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Integrated Smoking Cessation and Binge Drinking Intervention for Young Adults: A Pilot Investigation

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Abstract

Background—Alcohol consumption is strongly associated with cigarette smoking in young adults.

Purpose—To evaluate the acceptability and estimate the magnitude of the effect of a novel integrated smoking cessation and binge drinking intervention for young adults compared to standard treatment control.

Methods—Participants were 41 young adult smokers (≥ 10 cigarettes per day) who regularly (≥ 2 times per month) binge drank who were randomly assigned to Standard Treatment ($n=19$) involving eight individual treatment visits plus eight weeks of nicotine patch therapy or the identical smoking cessation treatment integrated with a binge drinking intervention (Integrated Intervention; $n=22$).

Results—Participants rated Integrated Intervention as highly acceptable as indicated by 100% of participants rating helpfulness as 5 on 5-point scale. Using an intent-to-treat analysis for tobacco abstinence, at both week 12 end of treatment and week 24 follow-up, more participants who received Integrated Intervention were biochemically confirmed abstinent from tobacco than those who received Standard Treatment (36% vs. 21% at week 12; 23% vs. 11% at week 24). At week 24, change from baseline in binge drinking episodes, drinks consumed, and drinking days between treatment groups were similar (intent-to-treat analysis was not used for alcohol data).

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Competing Interests

The authors of this work have no competing interests.

Conclusions—Preliminary data supports the intriguing possibility that Integrated Intervention may enhance smoking cessation and reduce binge drinking.

Keywords

Smoking cessation; binge drinking; young adult; alcohol

Introduction

Cigarette smoking is the single most important preventable cause of morbidity, mortality, and excess health cost in the U.S., accounting for 438,000 premature deaths each year (1). Young adults aged 18 to 24 years have a high prevalence of cigarette smoking at 22% (2). Despite the high prevalence of smoking in young adults, few intervention trials have been designed specifically for this group. A review of the last 25 years of tobacco related research involving adolescents and young adults (i.e., 3) in conjunction with our own review of the recent literature, revealed only four published intervention studies focused on young adults; an uncontrolled investigation conducted in 24 university students that used a behavioral smoking reduction intervention (4); an intervention consisting of brief consultation by a physician and self-help booklets delivered to 172 college student smokers compared to a no treatment control group of 179 students (5); an intervention consisting of sensory deprivation combined with an anti-smoking message compared to the anti-smoking message only in 40 male undergraduate students (6); and a trial which compared brief office intervention only in 99 young adults to expressive writing plus brief office intervention in 97 young adults (7). Thus, based on the very limited existing literature, young adults stand to benefit greatly from the development of effective tobacco cessation interventions.

Binge drinking is generally defined as consumption of ≥ 5 standardized alcoholic drinks in a row for males or ≥ 4 drinks in a row for females. The Healthy People 2010 goals established by the U.S. Surgeon General seeks to achieve a 50% reduction in binge drinking by the year 2010. The year 2007 prevalence of binge drinking is highest among young adults aged 18 to 25 years in comparison to any other age group with a prevalence of 41.8% (8). Also of concern, the prevalence of binge drinking among young adults has remained stable in comparison to the prevalence reported by the prior 2001 survey. In addition to being a risk factor for poor treatment outcome following smoking cessation intervention (9), numerous adverse health consequences are associated with binge drinking including unintentional accidents or injuries, suicide, interpersonal violence, unintended pregnancy, child neglect, lost productivity, alcohol poisoning, hypertension, acute myocardial infarction, gastritis, pancreatitis, sexually transmitted diseases, meningitis, and uncontrolled diabetes (10).

Considerable evidence suggests alcohol consumption is strongly associated with cigarette smoking. Among heavy alcohol users aged 12 or older, 58.1% smoked cigarettes in the past month. In contrast, 19.0% of non-binge drinkers and 16.4% of persons who did not drink alcohol in the past month were current smokers (8). Higher levels of alcohol consumption is associated with more severe levels of tobacco dependence and poorer smoking treatment outcomes in adult smokers with current or past alcohol problems (11). Finally, although smoking and alcohol use are independent risk factors for cancer and cardiovascular disease, they also interact to synergistically elevate disease risk above the risk posed by use of either of these substances individually (12,13).

The objective of this investigation was to evaluate the acceptability and estimate the magnitude of the effect of a novel integrated smoking cessation and binge drinking intervention for young adults compared to standard treatment control. We hypothesized that our new integrated intervention would be acceptable to young adults as indicated by their

ratings of the helpfulness of the intervention and would favorably impact tobacco abstinence and binge drinking. The Integrated Intervention is based on the rationale that decreased smoking and improved maintenance of abstinence would result from a behavioral intervention to reduce binge drinking. This hypothesis is in turn supported by several lines of evidence including conditioning mechanisms in which craving to smoke is elicited by higher levels of alcohol consumption (14,15) and environmental factors such as parental and peer influence for concurrent use of cigarettes while engaging in binge drinking (16).

Methods

Participants

This study was approved by the Mayo Clinic Institutional Review Board. Participants included 41 young adult smokers who binge drink. Inclusion criteria included: aged 18–30 years, smoked ≥ 10 or more cigarettes per day during the past 6 months, and binge drank on ≥ 2 occasions per month during the past 3 months. Binge drinking was defined as consumption of ≥ 5 standardized alcoholic drinks in a row for males or ≥ 4 drinks in a row for females. Exclusion criteria included: current alcohol dependence as assessed by the Structured Clinical Interview for DSM-IV Axis I Disorders, Alcohol Dependence Module (17) or drug dependence as determined by Drug Abuse Screening Test-20 (18) score of ≥ 6 , current clinical depression as indicated by score ≥ 20 on Beck Depression Inventory-II (19), current use of nicotine containing medication or tobacco products other than cigarettes, current use of any other smoking cessation treatment involving behavioral or pharmacological interventions, any medical condition that would preclude use of the nicotine patch, and currently pregnant or breast feeding, or likely to become pregnant during the nicotine patch phase. Because a clearly established definition of young adults is lacking, with a number of other investigations operationalizing young adults as individuals 18–30 years of age, we used this age range for inclusion in an effort to enhance our recruitment.

Procedure

Participants with an interest in quitting smoking were recruited from the northeast Florida general community, local college campuses, and local businesses via advertisements in college newspapers and city wide publications targeted to young adults. This study employed a randomized, two-group design with repeated assessments at baseline, end-of-treatment (week 12), and end-of-study (week 24). Participants were paid \$130 for their completion of assessments. Blocked randomization stratified according to gender was used. Following the baseline assessment, participants were randomized to one of two treatment conditions: 1) an 8 session individual behaviorally-based smoking cessation intervention plus 8 weeks of nicotine patch therapy (i.e., standard treatment), or 2) the identical smoking cessation treatment integrated with a binge drinking intervention (i.e., integrated intervention). Treatment conditions were matched for total contact time and the same nicotine patch therapy treatment protocol was used in each condition consisting of 21 mg/24 hours for 4 weeks, 14 mg/24 hours for 2 weeks, and 7 mg/24 hours for 2 weeks. The target quit date for all participants was set for week 4.

Both treatments were manualized and the same master's level registered nurse experienced in the delivery of behavioral smoking cessation interventions from prior clinical trials delivered both treatment conditions. A second bachelor's level study coordinator, who was blinded to participant treatment condition assignment, was responsible for completion of all follow-up assessments. All treatment sessions were audio recorded and 25% of the sessions were reviewed (i.e., the selected sessions were reviewed in their entirety) by the principal investigator and corrective feedback was given to the research counselor as needed to ensure fidelity and discriminability of treatment delivery. Fidelity of receipt of the interventions by

participants was assessed at the end of each treatment visit and corrective feedback provided as needed. Fidelity of treatment enactment (i.e., participant's use in daily life of what they learned/were instructed to do) was monitored via participant compliance with treatment assignments and use of nicotine patch therapy. The content of the two treatment conditions is detailed below.

Standard Treatment—Consisted of eight, individual-based, semi-structured counseling sessions consistent with the United States Department of Health and Human Services (USDHHS) Clinical Practice Guideline for Treating Tobacco Use and Dependence (20) plus 8 weeks of nicotine patch therapy. The first six treatment sessions consisted of behavioral treatment and were 30 minutes in duration, while the final two treatment sessions were brief visits scheduled to dispense nicotine patches, monitor participant safety, and address any difficulties with the patches, and were ≤ 10 minutes in duration.

Integrated Intervention—Consisted of an eight session, individual-based, semi-structured, behaviorally-based intervention that integrated the USDHHS Clinical Practice Guideline for Treating Tobacco Use and Dependence (20) with Brief Alcohol Screening and Intervention for College Students (21). Participants randomized to this condition also received 8 weeks of nicotine patch therapy as described above for Standard Treatment. The first six treatment sessions consisted of behavioral treatment and were 30 minutes in duration, while the final two treatment sessions were brief visits scheduled to dispense nicotine patches, monitor participant safety, and address any difficulties with the patches, and were ≤ 10 minutes.

In an earlier phase of research a focus group and expert panel methodology was utilized to develop the Integrated Intervention, write a semi-structured treatment manual, and tailor the Integrated Intervention to young adults. The Integrated Intervention was designed as a smoking cessation approach that particularly focuses on how alcohol use relates to smoking behavior and seeks to concurrently eliminate tobacco use, binge drinking, and other high-risk forms of alcohol consumption. Examples of behavioral treatment strategies used include providing personalized feedback about use of alcohol including comparison of personal level of use to peer norms, identifying the role that high-risk drinking has played in maintaining smoking and, if applicable, in failure of prior quit attempts to quit smoking, self-monitoring of the relation of alcohol and tobacco use, alcohol moderation training including discussion and goal setting related to what the participant wants from drinking, limit setting, counting drinks consumed and monitoring of drinking behavior, altering how and what one drinks, and learning skills to manage drinking situations. During alcohol moderation training the Integrated Intervention approach highlights the rationale for focusing on reducing heavy drinking as a way to aid in stopping smoking. Other behavioral aspects of treatment include development of a relapse prevention plan and implementation of relapse prevention strategies as needed to overcome difficulties with sustaining abstinence from smoking and high-risk drinking. The Integrated Intervention treatment manual is available from the corresponding author upon request.

Measures

Demographic Data—Basic demographic information were assessed to evaluate the similarity of participants in the two treatment conditions.

Treatment Acceptability—Following conclusion of treatment, participants were asked to rate the helpfulness of treatment on a 5-point Likert scale (1="Didn't help me at all"; 5="Helped me a lot").

Tobacco Use—Biochemically confirmed 7-day point-prevalence tobacco use was evaluated at week 12 and 24. Participants were considered abstinent from tobacco if they self-reported no smoking (i.e., “not even a puff”) or use of any other form of tobacco over the previous 7-days. Self-reports of tobacco abstinence were biochemically confirmed using expired air carbon monoxide (< 8 ppm indicative of abstinence) at end of treatment (week 12) and salivary cotinine testing (< 15 ng/ml indicative of abstinence) at end of study (week 24).

Alcohol Consumption—Quantity and frequency of alcohol consumption was assessed using the Timeline Followback Interview (TLFB; 22) and used to compute the number of binge drinking episodes over the past 30-days. The TLFB is a self-report instrument that assesses quantity of alcohol consumed according to standard drinks. One standard drink is defined as 10 oz. of wine cooler, 5 oz. of wine, 12 oz. of beer, 6 oz. of malt liquor, 2.5 oz. of fortified wine, or one cocktail with 0.5 oz of ≥ 150 -proof distilled spirits, 1 oz. of 100-proof distilled spirits, or 1.25 oz. of 80-proof distilled spirits. Binge drinking was defined as consumption of ≥ 5 standardized alcoholic drinks in a row for males or ≥ 4 drinks in a row for females.

Statistical Analysis

Consistent with recommendations for stage one tobacco cessation behavioral development research (23,24) the sample size was based on the primary objectives of this investigation which were to pilot test our study methodology, evaluate the acceptability of the Integrated Intervention to young adults, and estimate the magnitude of the treatment effect compared to standard treatment control to aid in the planning a larger efficacy trial. As a result, this study was not adequately powered to evaluate treatment efficacy. Although it was not our intention to evaluate treatment efficacy in this preliminary study, we estimate that the sample size had a statistical power of 80% to detect a difference between groups consistent with an abstinence rate ratio of approximately 3.75. Baseline demographics of participants from each treatment condition were summarized and compared using the *rank sum test* for continuous variables and the *chi-square test*, or *Fisher's exact test* for categorical variables. Treatment acceptability was evaluated via computation of summary statistics from participant's 5-point Likert scale rating of perceived helpfulness of the intervention. Tobacco abstinence outcomes were analyzed using *Fisher's exact test* and alcohol use outcomes were evaluated using *analysis of covariance* with the baseline value of the given measure included as the covariate. In addition, for alcohol use outcomes the change from baseline was also calculated for each individual and compared between groups using the *rank sum test*.

Results

A total of 112 individuals were screened for study inclusion. Of these 112 individuals screened 45 did not meet inclusion criteria for the following reasons: 15 did not meet smoking inclusion criteria, 14 decided not to participate during screening process, 9 did not meet binge drinking study inclusion criteria, 4 did not meet age inclusion criteria, 1 was currently receiving treatment for smoking cessation, and 2 did not live in the local region. Of the remaining 67 individuals who passed the inclusion screening, 18 did not show for their baseline appointment and 8 presented for their baseline assessment but opted to discontinue participation before its completion. The remaining 41 participants (M=23 years, SD=3; 49% female; 93% White; 90% single/unmarried; 51% employed full-time) were enrolled in this pilot clinical trial and randomized to Standard Treatment (n=19) or Integrated Intervention (n=22). Of the 41 enrolled participants, 24 completed the study, 13 were lost to follow-up

(i.e., could not be contacted/located), 2 no longer wished to participate, and 2 were withdrawn as they no longer met inclusion criteria due to pregnancy.

Average cigarettes per day (14.4 ± 5.6 vs. 15.8 ± 6.0 , $p=0.45$ for standard treatment vs. integrated intervention respectively) and years of regular smoking (4.9 ± 3.0 vs. 4.9 ± 4.3 , $p=0.99$) were similar between conditions. Baseline alcohol use measures did not differ significantly between groups but tended to be higher in those assigned to the standard treatment (drinks per month: 78.5 ± 39.6 vs. 58.5 ± 52.7 , $p=0.18$; drinking days per month: 14.8 ± 5.8 vs. 12.1 ± 6.1 , $p=0.16$; binge drinking days per month: 8.2 ± 4.4 vs. 5.8 ± 5.1 , $p=0.12$). In the Standard Treatment condition 10 of the 19 participants (53%) attended all 8 treatment sessions and 15 of the 19 participants (79%) attended at least 6 of the 8 treatment sessions. Similar treatment attendance was observed in participants in the Integrated Intervention condition with 14 of the 22 participants (64%) attending all 8 sessions and 17 of the 22 participants (77%) attending at least 6 of 8 sessions.

Participants rated Integrated Intervention as highly acceptable as indicated by 100% of participants rating helpfulness of the intervention as 5 on 5-point scale. Using an intent-to-treat analysis, at both end of treatment (week 12) and end of study (week 24), a greater number of participants who received Integrated Intervention were biochemically confirmed abstinent from tobacco compared to those who received Standard Treatment (see Table 1), although the differences were not statistically significant. At both end of treatment (week 12) and end of study (week 24) change from baseline in binge drinking episodes, drinks consumed, and drinking days between treatment groups were similar (see Table 2). At the end of treatment, the number of subjects reporting no binge drinking episodes was 1 of 7 for the standard treatment group and 2 of 12 for the integrated intervention group. At the end of the study, the corresponding numbers were 0 of 9 for the standard treatment and 2 of 13 for the integrated intervention.

Discussion

This is the first published investigation pilot testing a smoking cessation treatment approach for young adults that integrates a behavioral treatment component to reduce binge drinking. Our study extends prior work that sought to address heavy drinking during smoking cessation in older adults (i.e., 25) to a young adult population of binge drinkers. The treatment approach was found to be highly acceptable to young adult smokers who are regular binge drinkers as indicated by their perception that the intervention was helpful. Although the results did not approach statistical significance with the small sample size, there is a trend suggesting that Integrated Intervention may improve tobacco abstinence but has little effect on drinking behavior. Treatment effects were largest at the week 12 end of treatment assessment, the trend for improved tobacco abstinence remained at the week 24 end of study follow-up. Collectively, these findings suggest that intervening simultaneously on smoking cessation and binge drinking may hold promise for improving both smoking cessation outcomes but has little effect on reducing the high-risk behavior of binge drinking in this challenging young adult treatment population. To put our preliminary findings in context of Kahler and colleagues earlier large study with older adults (25), our Integrated Intervention approach produced treatment effects similar to the greater smoking abstinence (i.e., adjusted odds ratio = 1.56) but did not yield the reduction in alcohol use (i.e., 20% fewer drinks per week) found in this earlier study.

Remarkably little effort has been made to develop effective treatments for young adult smokers and our unique integrated intervention approach may hold promise for improving smoking cessation outcomes. Although adequate for pilot studies (Lancaster et al., 2004; Rounsaville & Carroll, 2001), the results are limited by the small sample size which limited

our statistical power. In addition, the sample was fairly homogeneous with respect to racial and ethnic diversity.

Our retention strategies consisted of flexibility of scheduling including offering participants the option of being seen at one of several locations in our area and completion of study visits at a day and time of their choosing, use of monetary incentives, and collection of extensive contact information (e.g., home phone, cell phone, relatives, significant others who could provide contact information). In spite of these efforts we encountered difficulty with participant retention during the follow-up period that has plagued many other investigations involving this age group. As a result, caution must be used when drawing conclusions about the Integrated Intervention and additional evaluation of this new approach is clearly needed.

In spite of these limitations, our investigation provides preliminary data which supports the intriguing possibility that a smoking cessation approach that integrates a treatment component to address binge drinking could enhance smoking cessation treatment. However, our preliminary data suggests that this integrated treatment approach had little effect on binge drinking itself, thus the mechanism of action of the intervention is unclear. The preliminary data presented in this paper are encouraging and suggest a larger randomized trial with a more diverse sample to examine the efficacy of the intervention is warranted. However, further research will be needed to clarify the mediators associated with the efficacy of the intervention.

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Table 1

Biochemically Confirmed Cigarette and Tobacco Abstinence Outcomes (7-day point prevalence)

Characteristic	Standard Treatment (N=19)	Integrated Intervention (N=22)	Odds Ratio (95% C.I.)	P-value *
End of Treatment[†]				
Cigarettes	5 (26%)	10 (45%)	2.3 (0.6, 8.8)	0.33
All tobacco	4 (21%)	8 (36%)	2.1 (0.5, 8.7)	0.32
End of Study (24 weeks)[†]				
Cigarettes	2 (11%)	5 (23%)	2.5 (0.4, 14.7)	0.42
All tobacco	2(11%)	5 (23%)	2.5 (0.4, 14.7)	0.42

* Fisher's exact test

[†] For the end of treatment visit there were 16 subjects (9 Standard, 7 Integrated) who were classified as smoking because they did not attend the study visit and did not respond to repeated telephone contact attempts. At the end of study there were 15 subjects assumed to be smoking (7 Standard, 8 Integrated) of which 8 (3 Standard, 5 Integrated) had self-reported using tobacco at their last contact.

Table 2

Alcohol Use Outcomes

	Standard Treatment		Integrated Intervention		Treatment Effect*			$\rho_{XY,Z}$
	N [†]	Mean±SD	N [†]	Mean±SD	Estimate	(SE)	p-value	
End of Treatment								
Drinks per month	7	67.1±52.5	12	34.2±23.8	-18.8	(16.1)	0.259	-0.224
Δ from baseline		-26.1±53.7		-27.2±29.1			0.967	
Drinking days per month	7	11.0±6.8	12	7.9±4.5	-2.5	(2.1)	0.250	-0.222
Δ from baseline		-3.9±4.2		-5.7±6.0			0.640	
Binge drinking episodes per month‡	7	5.8±4.5	12	3.2±2.5	-1.6	(1.3)	0.242	-0.217
Δ from baseline		-3.4±4.7		-3.8±2.7			0.610	
End of study (24 weeks)								
Drinks per month	9	60.8±25.2	13	39.3±37.3	-8.0	(14.1)	0.596	-0.103
Δ from baseline		-35.0±43.8		-19.3±36.3			0.217	
Drinking days per month	9	12.4±5.9	13	7.7±5.6	-2.6	(2.1)	0.232	-0.210
Δ from baseline		-3.2±5.8		-4.2±5.0			0.763	
Binge drinking episodes per month	9	6.3±4.0	13	3.8±3.6	-1.4	(1.5)	0.365	-0.175
Δ from baseline		-3.7±5.6		-3.4±3.2			0.761	

* Analyses were performed separately for each outcome measure at end of treatment and end of study. Follow-up data were analyzed using analysis of covariance with the baseline value of the given measure included as the covariate. The findings from this analysis are summarized by presenting the parameter coefficient and standard error for the treatment effect (integrated intervention vs. standard treatment) as well as the semi-partial correlation coefficient ($\rho_{XY,Z}$). To supplement this analysis the change from baseline was also calculated for each individual and compared between groups using the rank-sum test.

[‡] Follow-up alcohol use outcomes were obtained from subjects who attended the given follow-up visits. No imputation was performed for subjects with missing information.