An integrated behavioural intervention combined with varenicline for heavy-drinking smokers: a randomized pilot study

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Abstract

Objectives.—Combined smoking and heavy drinking is a significant health burden. Varenicline, an efficacious tobacco pharmacotherapy that also shows promise for drinking, has yielded mixed results among heavy-drinking smokers. This pilot study investigated integrated tobacco and alcohol counselling plus varenicline for this vulnerable group.

Design.—Twelve-week parallel, randomized controlled pilot trial of two behavioural interventions in combination with open-label varenicline. Participants were randomized using computer-generated tables, stratified by sex.

Setting.—Outpatient academic medical centre research clinic.

Participants.—Volunteers who reported smoking and heavy drinking and sought tobacco or alcohol treatment (N = 26). Intervention. (1) Integrated tobacco + alcohol counselling (INT; n = 13) or (2) counselling focused on their presenting concern (i.e., tobacco or alcohol) (SINGLE; n = 13), plus varenicline (2 mg) for 12 weeks.

Main outcomes.—Feasibility/acceptability, smoking quit rates and heavy drinking.

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Conflict of interest. Dr. O’Malley reported having been a consultant or an advisory board member for Alkermes, Amygdala, Akeo, Cerecor, Mitsubishi Tanabe, Opiant, Pfizer; a member of the American Society of Clinical Psychopharmacology Alcohol Clinical Trials Initiative supported by Abbott, Amygdala, Ethypharm, Lilly, Lundbeck, Otsuka, Pfizer, Arbor Pharmaceuticals and Indivior; a coinvestigator on studies receiving donated medications from Astra Zeneca, Novartis; a site principal investigator for a multisite trial by Lilly; and a scientific panel member for Hazelden Foundation. Dr. Fucito reported registering with the US Patent and Trademark Office the name and content of a web-based program to help with sleeping and drinking (i.e., Call it a Night). Dr. Gueorguieva discloses consulting fees for Palo Alto Health Sciences, Mathematica Policy Research and Knopp Biosciences, a provisional patent submission by Yale University: Chekroud, AM., Gueorguieva, R., & Krystal, JH. ‘Treatment Selection for Major Depressive Disorder’ [filing date 3 June 2016, USPTO docket number Y0087.70116US00] and royalties from Taylor & Francis for an academic book. No other disclosures were reported.

Ethical standards. 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. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guides on the care and use of laboratory animals.
Results.—INT feasibility/acceptability was high among men but not women. More participants quit smoking in INT than SINGLE. This outcome was only in men, not significant, but had a medium effect size. Both conditions yielded significant drinking reductions.

Conclusion.—Integrated tobacco and alcohol behavioural counselling plus varenicline may be feasible and promote smoking cessation among men who smoke and drink heavily, but a larger sample is needed to replicate this finding.

Keywords
Alcohol; behavioural treatment; cigarette smoking; heavy drinking; smoking cessation; varenicline

Cigarette smoking is more than twice as common among individuals who report heavy drinking than among the general population, and heavy drinking rates are higher among individuals who smoke than among non-smokers (Dawson, 2000; Grant et al., 2015). Both cigarette smoking and heavy drinking are leading preventable causes of death (Mokdad, Marks, Stroup, & Gerberding, 2004), and when combined have negative synergistic health effects (Ko & Cho, 2000; Kuper et al., 2000; Pelucchi, Gallus, Garavello, Bosetti, & La Vecchia, 2008; Prabhu, Obi, & Rubenstein, 2014). Individuals who smoke and drink heavily are less successful quitting smoking and reducing drinking and have distinct treatment needs (Abrams et al., 1992; Cooney et al., 2007b; Falk, Yi, & Hiller-Sturmhofel, 2006; Fucito et al., 2012; Leeman et al., 2008; Roche, Ray, Yardley, & King, 2016). Use within the same occasion is common (Piasecki, McCarthy, Fiore, & Baker, 2008), and over time, one substance may become a conditioned cue for the other (Cooney et al., 2007a; Piasecki et al., 2011; Tiffany, 1995). Both substances may also potentiate the reinforcement of the other, which may further reinforce co-use (Kouri, McCarthy, Faust, & Lukas, 2004; Perkins et al., 1995; Ralevski et al., 2012). Thus, treating only one behaviour may inadequately address the needs of these individuals and limit their behaviour change success.

Research on effective integrated tobacco and alcohol interventions is limited. Among individuals seeking tobacco treatment, two randomized-controlled trials demonstrated that a brief alcohol intervention plus standard tobacco treatment (i.e., counselling + nicotine patch) resulted in higher smoking quit rates and facilitated greater drinking reductions than standard tobacco treatment alone (Kahler et al., 2008; Toll et al., 2015). Studies of tobacco interventions provided during or shortly following alcohol treatment increased smoking quit rates, but the rates were low and not sustained beyond treatment (Cooney et al., 2015; Kalman, Kim, DiGirolamo, Smelson, & Ziedonis, 2010; Prochaska, Delucchi, & Hall, 2004). This research area remains an important gap.

Varenicline, an approved smoking cessation medication, yields the highest smoking quit rates among all tobacco monotherapies (Anthenelli et al., 2016; Gonzales et al., 2006; Jorenby et al., 2006; Nides et al., 2006) and may also reduce alcohol use (Feduccia, Simms, Mill, Yi, & Bartlett, 2014; Kamens, Andersen, & Picciotto, 2010; McKee et al., 2009; Steensland, Simms, Holgate, Richards, & Bartlett, 2007). In preliminary tobacco trials for heavy drinkers seeking tobacco treatment, varenicline reduced alcohol consumption in the absence of alcohol counselling (Fucito et al., 2011; Mitchell, Teague, Kayser, Bartlett, & Fields, 2012). However, randomized-controlled trials of varenicline for smokers and non-
smokers seeking alcohol treatment have yielded mixed results (de Bejczy et al., 2015; Litten et al., 2013). Varenicline reduced drinking among all participants (Litten et al., 2013), among men only (O’Malley et al., 2017) or had no effects on drinking (de Bejczy et al., 2015). Further, smoking quit rates were low in these trials of participants seeking alcohol treatment. Together, these results suggest that the effect of varenicline on either behaviour may depend, in part, on the behavioural focus of treatment. Therefore, an important, untested empirical question is whether targeting both behaviours simultaneously during treatment with varenicline may improve tobacco and alcohol outcomes.

We conducted a preliminary trial of an integrated tobacco and alcohol behavioural intervention (INT) for heavy-drinking smokers who sought treatment for either behaviour in combination with varenicline. Compared to prior research, INT was: (1) intensive (i.e., delivered over 12 weeks), (2) focused on behaviour change techniques relevant for both and (3) delivered in conjunction with varenicline.

The main goal was to test the feasibility and acceptability of this integrated treatment approach. We also explored the preliminary efficacy of integrated tobacco and alcohol counselling (INT) on smoking quit rates and reductions in drinking compared to counselling focused only on the participants’ single presenting concern (i.e., tobacco or alcohol only) (SINGLE) among heavy-drinking smokers receiving varenicline.

Method

Study design

This study was a two-condition randomized-controlled pilot study of heavy-drinking smokers seeking treatment for either behaviour. Participants were randomized to: (1) integrated tobacco and alcohol counselling (INT) or (2) counselling focused on their presenting concern (SINGLE: TOB or ALC only). Randomization was stratified by sex based on prior research that men and women differ in their smoking and drinking behaviour and their response to smoking and alcohol treatment (Kahler et al., 2012; O’Malley et al., 2017), and evidence that addressing co-occurring alcohol and tobacco use may be more relevant for men than for women.

All participants received 12 weeks of varenicline. The trial, registered at clinicaltrials.gov (NCT02151591), was approved by the University Institutional Review Board.

Participants

Participants were recruited from April 2015 to March 2017 from the local community primarily through social media advertisements (i.e., Facebook) and flyers posted on public noticeboards. Advertisements targeted individuals who smoke and drink alcohol and were interested in changing either behaviour. The sample size we enrolled was based on practical considerations: (1) cost of varenicline and study therapists, (2) time, and (3) a reasonable number to evaluate feasibility and acceptability. The focus was not to recruit a sufficient number to establish statistical significance but rather a pattern of results that might suggest promising effects across outcomes. These data could then be used in power calculations for a larger randomized-controlled trial of this integrated treatment approach.
Interested volunteers who clicked on web-based advertisements were directed to the study website to complete a brief web-based pre-screener. Volunteers could also contact study staff to complete a brief phone pre-screener. Individuals who met initial eligibility were then invited to participate in an in-person intake appointment to verify final eligibility.

Eligibility criteria included: (1) ⩾ 18 years old, (2) smoke on average ⩾ 5 cigarettes on smoking days ⩾ 1 year and an expired breath carbon monoxide (CO) of ⩾ 5 ppm or a score of ⩾ 2 on a NicAlert instant urine cotinine dipstick (non-daily smoking was permitted), (3) interest in tobacco or alcohol treatment, and (4) heavy drinking. Heavy drinking was defined as consuming > 14 drinks/week or 5 drinks/day ⩾ once per month over the past 12 months for men and > 7 drinks/week or > 4 drinks/day ⩾ once per month over the past 12 months for women. (NIAAA, 2018) Exclusion criteria included: (1) unstable medical or psychiatric conditions or illness based on evaluation by the study physician or nurse, (2) risk of severe alcohol withdrawal based on medical history, evaluation by the study physician or nurse, and a cut-off score on a validated clinician-administered assessment of alcohol withdrawal, (3) current substance use disorder other than marijuana, (4) new psychotropic medications within the past 3 months, or (5) currently pregnant or nursing.

**Measures**

At intake, participants completed self-report measures of sociodemographic characteristics, smoking and alcohol history information, and readiness to quit smoking and reduce alcohol consumption using the Contemplation Ladder (Biener & Abrams, 1991). The Contemplation Ladder, a single-item 11-point scale (from 0 = ‘I have no interest in changing’ to 10 = ‘I have changed and will never go back to using’), was also used to determine the participants’ primary presenting concern for randomization purposes; higher scores indicate greater readiness. If participants reported being equally concerned about both behaviours, they were asked to choose which behaviour they would prefer to address first.

Tobacco use problem severity was assessed at intake using the Fagerström Test for Nicotine Dependence (FTND) (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991), a six-item validated self-report measure of physical dependence and compulsion to smoke cigarettes.

Alcohol use problem severity, both lifetime and current, was determined at intake using a semi-structured diagnostic clinical interview, i.e., the Structured Clinical Interview (SCID) for DSM-IV (First, Spitzer, Gibbon, & Williams, 2002). The SCID interview also assessed current and lifetime diagnoses of other Axis I disorders to determine eligibility to participate. The Clinical Assessment of Alcohol Withdrawal – Revised (Sullivan, Sykora, Schneiderman, Naranjo, & Sellers, 1989), a validated clinician-administered assessment, was used to determine the risk of a severe alcohol withdrawal syndrome. To be eligible, participants had to have a score of <8.

The Timeline Followback Interview (TLFB) (Robinson, Sobell, Sobell, & Leo, 2014; Sobell et al., 2003; Vakili, Sobell, Sobell, Simco, & Agrawal, 2008), a well-validated instrument for obtaining the retrospective estimates of substance use patterns, was conducted at intake and at each visit to assess the quantity and frequency of smoking and alcohol use. Breath carbon monoxide and alcohol levels were collected at each visit before any intervention. Medication
adherence was monitored with a count of pills returned. Participants were asked to bring their medication blister packs to each visit. Counselling adherence was operationally defined as attending nine or more sessions. At treatment termination, participants rated how much the treatment helped them change their smoking and drinking using a five-point scale (0 = not at all to 4 = a great deal). Participants submitted ratings to a research assistant and were informed that their ratings would not be shared with their counsellor.

**Study endpoints**

Primary outcomes included: (1) 7-day point prevalence smoking abstinence at 6 months (i.e., defined as self-reported no smoking, not even a puff in the last 7 days and a CO of \( \leq 4 \) ppm) (Perkins, Karelitz, & Jao, 2013) and (2) percentage of heavy drinking days (PHDD) summarized over 4-week periods at baseline, week 4, week 12 and 6 months. Participants who dropped were classified as smoking (West, Hajek, Stead, & Stapleton, 2005). One participant who completed the 6-month follow-up by phone was classified as abstinent because his non-smoking status was biochemically confirmed at the two prior visits (i.e., weeks 12, 16) and he had been continuously abstinent (biochemically-confirmed) since week 3.

**Procedures**

Telephone or web-based screening determined the eligibility for in-person informed consent. After consent, research staff assessed the eligibility criteria; a study nurse or physician determined final medical eligibility. Participants were not informed of the condition. Research staff were not informed of the hypotheses. Participants started treatment within 2 weeks of intake. During the first 4 weeks, participants attended weekly counselling appointments and then could return weekly or bi-weekly for counselling (i.e., weeks 4, 6 and 8 were optional). Participants attended two research follow-up appointments 4 and 16 weeks after completing the treatment (i.e., 6 months after starting the treatment). Participants were paid for assessments after each appointment ($10 for intake and in-treatment assessments; $20 for follow-up).

Counselling was manual guided and incorporated evidence-based content relevant for both behaviours in published tobacco guidelines and alcohol/tobacco treatment manuals (Fiore et al., 2008; Kahler et al., 2008; Kadden et al., 1992, 1995 revision): (1) motivation and confidence to change, (2) goal setting, (3) stimulus control, (4) managing urges and triggers, and (5) behaviour change maintenance. To enhance motivation, participants received personalized feedback at three time points (i.e., intake, midpoint, termination) about their tobacco and/or alcohol use and health status based on routine laboratory tests conducted for eligibility screening and ongoing medication safety monitoring.

Four study therapists (\( \geq \) Master’s level, all women), experienced in evidence-based substance use treatment, delivered counselling conditions using a crossed design (Rounsaville, Carroll, & Onken, 2001). To reduce contamination, therapists were carefully selected and trained, closely supervised and informed of the condition at the first session (Crits-Christoph & Mintz, 1991).
In INT, tobacco and alcohol use were discussed at each session. In SINGLE, the participants’ primary presenting concern was prioritized as the focus. If participants mentioned the other behaviour, the counsellor discussed it briefly and then focused on how the other behaviour was related to their primary concern. A similar approach has been used previously in the randomized-controlled trials of integrated versus single behavioural interventions for co-morbid psychiatric conditions (Weiss et al., 2007). Consistent with the Tobacco Clinical Practice Guidelines for individuals who report heavy drinking (Fiore et al., 2008), participants in both INT and SINGLE (if tobacco use was the presenting concern) received brief advice to abstain from or moderate alcohol use to promote cessation, information on moderate drinking recommendations for men and women, and strategies to reduce drinking.

INT was informed by the social-cognitive theory of behaviour (Bandura, 1998, 2004). According to this theory, individuals learn to use tobacco and/or alcohol through experience and/or observing others. Through these experiences, individuals acquire expectations about the consequences of their behaviour (i.e., outcome expectancies) and their ability to regulate their behaviour (i.e., self-efficacy). Thus, interventions that emphasize stimulus control to reduce cue exposure, target positive outcome expectancies for both behaviours and enhance self-efficacy for dual behaviour change are important for this vulnerable population.

**Statistical analysis**

Descriptive statistics were used to compare the groups on feasibility and acceptability measures (i.e., session attendance, treatment completion and treatment satisfaction ratings). To evaluate smoking quit rates at 6 months, we conducted Exact Logistic Regression, controlling for sex. To evaluate the change in PHDD at 6 months, we conducted a mixed-effects repeated-measures analysis with condition as a between-subjects factor, time as a within-subject factor and their interaction as a categorical predictor, controlling for sex. PHDD was log transformed due to violating normality assumptions. All available data were included (maximum likelihood was used to accommodate missing data in PHDD) and an unstructured variance–covariance matrix was used. Focused contrasts of least-square means were used to compare the conditions on change from baseline to 6 months. Least-square mean differences with 95% confidence intervals were used to estimate the effect sizes within and between groups (Gueorguieva, 2017).

**Results**

**Participants, feasibility and acceptability**

Thirty-six individuals attended an in-person intake appointment. Six were excluded for not meeting the eligibility criteria. Of the remaining 30 eligible individuals, four chose not to enrol. Of the latter group, one individual was not able to participate in the study because counselling was only available during regular business hours. Three other individuals indicated that they were no longer interested in participating after learning more about the study.
Twenty-six participants were randomized to either INT (n = 13) or SINGLE (n = 13) and attended the first session, which was balanced by sex (see Figure 1). Baseline characteristics, which did not significantly differ by condition, are shown in Table 1.

Participants in both conditions reported high overall treatment satisfaction ratings. They rated the treatment as helpful for their smoking, but only somewhat helpful for their drinking (see Table 2). Session attendance was high across both conditions (78%). Overall treatment completion (i.e., attending the last session at week 12) and varenicline adherence rates, however, were modest at 65% and 68%, respectively. Both rates did not differ by condition but were numerically lower in INT compared to SINGLE. This effect was largely due to the high drop out in INT among women (67%). In addition, more men seeking alcohol treatment did not complete the treatment compared to men seeking tobacco treatment (40% vs. 90%). Men seeking alcohol treatment reported significantly higher drinks per drinking day at baseline than men seeking alcohol treatment (M = 9.33, SD = 4.66 vs. M = 5.16, SD = 1.99; t(13) = −2.48; P = 0.03). Treatment completion and adherence exceeded 70% among men in INT and both men and women in SINGLE. Treatment completers had lower baseline readiness to change drinking scores than participants who dropped out (M = 2.47, SD = 3.45 vs. M = 5.89, SD = 3.10; t(24) = 2.49; P = 0.02).

Smoking and drinking outcomes

The likelihood of achieving biochemically-confirmed smoking abstinence at the 6-month follow-up among the whole sample was high (35%). Twice as many participants in INT quit smoking (46%) compared to the participants in SINGLE (23%). This smoking outcome was only observed in men and not statistically significant but had an effect size in the medium range (Exact Logistic Probability = 0.15, P = 0.17; d = 0.59) (see Table 3).

There was a significant effect of time on the PHDD (log transformed; F(3, 12.5) = 8.19, P = 0.03), but no effects of condition or condition × time (P > 0.60). Regardless of the condition, PHDD at all timepoints were significantly lower than PHDD at baseline: week 4, MDiff = 0.90, 95% CI [0.36, 1.45], P = 0.003; week 12, MDiff = 1.20, 95% CI [0.59, 1.81], P = 0.001; and 6 months, MDiff = 1.38, 95% CI [0.73, 2.02], P = 0.0004.

Discussion

To our knowledge, this is the first study to: (1) evaluate the feasibility, acceptability and preliminary efficacy of an integrated tobacco and alcohol behavioural intervention (INT) in combination with varenicline and (2) to test this intervention approach for individuals seeking either tobacco or alcohol treatment. We explored whether an integrated behavioural intervention would be feasible and acceptable and would increase smoking quit rates and drinking reductions relative to a behavioural intervention focused only on the participants’ single presenting concern (i.e., smoking or alcohol only). Although limited by the small sample size, our results provide partial support for an integrated behavioural intervention combined with varenicline. Based on attendance data and treatment satisfaction ratings, INT was feasible and acceptable among men but not women. Further, among men, more participants in INT quit smoking than in SINGLE. However, INT and SINGLE had similar effects on drinking; both promoted significant reductions in drinking over time.
In this open-label study, varenicline treatment was associated with a high smoking quit rate (~one-third) and significant drinking reductions over time by 6 months. These findings provide further evidence that varenicline is efficacious for increasing smoking cessation and decreasing alcohol consumption in this population (Fucito et al., 2011; Hurt et al., 2018; Litten et al., 2013; O’Malley et al., 2017). In addition, it provides new preliminary data about the effect of a combined tobacco and alcohol behavioural intervention added to varenicline on these outcomes. First, minimal advice may be sufficient to promote reductions in drinking with varenicline, particularly among heavy-drinking individuals seeking tobacco treatment. In the current study, all participants received at least a brief alcohol intervention (i.e., information about their alcohol use and recommended moderate drinking levels, advice to abstain from or moderate alcohol use, and specific evidence-based strategies for reducing drinking). Participants who presented for alcohol treatment received this brief alcohol intervention + comprehensive motivational enhancement counselling and coping skills training regarding their alcohol use in INT and SINGLE. Conversely, participants who presented for tobacco treatment received this brief alcohol intervention + comprehensive motivational enhancement counselling and coping skills training regarding their alcohol use in INT and only the brief alcohol intervention in SINGLE (i.e., consistent with the tobacco clinical practice guidelines). Second, integrating alcohol and tobacco counselling for heavy-drinking smokers receiving varenicline may increase smoking cessation outcomes for men but not women. Smoking quit rates were higher in INT than SINGLE among men, but women showed the opposite pattern. Women in INT may have perceived alcohol-related content to be irrelevant given that no women sought alcohol treatment and their average alcohol readiness to change score was numerically lower than the men’s score. Sex differences have also been observed for both smoking cessation outcomes (Smith, Bessette, Weinberger, Sheffer, & McKee, 2016) and alcohol treatment seeking (Agabio, Pisanu, Gessa, & Franconi, 2017). Larger follow-up studies using adaptive designs could further elucidate optimal tailoring and targeting of alcohol interventions (i.e., behavioural and pharmacological) among heavy-drinking smokers receiving varenicline and whether the effects of an integrated behavioural intervention differ by sex.

This study also yielded important feasibility and acceptability data. One, heavy-drinking smokers remain a difficult population to engage and retain in treatment. It took 2 years to enrol and treat 26 participants for this pilot study, despite using a flexible approach whereby individuals could select either behaviour to address. This finding aligns with the results of recent clinical trials of heavy-drinking smokers, which reported similar challenges meeting recruitment targets (Hurt et al., 2018; Kahler et al., 2017). Two, more heavy-drinking smokers may seek treatment for their tobacco use than alcohol use. Though study advertisements targeted individuals interested in addressing either behaviour, the majority of participants sought tobacco treatment. Moreover, readiness to change scores were high for smoking but low for drinking. These results are consistent with prior research which has shown most individuals who report heavy drinking do not seek or receive alcohol treatment (Witkiewitz, Dearing, & Maisto, 2014) due to potential barriers (Saunders, Zygowicz, & D’Angelo, 2006; Tucker & Simpson, 2011) and/or low perceived need (Edlund, Booth, & Feldman, 2009). Thus, tobacco treatment provides an opportunity to engage and treat individuals who drink heavily (McKee, Falba, O’Malley, Sindelar, & O’Connor, 2007).
Furthermore, varenicline may be a useful treatment approach for promoting drinking reductions among heavy drinkers presenting for tobacco treatment (Fucito et al., 2011). Three, motivation to change smoking may be high in individuals seeking alcohol treatment. Participants who preferred to first address their alcohol use had high readiness to quit smoking scores and these scores did not differ from participants who preferred to first address tobacco use. Therefore, it is important to assess tobacco use and offer tobacco treatment to individuals seeking alcohol treatment. The prevailing evidence indicates that providing tobacco interventions during alcohol treatment does not jeopardize and may even enhance alcohol behaviour change (Prochaska et al., 2004). Fourth, though integrated tobacco and alcohol interventions may be feasible and acceptable among men, this approach may have obstacles among women. Female sex is a predictor of substance abuse treatment drop-out (King & Canada, 2004) and may be due to greater mental health concerns (e.g., trauma, stress or negative mood) (King, Bernardy, & Hauner, 2003), role factors (e.g., parenting responsibilities) (King & Canada, 2004) and/or socio-economic barriers (King & Canada, 2004). The sample of women in INT also had additional characteristics that may have contributed to poor retention including numerically higher rates of alcohol use disorders and binge alcohol consumption than women in SINGLE and the highest overall number of non-white participants. Greater substance abuse severity has been previously identified as a predictor of lower retention in substance abuse treatment and clinical trials (Mertens & Weisner, 2000; Milligan, Nich, & Carroll, 2004). Likewise, several studies have reported that individuals who identify as the members of racial/ethnic minority groups may be more likely to withdraw from substance abuse treatment (King & Canada, 2004; McCaul, Svikis, & Moore, 2001; Mertens & Weisner, 2000; Milligan et al., 2004), potentially due to socio-economic barriers, stigma, stress, multicultural shortcomings of the treatment setting, staff, or intervention and/or lack of involvement of extended family/community (King & Canada, 2004). Thus, novel intervention strategies for heavy-drinking smokers that are scalable and could reduce engagement barriers (e.g., mobile interventions) warrant further study.

This investigation had several advantages. The novel design enrolled participants seeking treatment for either behaviour. Prior studies recruited participants based on only one presenting concern pathway (Apollonio, Philipps, & Bero, 2016; Kahler et al., 2008; Thurgood, McNeill, Clark-Carter, & Brose, 2016; Toll et al., 2015). Treatments that can efficiently and effectively target multiple health risks are needed (Pronk, Peek, & Goldstein, 2004) since negative health behaviours tend to cluster and increase disease risk in combination (Pronk, Anderson, et al., 2004). Additional advantages include the randomized design and standardization of counselling through manuals and close supervision. Study limitations should also be noted. The sample size was small and pilot study results should be interpreted cautiously (Kraemer, Mintz, Noda, Tinklenberg, & Yesavage, 2006). At baseline, most participants met the lifetime criteria for an alcohol use disorder and reported at least weekly heavy alcohol consumption on average. The results, however, may not generalize to a population that reports more frequent heavy drinking. Additional limitations include assuming that participants with missing data have resumed smoking, the lack of biochemical verification of drinking reductions, biochemical verification of smoking status limited to the
last 24 h and no objective measure of medication adherence. More research on integrated behavioural interventions alone and in combination with pharmacotherapy is warranted.

Acknowledgements.

We would like to thank Krysten Bold, Helen Sackler, Lisa Blumenthal, Denise Romano, Elaine LaVelle, Susan Neveu and Allen Zweben for their assistance with study implementation, evaluation and manuscript review.

Financial support. This research was supported by a grant from the National Institutes of Health K23AA020000 (LMF) and by the State of Connecticut, Department of Mental Health and Addiction Services (DMHAS).

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Fig. 1.
Consort Diagram.
Table 1.

| Variable                        | Men (N = 15) | Women (N = 11) |
|---------------------------------|--------------|----------------|
|                                 | INT (n = 7)  | SINGLE (n = 8) |
| Demographics                    |              |                |
| Race/ethnicity, n (%)           |              |                |
| White                           | 7 (100)      | 6 (75)         |
| Black/African American          | 0            | 1 (17)         |
| Other                           | 0            | 0              |
| Hispanic                        | 0            | 1 (17)         |
| Age, M (SD)                     | 38.86 (12.19)| 43.63 (14.47)  |
| Presenting concern to address first |          |                |
| Tobacco use, n (%)              | 5 (71)       | 5 (63)         |
| Alcohol use, n (%)              | 2 (29)       | 3 (37)         |
| Smoking characteristics         |              |                |
| Cigarettes per day, M (SD)      | 20.83 (10.05)| 16.45 (9.69)   |
| Daily smoker, n (%)             | 7 (100)      | 6 (75)         |
| Readiness to change, M (SD)     | 9.00 (1.83)  | 8.75 (1.39)    |
| FTND, M (SD)                    | 3.57 (3.15)  | 5.29 (1.50)    |
| Drinking characteristics        |              |                |
| % Heavy drinking day, M (SD)    | 48.00 (29.69)| 25.50 (31.42)  |
| Drinks per drinking day, M (SD) | 6.55 (1.85)  | 6.55 (4.78)    |
| Readiness to change, M (SD)     | 2.57 (3.36)  | 5.63 (4.03)    |
| Alcohol use disorder history, n (%) | 7 (100) | 6 (75)        |

FTND, Fagerström Test for Nicotine Dependence.

Note: Readiness to change scores are from The Contemplation Ladder. Scores ranged from 0 to 10 with higher scores reflective of greater readiness.
Table 2.

Adherence and treatment satisfaction by condition and sex

| Variable                     | Men (N = 15) | Women (N = 11) |
|------------------------------|--------------|----------------|
|                              | INT (n = 7)  | SINGLE (n = 8) | INT (n = 6)  | SINGLE (n = 5) |
| Completed treatment, n (%)   | 5 (71)       | 6 (75)         | 2 (33)       | 4 (80)         |
| % Sessions attended, M (SD)  | 76.19 (37.09)| 91.67 (19.47)  | 59.26 (28.69)| 82.22 (23.04) |
| % Pills taken, M (SD)        | 73.85 (43.10)| 86.44 (24.10)  | 49.60 (34.99)| 77.09 (29.64) |
| Treatment termination, M (SD)|              |                |              |                |
| Treatment helped with smoking| 3.20 (1.30)  | 3.60 (0.55)    | 4.00 (0)     | 3.25 (0.96)    |
| Treatment helped with drinking| 1.80 (1.10)  | 2.00 (1.23)    | 1.00 (1.41)  | 1.00 (1.16)    |

Note: Termination evaluation limited to 17 participants who attended the final counselling session at week 12. Rating scores ranged from 0 to 4 with higher scores reflective of more positive treatment evaluations.
Table 3.

Smoking cessation outcome by condition, sex and presenting concern

| Presenting concern - tobacco | Men (N = 15) | Women (N = 11) |
|------------------------------|--------------|----------------|
| 7-day PPA at 6 months, n (%) | INT (n = 5)  | SINGLE (n = 5) |
|                              | 5 (100%)     | 1 (20%)        |
|                              | INT (n = 6)  | SINGLE (n = 5) |
|                              | 1 (17%)      | 2 (40%)        |

| Presenting concern - alcohol | INT (n = 2)  | SINGLE (n = 3) | N/A | N/A |
|------------------------------|--------------|----------------|-----|-----|
| 7-day PPA at 6 months, n (%) | 0            | 0              | N/A | N/A |

*P < 0.05.

The overall comparison between INT vs. SINGLE among men is significant at P = 0.04.