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Integrated smoking cessation and binge drinking intervention for young adults: A pilot efficacy trial

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HIGHLIGHTS

- An integrated intervention for young adult smokers and binge drinkers was examined.
- Integrated intervention produced greater tobacco abstinence at 6-months.
- Integrated intervention was associated with less binge drinking at 6-months.

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ABSTRACT

Alcohol consumption is strongly associated with cigarette smoking in young adults. The primary aim of this investigation was to complete a pilot evaluation of the efficacy of an integrated intervention that targets both cigarette smoking and binge drinking on the cigarette smoking and binge behavior of young adults at 6-month follow-up. Participants were 95 young adult (M = 24.3; SD = 3.5 years) smokers (≥1 cigarettes per day) who binge drink (≥1 time per month) and who were randomly assigned to standard treatment (n = 47) involving six 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 = 48). Using an intent-to-treat analysis for tobacco abstinence, at both 3 month end of treatment and 6 month follow-up, more participants who received integrated intervention were biochemically confirmed abstinent from tobacco than those who received standard treatment at 3 months (19% vs. 9%, p = 0.06) and 6 months (21% vs. 9%, p = 0.05). At 6 months, participants who completed the study and who received integrated intervention consumed fewer drinks per month (p < 0.05) and number of binge drinking episodes per month (p < 0.05) than those who received standard treatment. Preliminary data supports that integrated intervention enhances smoking cessation and reduces binge drinking compared to standard treatment.

1. Introduction

Cigarette smoking is the single most important preventable cause of morbidity, mortality, and excess health cost in the U.S., accounting for 443,000 premature deaths each year (Centers for Disease Control & Prevention, 2012). Young adults aged 18 to 24 years have a high prevalence of cigarette smoking at 23%. Their patterns of smoking tend to differ considerably from those of older adults with a greater proportion of young adults smoking on a non-daily basis or smoking a low number of cigarettes per day (Solberg, Boyle, McCarty, Asche, & Thoele, 2007). Despite the high prevalence of smoking in young adults and distinctly different patterns of tobacco use, few intervention trials have been designed specifically for this group. A recent systematic review of the young adult smoking literature identified only 14 prior investigations that evaluated interventions specifically oriented for young adults (Villanti, McKay, Abrams, Holtgrave, & Bowie, 2010). Thus, based on the limited existing literature and the prevalence of the problem, young adults stand to benefit greatly from the development of effective tobacco cessation interventions.

Binge drinking in the U.S. is defined as consumption of ≥5 standardized alcoholic drinks (i.e., 1 standard drink contains 14 g pure alcohol) in a row for males or ≥4 drinks in a row for females. The Healthy People 2020 goals established by the U.S. Surgeon General seek to achieve a

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10% reduction in binge drinking by the year 2020. The year 2008 prevalence of binge drinking is the highest among young adults aged 18 to 25 years in comparison to any other age group with a prevalence of 41.0% (Substance Abuse & Mental Health Services Administration, 2009). Also of concern, the prevalence of binge drinking among young adults has remained stable in comparison to the prevalence reported by the prior 2007 survey. In addition to being a risk factor for poor treatment outcome following smoking cessation intervention (Murray, Istvan, Voelker, Rigdon, & Wallace, 1995), 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 (Naimi et al., 2003).

Considerable evidence suggests that alcohol consumption is strongly associated with cigarette smoking. Among heavy alcohol users aged 12 or older, 58.0% smoked cigarettes in the past month. In contrast, 19.2% of non-binge drinkers and 16.1% of persons who did not drink alcohol in the past month were current smokers (Substance Abuse & Mental Health Services Administration, 2009). 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 (Cook et al., 2012). 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 (Turati et al., 2013).

We published an earlier investigation (Ames et al., 2010) which serves as the foundation for the current study that developed the experimental integrated invention approach that is the focus of the present manuscript. Our earlier study found that the integrated intervention was highly acceptable to young adults. More participants who received integrated intervention were biochemically confirmed abstinent from tobacco than those who received standard treatment (36% vs. 21%, Fisher's exact test $p = 0.28$ at week 12; 23% vs. 11%, $p = 0.30$ at week 24). Additionally, at week 24 participants who received integrated intervention reported fewer binge drinking episodes compared to those who received standard treatment (treatment effect = 1.4 fewer binge drinking episodes in the last 30 days, $p = 0.37$ from ANCOVA with number of episodes reported at baseline included as a covariate). Based on this preliminary data, we proceeded with this pilot efficacy trial.

The primary aim of this investigation was to pilot test the efficacy of an integrated intervention that targets both cigarette smoking and binge drinking on the cigarette smoking and binge behavior of young adults at 6-month follow-up. We hypothesized that integrated intervention would be associated with significantly higher biochemically-confirmed 7-day point-prevalence tobacco abstinence rate and fewer binge drinking episodes than standard treatment at 6 month follow-up. 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 (Burton & Tiffany, 1997; King & Epstein, 2005) and environmental factors such as parental and peer influence for concurrent use of cigarettes while engaging in binge drinking (Hoffman, Welte, & Barnes, 2001). Thus, we also wished to examine the effect of the integrated intervention on several possible mediators of change that correspond to these mediating mechanisms including cravings to smoke, perceived similarity to the typical smoker, and self-efficacy for smoking abstinence. We hypothesized that the integrated intervention would decrease cravings to smoke, decrease perceived similarity to the typical smoker, and increase self-efficacy for smoking abstinence.

2. Methods

2.1. Participants

This study was approved by the Mayo Clinic Institutional Review Board. Participants included 95 young adult smokers who binge drink. Inclusion criteria included: age 18–30 years, smoked ≥1 or more cigarettes per day during the past 6 months, and binge drank on ≥1 occasion 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 (First, Spitzer, Gibbon, & Williams, 2004) or drug dependence as determined by Drug Abuse Screening Test-20 (Skinner, 1982) score of ≥6, current clinical depression as indicated by score ≥20 on Beck Depression Inventory-II (Beck, Steer, & Brown, 1996), 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.

2.2. Procedure

Participants with an interest in quitting smoking were recruited from two study sites in north Florida. Participants were recruited from the general community, local college campuses, and local businesses via active (i.e., intercept sampling) and passive methods (i.e., advertisements in college newspapers and city wide publications targeted to young adults). Intercept sampling consisted of young adult research assistants approaching young adults in public places that were observed to be smoking and asking them if they would be interested in learning about participation in our smoking cessation study. Interested individuals were provided with a flyer with the study contact telephone number and asked to call to complete screening.

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 $270 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) a 6 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 according to the participant's level of cigarette smoking. Participants smoking 10 or more cigarettes per day were treated with 21 mg/24 h for 4 weeks, 14 mg/24 h for 2 weeks, and 7 mg/24 h for 2 weeks. Participants smoking 9 or fewer cigarettes per day were treated with 14 mg/24 h for 6 weeks and 7 mg/24 h for 2 weeks. The target quit date for all participants was set for the day of the week 4 treatment visit and nicotine replacement therapy was initiated on this day for all participants.

Both treatments were manualized and master's degree level research coordinators who had received training from the principal investigator on smoking cessation intervention delivered both treatment conditions. A second study coordinator, who was blinded to participant treatment condition assignment, was responsible for completion of all assessments. All treatment sessions were audio recorded and 25% of the 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.

2.2.1. Standard treatment

Standard treatment consisted of 6, 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 (Fiore, Jaén, Baker, et al., 2008) plus 8 weeks of nicotine patch therapy. The first six treatment sessions consisted of behavioral treatment and were 30 min in duration, while the final two treatment sessions were brief visits scheduled to dispense nicotine patches, assess compliance with nicotine patch use, monitor participant safety, and address any difficulties with the patches, and were ≤10 min in duration.

2.2.2. Integrated intervention

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 (Fiore et al., 2008) with Brief Alcohol Screening and Intervention for College Students (Dimeff, Baer, Kivlahan, & Marlatt, 1999). 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 min in duration, while the final two treatment sessions were brief visits scheduled to dispense nicotine patches, assess compliance with nicotine patch use, monitor participant safety, and address any difficulties with the patches, and were ≤10 min.

Development of the integrated intervention is described in our prior publication and the treatment manual is available from the corresponding author upon request (Ames et al., 2010). 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.

2.3. Measures

2.3.1. Demographic data

Basic demographic information was assessed to evaluate the similarity of participants in the two treatment conditions.

2.3.2. 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").

2.3.3. Tobacco use

Biochemically confirmed 7-day point-prevalence tobacco use was evaluated at weeks 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).

2.3.4. Alcohol consumption

Quantity and frequency of alcohol consumption was assessed using the Timeline Followback Interview (TLFB; (Sobell & Sobell, 1995)) 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.

2.3.5. Measures to evaluate mediators of change

We evaluated the effect of integrated intervention on three possible mediators of change including cravings to smoke, perceived similarity to the typical smoker, and self-efficacy for smoking abstinence using the Questionnaire of Smoking Urges—Brief (Cox, Tiffany, & Christen, 2001), Perceived Similarity to the Typical Smoker (Gerrard, Gibbons, Lane, & Stock, 2005), and Confidence Inventory—Revised (Velicer, Diclemente, Rossi, & Prochaska, 1990). These mediators are related to the conditioning and environmental mechanisms that have been proposed to account for the relationship between cigarette smoking and consumption of alcohol, and thereby the hypothesis that the rate of smoking cessation would be enhanced by integrating a behavioral intervention to eliminate binge drinking into smoking cessation intervention (Drobes, 2002; Littleton & Little, 2002). The mediators were assessed at two time points; at baseline and at end of treatment (week 12).

2.4. Statistical analysis

The present study utilizes a randomized phase II study design. The objective of a phase II trial is to determine whether further study of the experimental intervention is warranted and to provide preliminary data for designing a larger trial. Although there has been debate about the value of formal statistical comparisons in phase II trials, we agree with those who propose that formal comparisons are appropriate with the qualification that phase II studies are not expected to provide definitive comparisons using the conventional two-sided type I error rate of 0.05 (Ratain & Sargent, 2009; Rubinstein et al., 2005). For a randomized phase II trial, a one-sided test with a false-positive (type I error) rate of 0.20 has been suggested as appropriate for the primary comparison to assess whether additional studies of the experimental intervention are warranted (Ratain & Sargent, 2009; Rubinstein et al., 2005).

Analysis adhered to an intention to treat approach. The intention to treat approach includes all randomized participants in the statistical analysis in the groups to which they were randomly assigned, regardless of their adherence to treatment, withdrawal from treatment, or any other deviation from the study protocol. Thus, intention to treat analysis avoids overestimates of the efficacy of an intervention that results from removal of non-compliers and accepts that noncompliance and protocol deviations are commonplace in actual clinical practice. 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. Tobacco abstinence outcomes were analyzed using logistic

regression and alcohol use outcomes were evaluated using analysis of covariance with the baseline value of the given measure included as the covariate. The primary endpoint was 7-day point prevalence smoking abstinence at 6 months which was analyzed using logistic regression. For this endpoint, a one-tailed p-value of ≤0.20 was considered sufficient evidence to recommend pursuing additional studies of the integrated intervention. For consistency, one-tailed p-values are presented for all tobacco use outcomes. For all other analyses two-tailed p-values are reported.

3. Results

A total of 463 individuals were screened for study eligibility. Of these, 220 were excluded during the pre-screening (n = 96) or phone screening (n = 124) phases. Pre-screenings were conducted for intercept sampling and assessed general study eligibility requirements (e.g., to ensure met age requirement). Participants excluded in this phase were due to ineligibility in one, or a combination, of the following reasons: (1) outside of targeted age range, (2) frequency of smoking, (3) regular use of other forms of tobacco, (4) not residing in study area, (5) pregnant, (6) unwilling to take nicotine replacement therapy (NRT), (7) unwilling to come for counseling, (8) does not drink alcohol or, (9) denies binge drinking. Intercepted participants who passed pre-screening gave contact information where research assistants followed up with a more in-depth phone screening, which was similar to the pre-screening questionnaire but more detailed. Those passively recruited through flyers, advertisements, or word of mouth as well as those recruited via intercept were phone screened. Participants were excluded in this phase for one, or a combination, of the reasons mentioned above. Following screening, 243 participants were eligible for baseline appointments. Of those, 148 were excluded due to the following reasons: (1) unable to contact to schedule baseline (n = 89), (2) no show after scheduling baseline and unable to contact (n = 41), and (3) excluded due to study eligibility requirements (n = 18) (e.g. drug use and psychological questionnaires).

The remaining 95 individuals included 42 females and 53 males with mean (SD) age of 24.3 (3.5) years. These individuals were enrolled in the study and randomized to standard treatment (N = 47) or integrated intervention (N = 48). Demographics, tobacco use history and alcohol use history did not significantly differ between intervention groups (see Table 1).

Of the 47 participants assigned to standard treatment, 23 (49%) attended all 8 treatment sessions and 35 (74%) attended at least 6 of the 8 sessions. Similar attendance was observed among the 48 participants assigned to the integrated intervention group with 18 (38%) attending all 8 sessions and 32 (67%) attending at least 6 of the 8 sessions. There were 13 (28%) participants in the standard treatment and 20 (42%) in the integrated intervention group who discontinued all study participation prior to their last scheduled behavioral treatment session. In both treatment groups, those who completed the study considered their intervention helpful as indicated by 100% of those in the integrated intervention and 92% of those in the standard treatment providing a rating of 4 or 5 on a 5-point Likert scale.

The smoking abstinence rates at 3 (end of treatment) and 6 months are presented in Table 2. At 6 months following randomization, the biochemically confirmed, 7-day point prevalence tobacco abstinence rate (primary endpoint) was 21% for the integrated intervention and 9% for standard treatment (odds ratio = 2.8, 90% C.I. 1.0 to 8.0, one-tailed p = 0.050). Similar results were obtained for the secondary smoking abstinence endpoints of biochemically confirmed 7-day and 30-day point prevalence abstinence at 3 months and 30-day point prevalence abstinence at 6 months.

Alcohol use at baseline and 6-months is summarized in Table 3. Among participants who attended the 6-month follow-up visit (25 standard treatment, 17 integrated intervention), average reported alcohol use was lower at 6-months compared to baseline. From analysis of covariance, adjusting for baseline use, the integrated intervention was found to be associated with fewer drinks per month at 6 months (treatment effect = −20.6, 95% C.I. −37.5 to −3.7 drinks per month), and fewer binge drinking episodes per month (treatment effect = −2.4, 95% C.I. −4.6 to −0.2 episodes per month).

The mediator variables (confidence score, distancing score, craving score) were analyzed for participants who attended the end of treatment visit (N = 22 standard treatment, N = 17 integrated intervention). Among these participants, each potential mediator variable was found to have a significant change in the anticipated direction from baseline to end of treatment. Treatment group effects were evaluated for each potential mediator using analysis of covariance with the baseline measurement included as a covariate. From these analyses, no

Table 1
Baseline subject characteristics.[a]

Characteristic	Standard treatment (N = 47)	Integrated intervention (N = 48)
Age, years	24.4 (3.3)	24.1 (3.7)
Gender, n (%)		
Female	20 (43)	22 (46)
Male	27 (57)	26 (54)
Race/ethnicity, n (%)		
Caucasian, non-Hispanic	40 (85)	40 (83)
Caucasian, Hispanic	0 (0)	4 (8)
Black/African American	4 (9)	0 (0)
Asian/Pacific Islander	1 (2)	1 (2)
Multiple races indicated	2 (4)	3 (6)
Cigarettes per day	13.4 (6.1)	13.3 (6.6)
Age began regular smoking	18.0 (2.3)	16.8 (2.7)
Other smokers in the household, n (%)	23 (49)	28 (58)
Number of drinks per month		
Mean (SD)	60.3 (50.6)	60.6 (46.2)
Median (25th, 75th)	44 (27, 82)	47 (27, 88)
Number of drinking days per month		
Mean (SD)	11.9 (6.7)	12.3 (7.4)
Median (25th, 75th)	11 (7, 16)	10.5 (6, 17)
Binge drinking episodes per month		
Mean (SD)	5.9 (5.9)	5.8 (5.2)
Median (25th, 75th)	4 (2, 9)	5 (2, 8)
Age began regular use of alcohol	18.1 (2.2)	17.5 (2.5)
Other alcohol users in the household, n (%)	37 (79)	40 (83)

[a] Unless indicated otherwise, data are reported as mean (SD) for continuous variables and n (%) for categorical variables.

Table 2
Tobacco abstinence outcomes.[a]

	Standard treatment	Integrated intervention	Odds ratio		
	(N = 47)	(N = 48)	Estimate	(90% C.I.)	p[b]
End of treatment					
7-day point prevalence	4 (9)	9 (19)	2.5	(0.9 to 7.1)	0.078
30-day point prevalence	3 (6)	8 (17)	2.9	(0.9 to 9.5)	0.065
6-months					
7-day point prevalence	4 (9)	10 (21)	2.8	(1.0 to 8.0)	0.050
30-day point prevalence	3 (6)	8 (17)	2.9	(0.9 to 9.5)	0.065

[a] Participants met criteria for point-prevalence tobacco abstinence if they self-reported not using any tobacco in the last 7 days (or last 30 days) and had expired CO < 8.0 ppm (at end of treatment) and salivary cotinine < 15.0 ng/ml (at 6-months). In all cases, participants with missing information were assumed to be using tobacco.
[b] One-tailed, Chi-square test.

significant treatment group effect was identified (confidence score: estimate = +2.1, SE = 5.6, p = 0.71; distancing score: estimate = −3.1, SE = 7.5, p = 0.68; craving score: estimate = +1.8, SE = 3.2, p = 0.57).

4. Discussion

This is the first published preliminary efficacy trial of a novel integrated smoking cessation and binge drinking intervention for young adults. This study extends our prior work (Ames et al., 2010) that evaluated the acceptability and estimated the magnitude of the effect size of our intervention approach. A significantly greater number of participants who received our novel integrated smoking cessation and binge drinking intervention were abstinent from tobacco at 6-month follow-up. In regard to alcohol use, for participants who attended the 6-month follow-up visit, the integrated intervention was found to be significantly associated with both fewer drinks and binge drinking episodes per month than standard treatment. Unfortunately, this finding does not extend to all participants, including those who were lost to follow-up prior to the 6-month (end of study) assessment. One possible explanation for this finding is that participants who failed to complete the study may not have continued to utilize the alcohol use moderation strategies they learned or may have been less engaged in treatment from the outset. Future studies could investigate these issues further for study non-completers. Collectively, these findings provide preliminary support for the efficacy of our novel integrated treatment approach and suggest that a large scale efficacy trial is warranted in a more diverse sample.

We investigated three possible mediators of change in the study completers that correspond to mechanisms that have been proposed to account for the relationship between cigarette smoking and alcohol use, including cravings to smoke, perceived similarity to the typical smoker, and self-efficacy for smoking abstinence. Although no significant differences were found in the mediator variables between the two treatment conditions for study completers, each mediator was found to change significantly in the anticipated direction from baseline to end of treatment. The exploration of the common third variable(s) that accounts for the co-occurrence of cigarette smoking and alcohol use remains a fertile area of research that future investigations should continue to explore.

We encountered challenges with recruiting and retaining participants, which has proven notoriously difficult in many other investigations involving older adolescents and young adults (Ramo, Hall, & Prochaska, 2010). Our recruitment strategies consisted of passive methods including advertisements in young adult oriented publications and group e-mails to students at local universities in addition to active intercept sampling recruitment that involved approaching young adults observed to be smoking in public places. Our retention strategies consisted of flexible appointment scheduling, use of monetary incentives, reminder phone calls or e-mails as preferred by the participant,

Table 3
Alcohol use at baseline and 6-months.

	Standard treatment		Integrated intervention		Treatment effect[a]		
	N	Mean (SD)	N	Mean (SD)	Coefficient	95% C.I.	p
Study completers							
Drinking days per month							
Baseline	25	13.4 (6.7)	17	12.7 (7.7)			
6-months	25	10.8 (7.5)	17	7.4 (6.2)	−3.2	(−7.1 to +0.8)	0.122
Number of drinks per month							
Baseline	25	66.6 (48.2)	17	57.9 (49.4)			
6-months	25	49.7 (38.5)	17	25.5 (23.0)	−20.6	(−37.5 to −3.7)	0.022
Binge drinking episodes per month							
Baseline	25	7.3 (6.3)	17	5.7 (6.2)			
6-months	25	5.0 (4.8)	17	2.1 (2.9)	−2.4	(−4.6 to −0.2)	0.039
All participants							
Drinking days per month							
Baseline	47	11.9 (6.7)	48	12.3 (7.4)			
6-months	47	10.5 (6.9)	48	10.4 (7.3)	−0.2	(−2.6 to +2.2)	0.878
Number of drinks per month							
Baseline	47	60.3 (50.6)	48	60.6 (46.2)			
6-months	47	51.3 (45.6)	48	49.2 (42.3)	−2.3	(−12.9 to +8.2)	0.665
Binge drinking episodes per month							
Baseline	47	5.9 (5.9)	48	5.8 (5.2)			
6-months	47	4.7 (4.9)	48	4.5 (4.4)	−0.2	(−1.5 to +1.1)	0.703

[a] To assess for treatment effects, measurements at 6-months were analyzed using analysis of covariance (ANCOVA) with treatment (0 = standard treatment, 1 = integrated intervention) as the independent variable and the baseline value of the given characteristic included as a covariate. One analysis was performed that included only participants who had information available for the 6-month visit and another analysis was performed which included all randomized participants. For the analysis that includes all randomized participants, those with missing data at 6-months are assumed to have no change in alcohol consumption from baseline (i.e. baseline values imputed at 6-months).

and collection of extensive contact information (e.g., home phone, cell phone, e-mail, 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 focus on including innovative recruitment and retention strategies in future studies is clearly needed.

4.1. Conclusions

Our findings provide preliminary support for the efficacy of a novel treatment approach that targets both cigarette smoking and binge drinking in young adults. The preliminary data presented in this paper are encouraging and suggest that a large-scale efficacy trial is warranted. Future research will be needed to clarify the mediators associated with the efficacy of the intervention and innovative recruitment and retention strategies will need to be included to overcome the challenges of working with this age group.

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Contributors

Dr. Ames designed the study, wrote the protocol, and created the integrated invention that is the focus of this study. Dr. Pokorny devised the intercept sampling recruitment methods that were an important aspect of our methodology and was the principal investigator of one of the two study sites and directed the day to day operations of this study at his site. Mr. Schroeder wrote and conducted the statistical methods. Dr. Tan served as study physician and oversaw the monitoring of participant safety. Dr. Werch contributed to the design of the research methods and, in particular, to the recruitment methods. All authors contributed to and have approved the final manuscript.

Conflict of interest

The authors of this work have no conflicts of interest to disclose.

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