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Drug and Alcohol Dependence

journal homepage: www.elsevier.com/locate/drugalcdep



An exploratory randomized controlled trial of a novel high-school-based smoking cessation intervention for adolescent smokers using abstinence-contingent incentives and cognitive behavioral therapy



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ARTICLE INFO

Article history: Received 1 February 2013 Received in revised form 3 March 2013 Accepted 4 March 2013 Available online 22 March 2013

Keywords:
Adolescents
Smoking cessation
Tobacco
Contingency management
Incentives
Cognitive behavioral therapy

ABSTRACT

Background: There are few effective smoking cessation interventions for adolescent smokers. We developed a novel intervention to motivate tobacco use behavior change by (1) enhancing desire to quit through the use of abstinence–contingent incentives (CM), (2) increasing cessation skills through the use of cognitive behavioral therapy (CBT), and (3) removing cessation barriers through delivery within high schools.

Methods: An exploratory four-week, randomized controlled trial was conducted in Connecticut high schools to dismantle the independent and combined effects of CM and CBT; smokers received CM alone, CBT alone, or CM+CBT. Participants included 82 adolescent smokers seeking smoking cessation treatment. The primary outcome was seven-day end-of-treatment (EOT) point prevalence (PP) abstinence, determined using self-reports confirmed using urine cotinine levels. Secondary outcomes included one-day EOT PP abstinence and cigarette use during treatment and follow up.

Results: Among participants who initiated treatment (n=72), group differences in seven-day EOT-PP abstinence were observed (χ^2 = 10.48, p < 0.01) with higher abstinence in the CM+CBT (36.7%) and CM (36.3%) conditions when compared with CBT (0%). One-day EOT-PP abstinence evidenced similar effects (χ^2 = 10.39, p < 0.01; CM+CBT: 43%, CM: 43%, CBT: 4.3%). Survival analyses indicated differences in time to first cigarette during treatment (χ^2 = 8.73, p = 0.003; CBT: Day 3, CM: Day 9, CM+CBT: Day 20). At one-and three-month follow ups, while no differences were observed, the CM alone group had the slowest increase in cigarette use.

Conclusions: High-school, incentive-based smoking cessation interventions produce high rates of short-term abstinence among adolescent smokers; adding cognitive behavioral therapy does not appear to further enhance outcomes.

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1. Introduction

Tobacco smoking, a leading preventable cause of premature death in the United States and worldwide, is a pediatric disease (Kessler et al., 1997). The majority of adult smokers start smoking during adolescence (Centers for Disease Control, 2001). Current estimates indicate that in the United States alone around 2.6

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million adolescents are current tobacco users and that more than one-fifth of adolescents are smokers by the time they leave high school (Centers for Disease Control, 2010). There is an imperative need for targeted interventions that can be applied prior to the establishment of entrenched, lifelong patterns of tobacco use and other negative health outcomes. Among adolescent smokers, a significant number (61%; Centers for Disease Control, 2001) indicate interest in quitting smoking and report having made a quit attempt in the past 12 months, but success rates are low (between 7% and 12%; Grimshaw and Stanton, 2006; Sussman, 2002). Existing behavioral and pharmacological smoking cessation treatments for adolescents have had limited success (Grimshaw and Stanton, 2006; Sussman, 2002). Effective methods based

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on a developmental understanding of adolescence are urgently needed.

Emerging neurobiological evidence suggests that adolescence is associated with heightened sensitivity to behaviors driven by emotions and rewards (Somerville et al., 2010). Of significance, behavioral interventions that provide performance-contingent rewards have been used to motivate change in academic performance and other behaviors in adolescents (Eisenberger and Rhoades, 2001; Gottfried, 1985; Pintrich and De Groot, 1990). Among adult substance users, incentive-based interventions (also called contingency management or CM) have demonstrated efficacy reducing use of many substances including tobacco (Higgins et al., 2004, 2008; Petry and Simcic, 2002; Volpp et al., 2009; Tidey, 2012; Sigmon and Patrick, 2012). Based on operant behavior reshaping concepts, these interventions follow two simple principles: first, that substance use is maintained by the reinforcing effects of the drug, and second, that substance use can be decreased by the availability of alternative, non-drug reinforcers.

If adolescents are indeed more sensitive to rewards, they may be responsive to the use of CM interventions to motivate change in substance use behaviors (Krishnan-Sarin et al., 2008; Richards et al., 2012; Stanger and Budney, 2010). Emerging evidence supports the use of such interventions for adolescent smoking cessation (Corby et al., 2000; Gray et al., 2011; Weissman et al., 1987; Roll, 2005; Krishnan-Sarin et al., 2006; Cavallo et al., 2007). However, implementation of such interventions is challenging due to the need for rapid, accurate monitoring of tobacco use and immediate delivery of rewards for abstinence. To address these challenges, we developed a novel smoking cessation intervention for adolescents that provided reinforcement for abstinence, and enhanced its feasibility through delivery in local high schools, and use of once-daily urine cotinine to monitor tobacco use (Schepis et al., 2008). We also sought to enhance the durability of effects by combining it with cognitive behavioral therapy (CBT) (McDonald et al., 2003). Two pilot studies yielded robust end-of-treatment abstinence rates (Krishnan-Sarin et al., 2006; Cavallo et al., 2007), but they were small trials and it was not possible to attribute changes to CM, CBT, or the combination. Thus, in the current study, we conducted the first randomized controlled trial that explored the independent and combined efficacy of CM and CBT for adolescent smoking cessation. We hypothesized that the combined use of CM for abstinence and CBT would result in better end-of-treatment (EOT) abstinence rates and through a one- and three-month follow up than either condition alone.

2. Methods

This was a single center, randomized, parallel group study with three treatment conditions: CM alone, CBT alone and CM + CBT. Urn randomization was used to balance the groups on gender and race. The intervention was four weeks in duration based on our published pilot studies (Krishnan-Sarin et al., 2006; Cavallo et al., 2007) and findings (unpublished) from a pilot eight-week trial where we observed very high rates of drop out after the first four weeks.

2.1. Participants

Treatment-seeking adolescent smokers recruited from local Connecticut high schools during academic years 2008–2009 and 2009–2010. The study protocol was approved by the Yale School of Medicine Human Investigation Committee and by the local school boards. Information sheets detailing the intervention were mailed out to all parents in the participating schools prior to the beginning of each academic year. Parents were told that if their child was a smoker they (the child) would have the option of participating in the research intervention, and if they (the parent) did not want their child to participate they needed to call and inform the schools; active parental consent was not required. Interested adolescents could either sign up at recruitment tables (set up at lunch periods or during home rooms) or privately by calling the researchers or entering their information on sign up cards maintained in locked boxes at the school. Interested adolescents, who were not denied permission to participate by parents, were scheduled for an initial screening appointment at the

local school where assent was obtained from adolescents aged 14–17, and consent was obtained from those aged 18 or older.

Adolescents were included if they reported smoking at least five cigarettes per day for the past six months and had quantitative urine cotinine levels of 350 ng/ml or higher (Graham Massey Analytical Labs, Shelton, CT); these criteria were chosen in order to ensure that participants were regular smokers. The Diagnostic Predictive Scale (DPS; Lucas et al., 2001) and an evaluation by a clinical psychologist were used to exclude those with any current DSM-IV Axis I disorders (including any other current substance dependence disorder other than nicotine dependence), any significant current untreated medical condition, or current suicidal/homicidal risk.

2.2. Interventions

All interventions were manual-guided and supervised by a licensed clinical psychologist based on our previous work (Krishnan-Sarin et al., 2006; Cavallo et al., 2007). Eligible adolescents scheduled a quit date and received a 45-min "preparation to quit" session, 4–7 days prior to their quit date, during which motivational and cognitive behavioral strategies were used to emphasize the risks of continued smoking and the benefits of quitting, as well as teach strategies to initiate cigarette abstinence. At the end of this session, adolescents were randomly assigned using a computer generated randomization list to receive one of three treatment conditions for the remaining four week treatment period: CBT alone, CM alone, or CBT+CM

2.2.1. Cognitive behavioral therapy (CBT). Participants in this condition participated in CBT sessions (approximately 30 min in duration) starting on their quit day and continuing weekly for the remaining treatment period. Overall, participants were taught self-control strategies to avoid tobacco use as well as identify high-risk situations and use coping skills including problem solving, peer refusal skills, stress reduction, obtaining social support, and relapse prevention.

Five counselors (two with bachelors' degrees in psychology and four years of experience providing smoking cessation counseling to adolescents and three with doctoral degrees in clinical psychology) provided CBT. All counselors were trained on the manual-guided CBT by a licensed clinical psychologist with extensive experience in smoking cessation (JLC), and participated in weekly supervision to discuss cases with a supervisor (JLC and DC) and maintain adherence to manual guidelines.

2.2.2. Contingency management (CM) for abstinence. CM appointments to monitor and reinforce abstinence were initiated on quit day. Abstinence was determined using breath CO levels (<7 ppm; Vitalograph Breath CO, Bedfont, MA) and semi-quantitative urine cotinine readings [during the first week: less than the level on the earlier day or ≤level 2 (30–100 ng/ml); during the subsequent weeks: ≤level 2 (30–100 ng/ml); NicAlert Immunoassay Test Strips; Jant Pharmacal Corporation, Encino, CA], and ascertained once daily in the first two weeks and once every other day during the third and fourth weeks (Schepis et al., 2008).

Participants in the CM condition were reinforced for abstinence on an escalating magnitude schedule of reinforcement with a reset contingency (Krishnan-Sarin et al., 2006). Participants were paid \$2.00 for the first assessment that was negative, with payments progressively increasing by \$1.00 for each subsequent negative assessment. Participants for whom abstinence was not confirmed were not paid for that assessment and had the payment for their next assessment reset back to the initial level of \$2.00. Participants in the CM condition could earn up to \$262 if they were continuously abstinent after the quit day.

The CM appointments were 10 min in duration and were conducted by research assistants who were trained (by SKS and DC) to determine abstinence, provide CM payments and check on the participants progress but not provide any smoking cessation counseling. A centralized system including cell phone contact was used to keep track of payments and any deviations/problems were dealt with on an ongoing basis.

2.3. Other procedures

All weekday appointments (including counseling sessions) were conducted in the school nurse's office or the school library either after school or during free periods. Participants were not allowed to miss class to participate. Weekend CM appointments were conducted at public locations, including fast food restaurants, libraries, and other sites that were easily accessible to both the participant and research team and where biochemical measurements could be obtained; these appointments were conducted in quiet corners at each location and no information was shared with the proprietors at any locations.

Participants in all three groups were also provided with incentives for completing weekly assessments and attending CBT sessions. Payments for attendance were chosen to ensure fairly equivalent total incentives across groups (and minimize the possibility of differences in outcome being related to incentive amounts) and were as follows: (1) CM alone group: \$5 at each weekly appointment for completing assessments, (2) CM+CBT group: \$5 at each weekly appointment for completing assessments and \$5 for attending CBT sessions and (3) CBT alone group: \$20 at each weekly appointment for completing assessments and \$20 for attending CBT sessions.

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