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A Cognitive Behavioral Smoking Abstinence Intervention for Adults with Chronic Pain: A Randomized Controlled Pilot Trial

W. Michael Hooten, MD^{*}, Cynthia O. Townsend, PhD[†], J. Taylor Hays, MD[§], Kaye L. Ebnet, RN[‡], Thomas R. Gauvin, MS[§], Jessica M. Gehin, RN, MS[‡], Heidi J. Laures, BA[†], Christi A. Patten, PhD[†], and David O. Warner, MD^{*}

^{*}Department of Anesthesiology, Mayo College of Medicine, Rochester, MN

[†]Department of Psychiatry and Psychology, Mayo College of Medicine, Rochester, MN

[§]Department of Internal Medicine, Mayo College of Medicine, Rochester, MN

[‡]Department of Nursing, Mayo Clinic, Rochester, MN

Abstract

Current evidence suggests it may be difficult for patients with chronic pain to quit smoking and, based on previous formative work, a 7-session individual and group-based cognitive behavioral (CB) intervention was developed. The primary aim of this randomized controlled pilot trial was to test the hypothesis that abstinence at month 6 would be greater among patients with chronic pain who received the CB intervention compared to a control condition. Upon admission to a 3-week interdisciplinary pain treatment (IPT) program, patients were randomized to receive the CB intervention (n = 30) or the control condition (n = 30). The 7-day point prevalence of self-reported smoking status was assessed at week 3 (upon completion of the 3-week IPT program) and at month 6 in an intent-to-treat analysis. At week 3, 30% (n=9) of patients in the CB condition were abstinent from smoking compared to 10% (n=3) in the control group ($P=.104$). At month 6, 20% (n=6) of patients who received the CB intervention were abstinent compared to none in the control group ($P=.024$). At week 3, a significant group by time interaction effect was found where the CB patients experienced greater improvements in self-efficacy from baseline compared to the control

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Corresponding Author: W. Michael Hooten, MD, Associate Professor, Department of Anesthesiology, Mayo Clinic College of Medicine, 200 First St SW, Rochester, MN 55905, Ph 507-266-9877, hooten.william@mayo.edu.

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Contributors

WMH, COT, DOW, CAP and JTH designed the study and wrote the protocol. KLB, TRG and JMG screened potential study subjects, participated in the conduct of the trial and compiled outcomes data. HJL compiled data and conducted statistical analysis. WMH, COT, DOW, CAP and JTH wrote the first draft of the manuscript, and all authors contributed to and have approved the final manuscript.

Conflict of Interest

All other authors declare that they have no conflicts of interest.

The research was conducted at the Mayo Pain Rehabilitation Center, Department of Psychiatry and Psychology, and the Translational Research Unit for Chronic and Acute Pain, Department of Anesthesiology, Mayo Clinic, Rochester, MN.

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group ($P=.002$). A greater proportion of patients randomized to the CB group completed the IPT program ($P=.052$). The findings of this pilot trial suggest that integration of a CB-based smoking abstinence intervention into ongoing pain therapy may be an effective treatment for smokers with chronic pain.

1. INTRODUCTION

Current evidence suggests it may be difficult for patients with chronic pain to quit smoking (Fishbain, Lewis, Cole et al., 2007; Hooten, Townsend, Bruce, Schmidt et al., 2009), and there are no validated tobacco use interventions targeted to these patients. This is unfortunate, given that there is a strong association between smoking status and chronic pain (Shi, Weingarten, Mantilla, Hooten, & Warner, 2010). For example, smoking is associated with greater levels of pain mediated, in part, by greater levels of depression (Hooten, Shi, Gazelka, & Warner, 2011; Hooten, Townsend, Bruce, & Warner, 2009; Weingarten et al., 2008). Smoking has also been associated with an increased rate of analgesic medication use and consumption of greater dosages of opioids independent of depression (Hooten, Shi et al., 2011; Hooten, Townsend, Bruce, & Warner, 2009). The long-term treatment outcomes of smokers with chronic pain are generally worse compared to nonsmokers (Fishbain, Lewis, Cutler et al., 2007; Fishbain, Lewis, Gao, Cole, & Steele Rosomoff, 2009; Hellsing & Bryngelsson, 2000; Vogt, Hanscom, Lauerman, & Kang, 2002). Nonetheless, we found that the immediate outcomes of a 3-week interdisciplinary pain treatment (IPT) program, including the success of opioid tapering, were either similar or significantly better in smokers compared to nonsmokers (Hooten, Townsend, Bruce, Schmidt et al., 2009). These favorable immediate treatment outcomes for smokers suggest the clinical setting of an IPT program, which includes daily contact with clinicians, may provide an opportune environment to deliver tobacco use interventions.

As a first step toward designing a cognitive behavioral (CB) tobacco use intervention for adults with chronic pain who smoke cigarettes, we previously investigated the barriers and facilitators of smoking abstinence in patients undergoing IPT using qualitative methods (Hooten, Vickers et al., 2011). These patients reported smoking was an important coping strategy to distract from pain and avoid emotional distress. Perceived barriers to making a quit attempt during IPT included managing multiple treatment-related stressors and change in opioid use. Perceived facilitators of making a quit attempt included support from other patients and the structure of the IPT program which limited the opportunity to smoke. Based on the findings of this qualitative study, we developed a CB tobacco use intervention for patients with chronic pain undergoing IPT.

The aim of this pilot study was to evaluate the feasibility of the newly developed CB intervention and generate an estimate of the treatment effect size for use in planning a future efficacy trial. Adults with chronic pain admitted to a 3-week outpatient IPT program were randomized to receive either the CB intervention or standard control condition to test the hypothesis that the 7-day point prevalence self-reported smoking status at month 6 in an intent-to-treat analysis would be greater among patients who received the CB intervention compared to patients who received the control intervention. Secondary outcome measures, utilizing an intent-to-treat analysis, included determining the rate of smoking abstinence,

change in self-efficacy to quit smoking, and change in pain-related functional status immediately following completion of the 3-week IPT program (week 3).

2. METHODS

2.1 Participants and randomization

The study was approved by the Mayo Foundation institutional review board, and written informed consent was obtained from all study participants. All patients were recruited at admission to the Mayo Comprehensive Pain Rehabilitation Center in Rochester, MN, from November 2009 through January 2011. Inclusion criteria included smoking 10 cigarettes per day, admission to the 3-week outpatient interdisciplinary pain treatment program, age 18 years, and chronic non-cancer pain of at least 6 months duration. Exclusion criteria included major surgery within the past 6 months (e.g., spinal discectomy, laminectomy, or fusion; intra-abdominal or intrapelvic surgery requiring inpatient postoperative care; total hip, knee, or shoulder joint replacement), severe psychiatric symptoms or disorders that could limit the patient's ability to function in an ambulatory care environment (e.g., poorly controlled major depressive disorder, bipolar disorder, schizophrenia or schizoaffective disorder, dementia), and use of other tobacco products other than cigarettes (e.g., pipe or spit tobacco).

Study patients were randomized to the newly-developed CB intervention or control condition in 4 sequential blocks each containing 15 patients. The block randomization design was used to ensure an adequate number of patients were available to participate in the group component of the CB intervention. A period of one week was allowed to elapse between each sequential block of patients to ensure that patients in the CB group did not have contact with patients in the control group. A computer-generated randomization schedule was prepared by biostatistics personnel who were not involved in the clinical conduct of the trial. The random allocation sequence was held by a purpose-designed control center that serviced our institution. The investigators responsible for the clinical conduct of the trial did not have access to the allocation sequence and, using this approach, group allocation was concealed. However, it was not possible to blind the investigators or study patients to the CB intervention or control condition. All clinical outcomes were assessed by research personnel who were not involved in the clinical conduct of the trial.

2.2 Treatment setting

The study was conducted at the Mayo Clinic Rochester outpatient IPT program, a treatment setting that has been previously described (Townsend, Bruce, Hooten, & Rome, 2006). To summarize, the program was of 3 weeks duration. Admissions to the program occurred on a revolving basis, and patients attended 8-hours daily for 15 consecutive working days. A cognitive behavioral model served as the basis for treatment. The primary goal of treatment was functional restoration. During the course of treatment, patients were involved in daily physical reconditioning, biofeedback and relaxation training, stress management, chemical health education, activity moderation, and elimination of pain behaviors. Patients were also involved in daily cognitive behavioral group educational sessions where the aforementioned aspects of pain rehabilitation were addressed.

2.3 Smoking status assessment

Smoking status was assessed upon admission to the pain treatment program using the items employed by the Behavioral Risk Factor Surveillance System (Centers for Disease Control and Prevention (CDC), 1985): 1) Have you ever smoked a cigarette, even a puff? (Yes/No); 2) Have you smoked at least 100 cigarettes in your entire life? (Yes/No/Not sure); 3) Do you now smoke cigarettes every day, some days, or not at all? (Everyday/Some Days/Not at all). At the completion of the 3-week IPT program (week 3) and at month 6 follow-up, the self-reported 7-day point prevalence smoking status was assessed via telephone contact, as patients were not available for in-person follow-up. Those who did not complete the month 6 follow-up or had missing data were counted as smokers. This definition of abstinence is based on consensus statements from the Society for Research on Nicotine and Tobacco Subcommittee on Abstinence Measures that recommend using a 7-day period for point prevalence estimates of smoking abstinence (Hughes et al., 2003).

2.4 CB tobacco use intervention and control condition

2.4.1. CB intervention—The CB intervention was designed based on the findings of our previous formative research that utilized qualitative methods to identify the barriers and facilitators of smoking abstinence (Hooten, Vickers et al., 2011). The identified themes from this qualitative research and other components of the CB intervention were consistent with a taxonomy of 44 behavior change techniques (BCTs) used to support smoking abstinence (Michie, Hyder, Walia, & West, 2011). In the Michie et al. study, each BCT was assigned a unique code, and, in order to facilitate standardization of BCTs for smoking abstinence, the appropriate codes for the major components of the CB intervention have been provided. Prominent themes identified in the previous qualitative study (Hooten, Vickers et al., 2011) included; 1) smoking was a distraction from pain (BS1), 2) smoking was a coping strategy for emotional distress (BS1), 3) support from other patients with chronic pain was a benefit to quitting smoking (A2), 4) the structure and schedule of an IPT program was beneficial because it limited the opportunity to smoke (BS8), 5) making changes in prescription opioid use was a barrier to smoking abstinence (BS1), and 6) managing multiple changes and stressors during IPT was a barrier to quitting smoking (BS1). Other important themes identified in this formative work (Hooten, Vickers et al., 2011) included a preference for group versus individual sessions (RD1), recognition among patients that variation existed in the motivation to quit smoking (BM5), and acknowledgement that educational information about quitting smoking was motivational (BM1). In addition, the CB intervention also included 1) encouragement to enhance motivation and self-efficacy to quit smoking (BM2), 2) establishment of a quit plan (BS3) and quit date (BS4), 3) establishment of a relapse prevention plan (BS 2), 4) regular review of treatment goals (BS5), 5) assessment of current and past smoking behaviors (R11) including previous quit attempts (R13), 6) assessment of the readiness to quit smoking (R12), 7) information about nicotine withdrawal (R14), and 8) assessment for symptoms of nicotine withdrawal (RC6)."

A 7-session smoking abstinence intervention was developed comprised of 3 individual and 4 group sessions based on the barriers and facilitators identified in our formative work (Hooten, Vickers et al., 2011). A semi-structured interview was developed for each 30-minute group and individual treatment session. All individual sessions were conducted by a

specialty trained registered nurse or master's level psychologist who had previously completed a tobacco treatment specialist program that was accredited by the Council on Tobacco Treatment Training Programs. All group sessions were conducted by a pain specialty physician, a specialty trained registered nurse and master's level psychologist. Figure 1 depicts the sequence in which the individual and group sessions were administered during the 3-week course of the IPT program.

2.4.2. Control condition—The control condition consisted of a 1-hour smoking abstinence intervention that was provided by a trained tobacco treatment specialist in the Mayo Nicotine Dependence Center (NDC). The brief intervention involved development of a detailed treatment plan and relapse prevention plan (Hays et al., 2001; Hooten et al., 2005). The components of the single-session intervention were consistent with evidence-based practice guidelines that are in widespread clinical use (Fiore et al., 2008) and are the standard of care at our institution. In a prior study, this intervention was used at our interdisciplinary pain treatment program, and all patients who smoked at baseline continued to smoke at the time of program dismissal and at 6-month follow-up (Hooten, Townsend, Bruce, Schmidt et al., 2009). For patients randomized to the control group, no other intervention or self-help materials were provided, and the tobacco treatment specialist from the NDC had no further contact with the patient. There was no contact between the tobacco treatment specialist from the NDC and staff members from the IPT program who delivered the intervention to patients in the CB group.

2.5 Physician recommendations for pharmacotherapy

Following study recruitment but prior to receiving either the CB or control intervention (Figure 1), all study patients were evaluated by a physician from the Mayo Nicotine Dependence Center with expertise in the treatment of tobacco dependence for recommendations regarding the use of smoking abstinence pharmacotherapy (e.g., varenicline, bupropion, nicotine replacement products) (A1). All patients were evaluated in a general internal medicine outpatient clinic setting. The decision to use pharmacotherapy was at the discretion of the patient and physician. Following the specialty physician evaluation, the use of any recommended pharmacotherapy was under the management of the IPT program staff physician.

2.6. Self-report measures

2.6.1. Demographics and clinical characteristics—Baseline demographic and clinical characteristics were collected at admission including age, gender, ethnicity, employment status, pain duration, primary pain site, marital status, years of education and medication use.

2.6.2. Pain Severity and pain-related affective distress—Pain severity and affective distress due to pain were assessed using the respective subscales of the Multidimensional Pain Inventory (Kerns, Turk, & Rudy, 1985). This self-report questionnaire has proven reliability and construct validity (Bernstein, Jaremko, & Hinkley, 1995). Raw scores from the 52-item self-report questionnaire were converted to standardized *t*-scores with a normative value of 50 (range 0–100) and a SD of 10 (Rudy, 1989). These two MPI

subscales have been used to assess clinical outcomes of smokers with chronic pain admitted to our IPT program (Hooten, Shi et al., 2011; Hooten, Townsend, Bruce, Schmidt et al., 2009; Hooten, Townsend, Bruce, Shi, & Warner, 2009; Hooten, Townsend, Bruce, & Warner, 2009).

2.6.3. Physical and social functioning—Physical and social functioning were assessed using the Short Form-36 Health Status Questionnaire (SF-36) (McHorney, Ware, & Raczek, 1993; McHorney, Ware, Rogers, Raczek, & Lu, 1992; J. E. Ware, Jr. & Sherbourne, 1992). The self-administered 36-item questionnaire was scored on a 5-level Likert scale. Higher scores reflected a more favorable health status. The raw scores were converted to *t*-scores with a normative value of 50 and a SD of 10. Standardized *t*-scores were calculated with the use of published age and gender-specific mean scores (J. Ware, 1993). The physical and social functioning subscales have been previously used to measure outcomes of smokers with chronic pain admitted to our IPT program (Hooten, Townsend, Bruce, Schmidt et al., 2009; Hooten, Townsend, Bruce, Shi et al., 2009).

2.6.4. Depression—Depression was assessed at baseline using the Center for Epidemiologic Studies-Depression scale (CES-D), which has established reliability and validity in adults with chronic pain (Giesecke et al., 2005; Weissman, Sholomskas, Pottenger, Prusoff, & Locke, 1977). Scores range from 0 to 60, where higher scores indicate greater levels of depressive symptoms. The CES-D has been used to assess depressive symptoms of smokers with chronic pain admitted to our IPT program (Hooten, Shi et al., 2011; Hooten, Townsend, Bruce, Schmidt et al., 2009; Hooten, Townsend, Bruce, Shi et al., 2009).

2.6.5. Pain-related anxiety—The short version of the Pain Anxiety Symptoms Scale (PASS-20) was used to measure pain-related anxiety (McCracken & Dhingra, 2002). The 20-item self-report questionnaire has a score range of 0 to 100, where higher scores indicate greater levels of anxiety. The PASS-20 has been used to assess pain-related anxiety in smokers with chronic pain admitted to our IPT program (Hooten, Townsend, Bruce, Schmidt et al., 2009; Hooten, Townsend, Bruce, Shi et al., 2009).

2.6.6. Nicotine dependence—The severity of nicotine dependence was assessed using the Fagerström Test for Nicotine Dependence (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991). Scores range from 0 to 10, where higher scores indicate greater levels of nicotine dependence.

2.6.7. Self-efficacy to quit smoking—Perceived self-efficacy was assessed with the following item: “How confident are you in your ability to quit smoking?” The item was rated on a 10-point scale ranging from ‘1’ (not at all confident) to ‘10’ (completely confident).

2.6.8. Nicotine withdrawal—The severity of nicotine withdrawal symptoms was assessed using the Minnesota Nicotine Withdrawal Scale-Revised (MNWS-R) (Hughes, 2007; Hughes & Hatsukami, 1986). All 15-items were rated on a 5-point scale ranging from ‘0’ (not present) to ‘4’ (severe) based on symptoms occurring during the past 24 hours.

2.6.9. Determination of morphine equivalent dose—At admission, the daily opioid dose of each study patient was determined by self-report and review of pharmacy records, and the daily opioid dose was converted to daily morphine equivalents as previously described (Cunningham, Rome, Kerkvliet, & Townsend, 2009).

2.7. Data analysis

2.7.1. Sample Size—For purposes of this pilot trial, the main objective in determining sample size was to estimate the precision of the estimate of the intervention effect, important in planning the needed sample size for a future clinical trial. For the dichotomous variable of 7-day point prevalence of self-reported smoking status, we assumed that a between group difference in the 6-month abstinence rate of 20% would be clinically meaningful and consistent with the results of tobacco use interventions in general clinical practice. For 30 subjects in the CB group, the 95% confidence interval for an observed 20% abstinence rate would be 6–34%.

2.7.2. Data Analyzes—Demographics and baseline clinical characteristics were summarized for each study group. Between-group comparisons were made using the rank sum test for continuous variables, and the chi-square test or Fisher's exact test, where appropriate, for categorical variables.

The primary outcome measure was smoking status (self-reported 7-day point prevalence abstinence vs. current smoking) at month 6 in an intent-to-treat analysis. The secondary outcome measures were self-reported smoking status at week 3, change in self-efficacy to quit smoking and change in pain-related functional status from baseline to week 3 in an intent-to-treat analysis. The between-group comparisons for smoking status at month 6 and week 3 were made using Fisher's exact test. Those who did not complete month 6 or week 3 assessment were counted as smokers. The assessment of change in self-efficacy and pain-related functional status were made using repeated measures analysis of variance (ANOVA) utilizing generalized estimating equations including the main effect of time, and the interaction of time by group. The effect size (Cohen's d) of the change in self-efficacy and pain-related functional status were calculated for each group. Effect sizes were defined as small ($0.2 \leq d < 0.5$), medium ($0.5 \leq d < 0.8$) and large ($d \geq 0.8$) (Cohen, 1988). For patients who did not complete the secondary outcome measures at week 3, the baseline value of each missing end point was carried forward. Secondary analyses were conducted for completion of the interdisciplinary pain treatment program, opioid status at week 3 and use of smoking abstinence pharmacotherapy at week 3. Two-sided tests were used in all analyses, and the level of significance for all statistical tests was set at $p < 0.05$. Data were analyzed using IBM SPSS, version 21.0 (IBM, Chicago, IL).

3. RESULTS

3.1. Patient flow diagram and protocol adherence

Figure 2 provides a flow diagram of all patients who were assessed and randomized for study participation. Three patients did not receive the allocated intervention (CB group = 1, control group = 2). Eight patients were lost to week 3 follow-up (CB group = 1, control

group = 7) due to noncompletion of the IPT program, and 22 patients (CB group = 8, control group = 14) did not respond to month 6 follow-up.

Among patients in the CB group who received the allocated intervention ($n = 29$), 93% ($n = 27$) of patients attended all 3 individual sessions. One patient attended 1 of 3 individual sessions, and 1 patient attended 2 of 3 individual sessions. Similarly, among patients in the CB group who received the allocated intervention 72% ($n = 21$) attended all 4 group sessions. Five patients attended 3 of 4 group sessions, 1 patient attended 2 of 4 sessions, and 1 patient attended 1 of 4 group sessions. Overall, 93% of patients in the CB group attended at least 3 of 4 group sessions. All patients in the control group who received the allocated intervention ($n = 28$) completed the single session intervention.

3.2. Demographics and clinical characteristics

The majority of study participants were married Caucasian females and were not currently working (Table 1). An equal number of patients randomized to the CB and control groups were using opioids. The morphine equivalent dose of patients randomized to the control group was not significantly greater compared to the CB group. No significant group differences in age, sex, ethnicity, body mass index, marital or work status, years of education, pain duration, or primary pain diagnosis were observed.

3.3. Intent-to-treat analysis of smoking abstinence

At week 3, 30% of patients in the CB group self-reported abstinence compared to 10% in the control group (Table 2). At month 6, 20% of patients in the CB group self-reported abstinence compared to none in the control group. A greater proportion of patients in the CB group completed the IPT program compared to the control group (Table 2). The proportion of subjects in both groups using opioids a program completion was low and not significantly different between groups.

3.4. Intent-to-treat analysis of secondary outcome measures

Regarding pain-related outcome measures, a significant within-subjects effect of time was observed for all measures, indicating improvement in pain-related functionality during the course of the IPT program (Table 3). However, no significant time by group interaction effects were observed, indicating that the magnitude of improvement did not depend on treatment assignment.

Regarding other measures related to smoking behavior, the number of cigarettes smoked daily decreased, and the self-efficacy to quit smoking increased for both treatment groups. A significant time by group interaction effect was also observed for cigarettes smoked daily [$F(1,58) = 7.0, P = .024$] signifying patients in the CB group experienced significantly greater reduction in daily cigarette consumption. A significant time by group interaction effect was also observed for self-efficacy [$F(1, 58) = 10.3, P = .002$] signifying patients in the CB group experienced significantly greater improvement in self-efficacy compared to the control group. Nicotine withdrawal symptoms increased in both groups over the course of the IPT program, but no significant group by time interaction effects were observed.

Twenty-two (73%) patients in the CB group and 16 (53%) in the control group were using pharmacotherapy at week 3, proportions that were not significantly different ($P = .242$). Among patients who quit smoking at week 3, 6 of 9 patients in the CB group and 2 of 3 in the control group were using pharmacotherapy.

Among the 28 patients who were using opioids at baseline (14 in each group), 7 (CB = 5, control group = 2) quit smoking at week 3, and 2 (CB group = 2) were abstinent from tobacco at month 6.

4. DISCUSSION

The main findings of this randomized controlled pilot trial were that, 1) the newly-developed CB intervention for patients undergoing IPT was feasible, and 2) there is preliminary indication of efficacy at IPT program completion and at 6 months after completion based on self-reported smoking status.

Tobacco use interventions have been successfully integrated into the treatment protocols of several medical and mental health disorders (Awaisu et al., 2012; Hall et al., 2006; Hennrikus et al., 2010; Humfleet, Hall, Delucchi, & Dilley, 2013; McFall et al., 2010), but to our knowledge this is the first intervention targeted towards patients with chronic pain. We chose the setting of an IPT program for two main reasons. First, IPT utilizes a CB approach as the basis for treating chronic pain-related impairments in physical and psychosocial functioning (Gatchel & Rollings, 2008; Stanos, 2012). Therefore, the treatment protocols of an IPT program are poised to reinforce the behavioral changes targeted by a CB-based tobacco use intervention. The findings from our previous work suggest smokers with chronic pain may have underdeveloped coping skills, and they may experience greater benefits from CB-based treatment approaches for managing chronic pain (Hooten, Townsend, Bruce, Schmidt et al., 2009). As a result, several elements of the smoking abstinence intervention tested in this pilot trial were designed to encourage patients to adopt cognitive behavioral strategies for managing chronic pain to smoking abstinence. Second, the 3-week duration of the IPT program provided the opportunity to engage patients in an intensive 7-session smoking abstinence intervention. Previous treatment guidelines suggest that intensive CB-based smoking abstinence interventions were associated with greater abstinence rates compared to less intensive interventions (Fiore et al., 2008). This may be particularly relevant to smokers with chronic pain in that our previous research suggests that smokers with chronic pain may not be responsive to less intensive treatment approaches (Hooten, Townsend, Bruce, Schmidt et al., 2009).

The relationship between tobacco use and pain is complex (Shi et al., 2010). Although nicotine affects pain pathways, and nicotine withdrawal can affect pain perception, there are few data regarding the impact of abstinence on pain-related measures in patients with chronic pain. Our formative work identified that patients viewed smoking as an important means to cope with pain, and expressed some concerns that abstinence would interfere with pain treatment. However, no differences in pain-related outcomes at IPT program completion were noted between groups, suggesting that attempts to maintain abstinence did not adversely affect treatment responses to pain. Indeed, because the primary goal of the IPT

program was to enhance pain-related coping, removal of tobacco as a coping mechanism may have little impact on pain in this setting. In addition, in a prior large observational study of patients participating in our IPT program, smokers were nearly twice as likely to experience program non-completion compared to former and never smokers, independent of opioid use and pain severity at program admission (Hooten, Townsend, Bruce, & Warner, 2009). Of interest, a greater proportion of patients randomized to the CB group completed the 3-week IPT program. We speculate that desire to participate in tobacco use treatment may serve as an additional motivator to complete the IPT program, which would represent a significant additional benefit of tobacco use treatment. This hypothesis should be evaluated in future studies. Finally, even patients who were using opioids at baseline were also able to quit, suggesting that opioid use was not a barrier to intervention success.

A significant change in self-efficacy to quit smoking was observed in both groups from admission to completion of the 3-week IPT program. The observed change in self-efficacy in both groups could have been partly attributed to concurrent participation in the IPT program which could have led to improvements in the self-efficacy to manage chronic pain and other health-related problems, including smoking. In addition, the significant change in self-efficacy observed in the control group could have been attributed, in part, to the single session smoking abstinence intervention which also included contact with the smoking abstinence specialty physician. However, the CB intervention clearly enhanced self-efficacy, suggesting its potential role as a mediator of the observed treatment effect in terms of abstinence.

This pilot study has several limitations. The study population consisted of patients with long-standing chronic pain who are highly motivated to participate in an IPT program, and thus may not represent the general population of patients with chronic pain who smoke. However, the demographic characteristics of our cohort were similar to the characteristics of a random sample of community dwelling adults with chronic pain derived from the catchment area of our IPT program (Watkins, Wollan, Melton, & Yawn, 2008). The smoking status at month 6 was not biochemically confirmed which increases the potential risk of misclassification bias (Gorber, Schofield-Hurwitz, Hardt, Levasseur, & Tremblay, 2009). Additionally, due in part to the intensity of the CB intervention, self-report smoking status could have also been influenced by social desirability whereby patients may have been inclined to respond to inquires about smoking status in socially desirable terms. Although the control condition was consistent with current practice, a time-matched control condition was not used which could have impacted the smoking abstinence rate observed in patients who received the control condition. The secondary intent-to-treat analysis of self-efficacy included all study patients including those who were abstinent. Consequently, the significant time by group interaction effect observed for self-efficacy could have been related, in part, to actual abstinence rather than a specific treatment effect of the CB group. The sample size was powered to obtain a reasonable estimate of the magnitude of the effect of the newly developed CB smoking abstinence intervention; therefore, all findings of this pilot study require further evaluation in a larger randomized trial.

In conclusion, the findings of this pilot trial conducted in a 3-week IPT setting provide important preliminary data for development of a larger efficacy trial. These preliminary data

suggest that integration of a CB-based smoking abstinence intervention into ongoing pain therapy is feasible and may be efficacious. Prior to deployment for testing in a more conventional ambulatory pain clinic setting, it is anticipated the individual and group sessions will be further integrated. These preliminary findings also suggest that engaging patients in an intensive smoking abstinence intervention did not have an adverse effect on other immediate pain-related treatment outcomes. Indeed, involving patients in an intensive smoking abstinence intervention may actually improve adherence to ongoing pain therapy.

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Highlights

- Current evidence suggests it may be difficult for patients with chronic pain to quit smoking.
- An integrated smoking abstinence intervention may be effective for smokers with chronic pain.
- Smoking abstinence therapy may enhance compliance with treatment for chronic pain.

Figure 1.
Timeline of smoking cessation intervention.

Figure 2.
CONSORT 2010 Flow Diagram

Table 1

Baseline demographic and clinical characteristics.

Characteristic	Group	
	Control (N=30)	Cognitive Behavioral (N=30)
Age, years		
mean $\pm$ SD	40.4 $\pm$ 14.4	45.0 $\pm$ 12.5
Body mass index (kg/m ²)		
mean $\pm$ SD	31.5 $\pm$ 7.6	29.2 $\pm$ 5.3
Female, N (%)	25 (83.3)	22 (73.3)
Caucasian, N (%)	29 (96.7)	27 (90.0)
Married, N (%)	13 (43.3)	14 (46.7)
Currently working, N (%)	22 (73.3)	26 (86.7)
Education, years		
mean $\pm$ SD	13.6 $\pm$ 1.6	14.2 $\pm$ 2.2
Pain duration, years		
mean $\pm$ SD	8.0 $\pm$ 7.3	10.4 $\pm$ 8.2
Pain site, N (%)		
Fibromyalgia	7 (23.3)	6 (20.0)
Low back pain	8 (26.7)	5 (16.7)
Headache	1 (3.3)	3 (10.0)
Generalized	2 (6.7)	3 (10.0)
Abdominal	4 (13.3)	1 (3.3)
Pelvic	2 (6.7)	0
Upper extremity	1 (3.3)	2 (6.7)
Lower extremity	2 (6.7)	4 (13.3)
Facial	1 (3.3)	3 (10.0)
Neck	1 (3.3)	2 (6.7)
Chest wall	1 (3.3)	1 (3.3)
Currently using opioids, N (%)	14 (46.7)	14 (46.7)
Morphine equivalent dose (mg/day)		
mean $\pm$ SD	158.9 $\pm$ 145.1	84.1 $\pm$ 73.1

Table 2

Smoking abstinence and pain treatment program outcomes.

Characteristic	Group		<i>P</i> -value [*]
	Control (N=30)	Cognitive Behavioral (N=30)	
Smoking abstinence			
Week 3			
Abstinent, N (%)	3 (10)	9 (30)	.104
Month 6			
Abstinent, N (%)	0 (0)	6 (20)	.024
Pain treatment outcomes			
Completed program, N (%)	23 (76.7)	29 (96.7)	.052
Opioid use at program completion, N (%)	4 (13.3)	2 (6.7)	.671

* Fisher's exact test.

Table 3

Baseline and week 3 pain and tobacco use characteristics.

Variable	Control Group (N = 30)	Effect Size (<i>d</i>)	CB Group (N = 30)	Effect Size (<i>d</i>)
MPI pain severity				
Baseline	51.8 ± 6.0		53.5 ± 7.1	
Week 3	47.3 ± 10.0		45.9 ± 11.3	
Mean change	-4.4 ± 10.4	0.5	-7.6 ± 10.3	0.8
MPI affective distress				
Baseline	55.6 ± 9.9		53.9 ± 9.3	
Week 3	49.7 ± 14.5		43.5 ± 11.1	
Mean change	-7.0 ± 17.3	0.5	-10.1 ± 18.7	1.0
SF-36 physical function				
Baseline	22.5 ± 10.8		26.5 ± 12.4	
Week 3	35.6 ± 13.3		36.1 ± 13.3	
Mean change	12.9 ± 17.0	1.1	9.6 ± 16.3	0.7
SF-36 social functioning				
Baseline	27.0 ± 10.4		29.0 ± 13.8	
Week 3	34.9 ± 14.9		41.6 ± 11.4	
Mean change	10.3 ± 14.6	0.6	17.0 ± 14.2	1.0
CES-D				
Baseline	35.5 ± 15.1		30.4 ± 13.2	
Week 3	20.4 ± 16.4		19.6 ± 14.0	
Mean change	-15.2 ± 19.0	1.0	-10.8 ± 18.8	0.8
PASS-20				
Baseline	59.1 ± 20.2		51.8 ± 17.9	
Week 3	39.6 ± 21.4		30.6 ± 18.6	
Mean change	-19.5 ± 25.0	0.9	-21.2 ± 20.7	1.2
Cigarettes per day				
Baseline	18.1 ± 8.0		17.3 ± 8.0	
Week 3	14.1 ± 11.0		6.4 ± 7.4	
Mean change	-4.0 ± 10.6	0.4	-10.9 ± 9.8	1.4
Self-efficacy to quit smoking				
Baseline	3.8 ± 1.9		3.9 ± 2.7	
Week 3	5.8 ± 2.4		8.1 ± 2.4	
Mean change	2.0 ± 2.2	0.9	4.2 ± 3.2	1.6
MNWS-R				
Baseline	14.8 ± 9.8		15.7 ± 11.5	
Week 3	20.3 ± 6.1		21.0 ± 6.5	
Mean change	5.5 ± 10.3	0.7	5.4 ± 10.1	0.6
Fagerstrom Test of Nicotine Dependence				
Baseline	4.5 ± 2.0		4.4 ± 1.8	

MPI, Multidimensional Pain Inventory; SF-36, Short Form-36 Health Status Questionnaire; CES-D, Center for Epidemiologic Studies-Depression scale; PASS-20, Pain Anxiety Symptoms Scale short version; MNWS-R, Minnesota Nicotine Withdrawal Scale-Revised.

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