tobacco use cessation programs (or access to one)” (VHA, 1996). This led to the development of treatment guidelines and the requirement that primary care providers assess for tobacco use and recommend cessation to all smokers. Current smoking cessation programs at VA medical centers involve weekly walk-in groups that provide support and psychoeducation based on the National Cancer Institute guidelines (Rausch, Nicholson, Lamke, & Matloff, 1990). Of all medications provided for cessation, nicotine patches are the most common prescription (approximately 67% of cases), followed by bupropion SR (25% of cases) and nicotine gum (10% of cases). Investigators at the VA medical center in Richmond, Virginia (Kennedy et al., 2004) have found that combination therapy involving office spirometry to be useful in motivating patients. Spirometry is a brief evaluation of the patient’s current lung functioning (e.g., forced expiratory volume, forced vital capacity, and the ratio of these measures). Patients receive results in terms of their “lung age” which helps make the degree of lung damage done by smoking salient to the patient.

The cost of smoking cessation aids is low relative to the cost of treating smoking-related illnesses. Unfortunately, outpatient pharmacy expenditures for cessation treatments have not risen in recent years and only account for less than 1% of total VA expenditures (Jonk et al., 2005). Additionally, despite the development of cessation guidelines, efforts to improve cessation rates have been disappointing. In a study of 20 VA medical centers, Joseph, Arikian, and colleagues (2004) carried out an intervention with half of the participating sites to improve assessment and counseling among care providers. While some improvements in documentation of smoking were made with the intervention, no difference in point-prevalence cessation rates was observed among

smokers after 1 year. Only 11.4% of the intervention group achieved abstinence compared to 13.2% in the control condition. Fifty-nine percent of smokers in the intervention group received behavioral assistance and 21% reported some form of medication from VA providers, while 55% of controls received behavioral assistance and 19% received medication. These data indicate that veterans remain a particularly high-risk population for smoking-related illnesses and continue to remain underserved by VA health care professionals. Patient success rates are closely tied to use of multi-modal therapy and number of visits to cessation programs (Kennedy et al., 2004), indicating that VA health professionals must persist in their recommendations and motivate patients to consider all available treatment options.

Even following a successful quit attempt, relapse rates continue to remain high for the next 1-2 years. Krall et al. (2002) have examined smoking relapse after 2 years of abstinence in a Boston area VA sample. Ninety-three of the 483 men (19%) relapsed after 2 or more years of abstinence. Factors related to relapse included: drinking more coffee/tea or alcohol, and pipe or cigar smoking. These factors have clear implications for treatment programs. High-risk situations (gatherings with friends who smoke) and substances strongly associated with smoking (such as alcohol and coffee) may be countered with skills training aimed at cigarette refusal or alternative response making. These long-term follow-up data underscore the need for relapse prevention efforts that extend beyond the initial weeks of a patient's quit-date.

Psychiatric Factors Complicating Smoking Cessation among Veterans

Survey data from Joseph, Rice, An, Mohiuddin, and Lando (2004) indicated that 98% of continuing smokers at the Minneapolis VA who had failed to quit were willing to make another attempt. However, cessation may be particularly difficult for those with psychiatric and substance use disorders (Gritz, Stapleton, Hill, & Jarvik, 1985; Jonk et al., 2005). The VA Normative Aging Study documented that current smokers consistently report greater levels of depression on measures such as the Center for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977) and the Minnesota Multiphasic Personality Inventory-2 (MMPI-2), but that depression did not predict cessation failure (Kinnunen, Haukkala, Korhonen, Quiles, Spiro, & Garvey, 2006). Nevertheless, veterans with more complicated psychiatric and substance use histories may represent a difficult population to treat. In a recent VA smoking study with patients receiving substance use treatment (Saxon et al., 2003), 75% of the sample had an additional psychiatric diagnosis. The study suffered high dropout rates with only 15% of the sample completing all 8 sessions of smoking cessation treatment. Short-term abstinence rates were low with less than 8% of the total sample reporting prior week abstinence at Session 4. Grant and colleagues (2003) attempted to integrate smoking cessation into alcohol treatment due to high rates of co-occurrence. Their effort to provide integrated treatment failed, likely due to poor compliance with additional treatment requirements. These data highlight the need for new treatment approaches for patients with psychiatric diagnoses that result in lower attrition rates.

In addition to substance use disorders, posttraumatic stress disorder (PTSD) and depression are highly prevalent in the VA health care system. It has been estimated that

60% of patients with PTSD smoke and many are likely to be heavy smokers (Beckham, 1999). PTSD smokers are at particular risk for smoking-related illnesses due to cardiovascular differences observed in this population. For instance, Beckham, Gehrman, McClernon, Collie, & Feldman (2004) have studied the cardiovascular characteristics of PTSD and non-PTSD smokers. They found that, in comparison to smokers without PTSD, smokers with PTSD had higher diastolic and arterial blood pressure. This study complements earlier research showing that individuals with PTSD exhibit higher baseline cardiovascular activity and reactivity to trauma-related cues (Beckham et al., 2000; Keane et al., 1998). Taken together, these data suggest the interaction of PTSD and smoking may be associated with disproportionate risk for cardiac problems.

Depression is one of the most common psychiatric problems encountered in VA medical centers with approximately 32% of primary care patients endorsing symptoms of depression (Joseph, Arikian, et al., 2004). Depression appears to be a significant factor affecting quit rates. In a study by Rausch et al. (1990), the authors examined 4-week outcome data to uncover whether veterans who successfully quit ($n = 9$) differed from those who failed to quit ($n = 34$) on measures of affect. Profile of Mood States scores (POMS; McNair, Lorr, & Droppelman, 1971) and Zung depression scores (Zung, 1965) indicated that non-quitters had significantly higher depression scores. In a regression analysis, age with POMS depression scores represented the best model for predicting cessation status at the end of a 4-week treatment. Whether efforts to reduce negative affect before or during a quit attempt improve success rates needs to be addressed by future research.

Outcome data on VA smoking interventions demonstrate that veterans remain a difficult population to treat. Standard approaches to smoking cessation appear insufficient and new approaches designed for individuals with psychiatric comorbidity are needed. Treatments should be multi-modal to achieve optimal smoking outcomes and yet possess a high degree of patient acceptability to maintain low attrition.

The Relationship between Smoking and Depression

Nicotine, Depression, and Smoking Relapse. Research has demonstrated a significant correlation between depressed mood and smoking (e.g., Anda et al., 1990; Covey & Tam, 1990; Hall, Munoz, Reus, & Sees, 1993). While causal relationships remain unclear (Dierker, Avenevoli, Stolar, & Merikangas, 2002; Hughes, 1999), interaction models that include genetic vulnerability may best account for this relationship (Wilhelm, Wedgwood, Niven, Kay-Lambkin, 2006). Longitudinal studies with adolescents have shown that smoking predicts depression at 1-year (Steuber & Danner, 2006) and 5-year follow-up (Wu & Anthony, 1999). On the other hand, depressive symptoms have predicted heavy smoking after 10-year follow-up (Kandel & Davies, 1986). A widely held view is that depressed individuals smoke as a means of affect regulation. Nicotine is believed to have antidepressant effects and negative affect may increase with cessation (e.g., Kinnunen et al., 1996; Lerman et al., 1996; Pomerleau & Pomerleau, 1984).

Data from smoking cessation research indicates that rates of depression among smokers attempting to quit are high, with lifetime rates of Major Depressive Disorder (MDD) as high as 61% (Glassman et al., 1988). Depressed smokers also appear to have

higher rates of early relapse compared to non-depressed peers, with 1-week abstinence rates of approximately 37% compared to 56% for non-depressed smokers (Kinnunen et al., 1996). Despite the initial report of Glassman and colleagues (1988), lifetime history of MDD has proven to be an unreliable predictor of smoking relapse. In a meta-analysis of 15 treatment outcome studies, Hitsman, Borrelli, McChargue, Spring, and Niaura (2003) found that history of depression had no effect on short or long-term abstinence. Moreover, re-analyses disconfirmed the possibility these null findings could be explained by amelioration of depression by the antidepressant effects of smoking interventions (Covey, Bombback, & Wei Yin Yan, 2006; Hitsman et al., 2004). Given these results, it is likely that *history* of depression is simply too imprecise to be useful in predicting smoking relapse. A clear problem is that assessment for lifetime history does not differentiate those who experienced a single episode of depression from those who have recurrent episodes or current symptoms.

Current evidence supports the notion that the link between depression and smoking cessation failure lies with current depressive symptoms or in the pattern of mood change during treatment. Ginsberg, Hall, Reus, and Munoz (1995) found that smokers with a history of depression and a high level of baseline dysphoria were more likely to have short-term (2 week) relapse compared to smokers without a history of depression. Current depressive symptoms as assessed by the Beck Depression Inventory (BDI; Beck, Steer & Garbin, 1988) have been predictive of treatment failure in other studies as well (e.g., Brown et al., 2001; Blondal et al., 1999), but other studies examining baseline symptoms have added inconsistent results (e.g., Killen et al. 2000, Niaura et al 1999). For instance, Lerman et al. (2004) found that highly dependent

smokers experienced greater levels of baseline depression but that treatment of depression did not mediate abstinence rates. This has led researchers to turn their attention, yet again, toward the pattern of symptom change from baseline during a quit attempt. That is, how an individual is affected by depression during the initial days or weeks of cessation might ultimately best predict relapse.

Burgess and colleagues (2002) suggested that depressed smokers represent a heterogeneous population consisting of subgroups that can be identified by patterns of symptom change during cessation. The authors used cluster analysis to identify subgroups of depressed smokers based on whether depressive symptoms increased or decreased rapidly or slowly across 8 sessions of a standard smoking treatment or a CBT smoking intervention. Heterogeneity was observed in the overall sample, with approximately 40% of subjects showing a pattern of increasing symptoms across treatment and 47% exhibiting a profile of decreasing symptoms. Higher rates of abstinence at 12-month follow-up were achieved by participants with a delayed or rapid decrease in symptoms, with the group characterized by rapid decrease having significantly better overall outcomes. Conversely, individuals showing rapid or delayed increase in depressive symptoms were more likely to relapse during follow-up assessments. These data provided clear support for the theory that current depressive symptoms can negatively impact abstinence.

Pharmacotherapy for Depressed Smokers. Depression is widely treated with antidepressant medications. Because depressive symptoms are believed to interfere with smoking abstinence, antidepressant medications may help depressed patients quit.

Antidepressant medications that have received attention in the literature include bupropion, nortriptyline, fluoxetine, and sertraline.

As described above, bupropion has shown efficacy for helping smokers quit. Whether changes in depressive symptoms mediate the effects of bupropion on smoking abstinence is unclear. In a study with African-American participants, Catley et al. (2005) found that level of depression during treatment with bupropion, rather than at baseline, predicted abstinence at 6-weeks and 6-months. At the end of a 6-week treatment phase, change in depressive symptoms partially mediated smoking cessation. Because of the strong independent effects of bupropion on smoking cessation, a full mediation model was not supported. On the other hand, a study by Lerman and colleagues (2002) found that depressive symptoms did not mediate the effects of bupropion on smoking cessation. Bupropion was effective in ameliorating depressive symptoms for highly dependent smokers by the end of treatment. However, this effect was non-significant when controlling for baseline symptoms and a rebound in depression was observed for highly dependent smokers at 6-month follow-up.

Use of fluoxetine appeared promising based on Dalack and colleagues' (1995) early report of reductions in self-reported tension, anger, and depression among participants with a history of MDD after 3 weeks of treatment with the medication. A follow-up study of fluoxetine was conducted by Hitsman and colleagues (1999). These authors examined the efficacy of the medication as an adjunct to cognitive-behavioral treatment with predictions that subjects with higher levels of depression, concerns about weight gain, low self-efficacy, and higher nicotine dependence would benefit most from the addition of fluoxetine to CBT. While smokers with these characteristics derived little

benefit from the addition of the medication, at 3-month follow-up, fluoxetine did appear to show benefit for smokers with higher levels of baseline depressive symptoms.

Despite these encouraging findings, subsequent research has not been supportive of fluoxetine as a smoking cessation treatment. In a randomized, placebo controlled study with community participants (Blondal et al., 1999), subjects received 20 mg fluoxetine for 3-6 months after quitting and were instructed to use a nicotine inhaler 6-12 times per day for up to 6 months. Participants in a control condition received placebo pills and a nicotine inhaler. Regular follow-ups occurred at 6 weeks, and at 3, 6, and 12 months post quit-date. Contrary to predictions, no significant differences were observed between conditions at any follow-up point (e.g., 12-month abstinence rates were 21% and 23% for fluoxetine and placebo groups, respectively). More recently, Spring and colleagues (2007) found that fluoxetine enhanced abstinence for euthymic smokers with a history of depression only during the initial weeks of treatment. By 6-month follow-up, participants treated with fluoxetine were actually 3.3 times more likely to have relapsed compared to participants in the placebo condition. While fluoxetine may be protective against relapse among smokers at-risk for initial dysphoria, it does not appear useful in maintaining long-term abstinence.

Nortriptyline, a drug affecting the adrenergic system, was investigated by Hall and colleagues (1998) in a study that also included an evaluation of cognitive-behavioral treatment (CBT) for smokers with positive or negative history of MDD. Results indicated a main-effect for the medication and an interaction between psychological treatment and diagnosis. Participants history positive for MDD were more likely to remain abstinent in the CBT condition, relative to the education-group control condition,

and they achieved an abstinence rate comparable to that of MDD history-negative participants. No interaction of medication and diagnosis, or medication and psychological treatment was observed. Thus, nortriptyline demonstrated efficacy as a smoking cessation aid for smokers regardless of depression history. Because it is relatively inexpensive, nortriptyline may be a useful alternative to bupropion.

Covey, Glassman, Stetner, Rivelli, & Stage (2002) reported a randomized, placebo-controlled study of sertraline, which showed no benefit on smoking outcome at 18-week and 30-week follow-up among participants with history of at least one episode of DSM-III-R criteria major depression after 11 weeks of treatment. Results of Covey et al. indicated sertraline was effective in reducing many of the withdrawal symptoms reported by subjects (i.e., craving, irritability, anxiety, restlessness), but not effective in reducing depressed mood. A non-significant trend for higher abstinence rates in the sertraline group was observed at the end of treatment (33.8% vs. 28.8% abstinence). However, by 30-week follow-up, rates of abstinence had declined to 11.8% for sertraline and 16.7% for placebo. The authors speculated that the difference in efficacy observed between classes of antidepressants may be due to the different neurotransmitter systems these drugs affect. Both sertraline and fluoxetine are known to primarily affect the serotonergic system, whereas bupropion and nortriptyline affect the dopaminergic and adrenergic systems. Serotonin may not play a critical role in cessation. While bupropion and nortriptyline have demonstrated efficacy in treating depressed smokers, more research is needed with respect to the topography of symptom change during treatment as well as the influence of important sample characteristics such as level of nicotine dependence (Lerman et al., 2004).

Cognitive-Behavioral Approaches for Depressed Smokers. To address the need for a treatment designed for depressed smokers, Hall, Munoz, and Reus (1994), created an 8-week, 10-session, cognitive-behavioral intervention designed to prevent the occurrence of negative mood that depressed smokers might experience during a cessation attempt. Initial stages of this treatment included standard smoking education and self-monitoring (thoughts, daily activities, interpersonal contacts, and mood). The inter-relationships between these factors were discussed with participants, who were instructed to increase pleasant activities and social contacts. Skills for healthy behavior change, relaxation techniques, and monitoring and changing maladaptive thoughts were also taught. In this treatment, maladaptive thoughts were viewed as changeable and causative of negative emotions. Hall et al. (1994) found this cognitive-behavioral intervention to be significantly more effective for smokers with a history of depression than a 5-session standard cessation treatment (34% vs. 18% continuous 1-year abstinence). However, the intervention was not superior for smokers without a history of depression (24% vs. 16% in favor of the standard treatment).

The hypothesis that baseline dysphoria may best predict smoking abstinence was partially supported only for smokers history-positive for depression. The anger subscale of the Profile of Mood States (POMS; McNair et al., 1971) at baseline was predictive of failure to abstain, while history of depression alone was a poor predictor of cessation failure. These findings confirmed the notion that smokers with baseline symptoms respond more favorably to treatments that involve mood management. These data also suggested that assessment for history of depression without regard to baseline symptoms may result in poorer prediction. Unfortunately, a notable limitation of Hall and

colleagues (1994) was controlled treatment comparison. The mood management condition included twice as many sessions as the standard intervention. When a follow-up study matched therapist contact time between conditions, cognitive-behavioral mood management failed to benefit individuals with past depression and baseline dysphoria compared to the control condition (Hall et al., 1996).

The efficacy of CBT for smokers with a history of MDD has been evaluated by Brown and colleagues (2001). In their work, both treatments under investigation included cognitive-behavioral therapy for smoking (i.e., self-monitoring, avoiding cues, nicotine fading, relapse prevention, and social support). The depression treatment condition (CBT-D) also involved monitoring moods and thoughts, learning the relationship between mood and cigarette smoking, increasing pleasant activities, identifying and challenging cognitive distortions, and social skills training. Treatment for both groups was delivered over 6 weeks, and follow-up assessments occurred at 1-month, 6-months, and 12-months. No difference in abstinence rates was observed between groups at any follow-up point. However, in a covariate analysis, a significant interaction was found between treatment and two other variables. Heavy smoking level and history of recurrent depression predicted smoking in the CBT-D condition. While overall differences between treatment groups failed to reach statistical significance, 1-year follow-up data were promising (32.5% abstinence in the CBT-D group vs. 24.7% in the standard). The authors aptly pointed out that success rates in the standard treatment were high, indicating that the control condition served as a particularly stringent test of their CBT-D intervention.

Cognitive-behavioral treatments for depressed smokers appear to have merit. However, the best approach for incorporating depression treatment into smoking cessation programs remains unclear. Exactly what elements of CBT are critical for treating depression and smoking, the relative importance of each of these elements, and the optimal length of CBT treatment, should be the focus of future research. The restrictions of today's managed health care environments make these questions critical for the dissemination of CBT treatment into general practice.

Behavioral Treatments for Depression

Behavioral Activation. While cognitive-behavioral approaches for depressed smokers have shown promise, stand-alone behavioral interventions represent a concise alternative. One particular treatment for depression that has yet to be evaluated within the context of smoking cessation programs is behavioral activation (BA). BA is defined as a treatment for depression which emphasizes structured activities or behaviors which are likely to bring the patient into contact with reinforcing contingencies that produce corresponding improvements in thoughts, mood, and quality of life (Hopko, Lejuez, Ruggiero, & Eifert, 2003). Therefore, the underlying theoretical rationale of BA clearly lies within Skinner's (1953) operant model and utilizes core behavioral principles such as extinction, fading, and shaping. Depressive behavior, as any other behavior, is viewed as a function of reinforcement (or lack thereof) and punishment. Quite often depressed behavior is maintained because avoidance of situations provides immediate relief from punishing consequences. Because avoidance behavior serves to reinforce depression, maladaptive avoidance patterns need to be identified and extinguished in therapy.

Current conceptualizations of BA emphasize functional analysis as the guiding framework for interpreting behavior. Behavior is maintained by its consequences or function. The function of a behavior may be problem avoidance, such as sleeping during the day rather than facing the possible rejection associated with finding a job, or the problem behavior may represent an ineffective response to a particular situation, thought, or experience. In treatment, the therapist and patient seek to remove antecedents of problem behaviors and change the patient's responses to those that are more likely to result in favorable, reinforcing consequences.

The BA approach to depression emphasizes the environmental context of behavior, rather than the traditional internal context (i.e., medical or disease model). The patient's negative thoughts and moods are viewed as natural by-products of the relationship between behavior and the consequences of behavior. By programming healthy behavioral responses and pleasurable activities that have personally relevant and reinforcing consequences, the patient achieves self-efficacy and mastery in his environment. The patient's cognitions, feelings, and mood states are indirectly targeted through the creation of healthy behavior-consequence contingencies.

Early work in BA by Lewinsohn and colleagues (e.g., Lewinsohn & Graf, 1973; Lewinsohn, Sullivan, & Grosscup, 1980), showed that depressive symptoms could be successfully targeted through treatment programs that involved monitoring of activities and mood, scheduling pleasant activities, time management strategies, and social skills training when needed. While the simplicity of behavioral activation as a treatment for depression is one of its greatest advantages, its simplicity has also been viewed as a

shortcoming by critics who contend that a patient's cognitions should also be targeted directly in treatment through cognitive therapy.

In a component analysis of CBT for depression, Jacobson and his colleagues (1996) dismantled a larger CBT treatment approach into a behavioral activation component (BA condition), a cognitive component targeting dysfunctional automatic thoughts (AT condition), and a combined package that included the above elements but which also sought to produce changes in core dysfunctional schema (CT condition). In the BA condition, treatment centered exclusively on self-monitoring of activities, identification of activities that provide a sense of pleasure or mastery, behavior therapy techniques for dealing with problems, and social skills training when needed. Contrary to therapist expectations that CT would be most effective, all three treatment conditions had comparable results. Between-group differences in levels of depressive symptoms on the BDI (Beck et al., 1988) and the Hamilton Rating Scale for Depression (HRSD; Hamilton, 1967) were non-significant at post-treatment and 6-month follow-up. The percentage of patients no longer meeting criteria for MDD was comparable across groups at post-treatment and follow-up. CT was found to hold no advantage in preventing relapse of depression at 2-year follow-up (Jacobson & Gortner, 2000).

These data suggested that depressive symptoms can be effectively targeted by both behavioral and cognitive approaches, and that no significant therapeutic gains are achieved by full cognitive-behavioral treatment, or by treatment in which core cognitive schema are specifically targeted. Other studies have documented that maladaptive cognitions often change with specifically behavioral interventions, as they do with cognitive interventions (Simons, Garfield, & Murphy, 1984; Zeiss, Lewinsohn, &

Munoz, 1979). A simple BA component may be the preferred method of treatment for many patients because it is less intensive than full CT and does not require the level of therapist expertise required by cognitive therapists. Since Jacobson and colleagues' (1996) important component analysis, BA has been successfully elaborated into a comprehensive and cohesive treatment modality (Jacobson & Gortner, 2000; Jacobson, Martell, & Dimidjian, 2001).

Lejuez, Hopko, and Hopko (2001, 2003) and Martell, Addis, & Jacobson (2001) have described contemporary BA approaches that are specifically tailored to individual patient needs. Rather than simply scheduling pleasant activities and monitoring mood (e.g., as in Lewinsohn & Graf, 1973), the patient's needs and goals are assessed and utilized to form an idiographic BA treatment plan. The functional analytic method is taught to patients in session so that they may learn the connections between triggers, behaviors, thoughts, and mood, and act outside of session to change their usual behaviors and coping responses in ways likely to lead to positive consequences.

Brief Behavioral Activation Therapy for Depression (BATD). BATD (Lejuez et al., 2003) is an easily disseminated, manualized, contemporary behavioral activation approach. This brief program can be used alone or in combination with other treatments. Considerable flexibility is built into the program so that daily activities and long-term goals can be personalized to each patient. Patients are taught to recognize depression as they are introduced to the behavioral and environmental-based rationale of treatment. Patients are instructed to monitor activities and mood in order to chart progress, gain insight, and make choices that will lead to positive consequences. A hierarchy of personalized activities is constructed and patients successively master these activities,

beginning with those identified as easiest to accomplish and progressing to those considered more difficult. Monitoring of daily activities, mood, and progress toward goals continues between sessions for the entire course of treatment. When problems with accomplishing scheduled activities arise, functional analysis is used with the patient to troubleshoot the problem. For example, if a patient failed to meet a weekly goal (e.g., working 30 minutes per day on an art project), possible barriers would be explored in session. Is the activity one that actually engenders pleasure or mastery? Is the patient watching TV or sleeping when depressed rather than attempting the project? If so, what makes these less desirable behaviors more likely to occur and what strategies can be devised to replace depressive behaviors with healthier alternatives? Or was the weekly goal set too high? Goals may require adjustment as treatment progresses and they are set with respect to the patient's current level of functioning. Successes and failures are always viewed within the functional analytic framework with the objective that patients become more aware of environmental contingencies and the relationship between behavior and mood.

Initial case study reports have suggested BATD is an effective treatment (Hopko, Lejuez, Hopko, 2004; Lejuez, Hopko, LePage, Hopko & McNeil, 2001). To investigate the utility of BATD with hospital populations, Hopko, Lejuez, LePage, Hopko, and McNeil (2003) conducted BATD group treatment with a small sample of psychiatric inpatients and compared treatment outcome with a supportive therapy group. BDI scores of patients in the BATD group at post-treatment were significantly lower than the supportive condition. Furthermore, a large effect size ($d = .73$) was reported, indicating that the statistical difference in depressive symptoms was also of clinical significance.

BATD was recently applied to a small sample ($n = 6$) of depressed female cancer patients (Hopko, Bell, Armento, Hunt, & Lejuez, 2005). Pretreatment, post-treatment, and 3-month follow-up data were analyzed in repeated-measures analysis of variance. At post-treatment, significant improvement was observed on measures of depression, quality of life, and medical outcomes, with effect sizes ranging from .5 to 2.3. These clinically significant gains were maintained at 3-month follow-up. Patients reported strong satisfaction with BATD as well. Although, conclusions about the efficacy of BATD with this population cannot be made due to limitations in sample size and design, both this study and the data of Hopko et al. (2003) suggest that BATD may prove to be an effective, cost efficient treatment for hospital populations. Additional trials comparing BATD with other established depression treatments are needed.

Cuijpers, van Straten, & Warmerdam (2007) reported a recent meta-analysis of published data on the effectiveness of BA interventions. Most of the 16 studies used in this analysis were small samples and differed in treatment format (e.g., individual vs. group), and treatment length ranged between 4-20 sessions. The common element of all studies was a focus on activity scheduling for the treatment of depression. The mean effect size for 10 studies that included comparisons to a control group was large ($d = .87$, 95% CI .60-1.15). The effect sizes of BA when compared to other psychological interventions ($d = .13$) and to cognitive interventions ($d = .02$) were all non-significant, indicating that BA interventions were generally equivalent to other treatments. Across 5 BA interventions, the effect size of change between post-treatment to follow-up assessment (1-3 months) was small, but non-significant ($d = .18$). No evidence for

improvement from post-treatment to 4-6 month follow-up was observed across the 5 BA studies ($d = .03$).

Preliminary data on the efficacy of BA approaches for VA patients appear promising. In a recent study of BA treatment for PTSD with 10 VA patients, Jakupcak and colleagues (2006) demonstrated that half of their sample experienced significant improvement in clinician-rated and self-reported PTSD symptoms after 16-weeks of individual BA treatment. Surprisingly, only 4 individuals reported improvement in depressive symptoms and 4 others reported worsening of depression at the conclusion of treatment. Nevertheless, BA treatment appeared well-tolerated by VA patients and no one reported negative reactions to the treatment. Whether BA treatment is effective for VA patients with a primary diagnosis of depression remains to be investigated.

Overview and Aims of the Present Study:

A Behavioral Activation Approach to Smoking Cessation

Depression is highly prevalent among cigarette smokers and depressed smokers often experience poorer treatment outcome compared to non-depressed smokers. The Life Enhancement Treatment for Smoking (LETS-Quit) is a smoking cessation approach designed for depressed outpatient smokers that specifically incorporates behavioral activation principles with standard cessation techniques. The present study represents the initial treatment development and investigation into the effectiveness of this program for patients sampled at two VA medical centers. This particular population was chosen due to the high prevalence of both depression and cigarette smoking among veterans. Depressed VA patients who smoke may be underserved by current cessation programs,

creating a need for a brief but effective program for patients with complicated psychiatric and medical histories. Participants were assigned to LETS-Quit or a comparable intervention without behavioral activation for 3 sessions of treatment with follow-up assessment at 14-days and 30-days post-quit. While 3 sessions is considerably shorter than other smoking treatments, we wished to explore the initial feasibility of this approach while maintaining low attrition rates. With encouraging findings, the treatment may be lengthened in future studies to maximize effectiveness. All participants were encouraged to also use NRT during treatment and follow-up.

Major aims of the study were as follows:

- 1) Develop a brief smoking cessation treatment manual for use by VA care providers for treating depressed smokers. An 8-week group intervention for community participants was adapted into a brief treatment manual intended to have high acceptance among VA providers and patients. The VA LETS-Quit program is an individual-format smoking intervention that includes materials specifically designed for depressed VA smokers. The present study was intended to inform further revisions to the LETS-Quit manual and decisions about treatment delivery for future research.
- 2) Provide pilot comparison of LETS-Quit and control participants on smoking outcomes. It was hypothesized that LETS-Quit participants would report higher abstinence rates at each time-point and maintain higher rates of continuous abstinence during a 30-day follow-up period. Among participants who smoked after their quit-date, it was predicted that LETS-Quit would be associated with a longer number of days before first smoking lapse.

- 3) Evaluate effect of LETS-Quit on depressive symptoms. It was hypothesized that participants in LETS-Quit would report a decline in depressive symptoms at the end of treatment and at 30-day follow-up. Additionally, it was hypothesized that change in symptoms across treatment would predict smoking abstinence at 30-day follow-up. Depression was expected to partially mediate smoking abstinence, though the sample size precluded more formal mediation analyses.
- 4) Investigate whether reinforcement from activities predicts abstinence. LETS-Quit was expected to increase the level of reinforcement participants reported from their daily activities. Whether reinforcement from activities could predict smoking abstinence was investigated.

Chapter 2: Methods

Participants. Male ($n = 18$) and female ($n = 3$) military veterans receiving health care services at the Washington, D.C. VA (March-June 2006) and the Baltimore VA (April-June 2007) were recruited for the study. At each site, the research coordinator visited the weekly primary care smoking clinic to introduce the study by briefly explaining the purpose, number of visits required, and subject payment schedule. Patients were given a handout with the research coordinator's contact information and encouraged to ask questions. Interested patients scheduled an appointment to complete a brief screening assessment after the primary care smoking clinic ended. Additional recruitment occurred through mental health treatment provider referrals and advertisements posted throughout the building. A patient was eligible for screening if he

or she was a regular smoker (i.e., 10 or more cigarettes per day), between 18-65 years of age, and reported a strong desire to quit (operationalized as a rating of ≥ 7 on 0-10 scale).

Before screening measures were completed, patients provided informed consent per VA and University of Maryland institutional review board requirements. During informed consent, participants were reminded that a brief screening process was required to determine if inclusion/exclusion criteria were satisfied. Participants were administered the Beck Depression Inventory-II (BDI-II) and the Mini International Neuropsychiatric Interview (MINI). Patient medical records were reviewed to obtain psychiatric history and information on current prescriptions. Patients with a baseline BDI-II score ≥ 12 were considered eligible for participation. This cutoff represented the upper range of “minimal” depression defined by Beck et al. (1996) and was determined to offer an appropriate level of specificity and sensitivity for detecting patients with clinical depressive symptoms based on prior evaluation of the BDI-II in a primary care setting (Arnau, Meagher, Norris, & Bramson, 2001).

Patients with a diagnosis of schizophrenia were excluded because research has demonstrated that individuals with schizophrenia have nearly a 6-fold increased risk of smoking, experience lower cessation rates, and may require different smoking interventions (de Leon & Diaz, 2005). Patients reporting past-month illicit drug or alcohol abuse were also excluded. Individuals not meeting inclusion criteria were informed of the decision, provided with the first session of LETS-Quit, and referred to the primary care smoking clinic for follow-up cessation counseling. It must also be noted that we did not recruit patients with a diagnosis of PTSD at the Washington site to avoid

interference with an ongoing smoking study specific to PTSD veterans. PTSD patients were eligible at the Baltimore site.

Group Assignment. Participants were matched to either LETS-Quit or a standard treatment (ST) of comparable length and content on the basis of mood disorder diagnosis and active prescription for antidepressant medication. Because it was not feasible to exclude patients with a diagnosis of depressive or bipolar disorder, or patients prescribed antidepressant medication, this matching procedure was designed to prevent group disparity resulting from chance in random assignment with a small sample size.

Group assignment is provided in [Table 1](#). Mood disorder and medication status created 4 possible combinations. The first participant (#101) had a diagnosis of major depressive disorder and was treated with antidepressant medications, placing him in column 1 for assignment to LETS-Quit. The next participant enrolled in the study (#102) did not have a mood disorder, nor was he prescribed a medication classified as an antidepressant. Thus, he was placed in column 4 and also assigned to LETS-Quit. The following participant (#103) was diagnosed with depression and taking antidepressants, placing him in column 1 for assignment to ST.

Therapy Conditions. LETS-Quit and ST were each delivered in an individual format and both conditions were matched with respect to number and length of sessions. Three treatment sessions were spaced approximately one week apart: Visit 1 *Pre-Quit* (60 minutes), Visit 2 *Quit-Day* (60 minutes), and Visit 3 *One-Week Post-Quit* (50 minutes). The same therapist administered treatment for both conditions. Two brief follow-up assessments followed the treatment phase: Visit 4 *Two-Week Post-Quit* (15 minutes) and

Visit 5 *One-Month Post-Quit* (15 minutes). The content of LETS-Quit and ST is described below.

Life Enhancement Treatment for Smoking (LETS-Quit)

The LETS-Quit treatment protocol was adapted from an 8-week manualized treatment currently under investigation, but with two major differences: individual rather than group format and a reduced number of sessions. The decision to use an individual format was made to offer the greatest level of personalization and scheduling flexibility possible. The number of sessions was chosen based on high rates of attrition suggested by VA smoking interventions (Grant et al., 2003; Saxon et al., 2003) and personal communications with the Washington site primary care smoking clinic coordinator who reported inconsistent attendance and high psychiatric comorbidity among attendees. Therefore, the treatment was abbreviated as much as possible to increase its appeal and feasibility. LETS-Quit incorporated all of the elements of ST (described below) including NRT. Unique to LETS-Quit is behavioral activation therapy added to Visits 1-3.

How behavioral activation can lead to a more enriching nonsmoking lifestyle was presented to LETS-Quit participants. While the importance of healthy lifestyle choices was mentioned in the ST condition, particular emphasis on choosing and scheduling activities consistent with a healthy nonsmoking lifestyle, and that also provide a sense of mastery and pleasure, represented the focus of LETS-Quit. Core elements included: 1) Identification of values and goals within a variety of life areas including family, social or intimate relationships, education, employment/career, hobbies/recreation, volunteer

work/community involvement, physical/health issues, and spirituality; 2) Breaking down life goals into ideal goals and weekly goals; 3) Daily monitoring of progress toward meeting weekly goals; 4) Discussion of behavior-mood relationships and the effects of activity completion on mood; 5) Re-assessment and revision of plans so that activities were judged to be reinforcing and appropriate; 6) Progression toward achieving life goals.

Visit 1: Pre-Quit

Introduction and Motivation for Change. The participant was congratulated for deciding to quit smoking and instructed to write down personal reasons for quitting and reasons to smoke (Appendix A). Reasons for quitting were discussed and recorded to elicit motivation for change and the participant was educated about the benefits of quitting (e.g., health, finances, hygiene). Reasons to smoke were identified as "high risk" situations to be targeted in treatment.

Identification and Planning for High-Risk Situations. The therapist assisted the participant in recording high risk situations (situations, thoughts, feelings) that elicited the urge to smoke (Appendix B). Personalized plans to cope with each specific situation by altering or avoiding the activity or by substituting some other behavior in place of cigarettes were recorded on the form. The participant was instructed to record new situations and coping strategies during the week on a similar form.

Social Support. The role of social support was discussed and an important family member or friend was identified for behavioral contracting. The participant was instructed to think of helpful behaviors characteristic of the person identified, such as "provides verbal encouragement". The participant was also asked to identify unhelpful

behaviors demonstrated by the loved one, such as “always puts me down after a failure”. Finally, the participant was instructed to think of specific behavior changes he might request of the family member or friend to increase chances of success (e.g., asking the person to smoke outside). The *Social Support Contract* (Appendix C) was signed by both the participant and his family member or friend as homework to insure understanding of expectations.

Rationale for LETS-Quit and Monitoring. The participant was introduced to the rationale of the LETS-Quit treatment. The idea of beginning a healthy and more rewarding nonsmoking lifestyle to improve mood and help with smoking cessation was discussed.

Identification of Overall Life Goals within a Nonsmoking Lifestyle. With help from the therapist, the participant considered personal goals across a variety of life areas including improvements in family, social, and intimate relationships, educational goals, employment objectives, new hobbies and recreational activities or resuming past hobbies, participating in volunteer work or community events, beginning an exercise program and improving health, and spirituality interests such as going to church. The participant was given a form titled *Goals and Activities Worksheet* which listed goal areas, several examples, and space for recording personal goals (Appendix D). The participant was then introduced to the *Weekly Behavior Checkout* form (Appendix E), which was used to select specific activities in session and for self-monitoring of goal completion during the week. The therapist and participant selected 3-5 activities to add to the first *Weekly Behavior Checkout*. The number of activities selected was based on the number of goals identified and the patient's level of functioning. The long-term "ideal goal" for each

activity (e.g., going to church every week) was recorded next to the immediate goal for the upcoming week (e.g., visit new churches in the neighborhood or ask a friend about his church on Saturday). The participant was instructed to monitor completion of scheduled activities by circling the days of activity engagement and return the form the following week for review.

Setting and Preparing for Quit-Day. Participants were given a *Timeline Follow-Back (TLFB) Calendar* (Appendix F) to record the total number of cigarettes smoked each day. A baseline of smoking behavior for the prior week was recorded with the patient in-session using the TLFB method of Sobell & Sobell (1996). The importance of a clean environment and change of routine leading up to quit-day was discussed. The patient was instructed to clean and put away ashtrays, smoke outside, taper number of cigarettes, and delay smoking as long as possible in response to an urge. The patient was also instructed to buy new types of gum, candy, or other substitutions identified earlier in session. Most importantly, the patient was told to remove all cigarettes from the home the night before quit-day and have nicotine patches ready.

Nicotine Replacement Therapy. All participants were encouraged to use nicotine patches or nicotine gum as directed by the VA primary care smoking clinic coordinator beginning on quit-day. Participants were instructed to follow usage recommendations of the clinic coordinator and to promptly report occurrence of side-effects (e.g., nausea, dizziness, skin irritation, etc.).

Visit 2: Quit-Week

Review of Successes and Failures. The therapist reviewed homework forms with the participant with particular attention to high-risk situations and coping strategies. If the session fell on quit-day, successful strategies were reinforced and failure to quit was discussed with identification of problems and setting a new quit-date. The therapist discussed the "abstinence violation effect". The patient was reminded that one "slip" does not constitute relapse and that he should identify what led up to the act of smoking, avoid repeating the mistake, and develop a new plan for that particular "high risk" situation.

Progression of Behavioral Activation. Progress with the BA component was reviewed by examining the *Weekly Behavior Checkout* with the patient. If a goal was met the patient was praised and behavior-mood contingencies were noted. On a new Checkout form, the level of the activity was increased in order to move closer towards the ideal goal. If an activity was not completed as expected, reasons were explored and the activity was modified or eliminated and replaced with another activity on the new form.

Visit 3: Further Progress

Review of Successes and Failures. The therapist reviewed previously completed homework forms with the participant, and current high-risk situations and coping strategies were discussed. Successes were reinforced and the abstinence violation effect was reviewed. Any instances of smoking (i.e., "slips") were discussed using the functional analytic method by identifying antecedents to smoking and alternative behavioral responses. A new quit-date was set, if required.

Progression of Behavioral Activation. Progress with the behavioral activation component was reviewed by examining the *Weekly Behavior Checkout* with the patient. If a goal was met, the patient was praised and behavior-mood contingencies were noted. On a new Checkout form, level of the activity was increased in order to move closer toward the ideal goal. If an activity was not completed as expected, reasons were explored and the activity was modified or eliminated and replaced with another activity on the new form. The participant was given several additional copies of the *Weekly Behavior Checkout* in Visit 3 and instructed to continue scheduling activities, taking a step forward each week toward ideal goals. The participant was also presented with a new goal identification form labeled *Continuing Goals and Activities* (Appendix G) so that the original list of goals and activity ideas could be revised for future *Weekly Behavior Checkout* forms.

Standard Treatment (ST)

The standard smoking cessation treatment (ST) was a 3-session treatment developed for comparison with LETS-Quit. Rather than use the regular primary care smoking clinic classes as the control condition, ST was used to control for content and therapist contact time. ST included the same smoking cessation elements described in LETS-Quit but did not contain identification of life goals, activity selection, or behavioral contracting. Extra discussion time related to quitting was added to all sessions and progressive muscle relaxation was added to Visits 2 and 3 (approximately 15-25 minutes) to closely match for the extra time of behavioral activation in LETS-Quit.

Measures. Mini International Neuropsychiatric Interview (MINI). The MINI is a structured psychiatric interview used to assess for the following major DSM-IV Axis I disorders (American Psychiatric Association, 2000): Major depressive disorder, hypomanic/manic episodes, panic disorder, agoraphobia, social phobia, obsessive-compulsive disorder, generalized anxiety disorder, posttraumatic stress disorder, alcohol abuse/dependence, other substance abuse/dependence, and psychotic disorders. The MINI has shown to be valid and reliable in comparison to other DSM-IV based diagnostic measures (Sheehan et al., 2003) and have a brief time of administration (18.7 minutes, +/- 11.6 minutes).

Biological Verification: CO monitor breath samples. Expired breath carbon monoxide levels were assessed using a Bedfont Instruments Micro Smokerlyzer Carbon Monoxide Monitor. Detected values above the cutoff score of 5 ppm were considered indicative of recent smoking.

Demographics. Participants complete questions on age, ethnicity, education, occupation, income, and contact information.

Smoking History Questionnaire (SHQ). The SHQ was used to gather information about age of smoking initiation, length of smoking history, current and past smoking levels, and past quit attempts.

Fagerstrom Test for Nicotine Dependence (FTND). The FTND (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991) is a 7-item questionnaire used as a measure of nicotine dependence. The FTND has demonstrated internal consistency and reliability (Heatherton et al., 1991; Pomerleau, Carton, Lutzke, & Flessland, 1994). Among PTSD veterans (Buckley et al., 2005), the FTND has also demonstrated good test-retest

reliability (.82), convergent validity ($r = .40$ with expired CO) and divergent validity (i.e., no correlation with non-nicotine measures). Convergent validity has also been established with cotinine measures (Prokhorov, De Moor, Pallonen, Hudmon, Koehly, & Hu, 2000).

Timeline Follow-Back Interview (TLFB). The TLFB method (Sobell & Sobell, 1996) was used to track number of cigarettes smoked from Visit 1 until the last follow-up. The TLFB method has been used extensively in monitoring alcohol consumption and has shown to be a reliable and valid means of assessing alcohol outcomes (Maisto, Sobell, Cooper, & Sobell, 1979; Sobell & Sobell, 1980). In a study with smokers (Brown, Burgess, Sales, Whiteley, Evans, & Miller, 1998), the TLFB method was found to have high test-retest reliability over a 26-week period and high validity when compared to daily self-monitoring, report of significant others, and saliva cotinine measures. TLFB utilizes a calendar with key dates to facilitate the participant's recall of smoking over a specified time period. Participants were given copies of the TLFB calendar to complete during the follow-up period in order to track daily progress with quitting. However, if a participant arrived to a session without the calendar or incomplete information, a TLFB interview was conducted with him or her to gather missing information.

Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996). BDI-II was used as a measure of depressive symptoms. The BDI-II has demonstrated reliability with the BDI (.84 and .93) and other self-report and clinician-administered measures of depression (e.g., the Hamilton Rating Scales for Depression). One week test-retest reliability of .74 has been reported with a non-clinical sample (Beck, Steer, & Brown,

1996). Validity and reliability indexes for the BDI-II are excellent. In a study with primary care patients (Arnau et al., 2001), high internal consistency (Cronbach $\alpha = .94$) and criterion-related validity was demonstrated using diagnosis of major depressive disorder as the criterion.

Weekly Behavior Checkout, Goals and Activities Worksheet, and Continuing Goals and Activities. These monitoring forms were part of the behavioral activation intervention and were created based on the Brief Behavioral Activation Treatment for Depression (Lejuez et al., 2001). These materials were used to identify goals, select activities, and monitor goal completion. (Appendix D, E, G)

Environmental Reward Observation Scale (EROS). The EROS is a 10-item self-report measure that assesses general level of reward derived from daily activities (Armento & Hopko, 2007). The EROS has demonstrated good internal consistency (Cronbach $\alpha > .86$) and test-retest reliability ($r > .84$) as well as negative correlations with depression and anxiety measures. Confirmatory factor analysis demonstrated support for a unidimensional structure of the EROS. Convergent validity was demonstrated by moderate correlations with the Pleasant Events Schedule (PES; MacPhillamy & Lewinsohn, 1976), a measure of engagement in positively reinforcing activities.

Treatment Expectancy Questionnaire. This brief 3-item questionnaire was developed to assess participant expectations about the effectiveness of the treatment to be provided. The following items were rated on a 5-point Likert-type scale at the end of the first visit: "I think this treatment will help me quit smoking"; "I think this treatment will

help improve my mood"; "I expect to have a positive experience by participating".

(Appendix H)

Adherence to Nicotine Replacement Therapy. This checklist was developed to monitor participants' use of nicotine patches during treatment and follow-up to evaluate compliance with nicotine replacement therapy. Participants checked off the days they used a nicotine patch or nicotine gum during the past week. (Appendix I)

Nicotine Replacement Side-Effects Checklist. This checklist was used to monitor participants for adverse effects of nicotine replacement therapy (e.g., skin irritation, dizziness, nausea). If any significant side-effects were reported, the participant was instructed to discontinue use of the patch (or gum) and to contact the primary care smoking clinic coordinator for follow-up.

Program Evaluation Form. This 8-item questionnaire was used to evaluate participant satisfaction with services provided. Participants endorsed each item using a 4-point Likert-type scale.

Standard Treatment and LETS-Quit Integrity Checklists. Two independent raters reviewed 20% of Visit 1 therapy tapes and completed checklists to document that the elements of LETS-Quit listed above were carried out and that the ST condition did not contain behavioral activation discussion or forms. (Appendix J)

Procedure. At Visit 1, all participants completed the following measures: demographics, smoking history questionnaire, FTND, TLFB, BDI-II, EROS, and the Treatment Expectancy Questionnaire. Participants also gave a CO breath sample before the session began. Following the treatment session outlined above, participants were scheduled for their next visit and reminded to complete and return homework forms.

At Visits 2 and 3, participants gave CO breath samples and completed the following questionnaires: FTND, BDI-II, EROS, Adherence to Nicotine Replacement Therapy, and the Nicotine Side-Effects Checklist. Participants in LETS-Quit also completed the Weekly Behavior Checkout with therapist assistance if it had not been fully completed. Following the treatment session outlined above, participants were scheduled for their next visit and reminded to return completed forms.

Treatment sessions were audio taped unless the participant did not consent to taping. Twenty-percent of Visit 1 sessions were randomly selected and reviewed by an advanced graduate and undergraduate student with experience in behavioral activation. Raters used treatment integrity checklists to report treatment fidelity.

Follow-up assessments (Visits 4 and 5) were scheduled for 14-days and 30-days after quit-day. Participants were asked to give CO breath samples, complete the TLFB interview, and fill out the following questionnaires: FTND, BDI-II, EROS, Adherence to Nicotine Replacement Therapy, and the Nicotine Side-Effects Checklist. Participants were instructed to continue with plans as discussed in earlier visits and bring forms to each session, but no further help with activity scheduling was provided by the therapist during follow-up visits. Minimal support related to quit experiences was provided.

Participants were initially paid \$5 per visit for a total of \$25. Because of poor recruitment rates during the first weeks of data collection at the Washington site, compensation was increased to \$10 per visit from March – June 2006. The payment schedule at the Baltimore site was \$10 per visit with a \$5 bonus for returning completed forms to Visits 2-5 (e.g., TLFB calendar, Weekly Behavior Checkout, and other treatment forms) for a total payment of \$70 for full participation.

Chapter 3: Results

Treatment Integrity

Two students (an advanced graduate and undergraduate) with experience in delivering BA treatments rated 20% of randomly selected Visit 1 audio tapes according to checklists that outlined the treatment components of LETS-Quit and ST manuals. Both raters endorsed agreement that components specific to LETS-Quit were present only in LETS-Quit sessions. These components included 1) behavioral contracting, 2) discussion of rationale for making lifestyle changes and goal setting, and 3) completion of the Goals and Activities Worksheet and Weekly Behavior Checkout. Raters also agreed that elements intended to occur in both treatment conditions such as establishment of rapport were present in both. A high level of interjudge reliability was observed after correcting for chance (Cohen's kappa = .96).

Sample Characteristics

Demographics. Table 2 shows the demographics of all participants completing the 3 treatment sessions ($n = 21$) and a direct comparison of the characteristics of participants in LETS-Quit and ST groups. While there were no statistically significant differences between groups on any demographic characteristic, it should be noted that only 18% of LETS-Quit participants were married compared to 50% in ST. It is also notable that none of the LETS-Quit participants had lower than a high school education compared to 30% of ST individuals. There were no statistically significant differences between sites.

Pretreatment Smoking Characteristics. At baseline, the overall sample reported smoking a mean 17.2 cigarettes ($SD = 11$) per day in the last week with a 29.7 year ($SD = 10.2$) history of regular smoking. The sample reported a history of previous serious quit attempts ($M = 3.3$, $SD = 2.5$) with a mean 2.1 quit attempts ($SD = 1.6$) of at least 12 hours abstinence. Baseline smoking characteristics, including nicotine dependence (FTND) and age of smoking initiation, did not differ between LETS-Quit and ST groups. There were also no differences noted between sites on smoking characteristics.

Baseline Psychiatric Characteristics. As shown in [Table 3](#), 73% of participants in LETS-Quit and 78% of control participants had a current diagnosis of mood disorder. Diagnoses obtained through MINI neuropsychiatric interview were cross-referenced with the patient's computerized medical chart. If a discrepancy was noted between a MINI diagnosis and one listed in the patient's medical chart, MINI diagnosis was used unless the chart diagnosis had been established by formal psychological or psychiatric assessment. A total of 12 participants (6 in each group) were currently prescribed an antidepressant medication. No participants were receiving psychotherapy without conjunctive antidepressant treatment. In both LETS-Quit and ST, 2 of the 6 participants prescribed an antidepressant medication were taking bupropion SR. Other antidepressant prescriptions included sertraline, venlafaxine, citalopram, and paroxetine. There were no statistically significant differences in psychiatric characteristics between sites.

Attrition

A total of 5 participants failed to complete treatment. Four of the treatment dropouts only completed Visit 1 and the fifth participant completed Visits 1 and 2. Four

of the dropouts had been assigned to LETS-Quit. All treatment dropouts were African-American (vs. 62% of completers) and older ($M = 53.3$, $SD = 6.8$ vs. $M = 48.0$, $SD = 7.7$), but were otherwise similar to treatment completers.

Nicotine Patch Use

A total of 12 participants used nicotine patches beginning with quit-week (6 in each condition). By Visit 4, one participant in the ST condition was no longer using nicotine patches because of smoking relapse. At Visit 5, only 5 participants reported current use of nicotine patches (4 in LETS-Quit and 1 in ST). Both participants in LETS-Quit who stopped using patches had resumed regular smoking. Three of the four participants in ST who had stopped using patches by Visit 5 had also resumed regular smoking, whereas the fourth participant remained abstinent without continuing use of nicotine patches. None of the participants reported using nicotine gum.

Abstinence and CO verification

Participants were considered abstinent at each time-point if they reported no instance of smoking during the interval since the prior visit and had a current CO monitor reading between 0-5 ppm. Continuous abstinence was defined as no instance of smoking during the entire 30-day follow-up period. At no time did a participant report abstinence and have a current CO reading above 5 ppm. Among participants reporting at least one instance of smoking during the preceding interval, current CO breath samples were > 5 ppm in 68% of cases.

Correlation between Depression and Smoking

Table 4 shows correlations between BDI-II scores and key smoking variables across time-points in the overall sample. Strong negative point-biserial correlations were noted between smoking abstinence and BDI-II scores beginning with quit-week. These data suggested that participants with lower depressive symptoms were more likely to be abstinent at each follow-up period and also were more likely to maintain abstinence throughout the duration of the study. Data indicating the relationship of depression and smoking as a function of group are presented below.

Effect of Treatment on Smoking Outcome

Smoking Abstinence Rates. Point-prevalence smoking rates for 7-day, 14-day, and 30-day post-quit visits are presented by treatment group in Figure 1. Only 2 participants in LETS-Quit and ST maintained continuous abstinence by 30-day follow-up (18% vs. 20%, respectively). A total of three individuals in each group reported smoking ≤ 1 cigarette during the entire 30-day follow-up (27% vs. 30%, respectively). No statistically significant differences were noted between treatment groups in 7-day [$\chi^2(1) = .019, p = .89$], 14-day [$\chi^2(1) = 1.15, p = .28$], or 30-day [$\chi^2(1) = .44, p = .51$] point-prevalence abstinence rates. It is notable that participants in LETS-Quit appeared to improve over time with 27% point-prevalence at 14-day follow-up that increased to 55% by 30-day (all participants at 14-day had a 30-day visit). Mean FTND scores at each time-point are presented in Table 5. No significant between group differences were noted in FTND scores at any time-point.

Time to First Smoking Lapse. Time to first smoking lapse was defined as the number of days between the participant's quit-date and the first instance of smoking. No mean group differences in time to first smoking lapse were observed, $t(15) = -.079$, $p = .938$. Range of time to first smoking lapse was 0-8 days in LETS-Quit ($M = 2.4$ days, $SD = 2.8$) and 0-18 days in ST ($M = 2.6$ days, $SD = 6.2$). No significant correlations were observed between time to first lapse and BDI-II, EROS, or FTND in either treatment group or in the overall sample.

Effect of Treatment on Depressive Symptoms

BDI-II scores at baseline ranged between 12-56 in the overall sample and did not differ between treatment groups, $t(19) = 0.457$, $p = .653$. Mean BDI-II scores at each time-point are presented by group in [Table 5](#). From baseline to 30-day follow-up, participants in LETS-Quit reported a 10.6 point decline in BDI-II score ($SD = 5.5$) compared to a mean change of 4.1 points in ST ($SD = 8.8$). This represented a large effect size of LETS-Quit on depressive symptoms (Cohen's $d = .90$). [Figure 2](#) illustrates change in BDI-II scores across time-points for both groups. A repeated-measures ANOVA was conducted by treatment group. Mauchly's test indicated the assumption of sphericity had been violated; therefore, degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity ($\epsilon = .49$). The group x time-point interaction was non-significant [$F(2, 35) = 2.8$, $p = .08$]. An overall within-subject effect was observed across time-points [$F(2, 35) = 12.4$, $p < .001$], indicating a decrease in depressive symptoms across visits. Given the limited power to detect the interaction, change in depressive symptoms across visits was explored separately within each group.

Results indicated a significant change in depressive symptoms across time-points in LETS-Quit [$F(2, 15) = 16.1, p < .001$]. A significant change in depressive symptoms was not observed in ST [$F(2,17) = 1.6, p = .24$].

To evaluate whether depression diagnosis or antidepressant medication significantly confounded the relationship between treatment group and depressive symptoms, an ANCOVA analysis was conducted using these two variables and baseline depression as covariates. Results indicated that there was no significant effect of treatment on Visit 5 BDI-II when controlling for baseline depression, depression diagnosis, and antidepressant medication. Furthermore, neither depression diagnosis ($p = .45$) or antidepressant medication ($p = .94$) accounted for a significant portion of variance.

Relationship between Depressive Symptoms and Smoking Abstinence

Logistic regression was used to test whether baseline depressive symptoms (Visit 1 BDI-II) could predict continuous abstinence. As presented in Table 6, baseline depressive symptoms did not significantly predict abstinence ($p = .40$). A similar absence of findings was obtained using baseline BDI-II to predict time to first smoking lapse. Visit 2 BDI-II also did not significantly predict continuous abstinence ($p = .07$). As shown in Table 7, continuous abstinence could be predicted by depressive symptoms at Visit 3, the last treatment session ($p = .04$).

Level of Reinforcement Reported from Activities

Mean EROS scores are presented by group in Table 5. The EROS was significantly correlated with BDI-II scores ($p < .05$) at Visit 1 ($r = -.53$), Visit 3 ($r = -.46$), Visit 4 ($r = -.72$), and Visit 5 ($r = -.64$). From baseline to 30-day follow-up, a 3.2 point increase in EROS was noted in LETS-Quit ($SD = 4.2$), compared to a 1.4 point increase for ST participants ($SD = 2.3$). This represented a medium-sized effect of LETS-Quit (Cohen's $d = .52$). While it was expected that LETS-Quit participants would rate higher levels of reinforcement from activities based on their engagement in behavioral activation, no significant group x visit interaction was observed in repeated-measures ANOVA [$F(4,72) = 0.7, p = .60$]. A significant within-subjects effect was observed [$F(4, 72) = 4.5, p < .01$], indicating that EROS scores increased across visits in the overall sample. Given the limited power to detect the interaction, we also examined change in EROS across visits separately for each group. Change of EROS in LETS-Quit nearly achieved statistical significance [$F(4, 36) = 2.7, p = .05$] and similar results were observed in ST [$F(4, 36) = 2.6, p = .06$]. EROS did not predict continuous smoking abstinence in logistic regression at any time point (all p 's $> .05$).

Chapter 4: Discussion

The present study sought to develop and evaluate the feasibility of a BA treatment approach to smoking cessation for depressed patients at two VA medical centers. The goal of the study was to successfully adapt an 8-week BA intervention designed for community participants into a brief format that can be administered by VA mental health and primary care providers. The decision to reduce LETS-Quit to 3 treatment sessions

was based, in part, on discussions with the smoking clinic coordinator at the Washington, D.C. site who reported poor clinic attendance and high attrition rates with longer programs. Thus, the lengthier BA smoking intervention was reduced by editing the text of the manual, eliminating excess materials (i.e., handouts and homework forms), and simplifying core materials in new homework forms (Appendices A-G). Revisions continued until the treatment could be delivered in pre-quit, quit-date, and post-quit sessions, with each session approximately one hour in length. The degree of acceptability appeared to be high with 83% of participants who attended the first two treatment sessions completing all remaining visits.

Participants in LETS-Quit also appeared to be highly involved in the BA component of the program. Participants completed nearly 64% of the weekly goals they scheduled in their first two visits. LETS-Quit participants endorsed high treatment satisfaction on a program evaluation questionnaire completed at the final visit, and no differences in satisfaction were noted between LETS-Quit and the control group, suggesting that the additional efforts required of patients in LETS-Quit did not adversely affect its appeal to patients. These findings suggest that the addition of BA to smoking cessation was well accepted by participants. In light of prior research that indicates high attrition and poor smoking outcomes can be expected in VA samples with high rates of substance abuse and psychiatric disorders (Grant et al., 2003; Saxon et al., 2003), acceptable attrition rates and high patient satisfaction with LETS-Quit suggest that this treatment approach may be a welcome alternative to longer interventions with lower tolerability.

Main Outcomes

While a small sample size limited power to properly investigate treatment effects, there were no group differences in smoking outcomes. Point-prevalence smoking rates achieved at 30-day follow-up in LETS-Quit and ST (55% vs. 40%, respectively) appeared consistent with 30-day point prevalence data reported by Brown and colleagues (2001) in their behavioral treatment study (38% vs. 33%). The literature on VA smoking interventions indicates that long-term cessation rates among those receiving primary care services is approximately 12% (Joseph, Arikian, et al., 2004). Specialized smoking interventions that involve counseling and pharmacotherapy also produce modest 1-year abstinence rates. In one such intervention, nearly half of the participants failed to quit smoking for even a single day and only 24% of those achieving one day of abstinence successfully maintained abstinence long-term (Kennedy et al., 2004). Cessation rates among depressed VA patients are likely to be much lower than suggested by these data given the role of depression in smoking outcome (e.g., Burgess et al., 2002; Catley et al., 2005; Kinnunen et al., 1996). Thus, preliminary findings on short-term abstinence rates achieved by LETS-Quit in this difficult population are promising and suggest that future data collection is warranted to evaluate long-term outcomes.

In merely three sessions of treatment, the BA component of LETS-Quit acted as a powerful means of reducing depressive symptoms, producing a large effect ($d = .90$). The magnitude of this effect was similar to the effect size of .87 reported by Cuijpers and colleagues (2007) in a recent meta-analysis of 16 studies of BA treatment for depression. As these authors aptly noted, the effect sizes achieved by BA interventions are comparable to those of other psychological treatments and BA requires far less time and

therapist expertise to deliver. The finding that LETS-Quit produced a similar effect size in this pilot study with limited follow-up support is of note. Reductions in depressive symptoms are likely to benefit depressed smokers in quitting and findings suggested that LETS-Quit has potential value. Whether LETS-Quit produces lasting changes in behavior and mood without extended therapist assistance is unclear and may be addressed by future research.

In the present study, baseline symptoms did not predict smoking outcome. This finding was consistent with the results of others (Catley et al., 2005; Hayford et al., 1999; Killen et al. 2000; Niaura et al 1999; Vazquez & Becona, 1999). Repeated-measures analysis demonstrated a significant decrease in depressive symptoms across visits in LETS-Quit. Lower BDI-II scores appeared to predict abstinence at 7-day, 14-day, and 30-day follow-up in the overall sample. Brown and colleagues (2001) also found that declining depressive symptoms predicted abstinence in both their CBT treatment group and control condition.

The literature on the relationship between depressive symptoms and smoking outcome is difficult to interpret. Lifetime MDD has proven to be a poor predictor of smoking cessation (Hitsman et al., 2003) and focus has turned to the importance of baseline depressive symptoms (Kinnunen et al., 1996) and patterns of change (Burgess et al., 2003; Catley et al., 2005). These data point to the importance of examining change in depression across the initial weeks of treatment. Burgess and colleagues (2002) have shown that there is considerable heterogeneity in how depressive symptoms change during a quit attempt. Approximately 47% of depressed smokers in their sample experienced improvement in depression during treatment and maintained higher rates of

abstinence. The results of the present study appeared consistent with previous findings and demonstrated that lower BDI-II scores during treatment and follow-up predicted abstinence at each time-point as well as continuous abstinence.

The question of whether changes in depressive symptoms mediate the relationship between LETS-Quit and smoking outcome could not be adequately addressed by the current study. While it appeared that LETS-Quit had a large effect on depression and that change in depression was associated with smoking abstinence, LETS-Quit did not improve smoking outcome when compared to a control intervention. Furthermore, it would not be possible to uncover the direction of a relationship between depression and cessation without the ability to test mediation models. Successful treatment of depression may mediate smoking abstinence, but it also remains likely that abstainers feel less depressed because they have quit. They may feel rewarded by their efforts, have increased self-efficacy, and report improvements in physical health.

A moderate effect ($d = .52$) was observed for LETS-Quit participants to report a greater level of reinforcement from activities, and reliable negative correlations between BDI-II and EROS scores were observed. This was an interesting finding to support the theory that the mechanism of action in behavioral interventions for depression is getting patients into contact with reinforcing experiences in their environment. It is also interesting to speculate that greater reinforcement from one's environment produced by healthy lifestyle changes in BA might help smokers quit. LETS-Quit participants appeared to learn that completion of personalized activities had corresponding effects on mood. The idea of improving mood by doing more of what is enjoyed in life was intuitive and easily accepted by participants.

Limitations

There are several limitations of the present study that should be discussed in addition to inadequate power. A follow-up period of only 30-days was a significant limitation. The goal of any cessation intervention is long-term maintenance of treatment gains. Due to the time costs inherent in seeking institutional approval in medical settings, limited opportunity for recruitment and data collection, as well as limited personnel resources, a longer follow-up period was not possible. It can be expected that 30-day abstinence rates would decline with a longer follow-up period. The conventional follow-up period for similar studies wishing to demonstrate long-term treatment gains appears to be 6 months (Catley et al., 2005; Covey et al., 1999; Glassman et al., 1993) or 12 months (Brown et al., 2001; Ginsberg et al., 1995; Hall et al., 1996; Hayford et al., 1999).

Another consideration was potential researcher bias in the delivery of the two treatments. The lead author served as therapist for both treatment conditions. Integrity checklists helped ensure that basic elements of treatment were either present or absent when participants were presented with the treatment rationale and majority of instruction. Raters also reported that rapport was established in both conditions at Visit 1. The stringent control group comparison was considered a notable strength of the study. The ST group was roughly matched to LETS-Quit for therapist contact and involved more contact time than typically received by VA patients in primary care walk-in smoking cessation classes. Comparison of LETS-Quit to a treatment-as-usual control group may have increased the likelihood of finding a treatment effect, but interpretation would have been limited by differences in therapist contact time, as well as other therapist and contextual factors. At least one research group has demonstrated that amount of therapist

contact time significantly influences smoking outcome for depressed smokers (Hall et al., 1994; Hall et al., 1996). Whether LETS-Quit significantly improves long-term smoking outcome will need to be explored in future research using larger samples with similarly stringent control comparisons.

Research has tended to support the notion that smokers with a history of depression who are least likely to remain abstinent experience dysphoria after quitting (Ginsberg et al., 1995; Hall et al., 1996; Rausch et al., 1990). A limitation of the current study is that the BDI-II was the only mood measure used. Inclusion of a measure designed for current dysphoria such as the Profile of Mood States (POMS; McNair et al., 1971) or the Positive and Negative Affect Schedule (PANAS; Watson, Clark, & Tellegen, 1988) would have been useful as a predictor of smoking outcome. Additionally, it might have been interesting to have included measures of quality of life to assess the degree to which the treatment effects of LETS-Quit extended beyond symptomatic relief of depressive symptoms.

Another limitation was inconsistent use of nicotine patches across treatment groups. Only 12 participants used NRT beginning with quit-week and only 6 of these individuals used NRT consistently immediately following their quit-date throughout the study. Two participants using the patch maintained continuous abstinence. NRT is an effective smoking cessation aid, but it also has antidepressant effects (Salin-Pascual, Rosas, Jimenez-Genchi, Rivera-Meza, & Delgado-Parra, 1996). As Covey et al. (2004) have argued, NRT should no longer be considered a mood inert control condition. Thus, the disproportionate use of NRT represents a significant confound with respect to both depression and smoking outcome data. The decision to encourage, but not require,

participants to use nicotine patches was made because NRT represents standard care in VA medical centers and the literature suggests that success is associated multi-modal treatments (e.g., Kennedy et al., 2004). It must be noted that participants who resumed smoking after their quit-date had to stop using NRT. Therefore, NRT failure was not considered treatment non-adherence. It is also interesting to note that participants who did not use NRT had good compliance with other aspects of treatment. In future protocols, it may be decided to either require or disallow NRT as a provision of study participation.

A decision requiring interpretation is the effect of antidepressant medication on depressive symptoms and smoking outcome. Participants prescribed antidepressant medications at baseline were not excluded from participation. It would not have been possible to exclude depressed smokers receiving treatment for depression due to high utilization of mental health services by VA patients. However, it was assumed that antidepressant pharmacotherapy remained relatively consistent throughout the course of participation and was unlikely to account for the observed changes in depressive symptoms. Two of the 4 participants prescribed bupropion (1 in each group) achieved abstinence at the 30-day time-point. Bupropion is an antidepressant medication with demonstrated efficacy in smoking cessation, producing a 3-fold increase in abstinence rates when combined with the nicotine patch (Jorenby et al., 1999). Whether bupropion added to treatment of depression or smoking cessation was not clear based on present data. To avoid potential influence on outcome, it will be necessary to exclude participants taking antidepressant medications in future studies, particularly medications with proven efficacy in smoking cessation.

Conclusions and Future Directions for a VA LETS-Quit Intervention

Based on initial findings, development and evaluation of LETS-Quit is planned to continue. With respect to future treatment development, it may be beneficial to consider extending LETS-Quit by additional treatment sessions to maximize therapeutic gains while maintaining brevity. Some participants may have benefited from having two pre-quit sessions and an additional week to prepare for quit-day. This would have also allowed for greater progression with BA before reaching quit-day. Secondly, an additional treatment session occurring at 14-day post-quit may be advantageous for strengthening relapse prevention and increasing the likelihood that participants continue BA beyond the treatment phase. It would not be necessary to add materials to the program to include these additional sessions. The added therapy time would be used to review smoking and BA experiences during the preceding week through functional analysis of successes and failures and more discussion of the participant's path to achieving life goals by using BA materials. As one example, lengthening the program from 3 to 5 sessions would not significantly increase the complexity of the intervention, but would instead provide greater support and review.

LETS-Quit might also be successfully translated into a group format to further increase its economical value. Group treatment would require longer sessions for sufficient time to review each participant's smoking experiences and weekly activities. However, group treatment may offer certain advantages such as the sharing of social support related to quitting, help in identifying BA activities, and possibly greater compliance with treatment goals. However, due to the highly personalized nature of the program, it likely would be difficult to work with groups larger than 3-4 participants.

The current data served as an interesting pilot study for exploring the feasibility of a BA-based smoking cessation program with VA patients. The primary purpose of the study was to develop an easily disseminated BA treatment based on a lengthier intervention. VA patients have complex medical and psychiatric histories, higher rates of smoking, and require brief treatment approaches. Importantly, administration of LETS-Quit appeared feasible in a setting of limited resources and high patient acceptance was noted. Pilot data also suggested that higher rates of abstinence may be possible in comparison to current VA smoking interventions. Despite modest smoking outcomes that did not differ from a control group, the effect of LETS-Quit on depression suggests that additional investigation of a BA approach to smoking cessation is warranted in a more powerful study with a longer follow-up phase.

Table 1: *Assignment to Therapy Condition Based on Mood Disorder Diagnosis and Current Antidepressant Medication with Participant ID Number Listed .*

| Diagnosis (Y) Medication (Y) | Diagnosis (Y) Medication (N) | Diagnosis (N) Medication (Y) | Diagnosis (N) Medication (N) | Therapy Condition |
|---------------------------------|---------------------------------|---------------------------------|---------------------------------|------------------------------|
| 101 | 113 | | 102 | LQ |
| 104 | 118 | | 103 | ST |
| 107 | 119 | | 108 | LQ |
| 109 | 123 | | 110 | ST |
| 114 | | | 111 | LQ |
| 115 | | | 112 | ST |

Table 2: *Demographics of the Total Sample (n=21), LETS-Quit (n=11), and Standard Treatment Control Group (n=10).*

| | Total Sample (n = 21) | LETS- Quit (n = 11) | Standard Treatment (n = 10) |
|---------------------------|-----------------------------|---------------------------|-----------------------------------|
| Mean Age (<i>SD</i>) | 48.0 (7.7) | 47.0 (8.4) | 49.2 (7.2) |
| Male | 18 (86%) | 9 (81%) | 9 (90%) |
| Marital Status | | | |
| Single | 9 (43%) | 7 (73%) | 2 (22%) |
| Living with Partner | 3 (14%) | 2 (18%) | 1 (11%) |
| Married but Separated | 2 (10%) | -- | 2 (22%) |
| Married | 7 (33%) | 2 (9%) | 5 (50%) |
| Ethnicity | | | |
| African-American | 13 (62%) | 7 (55%) | 6 (60%) |
| Caucasian | 7 (33%) | 3 (36%) | 4 (40%) |
| Asian-American | 1 (5%) | 1 (9%) | -- |
| Education | | | |
| Some High School | 2 (10%) | -- | 2 (20%) |
| GED | 1 (5%) | -- | 1 (10%) |
| High School Grad | 7 (33%) | 5 (46%) | 2 (20%) |
| Some College | 6 (28%) | 4 (36%) | 2 (20%) |
| Technical/Business School | 5 (24%) | 2 (18%) | 3 (30%) |
| Currently Employed | 11 (52%) | 5 (45%) | 6 (60%) |
| Median Annual Income | \$20k-\$29k | \$20k-29k | \$20k-29k |

Note: No statistically significant differences observed between groups for any variable presented above.

Table 3: *Prevalence of Current Axis I Psychiatric Diagnoses among LETS-Quit and Standard Treatment Control Participants.*

| | LETS-Quit (n=11) | Standard Treatment (n=10) |
|---|---------------------|------------------------------|
| Total Mood Disorder | 9 | 7 |
| Major Depression | (5) | (6) |
| Bipolar Disorder | (2) | (1) |
| Dysthymia | (1) | (0) |
| Schizoaffective Disorder | (1) | (0) |
| Mood Disorder Plus Other Diagnosis | 5 | 6 |
| Total Anxiety Disorder | 3 | 4 |
| PTSD | (2) | (2) |
| Social Phobia | (1) | (0) |
| Panic Disorder | (0) | (1) |
| Generalized Anxiety Disorder | (0) | (1) |
| Total Substance Use Disorder | 3 | 6 |
| Within Last Year | (1) | (2) |
| In Remission | (2) | (4) |
| Participants with at Least One Psychiatric Diagnosis | 9 (82%) | 9 (90%) |

Table 4: *Correlation of Depression and Smoking Variables in the Total Sample.*

| | Visit 1 | Visit 2 | BDI-II Visit 3 | Visit 4 | Visit 5 |
|--|---------|---------|--------------------------|---------|---------|
| Time to First Smoking Lapse^a | .05 | .15 | .16 | .26 | .09 |
| Point-Prevalence Abstinence^b | | | | | |
| Visit 2 (Quit) | -.04 | -.14 | -.06 | -.14 | -.06 |
| Visit 3 (7-Day) | -.16 | -.38 | -.45* | -.53* | -.40 |
| Visit 4 (14-Day) | -.20 | -.45* | -.49* | -.54* | -.42 |
| Visit 5 (30-day) | -.37 | -.58** | -.64** | -.70** | -.63** |
| Continuous Abstinence^b | -.20 | -.45* | -.53* | -.57** | -.50* |

Note: ^a Pearson correlation, ^b point-biserial correlation, * $p < .05$, ** $p < .01$.

Table 5: Mean (SD) Values for Outcome Measures Across Time-Points for LETS-Quit and Standard Treatment (ST).

| | Visit 1 (Pre-Quit) | Visit 2 (Quit-Week) | Visit 3 (7-Day) | Visit 4 (14-Day) | Visit 5 (30-Day) |
|---|-----------------------|------------------------|--------------------|---------------------|---------------------|
| FTND | | | | | |
| LETS-Quit | 6.1 (2.9) | 5.0 (3.3) | 3.6 (4.0) | 1.8 (3.4) | 2.7 (3.9) |
| ST | 4.0 (3.5) | 3.5 (3.5) | 2.5 (3.6) | 2.7 (3.8) | 3.1 (4.0) |
| BDI-II | | | | | |
| LETS-Quit | 25.8 (14.5) | 20.1 (12.1) | 17.7 (11.3) | 16.6 (12.5) | 15.2 (13.1) |
| ST | 23.3 (10.1) | 20.9 (11.6) | 20.6 (12.8) | 19.3 (13.8) | 19.2 (13.3) |
| EROS | | | | | |
| LETS-Quit | 22.5 (5.6) | 23.8 (3.1) | 24.5 (4.3) | 26.0 (3.4) | 25.6 (4.3) |
| ST | 24.6 (2.7) | 25.6 (2.6) | 25.0 (2.9) | 27.0 (3.7) | 26.0 (3.7) |
| Program Evaluation Questionnaire | | | | | |
| LETS-Quit | | | | | 25.9 (4.0) |
| ST | | | | | 26.7 (4.8) |

Note: No statistically significant differences observed between groups for any variable presented above. FTND = Fagerstrom Test for Nicotine Dependence; BDI-II = Beck Depression Inventory-II; EROS = Environment Reward Observation Scale.

Table 6: *Logistic Regression Model for Predicting Smoking Abstinence as a Function of Baseline BDI-II Score.*

| | <i>B (SE)</i> | <i>p</i> value | Lower | 95% CI for exp <i>b</i> Exp <i>b</i> | Upper |
|----------------|---------------|----------------|-------|---|-------|
| Constant | -.14 (1.52) | .93 | | | |
| Visit 1 BDI-II | -.06 (.07) | .40 | .82 | .94 | 1.08 |

Note $R^2 = .07$ (Nagelkerke). Model $\chi^2 (1) = .988, p = .32$.

Table 7: *Logistic Regression Model for Predicting Smoking Abstinence as a Function of Visit 3 BDI-II Score.*

| | <i>B (SE)</i> | <i>p</i> value | Lower | 95% CI for exp <i>b</i> Exp <i>b</i> | Upper |
|----------------|---------------|----------------|-------|---|-------|
| Constant | 2.17 (1.58) | .17 | | | |
| Visit 3 BDI-II | -.29 (.14) | .04 | .56 | .75 | .99 |

Note $R^2 = .58$ (Nagelkerke). Model $\chi^2 (1) = 9.44, p = .002$.

Figure 1: *Point-Prevalence and Continuous Abstinence Rates in LETS-Quit and Standard Treatment.*

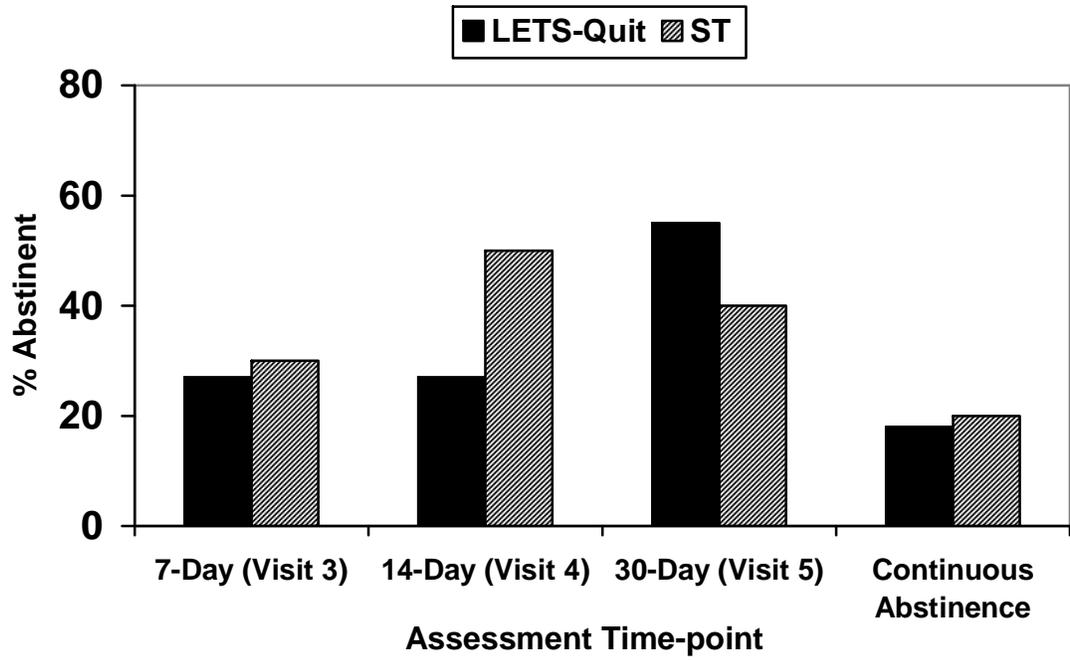
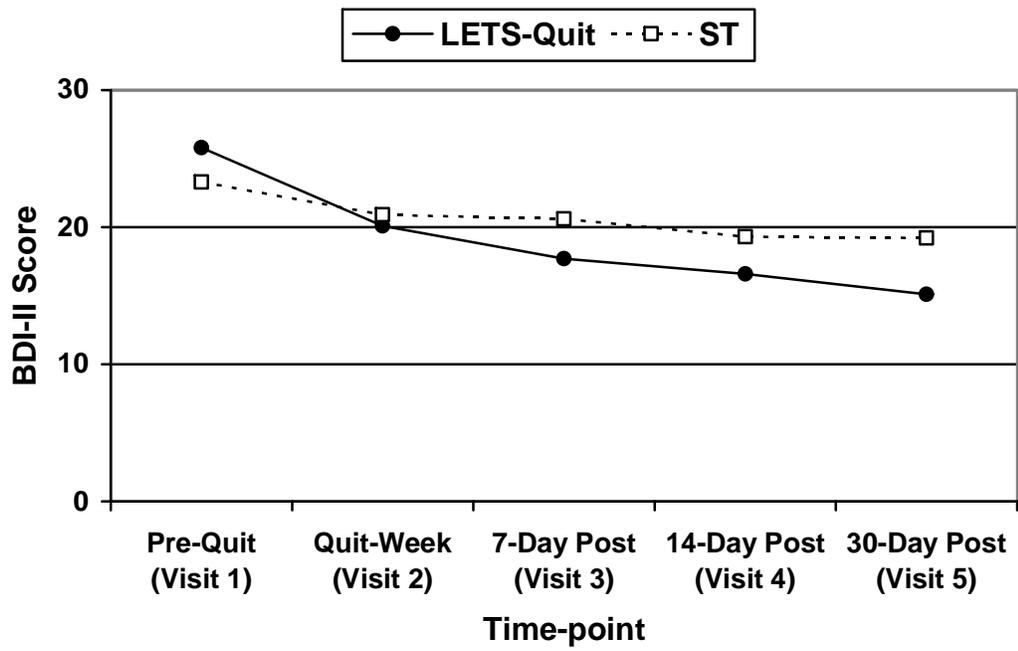


Figure 2: Mean BDI-II Scores for LETS-Quit and Standard Treatment across Visits 1-5.



Why Quit? Why Quit Smoking Questionnaire



In order to quit smoking, it is important to think about your reasons for making this change. For this exercise, consider **reasons to quit smoking**, and any **reasons to continue smoking**. Try to be as specific as possible.

Reasons to Quit

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

Reasons to Smoke

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____



“High-Risk Situations” for Smoking

Think about the different times or situations in which you usually smoke.

For example, these situations may involve a time of the day, a stressful thought or feeling, or being around others who smoke.

We call these behaviors, thoughts, and moods “**High-Risk Situations for Smoking**” because they trigger the urge to smoke.

Identify your own high risk situations. Describe the event or the feeling that makes you want to smoke. List specific coping strategies you will use to avoid smoking in each situation.

Key Words: Avoid, Alter, Substitute.

High Risk Situation

Specific Coping Strategies

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

Appendix C

LETS-Quit Social Support Contract

Name of family member/friend/significant other

1) Things this person does that are helpful to your not smoking. (Keep it up!)

2) Things this person does that are NOT helpful to your quit attempt. (Stop doing this!)

3) Other things this person can do that would be helpful for you to stay quit. (Please help!)

Has _____ read and agreed to the above? _____

His or Her Signature: _____

Your Signature: _____

Appendix D
Goals and Activities Worksheet

Instructions: Consider activities that you would like to accomplish in these life areas.

1. Family Relationships. For example: Spending more time with spouse or child, weekend calls to a family member.
2. Social Relationships. For example: Meeting new friends, increasing activities with old friends.
3. Intimate Relationships. For example: Increasing activity with significant other, dating someone new if single.
4. Education/Training. For example: Taking a new class for work or just for fun.
5. Employment/ Career. For example: Are you interested in a new job? What would that be?
6. Hobbies/ Recreation. For example: learning an instrument, playing cards, bowling, pool, fishing, hiking, joining a club or league.
7. Volunteer Work/ Charity/ Political Activities. For example: volunteer at a community center, fundraiser, or church.
8. Physical/ Health Issues. For example: morning walks, biking, eating a healthy lunch at your favorite restaurant.
9. Spirituality. For example: attending church services, reading books about spirituality or other religions.



Now list some of the ideas you have so we can identify your long-term goals:

Appendix E
Weekly Behavior Checkout
 For the Week of: _____

| <u>Activity</u> | <i>Ideal goal (freq and duration)</i> | <u>This week's goal</u> | <u>Mon.</u> Done? | <u>Tues.</u> Done? | <u>Wed.</u> Done? | <u>Th.</u> Done? | <u>Fri.</u> Done? | <u>Sat.</u> Done? | <u>Sun.</u> Done? | Check if weekly goal met |
|------------------------|---------------------------------------|--------------------------------|------------------------------|-------------------------------|------------------------------|-----------------------------|------------------------------|------------------------------|------------------------------|--------------------------|
| | | | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | _____ |
| | | | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | _____ |
| | | | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | _____ |
| | | | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | _____ |
| | | | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | Yes or No | _____ |

Appendix F
Timeline Follow-Back Calendar

Instructions for Filling Out the Timeline Cigarette Use Calendar

To help us evaluate your cigarette use, we need to get an idea of what your smoking was like in the past ____ days. To do this, we would like you to fill out the attached calendar.

- ✓ Filling out the calendar is not hard!
- ✓ Try to be as accurate as possible.
- ✓ We recognize you won't have perfect recall. That's OKAY.

✓ **WHAT TO FILL IN**

- The idea is to record how many cigarettes you smoked for **each day** on the calendar.
- On days when you **did not smoke cigarettes**, not even one, you should write a "0."
- We realize it isn't easy to recall things with 100% accuracy.
- If you are not sure whether you smoked 15 or 16 cigarettes or whether you smoked on a Thursday or a Friday, give it your best guess! What is important is that 15 or 16 cigarettes is very different from 1 cigarette. The goal is to get a sense of how frequently you smoked and your patterns of smoking.

It's important that something is written for every day, even if it is a "0".

✓ **YOUR BEST ESTIMATE**

- We realize it isn't easy to recall things with 100% accuracy.
- If you are not sure whether you smoked 15 or 16 cigarettes or whether you smoked on a Thursday or a Friday, **give it your best guess!** What is important is that 15 or 16 cigarettes is very different from 1 cigarette. The goal is to get a sense of how frequently you smoked and your patterns of use.

✓ **HELPFUL HINTS**

- If you have an appointment book you can use it to help you recall your use.
- Holidays such as Thanksgiving and Christmas are marked on the calendar to help you recall your smoking. Also, think about how much you smoked on personal holidays & events such as birthdays, vacations, or parties.
- If you have **regular patterns to your smoking**, you can use these to help you recall your use. For example, some people may only smoke during social situations.

✓ **COMPLETING THE CALENDAR**

- A blank calendar is attached. Write in the number of cigarettes you smoked on **each day**.
- The time period we are talking about on the calendar is
 from _____ to _____
- In estimating the number of cigarettes you smoked, be as accurate as possible.
- **DOUBLE CHECK THAT ALL DAYS ARE FILLED IN BEFORE RETURNING THE CALENDAR.**
- Before you start look at the **SAMPLE CALENDAR**

✓ **SAMPLE CALENDAR**

| | SUN | MON | TUES | WED | THURS | FRI | SAT |
|---|----------|-------------------|----------|----------|----------|----------|----------|
| | | | | | | 1 20 | 2 0 |
| S | 3 20 | 4 Labor Day 20 | 5 23 | 6 28 | 7 21 | 8 20 | 9 23 |
| E | 10 20 | 11 20 | 12 20 | 13 28 | 14 25 | 15 0 | 16 24 |
| P | 17 20 | 18 20 | 19 20 | 20 20 | 21 22 | 22 22 | 23 24 |
| T | 24 21 | 25 22 | 26 26 | 27 24 | 28 23 | 29 0 | 30 22 |

Appendix G
Continuing Goals and Activities
Refer back to your original goals and activities worksheet

Instructions: Consider additional goals you have in the major life areas.

1. Family Relationships. _____

2. Social Relationships. _____

3. Intimate Relationships. _____

4. Education/Training. _____

5. Employment/ Career. _____

6. Hobbies/ Recreation. _____

7. Volunteer Work/
Community Activities. _____

8. Physical/ Health Issues. _____

9. Spirituality. _____

Now based on these goals, list some activities you can add to future Behavior Checkouts:

| Life Area # | Activity |
|-------------|----------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

Appendix H

Treatment Expectancy Questionnaire

Please rate whether you agree or disagree with the following statements using this scale:

- 1) definitely disagree
 - 2) disagree
 - 3) not sure
 - 4) agree
 - 5) completely agree
-

1. I think this treatment will help me quit smoking. _____

2. I think this treatment will help improve my mood. _____

3. I expect to have a positive experience by participating. _____

Appendix I

Adherence to Nicotine Patch or Gum Questionnaire

1. If you are using the patch, what is level of current patch: _____ mg.
2. Think back over the past 7 days. Please check off the days you used the patch or gum:

Monday _____

Tuesday _____

Wednesday _____

Thursday _____

Friday _____

Saturday _____

Sunday _____

Appendix J

Treatment Integrity Checklists (ST)

Subject ID number: _____

Rater: _____

Session 1

Check if met

1. Presented/discussed “Reasons to Quit” _____
2. Outlined benefits of quitting _____
3. Discussed past quit attempts _____
4. Discussed high-risk situations and coping _____
5. Discussed getting social support _____
6. Did NOT discuss rationale of making
“life style changes” _____
7. Did NOT present Activity Identification/
Behavioral Checkout Sheet _____
8. Discussed setting quit day and
preparing for quit day _____
9. Discussed information on nicotine patches _____
10. Did the therapist develop rapport? _____

Total: ____/10

Treatment Integrity Checklists (LETS-Quit)

Subject ID: _____

Rater: _____

Session 1

Check if met

1. Presented/discussed “Reasons to Quit” _____
2. Outlined benefits of quitting _____
3. Discussed past quit attempts _____
4. Discussed high-risk situations and coping _____
5. Discussed getting social support/
Behavioral Contract _____
6. Discussed rationale of making
“life style changes” and goal setting _____
7. Presented Activity Identification & how to do
Behavioral Checkout Sheet _____
8. Discussed setting quit day and
preparing for quit day _____
9. Discussed information on nicotine patches _____
10. Did the therapist develop rapport? _____

Total: ____/10

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