Integrating a Behavioural Sleep Intervention into Smoking Cessation Treatment for Smokers with Insomnia: A Randomised Pilot Study

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**Introduction**: Sleep disturbance is common among cigarette smokers and predicts smoking cessation failure. **Aims**: The purpose of this study was to conduct a pilot test of whether provision of a sleep intervention might bolster smoking cessation outcomes among this vulnerable group. **Methods**: Smokers with insomnia (N = 19) seeking smoking cessation treatment were randomly assigned to receive 8 sessions over 10 weeks of either: (1) cognitive-behavioural therapy for insomnia + smoking cessation counselling (CBT-I+SC; n = 9) or (2) smoking cessation counselling alone (SC; n = 10). Counselling commenced 4 weeks prior to a scheduled quit date, and nicotine patch therapy was also provided for 6 weeks starting on the quit date. **Results**: There was no significant effect of counselling condition on smoking cessation outcomes. Most participants had difficulty initiating and maintaining smoking abstinence in that 7-day point prevalence abstinence rates at end of treatment (CBT-I+SC: 1/7, 14%; SC: 2/10, 20%) and follow-up (CBT-I+SC: 1/7, 14%; SC: 0/10, 0%) were low for both conditions. CBT-I+SC participants reported improvements in sleep efficiency, quality, duration and insomnia symptoms. Sleep changes were not associated with the likelihood of achieving smoking abstinence. **Conclusions**: This randomised pilot study suggests that behavioural interventions may improve sleep among smokers with insomnia, but a larger sample is needed to replicate this finding and evaluate whether these changes facilitate smoking cessation.

**Introduction**

An estimated 75–80% of smokers who attempt to quit will relapse within six months of initiating abstinence (Zhou et al., 2009). Predictors of smoking quit attempts and relapse include demographic, psychological, biological and behavioural factors (Hyland et al., 2004; Vangeli, Stapleton, Smit, Borland, & West, 2011). Sleep disturbance is emerging as a potential neurobiological factor in smoking relapse (Brower & Perron, 2010; Peters, Fucito, Novosad, Toll, & O’Malley, 2011). In this randomised pilot study we evaluated the effects of a standard smoking counselling intervention in comparison with counselling enhanced with cognitive-behavioural therapy for insomnia on smoking and sleep outcomes.

Compared to non-smokers, smokers are at increased risk for insomnia and poor sleep quality (Jaehne et al., 2012; Riedel, Durrence, Lichstein, Taylor, & Bush, 2004; Wetter & Young, 1994). Among smokers, insomnia may be primary or secondary to other conditions such as depression (Ford & Kamerow, 1989) or nicotine dependence (Wetter & Young, 1994). As a stimulant, nicotine lengthens sleep latency and decreases total sleep duration, particularly during deeper sleep stages (Phillips & Danner, 1995; Soldatos, Kales, Scharf, Bixler, & Kales, 1980; Wetter & Young, 1994; Zhang, Samet, Caño, & Punjabi, 2006). Nicotine withdrawal also fragments sleep resulting in daytime sleepiness, impaired cognitive functioning and dysphoric mood (Fortier-Brochu, Beaulieu-Bonneau, Ivers,
Method

Participants

Participants were recruited through newspaper advertisements, flyers posted in the community, notices on our website, and mailings to health care providers. Advertisements indicated that the purpose of the study was to test smoking cessation treatment for smokers with sleep problems. To be eligible, participants had to: (1) smoke five cigarettes per year for at least one year (verified by breath carbon monoxide levels of >10 ppm), (2) report current DSM-IV symptoms of insomnia (based on clinical interview), (3) report at least six occasions within the past month of sleep latency or waking after sleep onset >30 minutes, (4) be between the ages of 18 and 75, and (5) be able to read English and complete assessments. Exclusion criteria included: (1) medical/psychiatric conditions contraindicated for CBT-I (seizure disorders, severe excessive daytime sleepiness defined as Epworth Scale score (Johns, 1991) of >18, bipolar disorder), (2) lifestyle factors that would interfere with CBT-I efficacy (current night or rotating shift work, proposed travel across ≥2 time zones), (3) current serious and/or unstable physical disease, (4) new psychiatric illness and/or psychotropic medication within the past 3 months, (5) current DSM-IV diagnosis of drug dependence other than nicotine, (6) use of tobacco products other than nicotine, (7) intention to use varenicline or bupropion during study participation, (8) co-morbid sleep apnoea or restless leg syndrome, or (9) females who were pregnant, lactating, or unwilling to use a reliable method of birth control due to the potential risk of harm of nicotine transdermal patch therapy in pregnancy/lactation.

Measures

All measures were paper-and-pencil based. At intake, potential participants completed the Fagerström Test for Nicotine Dependence (FTND; Heatherton, Kozlowski, Frecker, & Fagerström, 1991), psychosis screen and mood and substance use disorders sections of the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID; First, Spitzer, Gibbon, & Williams, 2002), and the Berlin Questionnaire, a 10-item screening tool for sleep apnoea syndrome (Netzer, Strohs, Netzer, Clark, & Strohl, 1999). Following intake, all participants monitored their sleep using daily Pittsburgh Sleep Diaries (PSD; Monk et al., 1994), which is valid relative to polysomnography, for two weeks prior to starting treatment to evaluate daytime sleep-related behaviours (e.g., use of caffeine, exercise) and quantitative characteristics of nocturnal sleep. Measures administered at all time points (intake, treatment and follow-up) included the Insomnia Severity Index (ISI; Bastien, Vallerier, & Morin, 2001) and Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupfer, 1989), both of which are reliable, valid tools for assessing insomnia symptoms and detecting “good” versus “poor” sleepers as well as smoking frequency and quantity using the reliable and well-validated timeline follow-back methods (Brown et al., 1998). All participants resumed sleep monitoring using daily diaries during the last two weeks of treatment.

After each counselling session, participants completed a session report to assess their: (1) satisfaction with the overall session (1 = very poor to 5 = best session), perceptions of the helpfulness of the session (1 = worse off to 5 = very helpful), and (3) perceptions of how well their study therapist understood them (1 = misunderstood to 5 = understood very well); at treatment termination, participants rated how helpful counselling was in facilitating smoking cessation using a scale (1 = not at all to 5 = extremely). Participants submitted session reports to a research assistant and were informed that their ratings would not be shared with their counsellor.
The primary smoking outcomes were the likelihood of achieving 7-day point prevalence smoking abstinence (defined as no smoking at all in the previous 7 days) at the end of treatment and research follow-up. Point prevalence abstinence (defined as no smoking, not even a puff, for 7 days; coded: 1 = yes, 0 = no) was biochemically confirmed with breath carbon monoxide (CO) levels <10 ppm (SRNT, 2002). Participants who dropped out were conservatively classified as relapsed to their baseline smoking level, which is the standard in the field of nicotine and tobacco research (West, Hajek, Stead, & Stapleton, 2005). Number of days to relapse was defined as the number of days until the first of seven consecutive days of smoking. The primary sleep outcome was self-reported sleep efficiency at Week 4 (day before quit date) on the PSQI. We also conducted exploratory analyses of PSQI self-reported total sleep duration and perceived sleep quality and ISI insomnia symptoms. Medication adherence was monitored with a count of returned nicotine patches at each post-quit appointment.

Procedures

This study was a two-condition randomised controlled pilot study conducted with treatment-seeking smokers who reported insomnia. Participants were randomised between 9 February 2011 and 6 December 2011, and the last follow-up appointment was completed on 30 March 2012. Prospective participants were screened by telephone and at a subsequent in-person intake appointment. Following screening, participants were randomised to one of two treatment conditions over 10 weeks: (1) cognitive-behavioural therapy for insomnia (CBT-I) + smoking cessation counselling (CBT-I+SC) or (2) smoking cessation counselling alone (SC) with randomisation stratified by sex using an allocation sequence established before study enrollment began. The Institutional Review Board of Yale School of Medicine approved this trial.

Participants were not informed of treatment condition assignment. Research and counselling staff involved in the delivery of the intervention were not informed of the study hypotheses. Two weeks after intake, eligible participants started treatment. Prior to their first treatment appointment, participants in both conditions monitored their sleep using daily sleep diaries and brought these to their first counselling session. To enhance adherence, participants were compensated for returning their diaries ($20 for the 2 weeks prior to intake; $30 for the last 2 weeks of treatment). During the 4-week pre-quit phase of the study (Weeks 0–3), participants attended weekly appointments to receive individual smoking counselling and complete research assessments. During this time, only participants in the CBT-I+SC condition continued sleep monitoring using daily diaries.

At the week 4 visit (day before quit attempt), all participants received a 2-week supply of nicotine patches, information and advice about taking the medication, and instructions to return their unused patches (or empty patch envelopes) at each session. Participants who reported smoking ≥10 cigarettes/day at the session before the scheduled quit date were provided with 21 mg patches; participants smoking <10 cigarettes/day were provided with 14 mg patches. Participants remained on their starting nicotine patch dose for the 6-week time period. Within three days of the scheduled quit date, the study therapist contacted participants by phone to assess their experience quitting and using the nicotine patch.

During the 6-week post-quit phase (Weeks 4–10), participants were offered bi-weekly counselling and research appointments, additional supplies of nicotine patches and brief phone contact with a study therapist. Participants in the CBT-I+SC condition monitored their sleep during this entire post-quit period to facilitate treatment planning; they were not compensated for completing diaries during this time. For the last 2 weeks (Weeks 9–10), participants in the SC condition resumed monitoring their sleep using daily diaries; participants in both conditions were compensated for completing diaries for Weeks 9–10. Four weeks after completing treatment, participants completed a final research follow-up appointment.

Counselling Condition

Five counsellors provided either CBT-I+SC or SC separately in each condition. All counsellors had smoking cessation counselling experience, those in the CBT-I+SC condition also had expertise in CBT. All therapists completed additional protocol training. Provision of counselling was manualised (American Lung Association, 2013; Perlis, Jungquist, Smith, & Posner, 2005; Strecher, Rimer, & Monaco, 1989), sessions were audiotaped, and weekly supervision provided by one of the authors (LMF) to promote fidelity.

The smoking cessation portion of both conditions was adapted from the American Lung Association Freedom from Smoking® programme (American Lung Association, 2013; Strecher et al., 1989) and emphasised: (1) motivation and confidence to quit smoking, (2) quit plan, (3) stimulus control, (4) coping skills to manage urges and withdrawal and (5) relapse prevention.

The CBT-I portion incorporated cognitive, behavioural and psycho-educational strategies to target perpetuating insomnia factors (Morin & Espie, 2003), including distorted beliefs about sleep, smoking, quitting and unrealistic night-time worries. Behavioural strategies included stimulus control (keeping a consistent sleep-wake schedule, re-establishing sleep cues) sleep restriction and relaxation. Sleep restriction focused on limiting time spent awake in bed to improve sleep efficiency. Participants were prescribed a bedtime that was gradually increased until optimal sleep efficiency was achieved (i.e., asleep ≥85% of time spent in bed defined as total hours asleep/total hours in bed x 100%). Relaxation involved a 15-minute, within-session progressive muscle relaxation exercise using a standardised relaxation script. Participants were provided with an audio recording of the exercise to practice in
their own time. Sleep hygiene education focused on establishing good sleep habits (e.g., creating a sleep-conducive environment; limiting caffeine). All strategies were covered prior to the scheduled quit date to provide time for sleep improvement. Post-quit sessions reviewed this material and emphasised sleep relapse prevention.

Steps were undertaken to enhance the face validity of both groups. The first session of both conditions included an overview of: (1) insomnia, (2) the associations among smoking, smoking cessation and sleep problems, (3) and the effect of insomnia/sleep problems on smoking cessation success. All participants were advised that quitting smoking would help their sleep, regardless of the cause of their insomnia and to remove their nicotine patch at night if it impacted negatively on their sleep (no participants reported removing the patch at night due to negative patch effects on sleep).

Statistical Analyses
T-tests and chi-squared tests were used to evaluate potential condition differences at baseline. Primary analyses focused on the likelihood of achieving smoking abstinence and secondary analyses examined sleep outcomes. Sex, a stratification variable, was added as a covariate to models assessing outcomes. To examine the predictive role of counselling condition we conducted Fisher’s exact tests on quit status (7-day point prevalence abstinence) at the end of treatment and research follow-up. Analyses of variance were used to compare conditions on number of days to relapse, sleep outcomes at Week 4 (i.e., efficiency, duration, quality, insomnia symptoms), number of sessions attended, nicotine patch adherence, and treatment termination and session ratings. For analyses of sleep outcomes, baseline sleep scores were added as covariates to models.

Results
Participants, Feasibility, Acceptability
Twenty-eight smokers attended an in-person intake appointment. Four were excluded for medical reasons and one was excluded for limited English comprehension. Of the remaining 23 eligible individuals, 4 chose not to enrol. Nineteen participants were randomised to either CBT-I + SC (n = 9) or SC (n = 10); 17 participants attended the first treatment session, which was balanced by sex (eight men, nine women). This subsample was primarily Caucasian (90%), had a mean age of 51.47 (12.25) years, and smoked an average of 21.53 (5.96) cigarettes per day for a mean of 33.00 (14.16) years. Participant demographic and clinical characteristics at baseline are displayed in Table 1. Scores on the ISI and PQSI were characteristic of moderately severe insomnia symptoms, short sleep duration and poor sleep quality. The two conditions were equivalent at baseline on all demographic, smoking and sleep variables except for marital status. The majority of SC participants were single whereas the majority of CBT-I + SC participants were married or cohabitating ($\chi^2 = 10.29, p = .04$).

Participants in both counselling conditions rated treatment positively (see Table 2). Likewise, session attendance was high across both conditions at 78%. The overall treatment completion rate (defined as attending the last treatment session at Week 10), however, was modest at 47% and did not differ by condition. Among all participants, all but one completed the entire pre-quit treatment phase (94%) by attending the first five counselling sessions. Treatment completers did not significantly differ from dropouts on demographic, smoking or sleep variables. There was a non-significant trend toward participants assigned to SC having greater nicotine patch adherence than those assigned to CBT-I + SC.

Preliminary Efficacy Findings
Smoking cessation. Table 3 presents smoking outcomes by condition. The likelihood of achieving point prevalence smoking abstinence at the end of treatment [18%; 3/17] and follow-up [6%; 1/17] was low across both conditions. Participants enrolled in CBT-I + SC exhibited a somewhat slower time to relapse than SC participants (13 vs. 10 days). This effect was not statistically significant, but had an effect size in the medium range.

Sleep. As shown in Table 4, participants enrolled in CBT-I + SC reported better sleep efficiency and sleep quality, longer sleep duration and fewer insomnia symptoms at

<table>
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<th>Table 1</th>
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<td>Pre-treatment characteristics of participants by condition</td>
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<table>
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<tr>
<th>Characteristics</th>
<th>CBT±SC (n = 7)</th>
<th>SC (n = 10)</th>
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<tbody>
<tr>
<td>Age in years, M (SD)</td>
<td>51.86 (15.07)</td>
<td>51.20 (10.73)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>3 (43)</td>
<td>5 (50)</td>
</tr>
<tr>
<td>Caucasian, n (%)</td>
<td>6 (86)</td>
<td>9 (90)</td>
</tr>
<tr>
<td>Marital status, n (%)*$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married or cohabitating</td>
<td>5 (72)</td>
<td>0</td>
</tr>
<tr>
<td>Divorced or separated</td>
<td>1 (14)</td>
<td>3 (30)</td>
</tr>
<tr>
<td>Single</td>
<td>1 (14)</td>
<td>7 (70)</td>
</tr>
<tr>
<td>Education, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school graduate or less</td>
<td>1 (14)</td>
<td>3 (30)</td>
</tr>
<tr>
<td>Some education after high school</td>
<td>5 (72)</td>
<td>3 (30)</td>
</tr>
<tr>
<td>College graduate or more</td>
<td>1 (14)</td>
<td>4 (40)</td>
</tr>
<tr>
<td>Employment, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part or full time employment</td>
<td>3 (43)</td>
<td>3 (30)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>1 (14)</td>
<td>3 (30)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (14)</td>
<td>4 (40)</td>
</tr>
<tr>
<td>Years smoking, M (SD)</td>
<td>37.43 (14.70)</td>
<td>29.90 (13.65)</td>
</tr>
<tr>
<td>No. cigarettes per day, M (SD)</td>
<td>20.00 (7.64)</td>
<td>22.60 (4.60)</td>
</tr>
<tr>
<td>Nicotine dependence (FTND)$^*$, M (SD)</td>
<td>7.29 (1.38)</td>
<td>6.10 (1.20)</td>
</tr>
<tr>
<td>Night smoking, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No.</td>
<td>2 (29)</td>
<td>7 (70)</td>
</tr>
</tbody>
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Note. *p < .05; $^*$ FTND = Fagerström Test for Nicotine Dependence.
Week 4 than participants enrolled in SC. Again, while effects were not statistically significant, estimated effect sizes were in the medium to large range. Regardless of condition assignment, sleep outcomes at Week 4 were not associated with the likelihood of achieving smoking abstinence.

**Discussion**

To our knowledge, this is the first study of an integrated sleep and smoking behavioural intervention for smokers with insomnia. We examined whether providing specific strategies to improve sleep along with standard smoking cessation counselling would improve smoking quit rates in this population. Although limited by the small sample size, the integrated treatment (i.e., CBT-I+SC) resulted in improvements in some sleep indicators, compared with standard smoking counselling. These effects sizes are consistent with other cognitive-behavioural trials for insomnia (Morin et al., 2006) and highlight the potential promise of this intervention for treating insomnia in smokers. There was less benefit from the integrated treatment for smoking cessation. Though the integrated treatment was associated with longer time to relapse than standard smoking counselling, it did not yield better smoking quit rates. Moreover, improvements in sleep were not associated with the likelihood of achieving smoking abstinence. These findings confirm prior research that sleep disturbed smokers...
have substantial difficulty quitting smoking (Augustson et al., 2008; Boutou et al., 2008; Peters et al., 2011). The interpretation of these results, however, is limited by the small sample size.

Both interventions were rated highly by participants and all but one participant attended the five pre-quit date counselling sessions (i.e., when sleep strategies were introduced and implemented in the CBT-I+SC condition). Thus, our preliminary results suggest that adding sleep content to smoking cessation treatment is acceptable to smokers with insomnia. Limited efficacy and post-quit treatment retention, however, suggest that our particular model of integrated care may have obstacles with this population. Regardless of condition, half of the participants dropped out of treatment after the scheduled quit date. Extending the pre-quit phase to allow time for sleep improvements may have reduced motivation to quit smoking. Few participants, however, reported a decrease in motivation from baseline to quit date.

Smokers with insomnia may benefit from flexible quit dates and more intensive smoking pharmacotherapy treatment. Clinical trials of NRT and varenicline show that gradual smoking cessation while on medication (i.e., allowing for smoking reduction and flexibility to delay quitting until later in treatment) is just as effective as abrupt cessation through a scheduled quit date (Hughes, Solomon, Livingston, Callas, & Peters, 2010; Rennard et al., 2012; Shiffman, Ferguson, & Strahs, 2009). Many smokers, particularly those who smoke heavily, also prefer flexible reduction to abrupt cessation (Hughes, Callas, & Peters, 2007; Shiffman et al., 2007). Thus, having flexible quit dates and/or starting nicotine patch therapy in advance of the quit date may better facilitate treatment retention and maximise CBT-I+SC efficacy. Likewise, smokers with insomnia may have higher nicotine dependence scores that warrant more intensive pharmacotherapy treatment such as dual nicotine replacement therapy (Piper et al., 2009). Future studies should investigate alternate smoking cessation paradigms alone and in conjunction with sleep interventions for smokers with insomnia.

We investigated an integrated model of care as opposed to a sequential treatment model in which individuals receive treatment for one problem at a time (Mueser, Nordy, Drake, & Fox, 2003). A disadvantage of integrated models is that it may be difficult to treat adequately both issues concurrently. Improving sleep in CBT-I+SC may have limited the smoking cessation portion of treatment. On the other hand, sequential models do not account for the interactive nature of dual disorders such that the untreated problem may continue to worsen the treated problem. Participants in SC reported poor sleep outcomes and limited success quitting smoking. More research on sequential versus integrated models of care for smoking cessation and sleep is warranted.

This investigation had several advantages. We tested a novel, integrated treatment for smokers with insomnia, utilised a randomised design, and standardised the provision of counselling through the use of manuals and close therapist supervision. Study limitations should also be noted. The sample size was very small; effect size estimates from pilot studies should be interpreted cautiously (Kraemer, Mintz, Noda, Tinklenberg, & Yesavage, 2006). We assessed sleep outcomes using subjective methods. Medication adherence was based on participant self-report. Smokers in the CBT-I condition reported adequate sleep efficiency at baseline but had moderately severe insomnia symptoms, short sleep duration and poor sleep quality, which may differ from the sleep complaints among individuals who derive the most benefit from CBT-I. The difference in marital status between conditions may have affected sleep outcomes.

Sleep disturbance, particularly insomnia, is common among smokers and a predictor of smoking cessation failure (Augustson et al., 2008; Boutou et al., 2008; Brower & Perron, 2010; Peters et al., 2011). Cognitive-behavioural therapy for insomnia shows promise for treating insomnia among smokers but it remains to be determined whether improving sleep in this population actually facilitates quitting smoking. A better understanding of the mechanisms by which insomnia promotes smoking relapse is important for targeting and tailoring smoking cessation interventions for individuals with insomnia.

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Conflict of interest

Dr Toll has received investigator initiated funding from Pfizer. All other authors report no conflicts of interest.

Ethical standards

The Institutional Review Board of Yale School of Medicine approved this trial. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.
References


