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SAN DIEGO STATE UNIVERSITY

Effects of Proactive Telephone Counseling on

Cessation Rates of Smokers with Major Depression

A dissertation submitted in partial satisfaction of the requirements for the degree Doctor

of Philosophy

in

Clinical Psychology

by

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2010

The Dissertation of Kiandra K. Hebert is approved, and it is acceptable in quality and

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TABLE OF CONTENTS

LIST OF TABLES

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Zhu, S.H., Hebert, K., Wong, S. Cummins, S., & Gamst, A. (2010). Disparity in smoking prevalence by education: Can we reduce it? *Global Health Promotion, Supp 1,* 29–39.

Hebert, K.K., Hernandez, S., Cummins, S.E., Tedeschi, G.j., & Zhu, S.H. Major Depressive Disorder among Smokers Using a State Quitline (submitted). *American Journal of Preventive Medicine.*

ABSTRACT OF THE DISSERTATION

Effects of Proactive Telephone Counseling on

Cessation Rates of Smokers with Major Depression

by

Kiandra K. Hebert

Doctoral of Philosophy in Clinical Psychology

University of California, San Diego, 2010

San Diego State University, 2010

Professor Shu-Hong Zhu, Chair

Smokers with depression are less likely to quit smoking. Recently a state quitline found 1 in 4 callers met criteria for current major depression and were significantly less likely to quit smoking. The present study tested an enhanced telephone counseling protocol where counselors proactively called to provide additional sessions of telephone counseling targeting mood management in an attempt to improve quit rates. The study's aims were to demonstrate smokers would participate in significantly more sessions and to improve quit rates for smokers receiving the enhanced protocol. The goal was to increase the quit rate by 10 percentage points in the enhanced treatment (ET) compared to the standard treatment (ST), but the study was not powered at a sample size to demonstrate a statistically significant difference. It was determined a minimum of a 5 percentage point increase in quit rate was necessary for it to be clinically meaningful. A total of 92 smokers with current major depression were randomized into the two groups. The ST consists of up to 5 sessions over a 1 month period. The ET includes additional content on

mood management and up to 15 counseling sessions over a 2 month period. Current depression was measured by Patient Health Questionnaire mood module (PHQ-8) at intake. Smokers in the ET received on average 3 more counseling sessions than the standard protocol (6.8 vs. 3.6, p<0.01). At the three month follow up, participants in the ET quit smoking at a higher rate than those in the ST with 7-day point prevalence quit rate, 29.4% vs. 17.5% and 30-day, 17.7% vs. 12.5%, respectively. Fewer of those in the ET met criteria for current major depression at follow-up (14.7% vs. 28.2%). These differences were not significant due to the small sample size but the study met all the goals established during the study's design. The results of the study show the promise of providing additional mood management counseling to smokers with current major depression helping to further a larger research agenda to improve quit rates among smokers with depression calling the 50 U.S. state quitlines which collectively serve a large number of smokers each year (> 400,000 annually).

Effects of Proactive Telephone Counseling on

Cessation Rates of Smokers with Major Depression

Introduction

Smokers are more likely to be depressed than nonsmokers (Anda et al., 1990; Wilhelm, Wedgwood, Niven, & Kay-Lambkin, 2006). Studies have found smokers with depression are less likely to quit (Berlin & Covey, 2006). Studies which have tried to improve quit rates among smokers with indictors of depression have achieved mixed results (Haas, Muñoz, Humfleet, Reus, & Hall, 2004). Most intervention studies, however, have excluded smokers with current major depression. Several intervention studies have examined whether specialized interventions can improve quit rates among smokers with a history of major depression. Yet a history of depression was found not to predict worse quitting outcomes across cessation treatment studies (Hitsman, Borrelli, McChargue, Spring, & Niaura, 2003). This may help to explain the mixed results found in intervention studies targeting this subpopulation. This has led to the recommendation intervention studies should instead focus on improving outcomes for smokers with current depression (Muñoz et al., 2006). In the past few years, the cessation treatment field has begun to address how to help those with current mental health problems quit smoking. Although some clinical studies may screen out those with current depression, there are other settings which are obligated to serve a wider population of smokers. One of these settings is state quitlines which collectively serve about 400,000 smokers annually (Cummin, Bailey, Campbell, Koon-Kirby, & Zhu, 2007). State quitlines provide free telephone counseling and materials to help smokers quit. Generally state

quitlines have not assessed for depression yet are likely providing services to a large number of depressed smokers.

Recently, the California Smokers' Helpline (CSH) assessed for current major depression among callers. CSH is a Substance Abuse and Mental Health Services Administration (SAMHSA) model program which serves over 30,000 smokers annually. The study found 24.2% of smokers calling CSH met criteria for current major depression (Hebert et al., submitted). Smokers with current major depression were significantly less likely to have quit by two month follow-up compared to those not meeting criteria for major depression when treated under the quitline's standard counseling protocol (18.5% vs. 28.4%, P=.03). This finding suggests a need to develop a specialized protocol to improve quitting among smokers with current major depression calling the CSH.

Smokers with current major depression receive services through the CSH but are not benefiting as much as those without depression. This provides a setting where an intervention can be developed and tested to improve quitting outcomes among a subgroup of smokers who are not as likely to quit when provided the standard services. This type of study is important as there is no established telephone counseling cessation interventions for smokers with current depression. These considerations prompted the development of a telephone counseling treatment protocol aimed at improving quitting outcomes for smokers with current major depression at CSH.

Increasing the intensity of services provided has been one approach leading to improved quitting outcomes among quitline users (Stead, Perera, &Lancaster, 2007; Zhu et al., 1996). Mood management counseling has also been used in targeting smokers with

depression (Hitsman et al., 2003; Hall et al., 2006). The enhanced protocol developed increased the number and length of counseling sessions and addressed ways to improve the smoker's ability to cope with depressed mood using cognitive-behavioral strategies.

In this study, ninety-two smokers endorsing depression at screening were randomly assigned to receive the enhanced treatment (ET) or the standard treatment (ST). A three month follow-up evaluation assessed quitting, mood, and service satisfaction outcomes. The study examined the feasibility of whether those in the enhanced treatment protocol were receptive to receiving additional counseling sessions. The study also looked at the effect of the ET on quitting outcomes compared to ST, although was not powered to achieve statistical significance. Additionally, those in the enhanced treatment were hypothesized to show improvements in mood and satisfaction with the services received. If the study's aims are met it will help support continuing this line of research in order to establish an efficacious quitline treatment protocol for depressed smokers.

This project is an important step in establishing a well-specified and novel telephone counseling treatment protocol for smokers with current depression. This study provides guidance for developing larger scale studies to try to improve outcomes among smokers with depression. The long term objectives of this research agenda are to improve treatment options and outcomes for smokers with current depression by creating a tailored telephone counseling protocol. Potentially CSH and other state quitlines could offer this protocol to callers in order to improve the quality of treatment and quit rates. This research agenda also has clinical implications for how to improve quit rates among smokers with mental health problems.

Developing an intervention to improve quitting outcomes among a subpopulation at increased risk of continued smoking is consistent with the goals of CSH improve quitting outcomes and services. Quitline research has focused on developing practical interventions protocols which can be tested within the context of a quitline allowing for improved translation of research into practice (Lichtenstein, Zhu, & Tedeschi, 2010). The CSH is the first and largest quitline which has been a leader in the widespread adoption of the service across the United States and abroad. An effective intervention developed at the CSH could be quickly adopted by other quitlines. Large scale use of a protocol which improves outcomes for a considerable subpopulation of smokers would have important public health benefits in decreasing the overall prevalence of cigarette smoking.

Depression among Smokers

Depression is one of the psychiatric disorders most frequently associated with cigarette smoking in adults (Glassman, 1993; Grant, Hasin, Chou, Stinson, & Dawson, 2004). There have been studies that have examined the relationship of negative affect, depressive symptoms, current major depressive disorder, and a history of major depression to smoking. Studies have varied in the types of assessments used and depression subtype measured. It is important to differentiate the way depression is being defined. For example, having current depression may be related to smoking more strongly than a history of depression.

Several early studies found smokers had significantly higher lifetime rates of major depression than nonsmokers (Breslau, Kilbey, & Andreski, 1991; Cohen, Schwartz, Bromet, & Parkinson, 1991; Kendler et al., 1993). In a catchment area survey,

the prevalence rate of lifetime major depression among ever smokers was 10% compared to 2.9% among never smokers, and 5% in the general population (Glassman et al., 1990). Additionally, lifetime major depression has been associated with being more nicotine dependent and a heavier smoker (Breslau, 1995; Kendler et al., 1993). Lifetime rates of major depression have been found to be particularly high among smokers seeking cessation treatment (22%-61%) (Ginsberg, Hall, Reus, & Muñoz, 1995; Glassman et al., 1988; Hall et al., 1996; Hall, Muñoz, & Reus, 1994; Hall et al., 1998) which is considerably higher than rates in the general population (13-17%) (Hasin, Goodwin, Stinson, & Grant, 2005; Lasser et al., 2000). Overall, these findings suggest smokers are more likely to have experienced major depression in their lifetime compared to nonsmokers. It is likely the factors influencing this relationship are complex with smoking increasing the risk of becoming depressed, depression vulnerability increasing the likelihood of smoking, and depression making it more difficult to quit.

Epidemiological studies have examined whether there is a higher incidence of current major depression among smokers compared to nonsmokers. In an Australian survey, smokers were more than 2.5 times as likely to have current major depression (past 30 day) compared to those who had never smoked (Wilhelm, Mitchell, Slade, Brownhill, & Andrews, 2003). In the National Household Survey on Drug Abuse, the rates of major depression (past 12 months) varied by smoking status, with 15% among dependent smokers, 8% nondependent, 5.8% former, and 4.7% among never smokers (Kandel, Huang, & Davies, 2001). This trend was confirmed in the National Epidemiologic Survey on Alcoholism and Related Conditions where the rate of major depression (past

12 months) was 16.6% among dependent smokers, 12% among daily smokers, 6% among nonsmokers (Grant et al., 2004; Husky, Mazure, Paliwal, & McKee, 2008). Another study using the 2006 Behavioral Risk Factor Surveillance System found adults who had current depression were significantly more likely than those without current depression to be smoking (37.9 vs 17.6) (Strine et al., 2008). A significant dose-response relationship between depression severity and smoking was also found with the highest rates of smoking found among those most severely depressed. There is also evidence current smokers are more likely to have symptoms of depression than non-smokers (Anda et al 1990; Campo-Arias, Martinez, & Rueda Jaimes, 2004; Haukkala, Uutela, Vartiainen, McAlister, & Knekt, 2000; Salive & Blazer, 1993; Son, Markovitz, Winders, & Smith, 1997).

It is difficult to determine whether there is a higher rate of current major depression among smokers seeking treatment as most studies screen out those meeting current criteria. A few studies on smoking cessation have provided estimates of the rates of current major depressive episode among those seeking help including several internet-based self-help smoking cessation trials with findings ranging from 11.4-23.8% (Muñoz et al., 2006; Muñoz et al., 2009). Overall the literature suggests smokers are more likely to have depression both in terms of a history of and current problems. It also appears smokers with current depression seek help to quit smoking.

Depression and Cessation

Depression has been associated with worse cessation outcomes (Berlin & Covey, 2006; Covey, Glassman & Stetner, 1998; Niaura et al., 2001; Cinciripini et al., 2003;

Ginsberg et al., 1995; Killen et al., 1996; Kinnunen, Doherty, Militello, & Garvey, 1996).

Again a distinction should be made between current and past (lifetime or history) major

depression in studies examining the relationship to quitting. Often the term depression

gets used without clearly differentiating whether it is major depression or subclinical

levels of depressed mood. Although there is some evidence a history of major depression

is associated with worse quitting outcomes, there appears to be stronger evidence for the

negative impact of current depression on quitting outcomes.

There is conflicting evidence for the relationship between a history of major

depression and smoking cessation outcomes. Some surveys have found lifetime major

depression is predictive of cessation outcomes (Glassman et al., 1990) while others have

not supported this result (John, Meyer, Rumpf, & Hapke, 2004a; John, Meyer, Rumpf, &

Hapke, 2004b). In some cessation trials, smokers with a history of major depression are

less likely to quit (Covey, Glassman, Stetner, & Becker, 1993; Glassman et al., 1993;

Glassman et al., 1988) while other studies have only found a trend towards significance

(Ginsberg et al., 1995; Hall et al., 1994). A meta-analyses of 15 studies concluded there

was no difference in abstinence rates between smokers with and without a history of

depression (Hitsman et al., 2003). Most studies were not designed to test whether a

history of depression influenced outcomes so most of the studies included active

cessation treatments. In re-analyses including only smokers in the control conditions, a

history of major depression was still not predictive of cessation outcomes (Covey,

Bomback, & Yan, 2006). Some have suggested a distinction needs to be made between

those with a history of a single episode of major depression and those having two or more

episode in the past. There is evidence recurrent major depression is a stronger predictor of lower quit rates (Brown et al., 2001; Ginsberg et al., 1995; Glassman et al., 1993). Overall, these findings suggest history of depression is not very predictive of worse quitting outcomes and more informative predictors such as current symptoms should be investigated (Hitsman et al., 2003).

Several epidemiological studies support current major depression being associated with worse cessation outcomes. The National Comorbidity Survey found the quit rate for those with current major depression (past month) was 26% compared to 42.5% among those with no mental illness (Lasser et al., 2000). The survey found the quit rate for those with a history of major depression was 38% which is similar to the rate for those without mental illness. This study suggests quit rates were more impaired by current major depression more than past episodes. A limitation of survey data is the reliance on retrospective reports of quitting and possible recall biases. It could also be complicated by smoking increasing the risk of having current depression. For example, a study examining a population-based registry of female twins found average lifetime daily cigarette consumption was strongly related to prospectively assessed 1-year prevalence of major depression (Kendler et al., 1993). This study further supports the high rate of comorbidity found between depression and smoking may be a result of a bidirectional relationship where smoking worsens mood and low mood makes it more difficult to quit.

Other studies have examined the impact of current depressive symptoms on quitting. A study of patients enrolled in drug or alcohol treatment who were trying to quit found those with fewer depressive symptoms were more likely to quit (Sonne et al.,

2010). A study found symptoms of depression predicted time to relapse after quitting

(Niaura et al., 2001). A number of prospective cessation treatment studies have found

pretreatment depressed mood predicts worse cessation outcomes even though these

studies excluded those with current depression (Berlin & Covey, 2006; Cinciripini et al.,

2003; Hall et al., 1993; Kinnunen et al., 1996). This suggests even when excluding those

with the most severe depression, smokers with less severe symptoms of depression are

still less likely to quit than those without current symptoms. There is also evidence the

negative effect of depressed mood on quitting is stronger in smokers with a history of

major depression than for smokers without a history of major depression (Hall et al.,

1994). This may partially explain why smokers with a history of major depression have

worse cessation outcomes since they tend to have higher levels of negative affect than

those without a history of major depression (Ginsberg et al., 1995; Hall et al., 1994).

Studies that have focused on smokers with a history of major depression who do not meet

current criteria and often find smokers with more severe depressive symptoms at baseline

are less likely to quit (Dalack, Glassman, Rivelli, Covey, & Stetner, 1995).

Depression may affect cessation outcomes due to a higher risk of relapse. When

compared to other symptoms of withdrawal, negative affect is consistently the strongest

predictor of relapse vulnerability (Kenford et al., 2002; Piasecki et al., 2000). In

retrospective studies, smokers report smoking lapses often occur in situations involving

negative moods such as anxiety, anger, and depression (Brandon, Tiffany, Obremski, &

Baker, 1990; Shiffman, 1982). Additionally, lapses which occur during negative affect

situations are more likely to lead to complete relapse (O'Connell & Martin, 1987). Since

withdrawal symptoms include depressed mood, quitters are at increased risk for experiencing depression. Smoker who experience greater depressed mood after quitting are more likely to relapse (Covey, Glassman, & Stetner, 1990; Ginsberg et al., 1995) and smokers with a history of major depression are more likely to report depressed mood during the week after quitting (Covey et al., 1990; Ginsberg et al., 1995).

There have been only a few treatment studies which have compared quitting between smokers with and without current depression (Muñoz, Marin, Posner, & Perez-Stable, 1997; Muñoz et al., 2006; Muñoz et al., 2009). In several internet based trails, smokers with current major depressive were less likely to quit in several trials (Muñoz et al., 2006). A study of hospitalized patients found a current diagnosis of major depression predicted relapse to smoking 6 months post discharge (Perez, Nicolau, Romano, & Laranjeira, 2008).

The review of the literature suggests current symptoms of depression may be a stronger predictor of lower quit rates than a history of major depression. Despite the relationship between depression and difficulties quitting, most cessation programs do not assess for depression. When treatment studies have assessed for current major depression it was usually in order to exclude these smokers from the study. It is somewhat unclear why most cessation trials have excluded smokers with current major depression. One rational for exclusion may be an assumption those with current major depression would be unable to quit. There may have been a concern including smokers with current depression would reduce the overall quit rate making the intervention appear less effective. Another concern may have been depressive symptoms would worsen after a

quit attempt. Some have recommend those with a current diagnosis should focus on getting help for their mental health problems prior to getting help with quitting.

There are many settings serving smokers with current depression yet there is limited research available to help these smokers. Some studies which included those with current depression have shown they are able to quit and may do better with treatment (Hall et al., 2006; Muñoz et al., 1997; Thorsteinsson et al., 2001). As for concern about worsening depressive symptoms during a quit attempt, a recent study found no difference in reoccurrence or worsening symptoms in smokers with current depression who quit or continued smoking (Prochaska et al., 2007). Additionally, the serious risk smoking poises to individual's health questions whether temporarily worsening of mood is worth the cost of not trying to quit (Prochaska et al., 2007). There have been recent recommendations that smoking cessation programs address needs specific to those who have mental illness (Lucksted, Dixon, & Sembly, 2000; Van Dongen, 1999). The increased attention to mental health problems has led to some community based programs assessing for depression.

Cessation Treatments for Smokers with Depression

The relationship between depression and lower quit rates has prompted researchers to try to improve quitting outcomes among smokers with major depression. The majority of this research has screened out smokers meeting criteria for current depression with studies instead focusing on improving quitting among smokers with a history of major depression. As mentioned, this may be due to research being conducted in freestanding clinics and not wanting to treat acutely ill patients (Hall, 2007). There

may also be a belief those with current major depression will be unable to quit and should not make an attempt when they are at increased likelihood to fail. There could be a concern that including smokers with major depression would reduce a study's overall quit rate.

Several studies have examined the hypothesis cognitive behavioral therapy (CBT) for mood management could improve cessation outcomes among smokers with a history of major depression. Although studies have provided some support for the hypothesis, there have been mixed results and limitations. Smokers with a history of depression and alcohol dependence had better cessation outcomes in cognitive behavioral mood management treatment compared to a behavioral skills control group (Patten, Martin, Myers, Calfas, & Williams, 1998). Since all participants had a history of depression it is unclear whether the beneficial impact of CBT mood management training was specific to this group or would be beneficial to smokers in general.

There were a series of studies by Hall et al. examining group CBT for mood management aimed at improving cessation outcomes among smokers with a history of major depression (1994, 1996, & 1998). Improved effects were only found when the CBT conditions provided more sessions than the control conditions making it unclear whether the specific content was the cause of the effect (Hall, 2007). The studies used 2 x 2 design assigning smokers to cessation medication or placebo and one of the counseling conditions. In the first study with nicotine gum, a 10 session mood management treatment was compared to the standard 5 session cessation treatment (Hall et al., 1994). Smokers with a history of major depression had a significantly higher rate of

abstinence in the mood management treatment than in the standard treatment (34% vs. 18%). There was no difference in abstinence rates between the two conditions for smokers with no history of major depression. The CBT condition did not affect mood after quitting. A criticism of the study was confounding contact time and specific therapeutic content, since the conditions differed across both dimensions. This makes it unclear whether the improvement was a result of the different therapeutic content or increased contact.

A follow-up study equated contact time to try to isolate the effect of the mood management content (Hall et al. 1996). The study assigned smokers to nicotine gum and placebo and counseling conditions. Both intervention groups received 10 sessions over 8 weeks and both interventions helped smokers develop a personalized plan to quit smoking. However, the mood management group also focused on developing skills to cope with depressive symptoms which can occur with quitting smoking (Hall et al., 1996). Although the study found participants who had a history of major depression had more depressive symptoms after quitting, there was no difference in quitting outcomes between the intervention groups either for the overall sample or for those who had a history of major depression. The study found an increase in negative mood immediately after quitting predicted smoking at follow-up.

A third study compared nortriptyline and placebo and counseling conditions where time was not controlled for (Hall et al., 1998). Once again, smokers with a history of major depression were more successful in the 10 sessions of mood management than 5 session of health education. Smokers without a history of major depression were equally

successful in the two treatments. Overall, these studies suggest additional contact time rather than the content of the sessions resulted in improved cessation outcomes (Brown et al., 2007). Analyses pooling the data across these three studies found a history of depression did not predict abstinence (Haas et al., 2004). For smokers with a history of recurrent major depression (more than one past episode) there was a higher rate of abstinence in the CBT compared to the control conditions even when controlling for current mood. Smokers with recurrent major depression had greater depressive symptoms compared to those with no history or only one past episode of major depression. Mood was a significant predictor of abstinence only when history of major depression was not controlled for. These findings suggest current symptoms likely influence quitting outcomes. This suggests providing additional support through more counseling sessions may be an important component in improving quitting outcomes among smokers with depression vulnerability.

Other research further supports the hypothesis CBT may be differentially effective for smokers with a history of recurrent depressive episodes rather than a single episode. A standard cessation treatment was compared to providing additional cognitive behavioral therapy components for depression in smokers with a history of major depression (Brown et al., 2001). Both treatment conditions provided eight two-hour sessions so were equated for contact time. Overall, the CBT treatment did not produce significantly higher cessation rates compared to the standard treatment. Subgroup analyses revealed smokers with a history of recurrent depressive episodes had higher abstinence rates in the CBT group compared to the standard treatment. A subsequent

study with bupropion and placebo used group treatments which were again equated for contact (twelve 90 minute sessions) and compared the cessation treatment that addressed depression to standard cessation treatment (Brown et al. 2007). This study found additional mood management treatment was not more effective than the standard treatment for the overall sample, for smokers with a single past episode of major depression, recurrent major depression, or elevated depressive symptoms. These findings may have been due to the low rate of recurrent major depression and depressive symptoms in the sample (Brown et al., 2007).

A problem with these studies is not focusing on smokers with depression. Most of these studies excluded those meeting criteria for current depression. Then the study tried to do subgroup analyses looking at those with a history of major depression or subclinical levels of depressive symptoms. A meta-analysis across these treatment studies found a history of major depression did not predict worse cessation outcomes (Hitsman et al., 2003). Further analyses found a history of major depression was not predictive even when including only those in the control treatment conditions (Covey et al., 2006). It is difficult to obtain a significant improvement for a subpopulation of smokers with a specialized treatment if the subpopulation is not doing worse than the general sample of smokers in the standard treatment. Recurrent major depression appears to be a stronger predictor of cessation outcome but this may because smokers with recurrent major depression have more severe current problems with mood. Those with only a single past episode of major depression may have less of the characteristics of depressive thinking and behaving which are targeted in the mood management

interventions. Although there were some indication those with more depressive

symptoms at baseline benefited more from mood management intervention these finding

may have been more robust and consistent if the samples were not limited in the severity

of current symptoms by excluding those with current major depression.

There have been limited studies looking at differential treatments effects for

smokers with current depression. One study, which did not exclude smokers with current

major depression, found a mailed written and audiotape mood management and cessation

treatment for Spanish-speaking Latino smokers had better 3 month cessation outcomes

compared to the smoking cessation guide alone (Muñoz et al., 1997). Those with a

history of major depressive episodes had a higher abstinence rate in the mood

management condition but there was no significant difference found for smokers with

current depression. The authors hypothesized individuals in the midst of a major

depressive episode do not have the energy to follow through with using a self help tool

supported by data showing dropouts from the study tended to have a higher depression

scores. There was also only a small sample size of smokers with current depression

especially after drop outs. Depression levels were not significantly reduced for those in

the mood management condition although there was a trend towards improvement. The

intervention not improving depressed mood may help to explain why there was no

significant difference in quitting among those currently depressed. In an internet based

study, two conditions with additional mood management methods did not yield higher

abstinence rates in those with past or current major depressive disorder compared to the

standard smoking cessation intervention (Muñoz et al., 2009). Another internet study,

however, found smokers with low positive affect assigned to a mood-management intervention had better 12 month abstinence than those assigned to the standard condition (Branstrom, Penilla, Perez-Stable, & Muñoz, 2010). A study of pregnant women found women with higher levels of baseline depressive symptoms treated with a cognitive behavioral intervention were significantly more likely to quit and have less depressive symptoms compared to those who received a health and wellness intervention (Cinciripini et al., 2010). Overall, these studies suggest the possible benefit of depression focused treatment in terms of improved smoking abstinence.

A study which focused on smokers with current major depression provided cessation treatment for outpatients with current depressive disorders who were receiving mental health services (Hall et al., 2006). Depressed smokers were assigned to a stepped care intervention or brief contact control. The intervention included staged care intervention with computerized motivational feedback and those in at least the contemplation stage were provided with additional services including nicotine patches and six sessions of smoking cessation counseling which included mood management content. The stepped care intervention was found to significantly increase abstinence rates (Hall et al., 2006). This study is one of the few intervention studies to treat smokers with current major depression and it had a sufficiently large sample size (N=322). It offered additional help to the intervention group without attempting to identify the specific treatment components responsible for success. Further, it took a broader public health approach by emphasizing the processes of getting currently depressed smokers into cessation treatment and providing them with effective help. Smokers with current

major depression were actively recruited, in contrast to previous studies that did subgroup analyses on smokers with subclinical symptoms or a history of depression.

To summarize, studies have mainly focused on smokers with a history of major depression which could be a possible explanation for mixed findings. It is less likely a specialized treatment would improve outcomes for smokers with a history of major depression if this variable is not a strong predictor of lower quit rates (Hitsman et al., 2003; Covey et al., 2006). Studies that did find differential effects provided more intensive treatment in addition to addressing ways for smokers to better manage depressed mood making it unclear whether the content alone would improve outcomes.

It is difficult to equate for the amount of contact time between a standard cessation treatment and providing additional intervention for mood management. In the Hall et al. study where both groups received ten sessions, the standard treatment included five sessions of health education (1996). If the standard condition spends the equated contact time discussing quitting, then the treatment group which provides additional mood management counseling would have to spend less time discussing smoking. Another consideration is the difficulty in smoking cessation treatments to increase the amount of contact beyond a certain number of sessions since it may be hard to keep people engaged in discussing the same topic of smoking.

Most of the studies examining mood management intervention in combination with smoking cessation treatment utilized a group setting. Group treatments require significant resources and may have limited impact outside of specialized smoking

cessation programs. In cessation treatment, it can be difficult to personalize treatment as there is usually a quit date set for the group.

Previous findings suggest future research should include smokers with current depression. Interventions for smokers with depression seem to be most likely to have a beneficial effect when they are both more intensive and include mood management components. In order to increase the quit rate of smokers with depression it is important to first establish those with depression are less likely to quit than those without depression. Based on previous research, current major depression may be a better predictor of difficulty quitting. Also the intervention studies support that increasing the intensity of services for smokers with depression may be an important component in effecting quitting outcomes. Most studies have focused on group intervention which limits the ability to tailor treatment to the individual smokers. The current study will address many of these issues by being conducted in a setting that already serves smokers with current depression. This study will include only those smokers with current major depression, attempt to increase the intensity of services through more counseling sessions, and be able to tailor the counseling through individual counseling.

Importance of Helping Smokers Quit

It is important to continue to develop interventions to help smokers quit. Smoking is the leading cause of preventable death and disability in the United States, accounting for over 440,000 deaths each year (CDC, 2005; Mokdad, Marks, Stroup, & Gerberding, 2004; USDHHS 2004). Smoking is estimated to be the cause of at least one-third of all cancer deaths in the United States and significantly increases the risk of heart

disease, stroke, and chronic obstructive pulmonary disease (USDHHS, 2000). Quitting

can significantly reduce the negative health risks associated with smoking (Doll, Peto,

Boreham, & Sutherland, 2004; IARC 2007; Kenfield, Stampfer, Rosner, & Colditz,

2008; Taylor et al, 2002). The negative health impacts of smoking and benefits of quitting

have led to increased support for smoking cessation research (Fiore et al., 2008b;

USDHHS, 2004). Despite the high desire among smokers to quit (70%), the one year quit

rate in the general smoking population is about 4-5% with approximately 90-95%

quitting on their own (Fiore et al., 2009). Although there is concern quitting can increase

depression, one study found no difference in depressive symptoms for those who did or

did not quit (Prochaska et al., 2007). The potential discomfort and worse mood caused

by quitting must be considered in contrast to the severe health impacts of continued

smoking. Additionally some studies have suggested that after initial withdrawal, overall

mood improves (Wilhelm et al., 2006). Developing effective interventions for depressed

smokers to improve quit rates could reduce the likelihood of death in this population.

Quitlines

Telephone counseling has been shown to be an effective way to deliver cessation

treatment to large numbers of smokers (Stead et al., 2007; Zhu et al., 2002). State

quitlines are free services which provide callers with telephone cessation counseling and

materials. State quitlines have a large reach serving over 400,000 smokers annually, yet

until recently there has been no systematic assessment of depression among callers

(Hebert et al., submitted). It is not clear how many smokers who are calling are

depressed and whether depression is related to lower quit rates in this population. The

association between depression and smoking found in epidemiological surveys suggests

quitlines are providing services to a large number of depressed smokers each year. The

large size and reach of quitlines make them well suited for carrying out tests of

behavioral interventions. To increase the impact of quitlines, one approach is to improve

effectiveness. One means of doing this is to identify subgroups of smokers who may

benefit from additional counseling (Lichtenstein et al., 2010). Smokers with current

depression may be a subgroup which would benefit from additional counseling. This

would have both practical value to quitlines and theoretical value for the smoking

cessation field. The large number of smokers served through quitlines allows for the

assessment of tailored intervention for subpopulations of smokers which would be

difficult to carry out in other settings. The findings from these large scale studies could

have implications for how to treat smokers in smaller clinic settings. Additionally,

quitlines use structured protocol which improves consistency across counselors making

sure each call is focused and covers the content areas. A structured specialized

intervention developed in a quitline could be quickly applied to other programs

nationwide.

There is extensive support for the efficacy and effectiveness of telephone quitlines

(Stead et al., 2007; Zhu et al., 2002). There have been three separate meta-analyses which

have supported the efficacy of telephone counseling for smoking cessation. The original

meta-analysis across 11 studies found those using quitline services were 30% more likely

to be abstinent at short term follow up and 20% after a year (Lichtenstein, Glasgow,

Lando, Ossip-Klein, & Boles, 1996). Another meta-analysis conducted as part of the

Clinical Practice Guidelines, reviewed 26 studies and concluded telephone counseling for

smoking cessation has established efficacy (Fiore, 2000a). The most recent meta-analyses

by the Cochrane Review further supported proactive cessation telephone counseling to be

able to increase success by 50% (Stead et al., 2007). Additionally, the strongest evidence

is for multisession, proactive protocols where the counselor initiates follow-up calls.

Across the meta-analyses the efficacy of telephone counseling was established and the

magnitude of the effect was equivalent to face to face interventions. Additionally,

telephone counseling has been found to be superior to cessation treatment provided

through primary care (An et al., 2006).

Quitlines are highly utilized, with the current U.S. state quitlines collectively

serving about 400,000 smokers each year (Cummins, Bailey, Campbell, Koon-Kirby, &

Zhu, 2007). Several studies have shown smokers are much more likely to choose

telephone services over face-to-face counseling (McAfee, Sofian, Wilson, & Hindmarsh,

1998; Zhu, Anderson, Johnson, Tedeschi, & Roeseler, 2000). Delivering counseling over

the telephone, allows smokers easier assess to the service (Shepard, 1987; Haas,

Benedict, & Kobos, 1996). Many smokers do not seek help due to cost, transportation

difficulties, inability to take time off from work, childcare concerns, inadequate

availability of non-English services, and concern about the stigma of seeking treatment

(Blumenthal, 2007; Myers, 2004). Telephone counseling is able to overcome many of

these barriers making services more accessible to underserved populations. Also if

smokers need additional help over time they can call back to reinitiate counseling

(Lichtenstein et al., 2010). This is important with a behavior such as smokers where multiple attempts to quit may be required before long term abstinence in achieved.

The greater accessibility of quitlines has resulted in a greater diversity of participants since it appeals to many smokers who would not seek services otherwise (Keller et al. 2007; McAfee 2007). Also having centralized locations allows some state quitlines to offer counseling in multiple languages more easily than cessation clinics. Studies have shown quitlines are effective in reaching African American, Latino, and smokers from rural areas, groups traditionally known to be less likely to seek treatment (Zhu et al., 1995). A study found CSH was utilized by young adult smokers living in poorer communities, which has been a difficult to reach population (Cummins, Hebert, Anderson, Mills, & Zhu, 2007). Utilization of quitlines is highly sensitive to advertising and marketing (Cummings, Sciandra, Davis, & Rimer, 1993; Pierce, Anderson, Romano, Meissner, & Odenkirchen, 1992). The sensitivity to media increases the ability of telephone counseling to be a cost effective and flexible means of delivery cessation treatments with the ability to target high risk and underserved populations of smokers who are difficult to treat.

Since quitlines provide help over the phone, they can have centralized operations with greater quality control and efficient use of resources. The large numbers of callers and ease of monitoring services allows ongoing assessment of services, evaluation of outcomes, and integration of research findings into practice (Anderson & Zhu, 2007; Cummins et al., 2007).

Quitlines' efficacy, ability to reach large numbers of smokers, and cost effectiveness led to the services being further integration into a comprehensive tobacco control program (Anderson & Zhu, 2007). Proactive telephone counseling for smoking cessation has received strong recommendations from the U.S. Public Health Service as a means of increasing access to evidence-based smoking cessation treatment (Fiore, 2000a; Fiore, 2000b).

There are quitlines available in all 50 states with a nationwide toll-free number (1-800-QUIT-NOW) which can be used by tobacco users from any state to be connected to services (Anderson & Zhu, 2007; Cummins et al., 2007). There are also quitline services in Europe along with UK Quit which is a broadly accessible telephone service (Lichtenstein et al., 2010). There are also quitlines available throughout Canada, Australia, and New Zealand (Borland, Segan, Livingston, & Owen, 2001). In Asian there are national quitlines in several countries. There are even some quitline operations in South Africa and in parts of South America (Lichtenstein et al., 2010). Consortia have been formed in North America and Europe to facilitate dissemination (Campbell et al. 2007; Bateman & Crone 2006). There has been increased information exchange among quitlines since the formation of the North American Quitline Consortium (NAQC, 2009). This wide spread reach and collaboration among quitlines means an effective counseling protocol for currently depressed smokers that is tested in the context of a quitline service would stand a strong chance of getting adopted quickly.

California Smokers' Helpline

The California Smokers' Helpline (CSH) was the first state quitline in the United States which has been in operation since 1992. It has played a strong role in showing the effectiveness of telephone counseling and increasing the reach of quitline services (Zhu et al., 2002). The CSH has taken a leadership role in disseminating effect telephone counseling protocols (Zhu et al., 2000). This has implication for the current examination of an enhanced protocol which has a good chance of being adopted by other quitlines if shown effective at CSH.

The CSH is administered by the Cancer Center at the University of California, San Diego. Program services are free and provide individual counseling, self help materials, and information related to tobacco cessation to over 30,000 smokers per year (Zhu et al., 2000). The large number of smokers which utilize the service each year shows the potential impact of an intervention which can improve quitting outcomes for a substantial subpopulation of smokers.

CSH's accessibility helps it reach diverse and underserved populations. Hispanic, African American, and Asian smokers are less likely to seek cessation services in the community, yet these ethnic groups are well represented among Helpline callers (Zhu, 1998). The Helpline provides services in six of the state's most common languages, including English, Spanish, Korean, Vietnamese, Mandarin, Cantonese, and has a TDD line for the hearing-impaired (Zhu et al., 2000). CSH is able to recruit large numbers of smokers including subpopulations of smokers which might be difficult to recruit in the community (Zhu et al., 2000). The Helpline has developed culturally sensitive counseling as well as specialized interventions to serve its diverse populations. CSH

closely integrates research and practice to better understand smoking behavior and improve cessation services. This allows results obtained from large trials to provide strong support the interventions tested are actually helpful.

In the proposed study, a new mood management protocol will be compared against the standard counseling protocol at the California Smokers' Helpline. CSH standard protocol provides multiple proactive counseling sessions which have been demonstrated in multiple randomized trials to be an effective intervention (Zhu et al. 1996; Zhu et al. 2002). Thus, the mood management protocol must outperform the existing standard protocol in order to show it is an improvement over existing services. CSH has previously developed and tested specialized counseling protocols for teen, pregnant, and Asian language smokers (Cummins et al., 2007; Tedeschi et al., 2005). Research on specialized interventions allows CSH to improve its own service, share protocols with other quitlines, and add to the field of knowledge about effective cessation treatments.

Depression among Quitline Callers

There has been little research on the prevalence of depression among smokers calling quitlines for cessation help. The American Cancer Society (ACS) telephone counseling cessation service found approximately 60% of callers endorsed a single item question on lifetime depression and 40% endorsed a single item question asking about feeling sad, blue, or depressed nearly everyday for the last two weeks of more (Rabius, personal communication, 2007). The high rate among ACS callers prompted the CSH to screen for depression among its callers.

Smokers calling CSH between August through November of 2007 were assessed for current major depression using the Patient Health Questionnaire Mood Module (PHQ-9) (Hebert et al., submitted). Callers were eligible for the study if they were current smokers or had recently quit smoking, age 18 or older, English speaking, not pregnant, and completed the standard intake assessment. A total of 5,594 callers met the eligibility criteria during this period of time, of which 861 were screened by the selected intake staff members and were asked additional questions assessing their depression. By this design, about 15% of incoming eligible calls to the Helpline during this time period were answered by the selected staff members.

There were 844 callers included in the study who completed the PHQ mood module. The study found 24.2% met criteria for current major depression while an additional 16.5% met criteria for minor depression using the algorithm score (Hebert, Cummins, Hernandez, Tedeschi, & Zhu, submitted). Given CSH provides services to about 30,000 smokers per year, this suggests about 7,000 smokers who call the service have current depression.

Callers endorsing current major depression at screening were significantly less likely to have quit at two month follow-up (18.5% vs. 28.4%, P=.03). Additionally, the data from this screening study found only those meeting criteria for major depression were less likely to quit. Smokers with mild to moderate symptoms had quit rates similar to those with minimal symptoms.

These findings identified smokers with current major depression as a subpopulation less likely to quit when provided the standard service. This suggests the

potential of an enhanced service to target this group of smokers in an attempt to improve quitting outcomes.

The Patient Health Questionnaire Mood Module

There are many assessments available to measure depression. The Patient Health Questionnaire mood module was chosen based on the strong support for its validity, diagnostic ability, and ease of administration over the phone. The Patient Health Questionnaire (PHQ) is a self-report questionnaire originally designed for primary care (Spitzer, Kroenke, & Williams, 1999; Spitzer, Williams, Kroenke, Hornyak, & McMurray, 2000). The PHQ-9 is the depression module, which has been shown to be effective in establishing DSM-IV diagnosis and can be used as a measure of symptom severity (Kroenke, Spitzer, Williams, 2001).

The PHQ mood module is the only self-report depression instrument validated as a screening, severity, and outcome measure (Löwe, Unützer, Callahan, Perkins, & Kroenke, 2004d). The measure has good sensitivity and specificity which varies depending of which cut off score is used. Using a cut-off score (sum ≥10) to identify those with moderate depression in 6000 patients resulted in sensitivity scores of 88% and specificity of 88% (Kroenke, Spitzer, & Williams, 2001). Sensitivity of 98% and specificity of 80% was found screening 500 outpatients (Löwe, et al., 2004a). PHQ mood module diagnostic algorithm was found to be not overly inclusive, but result in realistic estimates of base rates for depressive disorders (Rief, Nanke, Klaiberg, & Braehler, 2004).

Several studies provide evidence of the PHQ mood module superiority over other self-report measures in terms of psychometric properties and criterion validity. PHQ mood module has superior criterion validity as a diagnostic measure compared to the Hospital Anxiety and Depression Scale (HADS) and the WHO well being index (WBI-5), for both the DSM-IV and ICD-10 criteria (Löwe, et al., 2004a; Löwe, et al., 2004c). The PHQ mood module has been found to be sensitive to change and to accurately reflect outcomes in a naturalistic study (Löwe, Kroenke, Herzog, & Gräfe, 2004b), intervention study (Löwe, et al., 2004d), and anti-depressant medication trial (Löwe, Schenkel, Carney-Doebbeling, & Göbel, 2006).

This study used the PHQ-8 to assess for depression as has been done in previous telephone administered studies including the 2006 Behavioral Risk Factor Surveillance System (BRFSS) (Strine et al., 2008). The PHQ-8 does not include the ninth item which asks about "thoughts that you would be better off dead or of hurting yourself in some way." Several previous telephone studies have not included this item when interviewers are not able to provide adequate intervention by telephone (Kroenke et al., 2009). There is additional risk involved with being able to probe about positive responses to this item and then being able to take appropriate precautions against self harm. Also previous studies have found few of those endorsing the ninth item actually have true suicidal ideation when asked additional questions about their response (Pendergast, West, Wilson, Swindle, & Kroenke, 2000). Additionally the PHQ-8 and PHQ-9 have been found to have similar operating characteristics (Kroenke and Spitzer, 2002). The two original validation studies of the PHQ totaling 6000 patients established identical scoring

thresholds for depression severity could be used for the PHQ-9 and PHQ-8 (Kroenke and

Spitzer, 2002). Another study found administering the final PHQ-9 item assessing

suicidal ideation did not improve case finding over the PHQ-8 in identifying those with

depression (Corson, Gerrity, & Dobscha, 2004). The deletion of the ninth item has only a

minor effect on the PHQ-9 score since thoughts of death or self-harm are typically the

least common symptom (Kroenke et al., 2009). In a previous screening study conducted

at CSH which used the PHQ-9, it was found using the PHQ-8 instead would not have

changed whether any participant met criteria for major depression.

The PHQ-8 has 8 items which are scored from 0-3 for responses ranging from no

symptoms to daily symptoms (Kroenke et al., 2009). The PHQ-8 can be scored by either

a severity index ranging from 0-24 or by an algorithm which corresponds to the DSM-IV

diagnostic criteria for major depressive episode with at least five items endorsed

including either depressed mood or anhedonia. The measure is considerably shorter than

other self-report measures with fewer categories making it easier to administer over the

phone (Pinto-Meza, Serrano-Blanco, Peñarrubia, Blanco, & Haro, 2005).

Additional Sessions to Increase Quitting

This study aims to improve quitting outcomes among a subpopulation of smokers

who were less likely to quit when offered the standard quitline protocol. The aim of this

study is to try to create a specialized protocol to improve quitting outcomes among

smokers with current depression. In considering what approach might be effective in

improving quit rates for smokers with depression, previous quitline studies that have tried

to improve outcomes for the general population of callers were considered.

Among general quitline callers, additional sessions of telephone counseling have been found to improve cessation outcomes (Hollis et al., 2007; Stead et al., 2007; Zhu et al., 1996). At CSH providing up to six calls increased cessation rates compared to a single pre-quit call (Zhu et al., 1996). Greater benefits of multiple sessions were found among smokers with more risk factors for relapse (e.g. low social support, high nicotine dependence) (Zhu, 1996). This suggests smokers with depression would benefit from additional sessions of telephone counseling as current depression has also been found to be a risk factor for relapse at the CSH. In an Oregon study, an initial extended counseling call with the offer of four further calls significantly increased quit rates by about 1 percentage point over an extended counseling call and a brief reminder call (Hollis et al., 2005). Another study examining the frequency and duration of telephone counseling, found offering booster sessions improved quit rates (Rabius, Pike, Hunter, Wiatrek, & McAlister, 2007). Meta-analysis found those randomly assigned to receive multiple sessions of pro-active telephone counseling were significantly more likely to quit than smokers only receiving one session (Stead et al., 2007).

In studies assessing cognitive behavioral group therapy for smokers with a history of depression, treatment effects were more consistently found when the specialized intervention provided additional counseling sessions (Hall, 2007). In one of the few intervention studies of smokers with current depression, a more intensive step care intervention improved quitting over a minimal contact control (Hall et al., 2006). This suggests additional number of sessions may be an important element in improving cessation outcomes for depression vulnerable smokers.

Increasing the number of sessions provides additional support and encouragement for quitting. Increasing social support has been shown to improve cessation rates (Mermelstein, Cohen, Lichtenstein, Baer, & Kamarck, 1986). Additionally, social support has been found to moderate the impact of problems with mood on cessation outcomes (Turner, Mermelstein, Hitsman, & Warnecke, 2008). Those with depression may need more external reminders to increase their motivation for making positive behavior changes.

Summary and Rationale

Studies have found smokers with depression are less likely to quit. Most cessation intervention studies have excluded those with current major depression. Only recently has increased attention been directed towards the need to treat smokers with current depression. Quitlines serve a large population of smokers each year yet there are no studies examining the rate or impact of current depression among callers. A recent study at the CSH found a quarter of smokers met criteria for current major depression and were less likely to quit smoking when offered the standard counseling protocol compared to those who were not depressed. This finding suggests a need to improve quitting outcomes for callers with current depression. It also provides a setting to examine some of the theoretical issue of whether quitting outcomes can be improved among currently depressed smokers. The quitline setting is unique since it serves a large number of smokers each year, already provides services to smokers with current depression, and uses structured protocols which can be quickly adopted by other programs.

Providing more intensive treatment through additional counseling sessions is a widely accepted principle on how to improve outcomes and has been supported in the quitline setting with smokers at greater risk for relapse (Zhu et al., 1996). Studies of smokers with a history of depression also found improved cessation outcomes when additional counseling sessions were provided (Hall et al., 1994, 1998). A study of outpatients with current depression found an intensive treatment to be more effective (Hall et al., 2006).

An enhanced telephone counseling treatment protocol has been developed in an attempt to improve the quit rate among current depressed smokers by increasing the intensity of service and also addressing how to cope with depressive symptoms. The present study compares the enhanced counseling protocol to the standard counseling protocol. The current study has two main aims. The first is to demonstrate smokers are receptive to the enhanced protocol. This will be assessed through smokers being willing to engage in the additional sessions of counseling offered and through service satisfaction ratings at evaluation. The second aim is to increase the quit rate associated with the enhanced protocol. Although the study is not powered with a sufficient sample size to demonstrate statistical significant differences, clinically meaningful minimum differences were set prior to the start of the study.

CSH has continued to work to ensure the consistency and quality of services and the proposed study is consistent with these aims. This study will provide an estimate of the effect of the enhanced condition which will guide future research to establish the

efficacy of a specialized telephone counseling treatment protocol for currently depressed smokers.

Study Design and Methods

Problem to Be Investigated

This study examines whether cessation outcomes for smokers with current depression calling a quitline can be improved by providing enhanced telephone counseling services. It was hypothesized compared to smokers receiving the standard treatment (ST), smokers in the enhanced treatment (ET) would have improved quit rates at a 3 month follow-up evaluation. Specifically, the enhanced condition was hypothesized to increase quit rates by 10 percentage points. This hypothesis was based on a previous study found smokers with current major depression had quit rates 10 percentage points lower than those not meeting criteria for major depression. A minimum of a 5 percentage point improvement in quit rates in the ET compared to the ST was necessary for it to be clinically meaningful. The study was not powered to detect statistically significant difference between groups. Rather this study's aim was determine whether an enhanced protocol could have a clinically meaningful effect which would suggests future research in this area.

The other aim of this study was to show depressed smokers would be responsive to the enhanced protocol. The enhanced protocol provides more counseling sessions, but it is not clear whether smokers will engage in these additional sessions. This study will be able to examine whether those in the enhanced treatment condition receive significantly more sessions than those in the standard condition. This study will also

examine whether participants have a positive view of the enhanced protocol based on service satisfaction outcomes. The study will also examine other mood and smoking related outcomes to assess the potential impact of the enhanced condition.

Protocol Development

The counseling protocol was developed based on empirical literature of effective treatment for depression, considering other treatments that included mood management training for smoking cessation, and clinical experience. Developing this protocol within the CSH allowed greater tailoring to the needs of the callers. It also allowed for an enhanced protocol that would be able to be provided as an adjunct to the standard protocol. A collaborative group of clinical psychologists, graduate students, researchers, and counselors from CSH met to create mood modules which could be integrated into the standard smoking cessation protocol. The initial development phase utilized the skills and experience of the investigators and those with direct experience counseling smokers to develop a mood management intervention. The intervention provided structure guiding the counselor through series of questions, educational material, and interactions with the participant. After an initial protocol was developed, further modifications were made after consultation with Evette Ludman, Ph.D, a researcher with extensive experience in the development of telephone counseling interventions for mood management (Ludman et al., 2004).

Another important consideration involved how to integrate mood management with counseling for smoking cessation. In order to create a protocol that was more integrated, the initial module addresses how mood and smoking might be related for the

caller. Counselors were encouraged to address this topic again during subsequent calls as needed. Behavioral activation was presented as a way to improve mood and as a way to cope with urges to smoke. Several modules targeted challenging negative thoughts using a mnemonic device of catching, checking, and changing the thought (McQuaid et al., 2000). This including getting examples from the smoker of cognitive distortions around smoking and quitting.

Counselors were chosen to take part in this study based on their experience and willingness to work on this additional project. The counselors assigned to the mood management condition received training on cognitive behavioral techniques (Beck, Rush, Shaw, & Emery, 1979; Beck, 1995). The mood modules created were reviewed and role played. After initial training, counselors began using the protocol with smokers who reported having problems with depression during the initial counseling call. During weekly group meetings, counselors shared their experiences with the protocol and made suggestions for further improvements.

During the next phase of the project, a pilot was conducted where clients were randomized to receive the standard or the enhanced treatment conditions within counselors. Counselors screened new clients during the initial counseling call using the first two questions from the PHQ-8. Smokers who endorsed either of the first two items were randomized to either the standard or enhanced treatment protocol by the counselor. During this phase of the project, the emphasis was on contacting those in the enhanced condition every few days for follow-up to gain an understanding of the feasibility of more

frequent contact. The additional experience with using the mood protocols also helped counselors become more comfortable with the different modules.

The pilot study included a total of 50 smokers. Only a small increase in the number of contacts between conditions was found. Those in the enhanced counseling condition received a median of 5 counseling sessions compared to three sessions for the standard treatment condition. Smokers in the enhanced condition average a total of 78 minutes of phone time with counselors, compared to 44 minutes in the standard care group.

After this initial pilot project, there was concern about the feasibility of being able to provide significantly more sessions of counseling in the ET condition. Counselors reported difficulty being able to reach clients. Following this initial pilot, the development team spent time addressing ways to increase contact. It was believed one important aspect was getting smokers to believe in the potential benefit of spending additional time talking to their counselor and addressing how to manage mood. Changes were made to the protocol to spend time setting expectations about the frequency of contact. The protocol prompts a discussion about how sometimes participants may not want to answer the phone but to consider to potential benefit in helping with their quitting process. In this way, the counselor can try to preemptively address some clients' tendency to avoid phone calls.

During this revision, the modules were shortened in order to allow more fluidly discussion. The initial mood modules consisted of more heavily scripted intervention with a preset order. Counselors provided feedback that it often felt artificial and

restrictive using the script and having to address a specific topic when the client might be distressed about something else. It was decided rapport might be improved if counselors could address client's current concerns by choosing from a set of topics. The final mood protocol thus consisted of 10 brief modules including setting expectations, problems solving/getting things accomplished, increasing pleasant activities, mindfulness, relaxation, two which addressed increasing active behavior including social connectedness, and three different modules which addressed changing thoughts (See Appendix).

Conceptual Framework for the Proposed Study

Several considerations for the methodology of the proposed study will be addressed. An important issue was whether to equate for the amount of contact time across the two conditions. Having more contact time in the enhanced condition would not differentiate whether it was the increased contact time or content of the intervention that influenced outcomes. Alternatively, it would be difficult to deliver a comprehensive mood management treatment without additional contact time. One possibility would have been to add sessions to the standard protocol to make it as long as the enhanced but it would be difficult to determine what topic areas to address. Also this design would not be a test of whether the enhanced condition can lead to improved outcomes over the standard treatment. This study's aim is practical in trying to examine a potential way to increase quit rate among smokers having increased difficulty. The goal was to try to provide a better intervention in order to see if it was possible to increase quit rates among this subpopulation.

The guiding principle for the proposed study was to provide additional services to smokers with depression to improve their chance of quitting successfully. It is believed the content, quality, length, and number of contacts are potential ways to achieve this. Rather than test each aspect individually, it was decided the first step should be to gain evidence it is possible to improve quitting outcomes by improving the service as much as feasible. The literature suggests additional contact with counselors is important in improving quit rates. This study employed a design in which the enhanced condition received more counseling session with each session tending to be longer and more sessions resulting in a longer length of total contact time. The enhanced condition included additional content which provided cognitive behavioral mood management techniques. Although this study will not be able to distinguish whether the amount of contact or type of content results in differences between groups, the primary aim is to create protocol that is effective. The decision to include additional sessions for the enhanced counseling group is deliberate in an attempt to maximize quitting outcomes.

Another consideration was the timing of sessions. In the standard protocol, after the initial call the timing of subsequent calls is based on when the smoker sets a quit date. For the enhanced condition, it is important the standard sessions are still delivered at the appropriate time intervals. The enhanced condition was supposed to include the elements from the standard protocol and then provide additional assistance. Smokers vary on when they set their quit date so for this study only smokers planning to quit within a month were included. One possibility would be to schedule equal mood management sessions before and after the quit date. The problem could be that someone who sets their

quit date a month out will have only limited contact the first month. As the past pilot found it can be difficult to contact callers for follow-up, it was decided having a more flexible schedule could maximize the amount of contact in the enhanced condition. This flexible schedule includes a goal of reaching clients twice a week realizing the clients' schedules will not always permit this frequent of contact. For some clients, a set time each week may work best where others may prefer to set the time for the next call at the end of each session. It was decided having a more flexible approach for the additional sessions in the enhanced protocol while still adhering to the schedule based on the quit date for the standard sessions would be the best approach. The benefit of having mood management sessions prior to the quit date is the smoker may be able to use these strategies to improve their mood before attempting to quit and may be better able to cope with mood related withdrawal symptoms after quitting. Additional sessions closely following the quit attempt could be important in addressing changes in mood following the quit attempt. Smokers in the enhanced condition may also benefit from longer follow-up to prevent relapse. As the majority of relapse occur shortly after a quit attempt a goal was to have more calls prior to and closely following the quit attempt.

Study Design

The study used a 2 group randomized design with participants assigned to the enhanced treatment (ET) or the standard treatment control (ST). When smokers call into CSH they complete the standard screening. Those who met initial eligibility criteria were further assessed using the PHQ-8. Callers who met the cut-off for depression severity were asked for their informed concept to participate in the study. The participant was

then transferred or scheduled with one of the 8 counselors participating in the study. The computer randomized participants at the start of the initial counseling session. The initial design was to have randomization stratified by counselor so there would be an equal number from both conditions assigned to each counselor. Due to a programming error, randomization instead occurred using blocks of 4 to the two conditions (ET or ST) as the next eligible participant began the counseling regardless of counselor assigned.

The study started recruiting on February 1, 2010. The target sample size was 88 although in the end 92 clients were randomized into the study conditions. Recruitment was completed on March 12, 2010. Those in the standard treatment were scheduled to receive 5 sessions of cessation counseling with 1 pre-quit session plus up to 4 proactive follow up sessions over a 1 month period. Participants in the enhanced treatment were scheduled to receive the same cessation sessions plus an additional 10 sessions which would include mood management modules delivered over a 2 month period. The goal was to reach those in the enhanced condition twice a week. Counselors were asked to make 6-8 attempts to reach participants without any contact before closing the participants counseling file for both conditions. Attempts to evaluate participants for follow-up began 3 months after they were initially screened. Evaluation included assessment of quitting, mood, and service satisfaction outcomes.

Screening

Participants were recruited from callers to the California Smokers' Helpline (CSH). Smokers typically hear about CSH from the media and health care providers. The media campaign is already in place and is ongoing because it is part of California's

Tobacco Control Program, funded by a cigarette tax initiative and run by the California

Department of Public Health (Zhu et al., 1996). When a call comes in, a staff member

conducts a brief intake interview. The CSH online system prompts staff to ask each

question and information is entered directly into the online computer system. Eligible

participants are identified through the intake interview. Based on the callers' responses,

the computer determined eligibility for the study and prompted the staff to explain the

study and ask for consent to participate.

The intake included basic demographic information (ethnicity, age, gender,

education level), smoking behavior (number of cigarettes per day, time to first cigarette

of day, restriction on smoking in the home, when planning to quit, and use of cessation

aids), health related questions (diagnosis with various smoking related health problems

including high blood pressure, diabetes, heart attack, or stroke) and if they have mental

health problems including anxiety, bipolar, schizophrenia, or substance abuse. Callers

were asked to provide contact information and permission to be contacted for follow-up.

The proposed study included assessment using the eight item Patient Health

Questionnaire Mood Module (PHQ-8). Information collected during intake was used as

baseline data in analyses.

Patient Health Questionnaire Mood Module (*PHQ-8)*

The PHQ-8 has 8 items which correspond to the symptoms for major depression

in the DSM-IV. The questionnaire asks "Over the last 2 weeks, how often have you been

bothered by any of the following problems?" Each item is read along with the 4 response

options "not at all, several days, more than half the days, nearly everyday." Each item is

scored from 0-3 for responses ranging from no symptoms to daily symptoms. The PHQ-8 can be scored by either a severity index using the sum of the scores on the eight items therefore ranging from 0-24 or by an algorithm which matches the DSM-IV diagnosis criteria for major depression. To meet PHQ-8 criteria for current major depression requires either the first or second item of depressed mood or anhedonia to be present "more than half the days" and at least 5 of the 8 symptoms to be present "more than half the days." For minor depression 2 to 4 symptoms, including depressed mood or anhedonia, are required to be present "more than half the days." This scoring algorithm has been shown to be a valid measure of major depression (Kroenke, Spitzer, & Williams, 2001).

Eligibility Criteria

In order to be eligible for this study, callers had to be daily smokers, plan to quit within a month, call the English language line, provide adequate contact information, not have used CSH's services in the past 13 months, not be enrolled in another CSH study, age 18 or older, not pregnant, not endorse having other mental health problems including schizophrenia, bipolar, or current drug or alcohol problem which might interfere with quitting. In order to be eligible, participants had to endorse at least one of the first two items and at least four of the eight items on the PHQ-8 as a problem more than half the days in the past two weeks. Smokers who meet eligibility requirements were invited to participate in the research study and asked whether they would give their informed consent to participate in the research study.

Informed Consent

Since CSH provides services over the telephone, participants never see a staff member during the study process. Oral consent was obtained from participants over the phone and a cover letter, copy of a written consent, and the Experimental Bill of Rights were mailed by the following day. It was documented in the online system whether oral consent was given. The informed consent was designed to adhere to both UCSD and SDSU requirements. Smokers not interested in participating still received CSH's standard services. This project has received approval for the use of human subjects by both the UCSD and SDSU Institutional Review Boards.

Experimental Conditions

Participants who were eligible and agreed to participate were randomized at the start of their first counseling session. Randomization occurred in blocks of four as eligible calls were received by counselors participating in this project.

Standard treatment (ST). CSH standard smoking cessation counseling treatment (ST) includes a comprehensive pre-quit session about 30 minutes in length which addresses motivation, planning, setting a quit date, and the use of cessation aids. Callers can receive up to 4 proactive follow-up calls about 5-15 minutes in length which include a reminder call, quit day, 4-7 day, and 10-14 day call. In the standard treatment protocol, there are 4 structured follow-up calls and counselors make 6 attempts to reach the client before closing the file. The schedule of calls depends on when the smoker sets a quit date. Counselors try to reach the clients a few days before the quit day (reminder call), on the quit day, and then 2 more time during the first few weeks after the quit attempt. There could be weeks without contact between the initial pre-quit session and the

reminder call if the smoker sets a quit date several weeks away. The protocol is structured guiding counselors through interactions and topics to ensure important content areas are covered and to improve the consistency of the service. Content includes both behavioral and cognitive strategies related to quitting as well as information about quitting aids. Typically the initial call is the most comprehensive while the follow-up calls are generally brief, addressing whether the smokers have made an attempt, encouraging continued attempts, or identifying barriers to maintaining abstinence.

During the first session the counselors assesses the client's smoking situation, motivation to quit, and smoking patterns. Past quit attempts are discussed to identify what strategies contributed to success and what factors hindered previous attempts. The counselor asks about current smoking rate, assesses environmental factors such as the presence of other smokers in the household, and determines the degree of social support the client expects during quitting. Goals of enhancing motivation for quitting are pursued through discussion of reasons for quitting, examination of ambivalence about quitting, and through an accepting, nonjudgmental attitude by the counselor. Attempts are made to increase self-efficacy for quitting by identifying and challenging self-defeating thoughts such as reasons for previous failures and attributions of success to external events. In planning for the first day of quitting, counselor elicits difficult situations where the client will have to overcome the urge to smoke and help to make a plan for how to refrain from smoking. During this first session the client sets a quit date. Participants are asked to quit smoking upon awakening on the quit date.

The second counseling session is scheduled on or immediately after the quit day. Counselors often attempt to reach client a day or two before their quit date as a reminder call to briefly review the client's plan for quitting. During subsequent follow-up calls counselors provide individual support for clients during the early period of abstinence using a relapse-sensitive schedule of contacts. As risk for relapse is greatest in the first two weeks, telephone sessions are concentrated during this period. These contacts provide the opportunity for more tailored and elaborate discussion of quitting experiences and coping strategies during the period of highest risk for relapse. During these sessions there is assessment of quitting, coping techniques used, discussion of withdrawal, and continued work to increase self efficacy to refrain from smoking. There is a discussion of the possibility of lapses and the development of strategies to prevent complete relapse. Continued revision of a staying quit plan will be addressed. The counselor encourages the participant to adopt a non-smoker self image. All participants were sent the standard helpline mailings along with the consent form and experimental bill of rights the day after screening.

Enhanced treatment (ET). In the enhanced treatment condition (ET), counselors provided additional sessions increasing the number of contacts and addressing cognitive behavioral strategies to cope with depressed mood without smoking. The ET included the 5 session structured cessation protocol from the ST delivered according the standard schedule. Also the enhanced condition provided up to 10 additional counseling sessions that addressed mood management (Appendix). In the ET, more attempts were made to contact clients for follow-up, sessions were more frequent, sessions also could be longer

to cover additional material, and more sessions were planned to be provided. The goal was to have counseling session twice a week with those in the ET. If the call falls on the relapse sensitive schedule, the mood module will be used with the regular smoking cessation counseling call. If it falls outside the schedule, the counselor will essentially use a mood module although could still check in about smoking. With the additional calls the number of weeks the participant is in contact with their counselor could also increase with at least 5 weeks and up to 8 weeks to deliver the full protocol. A structured protocol was used with 10 mood modules which were to be incorporated into the cessation calls or delivered during separate calls (Appendix). Counselors selected the specific mood module to use for each call based on their interaction with the participant. Those in the enhanced condition were sent the standard helpline mailings along with the consent form and experimental bill of rights the day after screening. They were also sent a fact sheet on using the 3 C's to challenge negative thoughts.

Counselors

Counselors were chosen to take part in this study based on their work ethic, experience, and skill. The counselors in the study all have several years of experience providing cessation counseling for smokers with depression as there is a high prevalence rate of depression among CSH callers. Eight counselors were selected for the study and administered both the ET and ST conditions. Six counselors worked day shifts, 1 worked in the afternoon, and 1 worked in the evening. All the counselors received additional training on cognitive behavioral strategies for mood management and had experience using the mood modules. Before starting the project the counselors reported feeling

familiar with the protocol. Most of the counselors have been attending weekly mood

management meetings for almost two years prior to the start of the study. The weekly

meetings continued during the course of the study.

Outcome Measures

All participants were contacted for follow-up evaluation approximately 3 months

after enrollment into the study. Prior to the assessment participants were mailed two

dollars as an incentive to take part in the evaluation. The assessment included questions

from our standard service evaluation which includes questions about smoking status,

service satisfaction, and quitting. For this study it also included the PHQ-8, whether they

have seen a health professional for low mood or depression since they called three

months ago, whether they are currently in therapy, and whether they are taking

medication for depression.

During evaluation, data was directly entered into the computerized system.

Evaluators made about 30 attempts to reach participants for follow-up before closing out

the participants file. The CSH online system was used to collect information about the

length of counseling calls and number of sessions provided.

Risk Management

CSH already has procedures in place to address a crisis situation brought up

during counseling, intake, or evaluation. All employees who have contact with callers are

trained on risk assessment and referral procedures. In this study, there was assessment

for depression using the PHQ-8 and counselors addressed depression as a barrier to

cessation. This could potentially lead to disclosure about potential self harm or other

reportable concerns. The procedures already in place at CSH were used during this study.

Additionally, all participants in the study were given the feedback after they completed

the PHQ-8 "these questions indicate that you may have been experiencing low mood."

Participants were then encouraged to consider getting some extra support and their

county mental health number was given. This suggestion was also given at evaluation for

those participants still endorsing either depressed mood or anhedonia more than half the

days.

The procedure in place for any potential risk of self harm includes further risk

assessment and referral procedure. Depending on the assessed level of risk, the

procedure is for staff to get the caller connected with emergency services, a local crisis

number, or additional support. Staffs involved with this project reviewed all standard

referral procedures to ensure they were prepared when issues arise. Additionally,

supervisors were always available to assist counselors or talk with callers directly to

assess the situation.

Sample Size

This study recruit 92 participants with 46 assigned to each condition. This study

had no specialized funding so was restricted in size. Results from this study provide an

estimate of the effect of the enhanced protocol on cessation outcomes compared to the

standard protocol. A previous study at CSH, found smokers meeting criteria for major

depression at intake were significantly less likely to have 30 day point prevalence

abstinence at two month follow-up compared to those who did not meet criteria for major

depression (18.5% vs. 28.8%). If the enhanced treatment is able to get smokers with

major depression to behave as smokers without major depression, it could be expected those in the ET would have 10 percentage points higher abstinence rates as the ST condition. A 5 percentage points improvement in cessation rates compared to the previous finding of 18.5% abstinence among smokers with major depression would be the minimum clinically significant effect for a CSH cessation intervention. If it is assumed the enhanced treatment increases quitting by 10 percentage points, then there is an 80% chance this study will find at least a 5 percentage points improvement (from 19% to 24%) in the ET compared to the ST condition. The study sample size was chosen to provide an 80% chance of finding at least a 5 percentage points improvement in the enhanced condition given the hypothesized increase from 19% to 29%. If ET results in at least a 5 percentage points improvement over ST it would provide support for conducting a larger study.

Data Analysis

Statistical analyses were performed using the statistical software package SAS. Chi-square tests were used to compare proportions and independent t tests were used to compare means. Descriptive analyses included means and standard deviations for continuous variables and frequencies and confidence intervals for categorical variables. Descriptive statistics were calculated for selected baseline variables for the total sample and for each condition including cigarettes per day, PHQ-8 sum score, sex, age, ethnicity, education, time until first cigarette after waking, whether planned to use a quit-aid, and whether there was a home smoking ban. Baseline demographic, smoking, and mood

related characteristics were compared between treatment conditions. Independent t-tests were used to compare the average number and length of counseling between conditions.

The primary outcome analyses were comparing cessation outcomes between the two conditions. This study presented the quit rates using both the responder rate and intent to treat. The responder rate is the quit rate of the proportion who quit among those who were reached for follow-up evaluation. This study also reports the intent-to-treat quit rate which is the proportion whom quit among all who were randomized into the study regardless of whether they were reached for follow-up. This means all those who were not reached are considered daily smokers. This calculation produces a more conservative estimate of the quit rate for the study. The responder rate produces a higher quit rate than the intention-to-treat rate. It is also the rate the North American Quitline Consortium recommends (NAQC issue paper). Previous findings showed the responder rate was closer the actual quit rate. This is largely because not being reached for follow-up has not been found to be associated with quitting status (Tomson, Björnström, Gilljam, & Helgason, 2005).

Chi-square tests were used to compare rates of 7 and 30 day point prevalence quit rates using both intent-to-treat with those not reached for follow-up considered to be daily smokers and responders analyses. The odds ratios (OR) with 95% confidence intervals (CI) were calculated to express the proportion of quitters in the enhanced protocol compared to the standard protocol. Descriptive statistics and confidence intervals were also calculated for other smoking related outcomes between conditions including among those still smoking the average cigarettes per day, whether there was a

plan to try to quit again, and time until first cigarette. Similarly descriptive statistics of

mood related and service satisfaction variables at follow-up were presented by condition

and tested for differences between treatment conditions.

Results

The study randomized 92 participants with 46 into the enhanced treatment

condition (ET) and 46 into the standard treatment condition (ST). Consistent with the

eligibility criteria all participants were daily smokers at baseline who were calling for

themselves to get help with quitting and endorsed a plan to quit within a month. They

were all English speaking, not pregnant, and reported not having bipolar, schizophrenia,

or a current drug or alcohol problem. Six participants endorsed problems with drug or

alcohol in the past but reported none within the past month. The sample was 67%

female, 61% Caucasian, 73% had a high school diploma, and 47% had a child under age

18 living in the home (Table 1). The average age was 46 ($SD = 12.9$) with 54% between

the ages of 45-64. Most heard about the California Smokers' Helpline through a medical

facility (54.3%), followed by television (26.6%) while others heard about it through

friends and family (10.6%), or from a cigarette pack (6.4%). Most participants smoked

15 or more cigarettes per day (63.2%) with the average number of cigarettes consumed

per day being 18.6 ($SD = 11.7$). Most participants (56.8%) endorsed at least some

restrictions on smoking in their home with 46.4% banning smoking within the home.

Participants had to endorse at least one of the first two items and at least four of

the eight items on the PHQ-8 as a problem more than half the days in the past two weeks.

This meant most participants met criteria for major depression (70.5%) while the

remaining 29.5% met criteria for minor depression. On the PHQ-8 sum score which can range from 0 to 24, the average score was 15.0 (SD = 3.6) which indicates major depression, moderately severe according to standard cut off scores (Kroenke et al., 2001). A single item questions were also asked about anxiety as part of the standard screening. On the question asking "Do you have any current mental health problems such as an anxiety disorder?" 36.8% said yes.

Comparison of Study Arms

Participants did not differ significantly on any baseline demographic variables (Table 1). Baseline smoking and mood related variables by treatment condition are presented in Table 2. There were no significant differences between the conditions for any variables.

Delivery of Counseling Interventions

Of the 92 participants randomized into the study almost all completed at least one telephone counseling session. Two participants, one from each condition, were never able to be reached to receive their counseling session so were only sent materials through the mail. This was because immediately after the start of the counseling call after the participant was randomized the call got disconnected and the counselor was never able to reach the participant again.

Participants in the enhanced treatment received significantly more session of telephone counseling compared to those in the standard treatment (Table 3). Counselors were able to deliver on average an additional 3.1 (SDD = 0.87) sessions to those assigned to the ET compared to the ST (6.7 vs. 3.5), $t(90)=3.58$, $p<0.01$. The average length of the

first counseling call was significantly longer in the enhanced treatment at 39.6 minutes

compared to 33.0 in the standard treatment, a difference of 6.6 minutes (*SDD* =2.7), *t*(90)

= 2.43, *p* = .02. More sessions and longer sessions delivered in the enhanced condition

led to significantly more total contact time compared to the standard protocol.

Participants in the ET engaged in on average 114.2 minutes of telephone counseling

compared to 52.7 minutes for those in the standard treatment which is slightly over an

hour difference (61.5, SDD=13.2), *t*(90)=4.67, *p* =<.01.

Evaluation Contact Rates

Approximately three months after participants were randomized, attempts were

made to reach them for follow up evaluation. The response rate to the follow-up survey

was 80.4% (74 of 92). More participants in the standard treatment (n = 40, 87.0%) than

in the enhanced treatment (n = 34, 73.9%) were reached for the follow-up survey but this

difference was not significant *(p* = 0.08).

Service Satisfaction Related Outcomes

Service satisfaction related outcome variables by treatment condition are

presented in Table 4. There were significantly more in the standard treatment who said

they received too few counseling sessions (24.3% vs. 6.3%), $\chi^2(1) = 4.18$, *p*=0.04. Those

in the enhanced were also significantly more likely to rank their quit plan a 10 out of 10

compared to those in the standard condition (65.6% vs. 30.6%), $\chi^2(1) = 8.36$, *p* < 0.01.

There were no other significant differences between groups.

Quitting Outcomes

Table 5 presents quitting outcomes by treatment condition. The responder data (efficacy subset) included only those participants who were reached for follow-up evaluation. There was a trend towards more in the enhanced condition not smoking at the point of evaluation (31.4% vs. 17.1%), $\chi^2(1)= 2.20$, p=0.14. Smokers in the enhanced condition were 11.9 percentage more likely to have quit for at least 7 days compared to those in the standard treatment (29.4% vs. 17.5%), $\chi^2(1)=1.47$, $p=0.23$; OR=1.96, 95% CI [0.65, 5.90] (Bland & Altman, 2000). Although this difference was not significant it was greater than the target goal of increasing the quit rate by 10 percentage points. Smokers in the enhanced treatment had a 30 day point prevalence quit rate of 17.7% compared to 12.5% in the standard treatment, $\chi^2(1)= 0.38$, $p=0.54$; OR=1.50, 95% CI [0.41, 5.43]. This 5.2 percentage points difference was higher than the minimum clinically meaningful difference set prior to the start of the study of at least a 5 percentage points improvement in the ET compared to ST. Smokers assigned to the enhanced condition also made slightly more quit attempts (71.4% vs. 65.9%).

In the intent-to-treat analyses participants unable to be reached for follow up were considered to be daily smokers who made no attempt to quit. There were more in the enhanced condition who were currently not smoking (23.9% vs. 15.2%), $\chi^2(1)= 1.11$, $p = 0.29$. The difference was also in favor on the enhanced condition looking at 7 day quitting outcomes (21.7% vs. 15.2%); OR= 1.55, 95% CI [.53, 4.50]. Intent-to-treat data showed only a marginal difference in the number of smokers who had quit for 30 days in favor of the ET (13.0% vs. 10.9%), OR=1.23, 95% CI [0.35, 4.35]. Slightly more in the

standard treatment made a quit attempt (56.5% vs. 52.2) when all those not followed up

with were assumed to have not tried to quit.

Other smoking related outcome among those still smoking by treatment condition

can be found in Table 6. There were no significant differences between the two

conditions on any of these smoking related outcomes. Those in the enhanced tended to

be smoking fewer cigarettes per day at follow-up evaluation (5.9 vs. 9.1), $t(53)=1.89$,

$p=0.06$. There were more in the enhanced condition which used a quit aid, smoked fewer

than 15 cigarettes per day, and planned to quit within the next 30 days.

Mood Related Outcomes

Mood related outcomes by treatment condition of those reached for follow-up are

presented in Table 7. At follow-up there were half as many participants reporting major

depression in the enhanced treatment compared to the standard treatment (14.7% vs.

28.2%) but this difference was not significant, $\chi^2(1)=1.93$, $p=0.16$; OR=0.43, 95% CI

[0.14, 1.42]. The average PHQ-8 sum score also showed a trend towards being lower in

the enhanced treatment (8.8) compared to the standard treatment (10.3) but was again not

significant, $t(71)=1.08$, $p=0.29$. The average decrease in PHQ-8 sum scores from

baseline to follow-up tended to be greater in the ET (6.2) compared to the ST (4.7), $t(71)$

$= 0.76$, $p = 0.45$.

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Discussion

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This is the first study to assess the effect of a specialized counseling protocol that

aims to improve quitting outcomes among smokers with current major depression calling

a quitline. This line of research is important given the lower quit rate found among

smokers with current major depression calling the California Smokers' Helpline (Hebert et al., submitted). This study's primary goals were to establish the feasibility of the enhanced protocol and increase the quit rate associated with the enhanced protocol compared to the standard protocol. This study was able to successfully meet the goals set out for the study during its design. The results support the potential of providing additional counseling sessions that include mood management to smokers with current major depression in the context of a state quitline.

Responsiveness to the Enhanced Protocol

One of the primary aims of this study was to show smokers with current depression are responsive to the enhanced protocol developed. The results of this study support this aim in two ways: participation and satisfaction. Smokers in the enhanced treatment participated in significantly more counseling compared to the standard protocol including the number of sessions, length of initial session, and total contact time. Those in the enhanced treatment condition received on average 6.6 sessions of counseling which were 3 more sessions than for those in the standard treatment. The average length of the first counseling session was increased by an average of 6.3 minutes from 33.6 to 39.9 in the enhanced condition. The first session of counseling is important as this is where the quitting plan is developed, quit date set, initial rapport build, and expectations for future counseling sessions discussed. The enhanced condition was also able to more than double the total time spent talking with the counselor. This meant those in the enhanced condition spent on average an hour more on the phone over the course of the sessions

they received. These findings provide strong support for the responsiveness of the participants to the enhanced protocol.

Prior to the start of the study, it was a concern smokers in the enhanced condition would not be willing to participate in significantly more counseling sessions than were already being delivered through the standard cessation intervention.   The CSH's standard cessation intervention protocol provides up to 5 sessions yet the average number of sessions delivered is around 3. There was concern callers may have a low threshold for how many sessions they are willing to engage in. This study, however, found participants were willing to engage in more sessions when more were offered and more proactive counseling calls made. This suggests in order to increase the contact rate, the targeted number of sessions should be increased. The enhanced protocol developed had up to 15 session of counseling with the goal of providing two sessions per week and was able to deliver about half. Also this study found the average number of sessions for the standard protocol is comparable to what was found in previous quitline studies which demonstrates its efficacy.

One of the main objectives of the current study was to be able to significantly increase the counseling contact rate in the enhanced treatment condition in hopes this would lead to clinically meaningful differences in the services received between the conditions. It was also important to deliver more sessions in order to cover additional mood management content without reducing the time spent discussing smoking cessation. It was important participants in the enhanced condition continued to receive the full smoking cessation intervention as well as additional mood management

counseling. The current study was able to demonstrate it was possible to deliver a more intensive intervention to smokers with current major depression. The increase in contact time also provides support for smokers with current depression willingness to engage in a mood management intervention.

Further support for participants' responsiveness to the enhanced protocol comes from the service satisfaction assessment at the three month outcome evaluation. Most of the participants in the enhanced protocol condition responded positively to the increased counseling sessions. Most participants rated their counselor highly and reported being satisfied with the services received. Those in the enhanced treatment were also significantly more likely to rank their quit plan a 10 out of 10 compared to those in the standard condition. Most (84%) of them also endorsed receiving just the right number of sessions. This suggests quitline users are receptive to engage in more counseling calls as is provided through the enhanced treatment condition. Few participants (9%) in the enhanced condition felt they had received too many counseling sessions. In contrast, 23.7% in the standard treatment endorsed getting too few sessions. This is encouraging in trying to increase the number of the counseling sessions provided. The services satisfaction outcomes suggest those in the enhanced condition are satisfied with the services received.

Effect of Enhanced Treatment on Quitting Outcomes

Another primary aim of this study was to increase the quit rate associated with the enhanced protocol compared to the standard protocol. Before the study began, it was hypothesized the protocol would increase the quit rate by 10 percentage points. This was

based on a CSH study which found smokers with current major depression were 10 percentage points less likely to quit compared to those not meeting criteria for major depression. Optimally the enhanced intervention would cause smokers with current depression to have quit rates equivalent to those without depression. The 10 percentage point difference was used as an estimate for a reasonable goal of improvement in quit rate for those in the enhanced compared to the standard condition. It was determined at the outset a minimum of 5 percentage point increase in quit rate was necessary for it to be clinically meaningful and support continued research. The study was not powered at a sample size to demonstrate a statistically significant difference. Instead the percentage differences were to provide an estimation of the effect of the enhanced protocol.

The enhanced protocol was associated with a 12% increase in 7 day point prevalence quit rates compared to the standard treatment in the responders' analyses. This supports the enhanced protocol having a clinically meaningful effect of quit rates. The difference in quit rates from the standard to the enhanced treatment conditions (17.5% to 29.4%) is similar to the differences found in a previous screening study of smokers with and without current major depression (18.5% vs. 28.5%) (Hebert et al., submitted). The 30 day point prevalence quit rates were 5.2% higher in the enhanced condition compared to the standard treatment which supports a clinically meaningful effect of the enhanced condition. While none of these differences reached the conventional statistical significance level due to the small sample size, they have met all the goals set out for the study when it was designed.

Another important objective of this study was to provide an estimate of the effect of the enhanced counseling protocol on quitting outcomes over standard treatment. Before conducting a large scale study to test the efficacy of the enhanced treatment condition, research is needed to examine the size of the effect of the enhanced protocol and to determine whether this line of research is likely to be worthwhile. In this study the probability of smokers with current major depression quitting for 7 days was 1.68 times higher in the enhanced condition compared to the standard treatment. The effect of the enhanced condition on 7 day point prevalence quitting outcomes had an odds ratio of 1.96. The 30 day point prevalence quit rates shows a relative risk of quitting in the ET to be 1.42 compared to the standard treatment and an odds ratio of 1.50. In order to give some perspective of the size of this effect, a meta-analysis comparing multiple telephone counseling sessions to a single contact found the more intensive condition led to improved quitting outcomes with an odds ratio of 1.41, 95% CI [1.27, 1.57] (Stead, Perera, & Lancaster, 2007). In a meta-analysis of the effect of NRT, the relative risk of quitting using NRT compared to control was 1.58 (Stead, Perera, Bullen, Mant, & Lancaster, 2008). This suggests a considerable effect of the ET as the size of the effect was similar to that found for NRT and multiple sessions of telephone counseling.

Taken overall, the quitting outcomes from this study are encouraging that this line of research will lead to improvements for smokers with current major depression. It is difficult to get an additional intervention to be significantly more effective than a standard treatment which has already been found efficacious. The standard treatment at the CSH has been shown to be effective in improving quit rates over materials and single

session counseling (Zhu et al., 1996). The enhanced treatment was able to show an effect over the standard care similar to that found in meta-analyses of NRT and multiple quitline counseling session which supports the clinically meaningful impact of the enhanced condition on quit rates for smokers with current depression. These findings help to support a larger research agenda to establish a tailored telephone counseling protocol to increase the quit rate of smokers with current major depression.

Mood Related Outcomes

Fewer of those in the enhanced treatment met criteria for current major depression at follow-up, compared to those in the standard protocol (14.7% vs. 28.2%). The PHQ-8 sum scores for those receiving the enhanced treatment were on average 1.8 points lower than those in the standard treatment (8.7 vs. 10.5). A score of 8.7 indicates minimal symptoms with a score less than 5 indicating complete remission (Kroenke & Spitzer, 2002). Although both conditions showed improvements in PHQ-8 sum scores from baseline to follow-up, this was greater in the enhanced compared to the standard condition (6.2 vs. 4.7). A decrease of 5 or greater points is clinically significant and suggest a clinically significant treatment response (Kroenke & Spitzer, 2002).

These results are encouraging in terms of how the improvements in depression might impact quitting. Improving symptoms of depression may lead to better quitting outcomes among smokers with current major depression. If depressive symptoms interfere with quitting then remission of these symptoms might improve the smoker's likelihood of quitting. The reason the enhanced intervention includes the cognitive behavioral components aimed at improving mood is in the hope this will lead to a

reduction in depressive symptoms. One of the possible reasons previous cognitive

behavioral interventions did not have a more consistent effect on quitting is that most

studies focused on smokers with a history of major depression (Hitsman et al., 2003).

Although smokers with a history of depression might benefit from skills to cope with

negative affect situations without smoking, the effect of a counseling intervention for

depression is probably going to have less of an effect on those who are not currently

depressed. That the enhanced protocol was able to reduce rates of current major

depression compared to the standard treatment, suggests the intervention may also lead to

improved quitting outcomes. Further support is found by examining trends in smoking

and mood related outcomes. Most of the participants who quit for 7 days no longer met

criteria for major depression at follow-up. There were only 2 of the 16 participants

(12.5%) who quit who still met criteria for major depression (one from each condition)

compared to 25% of those who did not quit who were still depressed. It is unclear

whether quitting may have contributed to improvements in mood or whether feeling

better improved the likelihood of quitting, but the results suggest the enhanced condition

had a positive effect on mood.

Potential Barriers in Session Delivery

An important consideration in future research will be to significantly increase the

amount of contact in the enhanced condition replicating the findings of this study. In

order to do this it may be helpful to consider why it is difficult to deliver the full protocol

whether it is the 5 sessions in the standard or 15 sessions in the enhanced treatment.

Although the enhanced condition did have a significantly higher number of counseling

sessions delivered, the average number of session was 6.6 which was still considerably less than the target goal of 15 sessions. In fact, only 4 of the 48 participants in the enhanced treatment condition received 15 sessions. Promising was 14 participants received 10 or more sessions. The difficulty in reaching participants also occurred in the standard treatment. The rate of those not completing even half of the scheduled calls was 56.3% and 42.6% in the ET and ST respectively. This brings up the question of why it has been difficult to deliver the complete counseling protocols.

In some sense it would appear to be easy task to provide free services. Participants do not have to travel to attend the counseling or even to initiate the call, they simply have to answer the phone. The participants who only receive one counseling session had an impact of the average number of session received. Excluding those who only received 1 session increases the average number of sessions to 4.4 in the standard and 8.2 in the enhanced condition.

There are many possible reasons for the difficulty in delivering the full counseling protocol. Some reasons may simply have to do with time constraints on the part of the participant while others may be factors which can be changed through counseling. Some who call into the quitline may have no intention of participating in follow-up calls and may not even provide valid contact information. The enhanced condition had 6 and the standard condition had 2 participants who were never available for either counseling or evaluation after their first call into the CSH.

Another possibility for attrition is after completing the first session of counseling, the participant did not think it was helpful enough to take part in another call.

Alternatively, the participant could have felt like they discussed all relevant issues and did not want to discuss quitting further. Often when they first call into the CSH, smokers are unsure of what services are offered. Some are simply calling for materials or to see if they can get patches. Many want to complete one session of counseling in order to obtain a certificate which allows them to get free patches through MediCal. Counselors have shared how sometimes participants who seem fully engaged in the initial call will not be available for follow-up. That it is some negative characteristic of the counseling seems unlikely as the majority of callers complete multiple follow-up calls. There has been little research into why some callers do not participate in the follow-up calls.

There has been one study which explored possible reasons for not calling a quitline among a survey of smokers (Solomon et al., 2009). This study found low appraisal of the service, feeling they did not have a need for assistance, feeling they have others who will help them, and privacy concerns as the reasons that predicted a lower intention to call a quitline among smokers. Privacy concerns might be especially relevant for those receiving the enhanced condition. Unlike going to a counseling office where there is relative privacy, talking to a telephone counselor means others around the callers may overhear the discussion. This may be less of a concern when the focus of the call is on quitting smoking. Discussing triggers for low mood, however, are likely to involve more privacy concerns such as conflict with others in the home. This may sometimes be a barrier to taking the counseling call when they are not in a private location.

It might also be more difficult to reach smokers who are currently depressed. Depression tends to decrease motivation and increase isolation. A review of behavioral

medicine interventions found psychological problems were the most common factor associated with early attrition from treatment (Davis & Addis, 1999). Another study found higher levels of depression and current smoking were associated with attrition from obesity treatment (Clark, Niara, King & Pera, 1996). Depression is associated with more perceived emotional barriers to psychotherapy (Mohr et al., 2006). Another study, however, found no difference in adherence to an intensive cognitive behavioral group program for smoking cessation among those with and without a history of depression (Ginsberg, Klesges, Johnson, Eck, Meyers, & Winders, 1997).

Another possibility is the delivery of the intervention over the phone may increase early drop out from therapy. This could be due to forming less of a connection with a counselor over the phone. This hypothesis has not been supported by current research, with a meta-analysis examining the effects of telephone counseling for depression finding a mean attrition rate of 7.6% (Mohr, Vella, Hart, Heckman, & Simon, 2008) which is considerable lower than the attrition rate of 46.9% found in a meta-analysis of face-to-face psychotherapy (Wierzbicki & Pekarik, 1993). This suggests telephone counseling may tend to have lower attrition rates than face-to-face.

The protocol development team spent considerable time trying to address the most likely factors which interfere with increasing contact. For example, although this program provided free counseling this potentially may cause participants to undervalue the service they were being offered. The protocol tried to counter this possibility by pointing out to participants in the enhanced treatment the potential value of this type of service. Other possible concerns were too many calls would become overwhelming for

participants. Yet few participants endorsed believing there were too many sessions with only 9% from the ET and 5% from the ST. For some who had not quit, each call may have been a reminder of something they still hadn't accomplished. They may feel anxious about being held accountable to someone and thus want to avoid having to talk to this reminder. In early development of the protocol, counselor feedback suggested the initial more scripted and structured mood modules interfere with being able to have a more natural conversation with smokers. For this study, briefer more flexible modules were created to try to improve ease and connectedness.

There are obviously many possible reasons why the participants in either condition did not use the full extent of the services offered. The timing of when participants ended treatment likely also distinguishes participants with those ending after one session likely quit different from those ending after several sessions. Half in the enhanced condition completed at least 5 sessions suggesting many felt there was a benefit to the calls. Also encouraging is the counselors were able to engage smokers calling for help with quitting in a discussion about ways to improve their mood when this was not the services they were initially calling for.

Considerations in Study Replication

Examination of potential factors which contributed to the effect of the enhanced protocol and ways to replicate the findings can help to shape future research. For example this study included daily smokers planning to quit within a month. The effect of the enhanced condition over standard treatment may not be found among occasional smokers or those less motivated to quit. An important reason why the enhanced

treatment resulted in clinically meaningful effect is likely that it targeted smokers with current depression who have been found to be less likely to quit in a previous study. Eligibility criteria and assessment that is able to distinguish a subgroup at greater risk of not quitting would be important consideration in the development of future research.

During the protocol development, emphasis was placed on the goal of getting the participant to quit smoking. Mood was generally viewed as a means to help with quitting. There was a concern during the protocol development that too much emphasis might be placed on depression and that this would undermine the message to quit. It was important smokers did not get the message they could not quit because of their problems with low mood and that the goals set during the mood management did not become more important than the goal of quitting. Feedback from counselors and supervisors, suggests the emphasis remained on quitting with the mood intervention presented as a way to increase one's ability to stop smoking.

Another concern is the relative importance of the quality and intensity of the mood management. It is possible trying to provide more intensive mood management intervention may help with mood which may in turn help with quitting. The enhanced condition tended to improve depressive symptoms more than the standard treatment. Further improvements to the enhanced condition may lead to even more robust differences in mood related outcomes. Ways to attempt to improve the enhanced protocol might be to add more structure to the counseling protocol. Multiple session cessation counseling offered through a quitline was not found to be more effective than a single session when it was unstructured (Gilbert & Sutton, 2006). The authors proposed this

could have led to counselors being overly empathic about quitting and not focused enough on increasing motivation. Some have suggested treatment manuals increase the consistency and quality of the treatment delivered (Crits-Cristoph, Baranackie, & Kurcias, 1991). The initial mood modules were more heavily scripted and structured. The benefit of the modules in this form was counselors relatively inexperienced with addressing problems with mood could read through the scripting yet the drawback was possible interference with building rapport. A heavily scripted protocol might negatively impacted contact rates. This is why the modules were modified to be shorter and more flexible. With such abbreviated versions there may be a concern the counselors are just covering a small amount of mood management material, yet the length of the follow-up calls and counselor feedback suggests these topics areas were used to have more in depth conversations.

Potential Ways to Improve the Enhanced Treatment Protocol

Given the initial results from this study with indications the enhanced intervention was able to improve mood and increase quitting over those receiving the standard care, future studies should expand on the current intervention in order to optimize the potential to help smokers with major depression quit. Trying to further increase both the intensity and quality of the enhanced intervention may help to strengthen future outcomes. Some potential ways to do this would be to create a self help booklet on mood which could be sent to the participants in the enhanced condition. This booklet could address the same topics which are addressed in the counseling sessions. Another possibility would be to create audio recordings of a mood and smoking intervention. These recordings could

provide psychoeducation on cognitive strategies which could be used for both depression and smoking cessation. These recordings could potentially serve as a means to further increase the intervention delivered. This type of service could be provided by mailing CDs, sending MP3s through email, or having a number to call where participants could listen to the recordings through their phone.

Other means of intensifying the services would be to coordinate with participants primary care provider in order to better connect them with additional services for depression. In this way, a greater number of participants in the enhanced condition may be able to start psychotherapy or be prescribed medication for depression. This study did not find that those in the enhanced condition were more likely to seek help with their depression perhaps because they felt they were already getting help through the services at CSH. In the future, counselors in the enhanced condition may want to provide more assistance and encouragement in getting participants to seek care from a health care provider.

It will be important in trying to replicate the enhanced intervention to keep up the amount of contact the smoker has with the smoking cessation counselor. Continued efforts should be made towards increasing the number of sessions. Other possibilities to improve contact rates might be encouraging the participants in the enhanced condition to call CSH when they have time available. Incoming calls would likely not be able to be answered by the assigned counselor, but some support could be provided by someone else on the spot. Reminders of appointment times could be sent through email along with psychoeducational material and reminders of coping strategies.

This study suggests the number of sessions in the protocol effects how many are delivered. The protocol with a greater prescribed number of sessions led to twice as many sessions being delivered. Having more topic areas available for the counselors could use may help to keep up the number of contacts and keep the participant engaged. Some additional topics could include topics such sleep and exercising. Smokers tend to have worse sleep than non-smokers (Wetter & Young, 1994). Mood and anxiety disorders are the most common psychiatric diagnoses associated with insomnia and studies found sleep disturbances are more common in heavy smokers (Hughes et al., 1994; Wetter & Young, 1994). During initial withdrawal, smokers tend to experience more disruptions in their sleep which can lead to daytime fatigue and increased negative affect. Being tired may increase the desire for the arousing effect of nicotine (Colrain, Trinder, & Swan, 2004). This suggests improved sleep may also improve both depression and quitting outcomes. Sleep disturbance is commonly reported as a symptom during cessation (Hughes et al., 1994). It has been recommended treatment approaches targeting sleep be included as part of an overall smoking cessation strategy (Colrain, Trinder, & Swan, 2004). Psychological and behavioral therapies can produce improvements in sleep for insomnia (Morin et al., 2006). One approach could be to encourage participants to get enough sleep by trying to go to bed a half hour earlier each day. A module could focus on sleep hygiene and the basics of stimulus control therapy. Another study found perceived difficulty in falling asleep and staying asleep were negatively affected by tobacco withdrawal but this effect was moderated by exercise (Grove, 2006).

Another area which was only briefly addressed in the current modules was exercise. Encouraging patients to engage in regular exercise may improve both quitting and depression outcomes. Exercise has been found to improve mood, well being, and quality of life (Anderson, 2005; Atlantis, 2004). An exercise intervention for smokers resulted in improvement in depression (Patten, Vickers, Martin, & Williams, 2003). Another study found significant reduction in negative affect, nicotine withdrawal, and cigarette craving during an exercise intervention (Bock, 1999). There has been evidence of reasonable adherence rates to an exercise intervention among smokers (Trivedi, Greer, Grannemann, Chambliss, & Jordan, 2006). One study found the addition of vigorous exercise to a cessation program for women significantly improved levels of continuous abstinence at both short and long term follow up (Marcus et al., 1999). A review looking at the impact of exercise intervention on smoking cessation found mixed results for the effectiveness of exercise to improve cessation, but this was in part because of small sample sizes and limited studies (Ussher, Katomeri, & Taylor, 2005). Again, having flexibility and working with the participants to address the changes they are willing to make in creating a plan for quitting is important.

Limitations

The main limitation of this study is being underpowered with an insufficient sample size to detect significant results. Although the results suggest an effect on the enhanced condition on quitting outcomes, future research is required to establish efficacy. This study, however, did show delivering more sessions is feasible and gave supervisors

and counselors a better understanding of what is involved to carry out the enhanced protocol.

A potential limitation of the study's design is that contact time was not equated for across the two conditions. This study was not intended to inform whether trends in the differences in outcomes between the ET and ST conditions were a results of the number of sessions provided or additional mood management content. The design is based on the rationale an initial study should establish a treatment can work before it begins to test the minimum elements required to produce improvement. Additionally, this line of research will be integrated directly into practice so the main objective is to improve outcomes rather than understand the specific elements which cause the improvement. The question of whether content or contact is more important is mainly relevant to CSH in terms of creating a cost effective protocol as additional sessions is more costly than changing the content of sessions. There are also logistical problems in equating for the amount of contact. If the time was equated to match the current standard protocol, the enhanced protocol would have to cut some of the smoking cessation content in order to cover additional mood management material. It would be difficult to deliver a comprehensive mood management treatment in such a limited contact time. Alternatively, additional material could have to be added to the standard protocol to equate for time across conditions as has been done in previous studies (Hall et al., 1996). Another possible limitation was a lack of a control condition to estimate the efficacy of the two treatment conditions. A control condition was not used because of the objectives of this study to improve quit rates over that achieved with standard care.

Another limitation is not assessing for treatment fidelity. Although counseling calls are periodically monitored by supervisors including some calls from this study, there was no systematic assessment of the interventions being delivered. Although the counselors were trained on how to use a cognitive behavioral approach to mood management, it is not clear what was actually being delivered.

There was also a problem with programming in this study which led to a problem with randomization. Although randomization was designed to stratify by counselors, an error meant some counselors had more participants from one condition over the other. This also meant some counselors had more participants overall. Examining the overall quit rates by counselors and dividing the counselors into two groups based on their effectiveness, there were about equal participants assigned to the two divisions of counselors from each treatment condition.

There were fewer participants reached for follow-up from the enhanced condition. It is not clear if this could be a result of some factor associated with the enhanced condition or by chance. The differential contact rates likely impacted the quit rates. It is possible the responders quit rate for the enhanced condition was inflated and if more participants had been reached that more would have been still smoking. Previous research has not found an association between not responding and smoking status. Many of the contact numbers were no longer working by follow-up evaluation. One reason for this may be participants moved or they use more temporary cell phone services.

In the intent-to-treat analyses, the lower follow-up contact rate for the enhanced condition may have led to underestimation of the effect. For example, in the intent-treat

analyses all those not reached for follow-up were considered not to have even made a 24 hour quit attempt. Yet at least half the participants make a quit attempt which suggests counting all those not reached for follow-up as not having made an attempt probably underestimates the actual rate. As discussed in the methods, this study primarily focuses on the responder quit rates as has been recommended by the North American Quitline Consortium. This is in part because previous findings have shown responder rates to be closer to the actual quit rate than intent-to-treat rates (NAQC issue paper).

Another limitation in this study is not using a control condition where a third group received only materials. Although the standard treatment condition has been shown in past studies to be effective, it is not know whether it is still effective or whether it is effective among those smokers with current depression. These potential limitations should be taken into consideration when designing future research in this area.

Future Research

A future study with a larger sample size could be powered to test for significant effects of the enhanced condition over the standard condition. Using the results of 30 day quit from this study (17.7% vs. 12.5%) would require sample sizes around 1000 in each arm to find significant effects of the ET. Looking at the 7 day quit rates differences (29.4% vs. 17.5%), a study with 80% power to detect a difference at a 5% significance level would need 230 participants in each arm in the absence of cluster effects.

Additionally, a follow-up study may want to include additional baseline assessment such as level of depression related impairment and current treatment for depression. It may also be of interest to assess baseline level of anxiety as this has also

been shown to be related to problems quitting. A follow-up study may want to employ

some of the considerations mentioned previously such as additional modules on sleep and

exercise, additional mailings, and having counselors available in the evenings. A study

with multiple follow-up periods would allow additional assessment of the impact of the

intervention over time and could also examine how changes in depression severity impact

quitting. The study may also want to include cost-effectiveness analyses to see whether

the additional time spent with each smoker pays off in terms of more smokers quitting

compared to using that time to reach more smokers.

In regards to study design, decisions would have to be made whether it is better to

have the same counselors administered both conditions as in the current study. Having

the same group of counselors deliver both conditions has limitations such as potential

cross over effects on the standard treatment condition. Counselors having been

extensively trained on how to address mood may have allowed that to impact how they

were approaching those in the standard treatment condition. Alternatively, having one set

of counselors deliver the enhanced and another set deliver the standard care may lead to

error in one group of counselors being more effective. The possibility of this bias can be

reduced by randomly assigning the counselors to the two conditions.

Summary and Conclusions

This study was the first study to assess a specialized telephone counseling

protocol to use with currently depressed smokers in the context of a quitline. This study's

primary aims were to show smokers with current depression were willing to participate in

a more intensive protocol which addressed mood management and to examine the effect

of the enhanced protocol on quitting outcomes. Depressed smokers were responsive to the enhanced protocol participating in significantly more sessions of counseling and reporting they received the right amount of counseling. This suggests when callers are offered additional counseling and called proactively they will participate in more sessions. One way to increase the number of telephone counseling sessions delivered is to increase the number of sessions in the protocol, expecting only about half will be completed. Future studies should continue to aim for more frequent sessions in order to improve the contact rates.

The second aim was to increase quitting among smokers in the enhanced condition compared to the standard condition. The enhanced condition was able to improve quit rates more than the clinically meaningful cutoff set prior to the start of the study of 5 percentage points. Additionally, the effect of the enhanced protocol of quit rates was equivalent in size to the effect of NRT and multiple session of telephone counseling. The study provides estimates of the effect size of the ET which could be used to conduct power analyses for larger studies.

The results show the promise of providing additional counseling to smokers with current major depression in the context of a state quitline. The present study helps to further a larger research agenda to establish a tailored telephone counseling protocol to increase the quit rate of smokers with current major depression. The effect of the enhanced condition could help a large number of smokers if adopted at CSH. Based on estimates from the previous depression screening study, about 7,000 smokers calling each year meet criteria for current major depression. Based on the 7 day quit rates found in the

current study, about 1225 would quit if given the standard treatment compared to an

estimated 2058 who would quit in the enhanced condition which would mean over 800

more quitters per year. These figures are just speculative but do give some perspective on

how an intervention with this size effect could impact quitting when implemented in the

context of a quitline.

The role CSH has had in getting interventions adopted by other quitlines and the

increased collaboration among quitlines through consortiums such as NAQC, means a

specialized intervention for depressed smokers could be quickly adopted by other

quitlines. The 50 U.S. state quitlines currently serve over 400,000 annually and an

intervention which is able to improve quit rates even by a small percent can have a large

impact on the number of quitters nationwide. In addition to U.S. state quitlines, there are

now programs available around the world seeking ways to improve outcomes among

callers. Given the large reach of quitlines, this line of research is promising in being able

to target a subpopulation of smokers who have been shown to have more difficulty

quitting and provide more intensive services in an attempt to improve quit rates.

Table 1

Baseline Demographic Characteristics of Participants

	Enhanced Treatment		Standard Treatment	
	N	% (±95%CI)	N	% (±95%CI)
Gender				
Men	14	31.1 (13.5)	17	37.0 (14.0)
Women	31	68.9 (13.5)	29	63.1 (14.0)
Ethnicity				
non-Hispanic White	27	58.7 (14.2)	30	66.7 (13.8)
African American	12	26.1 (12.7)	5	11.1 (9.2)
Hispanic	7	15.2 (10.4)	8	17.8 (11.2)
Asian/Pacific Islander	0	0	1	2.2 (4.3)
Native American	0	0	1	2.2 (4.3)
Age				
$\leq$24	7	15.2 (10.4)	3	6.5 (7.1)
25-44	13	28.3 (13.0)	17	37.0 (14.0)
45-64	24	52.2 (14.4)	25	54.4 (14.4)
$\geq$65	2	4.4 (5.9)	1	2.2 (4.2)
Average Age (*SD*)	-	46.2 (13.4)	-	45.4 (12.8)
Education				
$\leq$12 years	25	54.3 (14.4)	25	54.3 (14.4)
>12 years	21	45.7 (14.4)	21	45.7 (14.4)
Child at home				
Yes	19	41.3 (14.2)	22	47.8 (14.4)
No	27	58.7 (14.2)	24	52.2 (14.4)

Table 2

Baseline Smoking and Mood Characteristics of Participants

	Enhanced Treatment		Standard Treatment	
	N	% (±95%CI)	N	% (±95%CI)
CPD				
<15	19	41.3 (14.2)	16	34.8 (13.8)
≥15	27	58.7 (14.2)	30	65.2 (13.8)
Mean CPD (*SD*)	-	17.2 (12.2)	-	19.4 (11.1)
Time until first cigarette				
within 30 minutes	39	84.8 (10.4)	36	78.3 (11.9)
after 30 minutes	7	15.2 (10.4)	10	21.7 (11.9)
Plan to use quitaid				
Yes	30	76.9 (13.2)	37	88.1 (9.8)
No	9	23.1 (13.2)	5	11.9 (9.8)
Home smoking ban				
Yes	22	47.8 (14.4)	20	43.5 (14.3)
No	24	52.2 (14.4)	26	56.5 (14.3)
Anxiety				
Yes	15	32.6 (13.5)	19	44.2 (14.8)
No	31	67.4 (13.5)	24	55.8 (14.8)
Mean PHQ-8 score (*SD*)	-	14.9 (3.5)	-	14.9 (3.7)

Note. PHQ-8 is the Patient Health Questionnaire Mood Module. CPD is cigarettes per day smoked.

Table 3

Mean Counseling Received by Standard and Enhanced Treatment Participants

| | Enhanced Treatment | | Standard Treatment | | | |
	Mean (*SD*)	±95%CI	Mean (*SD*)	±95%CI	T-test (df)	p value
Mean Number of Sessions	6.7 (5.3)	1.5	3.5 (2.6)	0.8	3.68 (90)	0.01
Mean Total Number of Minutes	114.2 (84.1)	23.8	52.7 (30.3)	8.5	4.66 (90)	0.01
Mean Length of First Call	39.6 (14.4)	4	33.0 (11.2)	2.9	2.45 (90)	0.02

Table 4

Service Satisfaction Outcomes by Treatment Condition

	Enhanced Treatment		Standard Treatment	
	N	% (±95%CI)	N	% (±95%CI)
Number of sessions				
Too Few	2	6.3 (8.4)	9	24.3 (13.8)
Just Right	27	84.4 (12.6)	26	70.3 (14.7)
Too Many	3	9.4 (10.1)	2	5.4 (7.3)
Overall Service Satisfaction				
Very Satisfied	24	72.7 (15.2)	22	66.7 (16.1)
Satisfied	9	27.3 (15.2)	11	33.3(16.1)
Counselor as Listener				
Very good	26	81.3 (13.5)	24	66.7 (15.4)
Good	6	18.8 (13.5)	12	33.3 (15.4)
Counselor as Nonjudgemental				
Very good	25	78.1 (14.3)	27	75 (14.1)
Good	7	21.9 (14.3)	9	25 (14.1)
Ranking of quit plan (0-10)				
10	21	65.6 (16.5)	11	30.6 (15.1)
less than 10	11	34.4 (16.5)	25	69.4 (15.1)

Table 5

Quitting Outcomes by Treatment Condition

| | Responders Quit Rate | | | | Intent-to-Treat Quit Rate | | | |
| | ET | | ST | | ET | | ST | |
	N	% (±95%CI)	N	% (±95%CI)	N	% (±95%CI)	N	% (±95%CI)
Made 24 hr Quit Attempt	24	70.6 (15.3)	26	65.0 (14.8)	24	52.2 (14.4)	26	56.5 (14.3)
Currently Not Smoking	11	32.4 (15.7)	7	17.5 (11.8)	11	23.9 (12.3)	7	15.2 (10.4)
7 Day Point Prevalence Quit	10	29.4 (15.3)	7	17.5 (11.8)	10	21.7 (11.9)	7	15.2 (10.4)
30 Day Point Prevalence Quit	6	17.7 (12.8)	5	12.5 (10.3)	6	13.0 (9.7)	5	10.9 (9.0)

Table 6

Smoking Outcomes Among Participants Still Smoking

	Enhanced Treatment		Standard Treatment	
	N	% (±95%CI)	N	% (±95%CI)
Used Quit Aid				
Yes	14	60.9 (19.9)	14	43.8 (17.2)
No	9	39.1 (19.9)	18	56.3 (17.2)
Confidence				
Very	4	18.2 (16.1)	5	15.6 (12.6)
Confident	6	27.3 (18.6)	11	34.4 (16.5)
Not Confident	12	54.5 (20.8)	16	50.0 (17.3)
Tried to Quit				
Yes	16	69.6 (18.8)	21	63.6 (16.4)
No	3	13 (13.7)	7	21.2 (13.9)
Cut down	4	17.4 (15.5)	5	15.2 (12.2)
CPD				
<15	21	91.3 (11.5)	24	75.0 (15.0)
≥15	2	8.7 (11.5)	8	25.0 (15.0)
mean CPD (SD)		5.9 (5.0)		9.1 (7.0)
Time until first cigarette				
within 30 minutes	11	47.8 (20.4)	14	42.4 (16.9)
after 30 minutes	12	52.2 (20.4)	19	57.6 (16.9)
Plan to quit within 30 days				
Yes	19	90.5 (12.5)	25	78.1 (14.3)
No	2	9.5 (12.5)	7	21.9 (14.3)

Note. CPD is cigarettes per day.

Table 7

Mood Outcomes by Treatment Condition

	Enhanced Treatment		Standard Treatment	
	N	% (±95%CI)	N	% (±95%CI)
Depression Status				
Major Depression	5	14.7 (11.9)	11	28.2 (14.1)
Mild Depression	7	20.6 (13.6)	8	20.5 (12.7)
Minimal Depression	22	64.7 (16.1)	20	51.3 (15.7)
Mean PHQ-8 (*SD*)	-	8.8 (6.5)	-	10.3 (6.0)
Mean Improvement in PHQ-8 (*SD*)	-	5.9 (6.4)	-	4.8 (5.9)
Taking Medication for Depression				
Yes	15	44.1 (16.7)	15	39.5 (15.5)
No	19	55.9 (16.7)	23	60.5 (15.5)
Sought Help for Depression				
Yes	14	41.2 (16.5)	18	47.4 (15.9)
No	20	58.8 (16.5)	20	52.6 (15.9)
Currently in Therapy				
Yes	10	28.6 (15.0)	10	24.4 (13.1)
No	25	71.4 (15.0)	31	75.6 (13.1)

Note. PHQ-8 is the Patient Health Questionnaire Mood Module.

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