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Cognitive Behavioral Therapy and the Nicotine Transdermal Patch for Dual Nicotine and Cannabis Dependence: A Pilot Study

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Abstract

We assessed the feasibility of a new cognitive behavioral therapy (CBT) manual, plus transdermal patch nicotine replacement therapy (NRT), to treat co-occurring nicotine and cannabis dependence. Seven of twelve (58.3%) adults with DSM-IV diagnoses of both nicotine and cannabis dependence completed 10 weeks of individual CBT and NRT. Participants smoked 12.6 ± 4.9 tobacco cigarettes per day at baseline, which was reduced to 2.1 ± 4.2 at the end of treatment ($F_{[5]} = 23.5, p < 0.0001$). The reduction in cannabis use from 10.0 ± 5.3 inhalations per day at baseline to 8.0 ± 5.3 inhalations per day at 10 weeks was not significant ($F_{[5]} = 1.12, p = .37$). There was a significant decrease from the mean baseline Fagerstrom Test for Nicotine Dependence scores at weeks 4, 6, 8, and 10 of treatment ($F_{[4]} = 19.8, p < 0.001$) and mean Client Satisfaction Questionnaire scores were uniformly high (30.6 ± 1.9). A CBT plus NRT treatment program significantly reduced tobacco smoking but did not significantly reduce cannabis use in individuals with co-occurring nicotine and cannabis dependence. There was no compensatory increase in cannabis use following the reduction in tobacco smoking, suggesting that clinicians can safely pursue simultaneous treatment of co-occurring nicotine and cannabis dependence. The intervention was well-liked by the 7 of the 12 enrollees who completed the study.

Keywords

cognitive behavioral therapy; nicotine dependence; cannabis dependence; smoking cessation; nicotine replacement therapy

INTRODUCTION

Tobacco and cannabis are often used together, and tobacco cigarette smokers are far more likely to also smoke cannabis than non-smokers.^{1,2} The co-occurrence of tobacco and cannabis smoking provides an opportunity to develop effective treatments for tobacco smoking cessation with a concurrent focus on cannabis use. While behavioral and pharmacological treatments for smoking cessation have improved in recent years,^{3,4} failure to address problems associated with cannabis dependence, including the feelings and

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situations associated with cannabis use as well as withdrawal symptoms such as anxiety and irritability,^{5,6} may make it difficult for smokers with both nicotine and cannabis dependence to engage in a smoking cessation program. Simultaneous treatment of nicotine dependence and co-occurring substance use disorders has been debated,^{7,8} and some patients and clinicians worry that for dually-dependent patients, use of other illicit drugs will increase if they are able to stop smoking tobacco cigarettes.^{9,10} Smoking cessation treatment has been identified as an important element of treatment for other substance use disorders,^{11,12} as it increases the likelihood of abstinence after treatment for substance use disorders,^{13–15} and those who continue to smoke tobacco are more likely to relapse to alcohol or other drugs.^{16,17}

Cognitive behavioral therapy (CBT) and nicotine replacement therapy (NRT) are effective treatments for nicotine dependence.^{18,19} CBT can also be integrated into a comprehensive smoking cessation program along with NRT for smokers with co-occurring psychiatric disorders.^{20,21} CBT is also a useful element of treatment for cannabis dependence; structured multicomponent therapy, including CBT and case management, has been shown to significantly reduce cannabis smoking and its consequences when compared to a control group.²²

Due to the common co-occurrence of nicotine and cannabis dependence, we assessed the feasibility of a comprehensive smoking cessation treatment program, CBT with elements simultaneously targeting both disorders, together with NRT. We hypothesized that an integrated treatment program of CBT and NRT for both nicotine dependence and cannabis dependence would be feasible and would have high levels of client satisfaction. We also hypothesized that CBT aimed at treating both disorders, along with NRT, would reduce both tobacco cigarette and cannabis use.

METHODS

Study Design

In this prospective pilot study aimed at testing the feasibility and promise of using CBT (targeted at *both* nicotine and cannabis cessation) plus transdermal patch NRT to treat co-occurring nicotine and cannabis dependence, potential participants were recruited from the Boston area via online and newspaper advertisements, as well as word-of-mouth. Ads with the heading “Marijuana and cigarette smokers wanted” asked for “smokers of both cigarettes and marijuana to participate in a study of treatment aimed at reducing tobacco and marijuana use.” Enrollment began on August 11, 2009 and was completed on July 21, 2010. The study was approved by the McLean Hospital Institutional Review Board and registered on ClinicalTrials.gov (identifier NCT01292642). Participants received 10 weeks of treatment and we measured changes in tobacco cigarette and cannabis use compared to baseline levels.

Screening Assessment

The Principal Investigator obtained informed consent during the initial screening assessment. Those agreeing to participate underwent a comprehensive evaluation that included medical, psychiatric, and drug use histories as well as physical, psychiatric, and laboratory examinations. All psychiatric and substance use disorder diagnoses were made using the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV (SCID).²³ All diagnostic interviews were conducted at study enrollment by trained research staff under the supervision of 2 of the authors (KPH, JR). Inclusion criteria were: 1) age range 18–65 years; 2) current DSM-IV cannabis dependence; 3) current DSM-IV nicotine dependence; 4) an expressed desire to quit cannabis and nicotine use within the next 30 days; 5) for women of childbearing age, a negative

pregnancy test at screening with agreement to use adequate contraception to prevent pregnancy; and 6) expired breath carbon monoxide (CO) ≥ 7 ppm over ambient values at baseline. Exclusion criteria were: 1) current diagnosis of other drug or alcohol dependence (other than cannabis or nicotine); 2) recent (within 3 months) significant cardiac disease; 3) current serious psychiatric illness or history of psychosis, schizophrenia, bipolar type I disorder, or significant current suicidal or homicidal thoughts; 4) current use of bupropion; 5) current NRT or other smoking cessation treatment; 6) current CBT or other behavioral treatments for cessation of cannabis or tobacco smoking; 7) current smokeless tobacco use; 8) inability to read or write in English.

Treatment

Behavioral Intervention—Based upon effective manuals for treatment of nicotine dependence and cannabis dependence,^{22,24} we developed a new integrated individual CBT manual targeted at both tobacco and cannabis smoking cessation. Based on a review of the literature of current evidence-based behavioral therapy treatment approaches to tobacco and cannabis cessation, the principal investigator for the study (KH) developed a 10-week, 50-minute individual CBT manual of a new integrated approach to tobacco and cannabis smoking cessation. Drafts and the final version of the manual were reviewed and edited by a substance abuse behavioral therapy treatment development expert (SFG). We incorporated key tobacco-specific elements of a CBT for smoking cessation program developed by Munoz et al. (1988) and the Marijuana Treatment Project (MTP) protocol,^{22,24} resulting in a program aimed at changing tobacco cigarette and cannabis use through skill building and the monitoring of thoughts, daily activities, interpersonal contacts, and mood. After assessing the participants' reasons for wanting to quit both tobacco cigarettes and cannabis, we addressed each separately. Approximately half of each session was devoted to discussion of tobacco cessation issues, and the remainder to cannabis cessation issues. Common situations that the participant identified as triggering craving or prompting use were regularly discussed in each session. We examined the thought processes surrounding both tobacco cigarette and cannabis use while working with participants to propose healthy alternative activities for each. For example, most participants smoked cannabis upon returning home from work as a “reward” for completing the day's tasks in a satisfactory manner. Cigarette smoking often arose from boredom or a fear of experiencing nicotine withdrawal symptoms during a meeting, for example. A target quit date for both tobacco cigarettes and cannabis was set for a date between the first and second CBT sessions. CBT was administered by an Addiction Psychiatrist experienced in CBT (KPH) and all sessions were audiotaped. A sample was rated for adherence to CBT principles by another experienced clinician (JR).

Medication—Transdermal nicotine patches (CVS, Woonsocket, RI) were purchased from an online store. Nicotine patches were distributed to participants at the first CBT session and every 2 weeks thereafter. Based upon the average number of cigarettes smoked per day at enrollment, participants either wore a 21-mg patch for 6 weeks followed by 2 weeks at 14 mg and then 2 weeks at 7 mg, or they wore a 14-mg patch for 8 weeks followed by 2 weeks at 7 mg.

Biochemical Monitoring

Urine tetrahydrocannabinol (THC) levels were recorded to verify participant self-report at the initial assessment interview and at the follow-up sessions held 4, 6, 8, and 10 weeks after the quit date. Saliva cotinine and alveolar carbon monoxide were measured at these time points as well; these were used to verify self-reported adherence with the nicotine patch and smoking prior to sessions, respectively.

Measures

We used the Timeline Follow Back interview (TLFB) to obtain retrospective estimates,²⁵ using a calendar, of participants' use of tobacco cigarettes and other drugs during the study. The Fagerstrom Test for Nicotine Dependence (FTND) was used to assess the severity of nicotine dependence in participants.²⁶ The Client Satisfaction Questionnaire (CSQ-8), a self-report instrument developed for to assess satisfaction with health services was used to assess participant satisfaction with the treatment.²⁷

Statistical Analysis

Data were analyzed using the SPSS statistical package (IBM, Somers, NY). Reductions in cigarette smoking and cannabis use from baseline through 10 weeks were analyzed using repeated measures analysis of variance (ANOVA). Similarly, repeated measures ANOVA was employed to determine the change in mean baseline FTND during the course of the study. *Post-hoc* pair-wise comparisons were performed using Fisher's Least Significant Difference test. Participants who did not see the therapist for 14 or more consecutive days or who missed 7 or more consecutive days of the nicotine patch were considered non-completers. Baseline data for completers and non-completers were compared with regard to demographic and clinical characteristics; because there were no significant differences, non-completers were not included in the analysis of outcomes data.

RESULTS

Participant Characteristics

The CONSORT diagram showing participant flow through the study is provided in Figure 1. A total of 326 participants responding to a general advertisement for cannabis smoking studies were assessed via telephone for eligibility, and 18 participants (10 female, 8 male) attended an in-person screening. The most common reasons for respondents being excluded on the basis of the phone screen were a current active Axis I diagnosis other than cannabis dependence or nicotine dependence ($n = 67$), an active medical issue ($n = 36$), not meeting smoking criteria ($n = 108$), and not wanting to quit smoking cannabis or cigarettes after hearing the details of the study ($n = 65$). Of those attending the in-person screening, four were determined to be ineligible due to significant active Axis I psychopathology other than nicotine or cannabis dependence, 1 was ineligible due to an active medical issue that was referred for treatment, and 1 was ineligible due to a positive urine toxicology screen for an illicit substance other than cannabis. Twelve participants (7 female, 5 male) were enrolled and 7 (4 female, 3 male) completed the treatment phase study, attending all sessions and assessments. All participants used the NRT while they were receiving treatment. Eleven participants were Caucasian, 1 was African-American, and all were employed with a mean age of 28.2 ± 11.0 years. Four individuals consented to treatment but dropped out after completing 0 to 2 CBT sessions. Another dropped out after missing multiple scheduled CBT sessions and follow-up sessions.

Outcomes

Seven participants completed the 10 week trial (58.3%). The 5 participants who did not complete treatment also did not complete follow-up assessments and were excluded from the analysis. However, we provide participant-specific data on number of sessions attended, cigarettes per day at baseline and time of dropout, and cannabis use at baseline and time of dropout for the non-completers in Table 1. They did not differ significantly from the 7 completers in demographics or baseline clinical characteristics. Mean CSQ-8 scores were uniformly high over the 10 weeks of the study (30.6 ± 1.9). There was a significant reduction in cigarette smoking over the course of the 10-week treatment ($F_{[5]} = 23.5$,

$p < 0.0001$) (Figure 2). Participants smoked 12.6 ± 4.9 cigarettes per day at baseline and smoked 2.1 ± 4.2 cigarettes per day at 10 weeks. An effect size of $r = .75$ for cigarette reduction was calculated by isolating the change in cigarette smoking at baseline and 10 weeks. Several pair-wise comparisons demonstrated a consistent decrease in the number of cigarettes smoked over the course of the 10-week treatment. Scores on the FTND declined during the ensuing weeks of the study. Repeated measures ANOVA revealed a significant decrease from the average baseline FTND scores at weeks 4, 6, 8, and 10 of treatment ($F_{[4]} = 19.8, p < 0.001$) (Figure 3). The change in participants' cannabis use as measured by number of inhalations per day, from 10.0 ± 5.3 at baseline and 8.00 ± 5.3 at 10 weeks, was not significant by repeated measures ANOVA ($F_{[5]} = 1.12, p = .37$) (Figure 4). Only 1 of the 7 completers increased their cannabis use during the 10 weeks of the study compared to baseline.

DISCUSSION

Our pilot study suggests that a smoking cessation program for smokers with co-occurring nicotine dependence and cannabis dependence, featuring a combination of CBT and NRT, is feasible. The intervention was well-liked by the 7 of 12 enrollees who completed the study. We do not have details on the reasons for drop-out for the 5 enrollees who discontinued the treatment study but we cannot exclude lack of satisfaction with the integrated treatment. While both recruiting patients with cannabis dependence into a comprehensive smoking cessation program and helping them adhere to treatment may be difficult for a variety of reasons including the patient's potential lower levels of motivation for cessation of their cannabis use in comparison to their cigarette smoking, those who completed the program benefitted. Participants were able to use the integrated CBT program aimed at cessation of both tobacco cigarette and cannabis use to reduce smoking of tobacco cigarettes during a 10-week period. Importantly, there was no significant difference in cannabis use during the 10-week period, suggesting that these disorders can be treated without a compensatory increase in cannabis use occurring after a reduction in tobacco cigarette smoking. The concern that patients might increase their use of other substances has been a barrier to engaging nicotine dependent patients with co-occurring substance use disorders in smoking cessation treatment.^{16,17,27}

There are several limitations to this pilot study. A large percentage (95%) of the potential participants either was not eligible for the study or elected not to participate upon learning more about the study. Similarly, slightly more than one-third of participants did not complete treatment. The small sample size and relatively high proportion of treatment non-completers limit our interpretation of the results; however, it is notable that our experiences with the proportion of individuals telephone screened who enrolled in studies, as well as the percent of treatment non-completers, are consistent with those of other recent studies of treatments for cannabis dependence and nicotine dependence.^{29–33} Other limitations of this study included duration of follow-up and heterogeneity of the sample with respect to baseline cigarette smoking. Previous studies utilizing CBT for substance use disorders suggest that the benefits of CBT may emerge months after treatment ends.^{34–36} Due to differences in the number of cigarettes smoked at baseline, not all participants began NRT at 21 mg per day. In addition, most participants were on similar, but not identical medication regimens, raising the possibility that these medications may have contributed to differences on outcome measures. Finally, we were unable to collect data on those who elected not to finish the study after they made a decision to drop out of treatment.

Differences in pharmacodynamics between nicotine and cannabis may have contributed to the lack of a significant change in cannabis use during the study. Nicotine has a short half-life and cigarette smoking provides multiple peaks in nicotine concentrations as well as

multiple reinforcing events that can be targeted by CBT. Cannabis has a longer half-life than nicotine and typical users smoke cannabis fewer times per day. This leads to a potentially longer withdrawal syndrome and fewer reinforcing events that may be targeted by CBT, suggesting that a longer treatment period of treatment may be necessary.

In spite of these limitations, this pilot study suggests that targeting nicotine and cannabis cessation together appears to be feasible and that the CBT designed to address both disorders simultaneously had high levels of participant satisfaction. In addition, we did not see any increase in cannabis use following the reductions in smoking of tobacco cigarettes. Cognitive behavioral therapy that addresses both tobacco smoking and cannabis use affords patients an opportunity to address their use of tobacco cigarettes without a compensatory increase in cannabis use. A longer treatment period or pharmacotherapy aimed at cannabis withdrawal symptoms may lead to additional reductions in cannabis use compared to those demonstrated in our study. Our difficulties in recruiting participants and the high number of non-completers underscore the challenges of treating nicotine dependence and cannabis dependence simultaneously. The over-representation of nicotine dependence in those with cannabis dependence makes it imperative to understand the effects of common treatments for smoking cessation on cannabis use, and our findings suggest that further investigation into this relationship is both warranted and feasible.

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FIGURE 1.
Flow diagram of participants recruited to trial.

FIGURE 2.

Cigarettes per Day during 10 Weeks of CBT and NRT.

CBT= cognitive behavioral therapy; NRT= nicotine replacement therapy. There was a significant reduction in cigarette smoking over the course of the 10-week treatment ($F_{[5]} = 23.5$, $p < 0.0001$).

FIGURE 3.

FTND Scores during 10 Weeks of CBT and NRT.

FTND= Fagerstrom Test for Nicotine Dependence; CBT= cognitive behavioral therapy; NRT= nicotine replacement therapy. Repeated measures ANOVA revealed a significant decrease from the average baseline FTND scores at weeks 4, 6, 8, and 10 of treatment ($F_{[4]} = 19.8, p < 0.001$).

FIGURE 4.

Cannabis Use during 10 Weeks of CBT and NRT.

CBT= cognitive behavioral therapy; NRT= nicotine replacement therapy. The change in participants' cannabis use as measured by number of inhalations per day was not significant by repeated measures ANOVA ($F_{[5]} = 1.12$, $p=.37$).

TABLE 1

Participant-specific data for study non-completers.

Participant Number	CBT sessions attended	Cigarettes Smoked Per Day at Baseline	Cigarettes Smoked Per Day at Dropout	Cannabis Use at Baseline (smoking sessions per day)	Cannabis Use at Dropout (smoking sessions per day)
003	0	8.0	8.0	2.0	2.0
006	2	10.0	3.9	1.0	1.0
010	1	20.0	20.0	1.0	1.0
011	4	15.0	5.1	3.0	2.0
013	2	15.0	2.9	5.0	5.0