Interventions for Unemployed Hazardous Drinkers
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PROTOCOL: Interventions for unemployed hazardous drinkers
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Despite recent improvements in the US economy, unemployment remains a significant concern, and estimates indicate that one-third of unemployed persons drink at hazardous levels, adversely impacting their health and abilities to find jobs. Reinforcement interventions are highly efficacious in reducing substance use, and they can be applied to increase job-seeking activities as well. In partnership with CT United Labor Agency, this project is designed to reduce hazardous drinking and enhance active participation in job-seeking activities among those with job loss. It will evaluate the independent and combined effects of reinforcing negative breathalyzer samples and job-seeking activities to ascertain the simplest and most cost-effective approach to improving outcomes in this population. Unemployed individuals with hazardous drinking (N = 280) will be randomly assigned to one of four conditions using a 2 x 2 design: standard care, standard care with reinforcement for submitting negative breathalyzer samples, standard care with reinforcement for job-seeking activities, or standard care plus reinforcement for both negative breathalyzer samples and job-seeking activities. Participants in all conditions will receive usual services part of CT United Labor Agency, along with a novel remote breath alcohol monitoring procedure. The study interventions will be in effect for three months, and participants will be followed for one year. Alcohol and other drug use, employment, psychiatric symptoms, and global measures of health will be assessed throughout treatment and follow-up. Reinforcing negative breathalyzer samples is expected to significantly reduce drinking, and reinforcing job-seeking activities is expected to increase re-employment rates and reduce time until job attainment. Reinforcing both negative breathalyzer samples and job-seeking activities is hypothesized to improve outcomes along both domains. The reinforcement interventions may also decrease psychiatric distress and slow progression of physical decline, common among the unemployed. If efficacious and cost-effective, results from this study may stimulate adoption of reinforcement interventions in the context of unemployment services. Reducing the adverse consequences of hazardous drinking and improving job re-entry may have pronounced benefits in a highly vulnerable segment of the US population.

Specific aims

With the economic transformations heralded by the recession of 2008, unemployment has become a significant concern, especially in some subgroups. Traditional health disparities high-risk groups, including members of racial and ethnic minorities, those with low education, and those prone to substance use problems, are greatly over-represented in populations impacted by lay-offs and job loss. These high-risk groups also experience greater adverse health and mental health consequences during periods of unemployment, and they have great difficulty finding and maintaining jobs.

Hazardous alcohol use, in particular, can lead to and stem from unemployment. Employed individuals with alcohol problems are much more likely than those without alcohol problems to have their jobs terminated (Baldwin et al. 2010), and unemployment leads to stress and unstructured time that can increase rates of drinking (Forcier, 1988). Novel methods are needed to break this cyclical pattern.

Reinforcement (or contingency management) interventions are widely researched and highly efficacious in reducing substance use, but to date they have been applied nearly exclusively in drug abuse treatment-seeking populations. We have pilot data demonstrating that reinforcement interventions can reduce alcohol use in the natural environment in hazardous drinkers not seeking treatment. Hence, this approach may be ideally suited toward unemployed hazardous drinkers, most of whom will not participate in traditional alcohol treatment programs. Reductions in drinking in unemployed persons may be associated with mental and physical health benefits, which in turn may improve job attainment.

Reinforcement interventions can also encourage participation in goal-related activities. Persistence at job seeking is positively related to securing employment, even during economic downturns (Kanfer et al., 2001; van Hooft & Noordzij, 2009; Wanberg et al., 2005). We have conducted numerous studies in drug abuse treatment clinics in which patients contract with research staff weekly to complete activities related to long-term goals and receive reinforcement for objective verification of completing activities. Given the high rates of unemployment in our substance abuse treatment samples, one of the most popular types of activities involve job attainment, such as writing resumes and filling out

job applications. Completing these activities relates to improved employment outcomes (Petry et al., in press a). Further, we have data from a randomized clinical trial showing that this reinforcement procedure enhances job-seeking and reduces time to job attainment in dual diagnosis veterans enrolled in a vocational training program (Drebing et al., 2007). Reinforcing job-seeking activities, therefore, may have direct benefits for the unemployed.

This study will examine methods to improve outcomes in unemployed hazardous drinkers referred to employment agencies, e.g. the Connecticut United Labor Agency (CTULA), the largest agency in the state that assists displaced workers. All participants will receive unemployment services plus alcohol monitoring, and some will be reinforced for abstaining from alcohol and/or participating in job-seeking activities. Primary aims are:

1. To assess the efficacy of reinforcing negative breathalyzer samples in the natural environment. Interventions that reinforce submission of negative breathalyzer samples are expected to decrease drinking and drinking-related adverse consequences relative to those that do not.
2. To determine whether reinforcing job-seeking activities enhances attainment of employment. Participants who receive reinforcement for completing job-seeking activities are expected to achieve earlier and higher rates of employment than those who are not reinforced for engaging in job-related activities.
3. To examine if a combined intervention results in the best outcomes. Those reinforced for both alcohol negative breath samples and job-seeking activities are expected to achieve the most benefits in both alcohol and employment domains.

The project will also evaluate the impact of the reinforcement interventions on secondary outcomes including psychiatric symptoms and health measures. Moderators and mediators of effects will be evaluated, with the expectations that heavier drinkers will experience poorer employment outcomes overall, and changes in drinking may mediate effects on finding employment and maintaining it long-term.

Additionally, this study will estimate the costs and cost-effectiveness of the reinforcement interventions relative to usual care. If they increase the proportion of individuals who transition to re-employment and reduce time to job attainment, reinforcement interventions may be cost-effective and ultimately integrated in the context of unemployment services. Importantly, reinforcement interventions are now being applied nationwide in the context of substance abuse treatment services (Petry et al., in press b) as well as in other health care arenas (National Business Group on Health, 2013). These dissemination experiences bode well for their ultimate adoption in the context of unemployment services, if benefits are found in this study.

Significance

The unemployment rate in the US remains 7.7% (Bureau of Labor Statistics, 2013), and this rate disguises a larger change in employment patterns, in which precarious or impermanent jobs, that encompass a triad of contingent duration of employment, absence of benefits, and reduced compensation, are increasing (Kalleberg et al., 2000). In part because of this trend, our nation is experiencing the highest poverty level since the early 1980s (Danziger et al., 2012), with a 45% increase in food stamp program enrollment between 2009 and 2012 (Tavernise, 2012). Health disparity groups, including racial/ethnic minorities and those with substance use problems, are most impacted by job loss and unemployment.

Recent data from the National Survey on Drug Use and Health (SAMHSA, 2011) indicate that 33.2% of the unemployed binge drink, and 14.8% have an alcohol use disorder, nearly double the rate of employed persons. The loss of a job, especially involuntary job loss, results in substantial financial, family, and personal stress, along with an increase in unstructured time, all of which can impact alcohol use (Forcier, 1988). Most cross-sectional studies have found greater frequency of hazardous drinking in unemployed versus employed samples (Bolton & Rodriguez, 2009; Dooley & Prause, 1998; Khalt et al., 2004; Mulia, et al., 2013). Longitudinal studies likewise demonstrate that loss of employment can result in greater alcohol consumption and problems (Catalano et al., 1993; Claussen, 1999; Davalos et al., 2012; Mossakowski, 2008; Popovici & French, 2013; Thomas et al., 2005), particularly among men (Virtanen et al., 2008; Deb et al., 2011) and individuals with lower educational attainment (Deb et al.,

2011). At the same time, problem drinking can lead to job loss and greater difficulty securing subsequent employment (Claussen & Aasland, 1993; Leino-Arjas et al., 1999; Mullahy & Sindelar, 1996; Virtanen et al., 2008). Thus, it is likely that both causal factors and selection biases are involved in the cyclical relationship between drinking and unemployment.

Hazardous drinking and unemployment are independently and synergistically related to morbidity and mortality as well. The health consequences of problem drinking are well established and include cirrhosis, pancreatitis, high blood pressure and cardiovascular disease, as well as forms of cancer (Parry et al., 2011). Unemployed individuals also face substantial mental health and mortality risks, even after adjusting for individual health and demographic risk factors (Burgard et al, 2009; Catalano et al, 2011; DeCastro et al, 2010; Gallo et al., 2004, 2006; McKee-Ryan et al., 2005; Mossakowski, 2009; Thomas et al., 2005). Scandinavian countries keep detailed national statistics on unemployment and medical records, allowing for comprehensive analyses of these associations. In the recession of 1987-1992, for example, when the Finnish unemployment rate grew from 5% to 19%, mortality rates rose by 279% in unemployed men and by 107% in unemployed women compared to their employed counterparts (Martikainen & Valkonen, 1996). Further, adjusted mortality rates from alcoholism among the unemployed exceeded those of the employed by a factor of 3.1 in men and 5.5 in women (Kivimaki et al., 2003). The associations between job loss and mortality appear strongest for alcohol-related causes, and they manifest within one to ten years after job loss (CDC, 2013; Eliason & Storrie, 2009; Lundin et al., 2010; Luoto et al., 1998; Osler et al., 2003; Roelfs et al., 2011; Sullivan & Wachter, 2009; Thomas et al., 2005; Tsai et al., 2010), suggesting the initial period after job loss may carry the greatest health risks. Importantly, these substantial rises in mortality are reported in countries with national health care and generous financial support systems (Lundin et al., 2010; Luoto et al., 1998; Martikainen & Valkonen, 1996; Osler et al., 2003). The negative health effects of unemployment are likely far more pronounced in the US (Bambra & Eikemo, 2009; Stuckler et al., 2009), which according to an Institute of Medicine report (Wolf & Aron, 2013) has the lowest income replacement for displaced workers in the industrialized world.

Theories attempt to explain relations between unemployment and poor health. The coping hypothesis argues that unemployment leads to adverse changes in health behaviors, including greater drinking (Claussen, 1999), that deteriorate health even in young adults (Hammarstrom, 1994). The “latent sickness hypothesis” suggests that pre-existing behaviors, including hazardous drinking, lead to both unemployment and adverse health (Jusot et al., 2008). Workers with poorer health are more likely to lose jobs (García-Gómez et al., 2010; Lindholm et al, 2001), and poor health may lead to longer periods of unemployment and greater difficulty obtaining subsequent employment (Stewart, 2001).

Although the temporal and casual relationships between unemployment and poor health are difficult to disentangle, the unemployed are clearly at high risk for medical, psychiatric, and substance use problems. Importantly, unemployment benefits confer protective effects on health behavioral changes (Bolton & Rodriguez, 2009), suggesting the adverse effects of job loss can be minimized. Existing service agencies in the US, however, address either employment issues (e.g., assistance with job placement, vocational training) or alcohol problems (e.g., substance abuse treatment). Although some substance abuse treatment clinics offer onsite employment services (i.e., job clubs), their effectiveness is debated, with little evidence that passive referral or provision of minimal employment services improves job attainment (e.g., Svikis et al., 2012). Similarly, employment agencies screen for substance use problems and refer for treatment, but many individuals fail to access such services in fear of stigmatization and reduced likelihood of obtaining employment if labeled with a substance use problem. Further, the vast majority of recently unemployed individuals with substance use problems are hazardous or binge drinkers-- not alcohol dependent (SAMSHA, 2011). Substance abuse treatment programs are geared toward those with more severe problems. Thus, existing services are not well tailored to the needs of those experiencing recent job loss.

Employment agencies are well-equipped to assist persons with job searches and training, and active efforts toward seeking employment are clearly and positively associated with job re-attainment (Kanfer et al., 2001; von Hoff & Noordzij, 2009; Wanberg et al., 2005). Nevertheless, because individual efforts are rarely successful, the process of searching for a new job can be discouraging, perhaps even worsening depressive symptoms and drinking (Wanberg, 1997; Warr et al., 1988). Providing tangible

reinforcers in direct proximity to job-seeking behaviors may mitigate against these effects. With reinforcement interventions, individuals may persist in job-seeking behaviors longer, and therefore, they may be more likely to obtain jobs.

This proposal seeks to assess the efficacy of interventions developed to address unique needs of unemployed individuals with hazardous drinking. It will evaluate the independent and additive effects of reinforcement interventions designed to reduce drinking and enhance job seeking activities. Both employment and alcohol outcomes will be assessed, along with indices of mental and physical health.

Innovation

This proposal is innovative on many levels, especially in terms of addressing both drinking and job-seeking behaviors. First, this study will apply a novel method to assess alcohol use in the natural environment. Common methods to ascertain drinking (breath, urine, and blood tests) can only detect use over very brief periods of time. New methods (e.g., DUI prevention devices, SCRAMx alcohol monitors) have been developed, but they are expensive (e.g., SCRAMx is $1500 plus $5/day in monitoring fees). Because these devices may be mistaken for criminal justice monitoring systems, they are inappropriate for job-seeking populations. The system we developed and are proposing utilizes commonly available technology in a novel manner combined with advances in alcohol monitoring to ascertain drinking in the natural environment. Specifically, participants will be provided with a handheld remote monitoring alcohol breathalyzer (Soberlink® technologies). The device will be programmed via an administrative website to send prompts (primarily when drinking is most likely, i.e., evenings, weekends) to conduct breath alcohol tests. On test completion, results are automatically pushed to the admin website via cellular services incorporated into the breathalyzer. In our pilot study on remotely monitoring drinking using less automated methods prior to this advance in technology (see prelim studies), we found procedures to be feasible and acceptable, and BrACs correlated highly with self-reports and other indices of alcohol-related problems. The more automated testing procedures incorporated into the current study should further improve feasibility and acceptability. Thus, our approach provides an innovative, and relatively low cost, method to assess drinking objectively in the natural environment, and as such it could be applied in other contexts (e.g., medication trials) that could benefit from comprehensive objective indices of drinking as well. This method is particularly well suited for job-seekers as it is non-stigmatizing (cell phones, small breathalyzers carried in pockets or purses) and allows flexibility regarding the conduct of BrAC tests (Human subjects).

Secondly, this study is novel in that it represents one of only a handful of studies examining reinforcement interventions for reducing drinking. These interventions are highly efficacious in decreasing illicit drug use (Lussier et al., 2006; Prendergast et al., 2006), with a meta-analysis reporting that reinforcement interventions have the largest effect size of all psychosocial interventions (Dutra et al., 2008). However, they have rarely been applied to alcohol using populations, primarily due to technical limitations in objectively monitoring drinking (Higgins & Petry, 1999). This will be the first large randomized trial applying breathalyzer and cell phone technology to reinforce reductions in drinking. If successful, this study holds potential to move this highly efficacious intervention to the largest group of substance using individuals, i.e., heavy drinkers.

Third, this study is novel in that it will apply reinforcement to non-treatment seeking individuals. To date, reinforcement interventions have been studied primarily in treatment samples. Although efficacious in a broad range of drug abusing populations, they are most efficacious for those with less severe drug use problems (Preston et al., 1998; Stitzer et al., 2007), especially when lower magnitude reinforcers are applied (Petry et al., 2012a; Silverman et al., 1999), as planned for this study. Only a small proportion of persons with alcohol problems ever seek services (Cohen et al., 2007), and reinforcement interventions may be particularly useful for those who do not desire or access traditional services, such as the vast majority of hazardous drinkers.

Fourth, this study will ascertain experimentally whether reducing drinking improves attainment and maintenance of employment. Most of this research has been correlational. If this study finds that decreases in drinking mediate employment outcomes, these results hold potential for more aggressively and systematically addressing alcohol use in the recently unemployed and those re-entering the

workforce. Notably, individuals may participate in this study (and potentially benefit) even without desiring to decrease drinking.

Reinforcement interventions can also successfully improve employment outcomes, but thus far this approach has been limited to groups with persistent drug use and employment problems. Silverman et al. (e.g., 2005,2007,2012) established a not-for-profit company for chronically unemployed persons with severe drug use problems who receive reinforcers for initially learning and then performing data entry. Milby et al. (e.g., 2003,2010) reinforce homeless drug abusers for constructing new homes. This study, for the first time, will apply reinforcement interventions toward a broader segment of the unemployed—those with recent job loss. Silverman's and Milby's interventions typically reinforce abstinence in conjunction with working, because their populations have severe drug use disorders. Reinforcing abstinence may, or may not, be necessary in groups with less substantial substance use problems. This study will evaluate independent and interactive effects of reinforcing negative breathalyzer results and completing activities that lead to competitive employment in the natural environment. Results will be applicable to a large and generalizable group of the unemployed.

Finally, this study represents a true partnership between community-based agencies and academics. The study evolved from discussions between leaders from community organizations (Ms. Blackwood and colleagues) and academic researchers with expertise in substance abuse and reinforcement interventions (Drs. Petry and Alessi) and occupational medicine (Dr. Cherniack). It is designed to address the most pertinent and pressing needs of the clients served, i.e., alcohol use and lack of persistence in job-seeking. The interventions may reduce drinking and adverse health consequences of alcohol use and unemployment, thereby improving the public health of a large proportion of unemployed persons. If reinforcement interventions enhance job acquisition, they may have widespread generalization to unemployment settings. The study will be conducted in the largest unemployment community service agency in CT, with parallels in every state. If efficacious in this study, the approach ultimately may be well suited for large-scale dissemination efforts, and this is an area in which we have demonstrated expertise as outlined below.

Preliminary studies

We are uniquely positioned to carry out the proposed project. Dr. Cherniack is a physician specializing in occupational medicine, with an extensive history of NIH support. He established strong working relationships with employment and labor agencies throughout the country, including CTULA. Dr. Petry is an expert in addictions and reinforcement interventions. She has successfully integrated these treatments in the context of randomized trials and clinical care in settings throughout the country. Recently, Drs. Petry and Cherniack published two studies together (Byrne et al., 2013; Petry et al., in press a), and Drs. Petry and Alessi have worked together for over 10 years. Dr. Olmstead is a health economist with experience estimating costs and benefits of treatments, and he and Dr. Petry have a 7-year history of collaboration (see biosketches).

We completed several directly related projects that suggest the proposed study is likely to yield the anticipated benefits. First, Alessi and Petry (2013) provided 30 non-treatment seeking hazardous drinkers with a cellphone, breathalyzer and training on video-recording alcohol breath tests (BrACs). Participants received up to three phone calls/texts daily, indicating that a BrAC test was due within the hour. They were randomized to: modest compensation for submitting dated time-stamped BrAC videos regardless of results, or the same plus reinforcement for submitting on-time alcohol negative tests (<0.02 g/dl). On average, 88.6%$\pm$10.4% of requested BrACs were submitted on time, with no differences in submission rates between groups. BrAC results correlated with self reports of drinking and drinking consequences, $p<.01$. Negative BrACs and longest periods of negative BrACs were significantly greater with reinforcement, with 87.1%$\pm$11.1% vs 66.9%$\pm$19.1% of BrACs testing negative in the reinforcement vs monitoring only conditions, and 16.8$\pm$10.1 vs 5.9$\pm$3.4 days of consecutive negative samples in the two respective conditions. Group by time interaction effects were significant for changes in severity of alcohol problems as assessed by the Drinker Inventory of Consequences and Addiction Severity Index-Alcohol subscale scores, with greater reductions over time in the reinforcement condition. These data suggest the feasibility and initial efficacy of cell phones with breathalyzers to reinforce reductions in alcohol use in non-treatment seeking hazardous drinkers.

In an ongoing study of smoking cessation, cigarette smokers (n=71) are given cellphones, a carbon monoxide (CO) monitor, and training on video-recording CO tests. For 12 weeks, they receive 1-3 calls daily at random times between 7am-10pm from an interactive voice response system indicating a test is due. To date, median videos submitted on time is 86.8%, further demonstrating feasibility and acceptability of procedures.

We also have data suggesting that reinforcing job-related activities improves employment outcomes. Petry et al. (in press a) conducted a secondary analysis of data derived from 185 drug abuse treatment patients randomized to interventions in which they selected activities related to long-term goals each week and received reinforcers for completing them. Activities included, for example, attending doctors' appointments if a goal was medical, or completing job applications if a goal was employment. Patients who completed job-related activities evidenced significantly greater reductions in employment problems, and improvements in quality of life, than those who did not engage in job-related activities, even after controlling for baseline differences between groups. The results, drawn from a retrospective analysis, indicate that reinforcing job activities may not only improve employment outcomes, but also have broad beneficial effects.

In a randomized clinical trial, we (Drebing et al., 2007) evaluated the efficacy of a reinforcement intervention in 100 veterans with significant psychiatric problems and drug dependence who were participating in a vocational rehabilitation program. Patients were randomly assigned to usual care vocational rehabilitation services alone or with reinforcement for 16 weeks. The reinforcement intervention offered up to $1,170 for drug and alcohol negative samples and completing tasks related to job search and maintenance. Relative to those in the vocational rehabilitation only group, those in the reinforcement intervention achieved more abstinence, completed more intensive job searches, and transitioned to competitive employment faster and at higher rates, with 50% vs 28% (p<.01) obtaining a job during the study period. These results suggest that adding reinforcement to vocational training programs holds potential to substantially improve outcomes along both employment and substance use domains. That study reinforced both substance negative samples and job-related activities. The present study will disentangle effects of the two behavioral targets as well as ascertain whether either is sufficient, or both are necessary, to improve outcomes, a question of theoretical and practical importance for bringing these interventions to community-based employment agencies.

We also have experience estimating cost-effectiveness. In prior studies, we demonstrated that our prize reinforcement system is not only efficacious but also cost-effective in improving outcomes (Olmstead et al. 2007abc, 2009; Sindelar et al., 2007ab). These data are particularly compelling in the context of unemployment agencies, which may realize overall cost savings by transitioning displaced workers more quickly into employment. Thus, we will estimate costs of interventions and their administration, as well as benefits from individual and societal perspectives. These data will help inform decisions about for whom and under what circumstances funders or society may be willing to pay for increased costs of these interventions.

Finally, we have been at the forefront of disseminating these interventions. Reinforcement interventions are often criticized for costs, but methods to reduce costs, including the prize approach we developed (Petry et al., 2000,2004,2005a) and tested in the NIDA Clinical Trials Network (CTN; Peirce et al., 2006; Petry et al., 2005b), have allowed their integration in multitudes of settings. We developed training materials (Petry, 2012), as well as adherence and competence indices, and demonstrated their relationships with patient outcomes (Petry et al, 2010a,2011a,2012bc). Clinicians readily learn to administer these interventions competently (Petry et al., 2010a, 2012bc; Squires et al., 2008). As evidence of acceptability in clinic settings, Hospital and Health Corp. in NY successfully applied prize reinforcers in its clinics (Kellogg et al., 2005), RI, NY and SC integrated reinforcers into drug abuse treatment (Henggler et al., 2008; McCorry et al., 2010; Squires et al., 2008), and England introduced reinforcers into its national health care system (NICE, 2007). The Veteran's Administration (VA) called for use of reinforcement interventions nationwide and contracted with us to provide training and implementation support in >120 clinics. We trained clinicians (Rash et al., 2013), and to date well over 1000 veterans have received reinforcers. Clinician-- and patient-- response is overwhelmingly positive (Petry et al., in press b), suggesting potential for wide-scale dissemination of reinforcement interventions such as these.

Methods

Participants will be recruited from individuals seeking services at The WorkPlace, Community Health Services Inc., The Village, InterCommunity, Inc., Recovery Network of Programs, or employment agencies, e.g. CT United Labor Agency (CTULA), a non-profit human service organization that aids displaced workers with assessment, career counseling and decision-making workshops, and computer literacy. It also assists with family crises and basic needs such as food and shelter. It maintains four regional offices in CT, that serve over 7000 clients/year, providing ample flow for study recruitment. Participants will also be recruited from previous study participants that signed off on a HIPAA form to be contacted for future studies.

Inclusion criteria are: (1) age 18-65 years; (2) not worked for pay in the formal economy for >4 weeks; (3) willing to participate in a workforce training program and willing to accept either part-time or full-time work; (4) hazardous alcohol use defined by AUDIT scores $\geq$8 (Saunders et al., 1993), a mean of $\geq$2 drinks/drinking day or $\geq$14 drinks/week in men ($\geq$1 drink/drinking day or >7 drinks/week in women) in the past 2 months, or submission of an alcohol positive breathalyzer ($\geq$0.02 g/dl) or EtG positive urine sample; (5) English or Spanish speaking and able to read at 5th grade level; (6) have a valid photo ID; (7) willing and able to use study equipment (see below) and sign an off-campus property transfer form. See Human Subjects for rationale of criteria.

Exclusion criteria are: (1) have begun receiving unemployment benefits within the past 4 weeks; (2) worked full- or part-time <3 months in the past 3 years in the formal or informal (i.e., under-the-table) economy; (3) physiological alcohol withdrawal symptoms (score $\geq$10 on Clinical Institute Withdrawal Assessment for Alcohol-revised; Sullivan et al, 1989); (4) physiological withdrawal symptoms from an illicit drug use disorder; (5) serious untreated psychiatric illness (e.g., schizophrenia, bipolar disorder, or suicide risk); or (6) in recovery from gambling disorder (Petry et al, 2006a). See Human Subjects.

Screening procedure: Subjects will be screened using a form that assesses initial eligibility for two studies. Both studies are employment studies with similar inclusion/exclusion criteria. This study serves who are hazardous drinkers while the other study serves persons living with HIV/AIDS (PLWHA). If the subject is initially qualified for both studies on the basis of the screen, they will be offered the study that can best accommodate an additional active participant.

Informed consent will be obtained by a research assistant (RA) under supervision of the PI. Electronic consent will be used. Electronic consenting protects potential participants from potential harm from a breach of confidentiality as the paper consent document will link the subject to the research. The consent process will be conducted in person; the RA will review the consent and HIPAA forms with the participant in REDCap. The participant and person conducting consent will both electronically sign through REDCap's "Signature" feature. PDFs of the signed consent and HIPAA will be printed from REDCap and provided to the subject. Completed consent and HIPAA forms will be stored in REDCap and backed up to a secure server. Paper forms will be available for use to participants who prefer that option. Anyone who decides not to participate, or who is found ineligible, will receive standard services at an employment agency, such as CTULA.

During the COVID-19 pandemic, some elements of the consent process may be conducted remotely via video conference or phone in order to reduce in-person contact time. One of the following approaches to consent will be used, based on participant's preference and capability (i.e., electronic access). Questionnaires are completed electronically (in REDCap), by phone, or in-person (with the goal of reducing in-person contact time).

1. Traditional, in-person consent (electronically or on paper, as described above)
2. Remote electronic consent: Consent documents will be sent to potential participants so that they may review the consent prior to the call. A research assistant will review the consent documents with the potential participant over video conference or phone, address questions, and the consenter and participant will sign the document (electronically in Redcap). The RA will confirm

the participant's signature over phone/video and witness the participant's signature through redcap.

3. Remote phone/paper consent: Consent documents will be sent to potential participants so that they may review the consent prior to the call. The RA will review the consent with the participant by video or phone and address questions. The RA will witness the participant's signature over video or will verbally confirm over phone. The participant will send back the signed document (by email, mail, fax, or by bringing the signed consent to the in-person intake), which will be joined with the copy signed by the consenter and retained for records.

In order not to delay research further, the lapse period between the consent being signed and receiving the physical copy back from the participant will be waived. Once the consent document is signed (and witnessed by the person obtaining consent via video, phone, or in redcap), the participant may begin the assessments and randomization process. Additionally, we will waive the need for an individual to witness the person obtaining remote consent. Assessment packets with self-report measures may be provided to participants to fill out and return, or completed via phone/video if requested by the participant. Assessments that are not self-report may be completed with the research assistant via phone/video.

Proof of a LAR is unlikely, but if needed proof of LAR will be shown through video or confirmed over phone and sent back with signed consent form.

Assessments. After informed consent, RAs will administer instruments with established psychometric properties to assess study entry criteria and outcomes (est. 3 hours). Except for those designated by an asterisk (administered at baseline [BL] only), measures will be collected at BL, and Months 1,3,6,9, and 12. Abbreviated versions will be administered at follow-up. Measures will be completed in person, over the phone, with a mailed or take home packet, or through REDCap surveys.

- DSM-5 criteria Checklist* (DSM) (APA, 2013) assesses alcohol, cocaine, methamphetamine, opiate, benzodiazepine and marijuana use disorder.
- Slosson Oral Reading Test* (SORT; 1990) assesses reading level.
- The NODS* assesses gambling disorder (Gerstein et al., 1999).
- Clinical Institute Withdrawal Assessment—Alcohol revised (CIWA; Sullivan et al, 1989) examines physiological withdrawal symptoms.
- Brief Symptom Inventory (BSI-53; Derogatis, 1992) is a widely used scale of psychiatric distress, including depression, and is sensitive to change with reinforcement interventions (Petry et al., in press c).
- Addiction Severity Index (ASI; McLellan et al., 1988) provides ratings on alcohol, drug, employment, medical, legal, psychiatric, social/family, and gambling problems (Petry, 2007). Brief sections on cigarette smoking and demographics are also included. An abbreviated version will be administered at follow-up.
- Timeline Follow-back (TLFB; Sobell et al., 1980) uses calendar prompts to elicit information about days and quantity of alcohol, cocaine, amphetamine, methamphetamine, opioid, benzodiazepine, marijuana or other drug use 3 months before treatment, weekly throughout treatment, and since the last interview at each follow-up.
- The AUDIT (Saunders et al., 1993) inquires about quantity/frequency of alcohol use and related consequences, with scores $\geq$8 indicating hazardous drinking. It will assess past two months alcohol use at baseline and the interviews at Months 1 3, 6, 9 and 12 and past 12 months at baseline and the interview at Month 12.
- The Short Index of Problems (SIP; Miller et al., 1995) is a 15-item questionnaire that evaluates consequences of alcohol use in the past 2 months. The SIP has good psychometric properties and correlates highly with the DrInC (Feinn et al., 2003; Forcehimes et al., 2007).
- Alcohol Abstinence Self-Efficacy (AASE) (DiClemente et al., 1994) assesses confidence in ability to abstain in high-risk situations related to negative affect, social/positive, withdrawal and urges, and physical and other concerns.

- Coping Strategies Scale (CSS; Litt et al., 2003) evaluates strategies to abstain from drinking along active-behavioral, active-cognitive, avoidant-behavioral, and avoidant-cognitive dimensions. The past month will be assessed at M1 and past 3 months at all other timepoints.
- An employment questionnaire will be administered. Using the Labor Utilization Framework (Lichter et al., 1991), *Unemployment/Underemployment* (Jensen& Slack, 2003; Hauser, 1974) and *Employment History* will be assessed (Creed & Machin, 2002), and *Work Ability* (Thorsen et al., 2013) to evaluate current capability to work. *Career Role Salience* (Lodahl & Kejner, 1965) assesses how involved one is personally in one's work. *Global Job Search* uses 6 items developed by Vinokur & Caplan (1987) to assess "instrumental attitude" and by Ajzen & Driver (1992) to assess "affective attitude." *Global Subject Norm* (Vinokur & Kaplan, 1987) assesses social support. A 4-item *Financial Strain Scale* (Ullah, 1990; Warr & Jackson, 1987) will measure overall financial concerns. *Re-employment Self Efficacy* (Wanberg et al., 2010) will be assessed by a 5-item scale. *Employment services* utilized will also be evaluated (SU; Rosenheck et al., 1995). An abbreviated version will be administered at follow-up.
- The Quality of Life Inventory (QOL; Frisch et al., 1992) evaluates 17 life areas including work, health, recreation, etc.; scores change in response to reinforcement interventions (Petry et al., 2007b).
- Service Utilization Form (SU; Rosenheck et al., 1995) examines substance abuse, employment, medical, and mental health treatments received, inquiring about services in the past year at BL and since the last interview at other time points. It also collects data on employment, income sources, homelessness, and criminal justice involvement. An abbreviated version will be administered at follow-up.
- The Short Form-12 (SF; Ware et al., 1994) assesses general physical and mental functioning.
- Urine and breath samples will be tested for alcohol, cocaine, amphetamine, methamphetamine, marijuana, benzodiazepine and opioids via standardized procedures. We will not collect office BrACs during the COVID-19 outbreak to reduce risk to research assistants.
- A post-use satisfaction survey will be administered at the month 3 follow-up

Assessment	Baseline	Wks1-12	Mo 1	Mo 3	Mo 6	Mo 9	Mo 12
DSM Checklist, SORT, NODS	X						
AUDIT,ASI,BSI,CIWA,SIP,AASE,CSS,Employment, QOL,SU,SF,	X		X	X	X	X	X
TLFB, Office BrAC, Utox (every other week during tx)	X	Weekly	X	X	X	X	X
BrAC via phones		≤3x daily					≤3x/ day for 2 wks

Compensation: Participants will receive a $25 gift card for completing the BL assessment and $50 gift cards or check for Mo 1,3,6,9, and 12 follow-ups. They will also receive unlimited use of a cell phone (or $35/month if they use their own phone with study compatible features), and compensation for complying with alcohol monitoring during the 12-week study period and for 2 weeks at the Month 12 follow-up. Specifically, they will receive $2 for each valid on-time test, and $26 per 7-day period for all completed BrAC recordings (est. $46 per week). Mean earnings for perfect adherence will be about $184/month, consistent with our pilot that achieved high adherence (Alessi & Petry, 2013). They also receive $50 for returning the phone (if applicable) and breathalyzer at Month 3, and $25 at Month 12. Participants may also receive bus passes to aid with transportation to study appointments. See Human Subjects.

Additionally, participants who are randomized into the study will be given cards to hand out to peers who they know are unemployed and use alcohol. Participation in the study will not be affected by whether or not a participant chooses to send referrals. The referral card will describe the study and include RA contact information. Each card will be given a unique code in order to link returned cards with the original

participant. Participants can earn $20 for each eligible (i.e. they are unemployed and drink/meet eligibility on screener) recruit (up to 5 referrals) who attends an intake appointment regardless of whether the recruit consents to participate in the study.

Study visits and follow-up assessments will be *scheduled* as described above and we have many procedures in place to schedule and complete visits as planned (e.g., collection of contact information, reminder calls and cards, etc.). However, some flexibility is required to protect participants from unnecessarily limiting study procedures to a specific calendar day. If a participant misses an appointment, research staff will attempt to contact and reschedule, but we anticipate late and missed appointments. Study visits may be completed over the phone or through mail as needed.

Incarceration: This is a minimal risk study that recruits non-prisoner participants. However, a portion of the study participants are likely to be incarcerated during the study period due to illegal activities that are common in this population. If a participant is incarcerated during study participation, all study procedures are suspended except the evaluations. In the ICF, participants indicate whether or not they would like the evaluation questionnaires sent to them in prison. The mailing delivered to the incarcerated participant only contains the evaluation questionnaires and a cover letter indicating the questionnaires are follow-up to a study the individual participated in at UConn Health. A stamped and addressed return envelope is also provided with the questionnaires. If the participant completes and returns the questionnaires for Month 1, 3, 6, 9, or 12, they will receive $25 in the form of a check. The participant will receive the check after their release from incarceration or they may designate a person that the check should be sent to during their incarceration. The participant is notified in the ICF that their participation in this study while incarcerated will have no effect on their eligibility for parole.

Equipment: Each participant will receive a Soberlink® remote breathalyzer, calibrated according to specifications. Breath test results are immediately and passively uploaded to a secure web portal via cellular services incorporated into the device itself. The device also stores dates, times and results of up to 100 tests. Stored tests will be uploaded at interviews at about Months 1 and 3 to serve as a backup (see below). Participants will also be provided a study cell phone (e.g., LG GoPhone) and accessories (charger) if they do not have (or choose not to use) their own cell phone. This study phone will be used to communicate with research staff and to receive automated messages about BrAC tests (prompts, successful submission of not missed tests, alcohol-positive tests).

Training in alcohol breath monitoring: Training in use of phones and the remote BrAC monitoring device will occur before randomization. RAs will detail the cell phone's functions, including how to call staff, how to use voice mail and SMS (text messaging) functions, how to password protect phones, and how to record and delete voice and text messages.

To record a BrAC, the breathalyzer is turned on, a breath tube installed, and the "submit a test" option pressed. "Wait for the flashing blue light" appears on the screen. When flashing, "Begin blowing. Blow for 4 seconds" is displayed, and breath is exhaled for 4 seconds. The device "pops" (heard and felt by hand holding the device) when the test is complete. If not completed (i.e., breath not exhaled with the required force or duration), "Unable to perform test. Breath was not detected. Please try again." is displayed. If successfully completed, the message, "Sending Test. Approx. 60 seconds" is displayed. The test is automatically and passively uploaded to a secure administrative website via cellular services within the device. When transmitted, "Compliant test has been sent" displays. Research staff also receive a text message and email indicating successful test submission (or missed or noncompliant test). Finally, research staff text the participant through the administrative website to communicate compensation earned for submitting the test (and for negative BrACs, if applicable). The entire process takes about 2 min. During training, participants practice all procedures with staff feedback until steps are completed in their entirety at least three times in a row.

After training, participants will be instructed to carry the cell phone and breathalyzer with them at all times for the next 12 weeks, and submit breath tests within an hour of a prompt. During the first 5 days of study participation, RAs may call within about 30 min of each prompt and inquire about any problems

experienced with the equipment. If tests were completed, participants will be thanked. If not, RAs will troubleshoot and walk participants through steps of completing the BrAC to earn compensation.

During the 12 weeks, if no recordings are made within the hour for 3 consecutive 1-hr prompt windows, RAs will phone participants to inquire about any problems experienced and remind them of the compensation for complying and penalties for non-compliance. Further, if >40% of tests are missed in a week, RAs will phone to remind them that the service will be disconnected (or the $35 monthly phone service fee forfeited) if they do not submit at least 50% of requested BrAC tests each week. To re-instate service, participants must submit an unprompted breathalyzer test. Phone service will only be reinstated once during weeks 1-12, such that missing >50% of prompts for two weeks during the three month intervention period will result in discontinuation of cell service (or cell phone payments) and BrAC payments throughout the remainder of intervention phase. Individuals who fail to participate in BrAC monitoring will be encouraged to continue with other aspects of study (and non-study) treatment and follow-ups, but they can also decline (see Human Subjects).

Two weeks before the 12-month follow-up, participants will be invited back for a brief re-training on remote BrAC procedures. They will be asked to complete BrACs when prompted for 14 days using similar procedures outlined above (and further detailed below).

Randomization: After completing BL and training, participants will be randomly assigned to a treatment group. A computerized urn randomization program (Stout et al., 1994) will balance participants on AUDIT scores (< or ≥12), time since last worked for pay (< or ≥12 months), and gender, variables likely to impact outcomes. Prior to randomizing participants, up to 10 pilot participants will complete a pilot study consent form and study procedures described for Group D below, through month 3 follow-up, for the purpose of monitoring staff on study procedures prior to the randomized trial. Pilot participants may not meet all inclusion or exclusion criteria, with the exception of those relating to safety and loss of benefits.

Group A (n=70; Standard services plus job activity contracting and alcohol monitoring)
participants will receive standard employment agency services, including access to workshops, trainings, computers, and a case manager. Study participants will also meet with RAs weekly for 12 weeks. During brief ~20 min meetings, RAs will assist participants in selecting 3 specific job-related activities they can accomplish in the upcoming week. A contract will detail activities, with the purpose of breaking goals into more readily achievable components. Examples include: attending a job club, meeting with a case manager or vocational training specialist, making a chart of potential employers and persons within each hiring agency to call about jobs, completing an in-person or online job training sessions, listing questions to ask at an interview, attending a mock job interview, coming to a clinic appointment dressed in an appropriate manner for a job interview, volunteering, completing a resume, filling out a job application, attending a job interview, writing a thank you note to an interviewer, etc. In initial weeks of the study and for low functioning participants throughout, activities may be simple such as handwriting a resume one week, incorporating improvements the next, then typing it, etc. A higher functioning patient may tailor resumes to specific jobs, attend an intensive workshop, and send in 5 job applications in a week. Once a job is obtained, activities may include going to work on time or enrolling in additional workshops to further skills. RAs will review and provide positive verbal feedback (albeit no tangible reinforcer) for each activity completed to equate for attention across conditions and isolate potential benefits of the activity reinforcement conditions explicitly to the tangible reinforcers. At brief weekly meetings, RAs will also obtain TLFB self-reports of drinking and drug use and provide compensation for BrAC tests, as outlined below.

Alcohol monitoring procedures: During weeks 1-12, participants will be prompted by text to conduct BrACs 0 to 3 times/day. Consistent with our pilot study (Alessi & Petry, 2013), prompts will occur up to 21 times per week (with an average of 10 tests per week; range 7-21 per week). Participants will be informed that there will be up to 21 BrACs possible per week to encourage compliance with keeping study equipment on hand and being ready to respond to test prompts, so that they do not alter drinking patterns once a set number of tests has occurred on a particular day or week. Test prompts will occur between 8am and 11pm, but most prompts will occur during evenings (6pm to 11pm) and weekends, when drinking is most likely. In terms of the specific schedule, calls typically will occur ≥4 evenings per

week between 6 pm and 11 pm, and at least twice on ≥2 evenings/week. Occasional morning, noon and early afternoon calls will occur, 1-2 times each per week on average. Schedules may be altered if the participant obtains a job, such that BrAC prompts will not be scheduled during verifiable work times so as not to disrupt work performance and because drinking on the job is unlikely (see Human Subjects). The exact number and timings of BrACs will be unknown to participants. When a scheduled BrAC occurs), the participant will be texted a request for a BrAC, within 60 min.

After completing a BrAC, if the BrAC is reported as <.02 g/dL, the participant is congratulated via text message (or call, if preferred) (and draws earned is stated, if applicable, along with maximal earnings for the next requested BrAC; see Groups B and D). Finally, the participant is informed of the amount earned for submitting the sample (e.g., $2) and when the next bonus for submitting all requested samples is possible, e.g., "Congratulations for testing negative. You earned $2 for submitting this sample, and your $26 bonus will be available as soon as next Wed, if you continue to submit all samples within 1 hour. Thanks!"

No earnings will be awarded, however, until RAs review the validated BrAC results. RAs will view BrAC results at set times daily on workdays, e.g., 9 am Mon-Fri.

Research staff will verify the timing and quality of BrAC tests in "real time" (i.e., upon receipt) during the first 5 days of study participation, and thereafter at least once a day on regular workdays. At a set time on standard workdays, RAs will contact participants by text (or phone or email, based on participant's preference) indicating amounts earned for compliance with BrAC tests since the last message (e.g., "Your 2 samples since yesterday were validated. You earned $4 for submitting those samples, plus a $26 weekly bonus for a total of $30. Thank you!"). If a valid BrAC test is not received, the message may state: "Your 9:15 to 10:15pm test last night was not made, so your next possible $26 bonus will be available next Thursday. Please carry your equipment and complete all requested tests. Thank you!" Earnings will be available as soon as test results are reviewed, or at the weekly visits. Total earnings for submitting all requested samples will average $552 over 12 weeks.

Group B (n=70; Reinforcement for negative BrACs) participants will receive the same employment agency services, compensation for complying with BrAC tests, and weekly job activity selections in Group A. Additionally, they will receive reinforcement for each BrAC completed within one hour of the prompts that tests alcohol negative (<0.02 g/dL). Specifically, participants will earn 1 draw for each negative BrAC provided, and bonus draws for each full week of negative samples. Bonus draws start at 5 for the first full week of all negative samples, and increase by 2 draws per week when all negative BrACs are submitted up to a maximum of 15 bonus draws per week. Draws possible will be specified during texted communications after a sample is received and verified by the RA, e.g., "You earned 1 draw because your BrAC is negative, and your 9 bonus draws for 3 weeks in a row of negative samples are possible by Thursday. You also earned $2 for testing, and your $26 testing bonus is possible on Friday."

When a BrAC tests positive or no valid test is submitted within 1 hr of a prompt, that test results in no draws (but participants are still compensated for adherence if they submit a positive sample). Bonus draws for the next week of negative samples also reset, such that the next negative BrAC restarts the week in terms of the bonus. After 7 days of negative samples, a participant would earn 5 bonus draws, and bonuses would then increase again by two draws for subsequent weeks of all negative samples. Earnings and bonuses for completing BrACs are separate from those for negative BrACs, such that bonuses for negative samples may occur on different days than bonuses for sample submission. As in Group A, samples will be verified before awarding actual draws. Participants will complete draws at weekly meetings (or more frequently if desired) and can earn up to an average of 266 draws if they submit all requested BrACs and all test negative.

The bowl from which participants will draw will contain 500 slips. Sixty percent (300) state "Good job!" but are not associated with a prize; 164 state "small," 35 state "large" and one states "jumbo." Small prizes are worth up to $1 and include batteries, socks, toiletries, food items, 2 stamps and bus tokens. Large prizes are worth up to $20 and include gift cards, watches, cameras, coffee makers, etc. The jumbo is worth up to $100, with TVs, DVD players, air conditioners as popular items. All slips are returned to the bowl after drawings so probabilities remain constant. Prizes are purchased in bulk/ on sale to reduce costs. There are 266 draws possible on average over 12 weeks.

Group C (n=70; Reinforcement for completing job-related activities) participants will receive employment agency services and compensation for complying with BrACs outlined in Group A. As in Groups A and B, these participants will complete an activity contract outlining 3 specific job-related activities each week. Participants in this group will receive 3 prize draws for each activity completed and verified. Acceptable forms of verification will be noted on the contract (e.g., attendance record, receipt, signed or completed form) and must be presented to earn draws. If participants complete 3 activities in a week, they earn bonus draws that start at 6 and increase by 2 draws for each successive week in which all 3 activities are completed, up to a maximum of 16 bonus draws/week (25 total draws/week). If they fail to complete or verify an activity, they earn no draws for that activity, and bonus draws reset to 6 for the next week in which all 3 activities are completed. Participants can earn up to 270 draws if they complete 3 activities/week for 12 weeks. Draws are from the same bowl described above.

Group D (n=70; Reinforcement for negative BrACs and completing job-related activities) participants receive both reinforcement interventions in Groups B and C. The sessions will review both earnings for submitting negative breath samples and earnings for completing job-seeking activities. In total, these participants can earn up to 536 draws (266 for submitting all negative samples and 270 for completing all job-related activities).

During the COVID-19 outbreak and depending on risk levels at the time to participants and research assistants, treatment sessions may be postponed or completed over the phone depending on recommendations by UConn and state and federal authorities. If completed over phone, participants will be encouraged to complete job-related activities they can do from home (such as working on resume, calling places to see if they are hiring, online job skills activities, etc) to reduce community exposure as much as possible and depending on participant comfort level. Participants will be informed of how much they will receive for submitting BrACs and how many prize draws they have earned, and will pick draws and prizes and payment at the next in person visit. If needed, participants may also have the choice to complete their draws and pick prizes on zoom/skype or over the phone, and prizes may then be mailed. Follow-ups may be conducted in person or partially by phone/redcap (with participants reporting for a short in-person appointment to complete the required in person pieces). Participants with health and safety concerns (i.e. compromised immune system) who complete follow-up visits completely remote will miss sample submissions but will receive the full $50 follow-up payment. Payments for completed mailed packets will remain $25. Coronavirus screening questions will be asked as needed until no longer needed based on guidance from university and federal agencies to determine risk.

Design considerations:

Will participants comply with BrAC procedures? The BrAC testing frequencies and procedures in this study are similar to those found acceptable and efficacious in reducing drinking in our pilots (Alessi & Petry, 2013; prelim studies), with >88% of requested BrACs submitted. We expect similarly high compliance in this study.

Why a < .02g/dL cutpoint? Reinforcing BrACs < .02g/dL will allow modest alcohol consumption without loss of reinforcement. If individuals drink no more than a single standard drink, for example, they will likely test below this level if they wait 60 min after consumption to provide the BrAC. This cutpoint minimizes false positives, yet it is likely to detect instances of drinking of ≥2 standard drinks/hour, rates that are likely to lead to binge drinking episodes and adverse consequences. Reinforcing this threshold was successful in reducing drinking, and drinking related consequences, in our pilot study (Alessi & Petry, 2013). Occasional drinking in moderation is unlikely to yield adverse effects in this population so this cutpoint appears appropriate. We also recognize that drinking very late at night will not be detected, as we elected to stop BrAC prompts after 11pm. This decision balances practical concerns (not prompting samples while people are sleeping) with ability to detect all drinking. In our pilot, undetected late night drinking was rare, because few people start drinking after 11 pm, and if late night drinking were heavy, it could still be detected during early morning prompts (8 am).

Why these parameters? The magnitude of reinforcement is similar to that efficacious in reducing drug use and enhancing activity completion, typically ~$400 in prizes over 12 weeks (Petry et al, 2005abc,2012abc). Although Group D participants can earn up to 50 draws/week if they submit all negative samples and complete all activities for >6 weeks in a row, opening 50 slips takes <5 minutes, and participants combine smalls, such that 20 smalls can be exchanged for one large prize. We have reinforced patients with high numbers of draws without problems (Petry et al., 2011a, 2012a). We considered equating draws in Groups B and C with Group D. However, reducing magnitudes of reinforcement for each behavior may diminish efficacy for altering drinking and job-seeking behaviors. The present design allows the most parallels across conditions.

Why 4 conditions? We considered evaluating just one or two of the reinforcement conditions relative to standard care to reduce study time and costs. Groups B and C, for example, are likely to improve outcomes of the behavior they reinforce, but they may not ameliorate both alcohol and employment problems. On the other hand, Group D, while likely efficacious (Drebing et al., 2007), involves more complex procedures reinforcing both negative BrACs and job-seeking activities; if reinforcing just one of these behaviors is sufficient, subsequent studies and dissemination efforts can focus on reinforcing either negative BrACs or job-seeking activities alone. Thus, this 2x2 design allows evaluation of important scientific, clinical and practical questions, and it eliminates the need to conduct subsequent studies to dismantle efficacious components if beneficial.

What about long-term effects? A common critique is that reinforcement interventions do not maintain benefits. These concerns, however, often do not acknowledge that some studies (e.g., Alessi et al, 2007; Higgins et al, 2000a,2003,2007; Iguchi et al, 1997; Petry & Martin, 2002; Petry et al, 2005c,in press d) **do** show benefits persist after reinforcers end. Further, there are **no** data to support the contention that individuals who receive reinforcers cease the previously reinforced behavior at faster rates than those who do not receive reinforcers. Finally, Higgins et al. (2000b,2007) and we (Petry et al,2005a,2006b,2007a,2010b, 2011a, 2012a) consistently show that a robust predictor of long-term outcomes is the longest duration of behavior change. These interventions reinforce sustained behavior change in hopes of leading to enduring benefits.

Why will RAs administer interventions? We have trained community case managers and therapists to deliver reinforcement interventions (Petry et al., 2010a,2011a,2012bc,in press b) and considered doing so for this study. However, time and resources for training employment agency staff would exceed that associated with using our researchers to administer interventions, and it would delay study start up. If employment agency staff turnover occurred, the study would risk not finishing in 5 years. Thus, for this study, we will use grant hired research staff to administer interventions; if efficacious, case managers can be trained readily in dissemination efforts.

Are interventions generalizable? As noted earlier, reinforcement interventions are now being implemented in community clinics, including nationwide throughout the VA (Petry et al., in press b). Their adoption in employment agencies may be more straightforward than in substance abuse clinics. For example, the National Business Group on Health (2013) reported that 85% of employers now use reinforcers to promote health behaviors, and section 2705 of the Affordable Care Act allows employers to use up to 50% of premiums for incentives. Thus, policy makers are recognizing the potential of reinforcers to positively impact behaviors. If efficacious in this study, unemployment agencies may integrate these procedures to improve outcomes and reduce overall job-placement costs, and/or portions of unemployment benefits ultimately may be contingent upon actively engaging in job-seeking or other health-related behaviors. Because many individuals lose jobs through clearly no fault of their own--especially in the case of large-scale layoffs, society may be particularly supportive of these interventions in the context of unemployment services (Promberger et al., 2012).

Data Quality Control: A project director will supervise treatment implementation and ensure equal BrAC

prompts across conditions and appropriate administration of reinforcers. Checksheets will be kept, listing data collected, draws earned and prizes won. Additionally, the brief weekly intervention sessions and BL/follow-up evaluations are audiorecorded (with participant permission), and a proportion are randomly selected for ratings of adherence and competence by ≥2 raters with IRR ≥80%. If adherence or competence decreases below acceptable standards, closer supervision and re-training are provided (Petry, 2012; Petry et al.,2010a,2012bc).

We achieve high rates of follow-up, with <6% of participants lost to follow-up completely (Petry et al, 2005ac, 2007a,2011a,2012a). We will assess for group differences in BrACs and follow-ups, but missing data have not differed between groups when adequate compensation is provided, as is planned for this study.

Timeline: Months 1-3 will be used for training, start-up efforts and pilots. We expect to randomize about 7-8 participants into the study each month in months 4-42. This rate of recruitment is feasible because over 500 unique clients receive services each month at CTULA, with an estimated 15-20% meeting all inclusion criteria (and <15% are expected to meet exclusion criteria). Given the number of clients served throughout this agency, we plan to limit recruitment to one or two of the employment agency sites, but can expand to other sites if needed. Recruiting more quickly would necessitate more study staff due to the number of intervention visits, and this rate is consistent with our substance abuse treatment studies. With this enrollment rate, all intervention should be completed by month 47 and final follow-ups by month 55, leaving 5 months for analyses and report writing.

Data Analysis: An important issue preceding analyses is to identify baseline differences between groups despite random assignment. Group differences that may relate to outcomes (e.g., psychiatric diagnoses, occupational or medical status, drinking severity, services received) will be used as covariates or fixed factors in analyses. All randomized participants will be included using intent-to-treat analyses. Four primary outcomes are determined a priori: longest duration of negative samples (LDNS), % negative BrACs, % days worked for pay, and time to job attainment. The first three are continuous variables that can be transformed if needed. Drinking outcomes rely primarily on objective indices (BrACs), with subjective reports supplementing objective indices, such that one can be considered drinking if either index is positive. For LDNS, missing BrACs will be considered to break a string of negative samples. For % negative BrACs and % days working, missing data will be considered missing (not impacting the denominator) in one analysis, and positive/not working in another to consider the range of possibilities. ANOVAs (or ANCOVAs) will be conducted for drinking data and % days employed, evaluating both short-term (BL to month 3) and longer-term (throughout follow-up) efficacy. Time to job attainment will be evaluated with Cox survivor analyses, including covariates if needed.

The design includes four treatment groups, allowing for examination of three main contrasts. Aim # 1 is to evaluate whether reinforcing negative BrACs reduces drinking. Contrast weights of +1 will be assigned to Groups B and D and weights of -1 to Groups A and C to evaluate differences in LDNS and % negative BrACs in those assigned to interventions reinforcing negative BrACs vs those not. Aim #2 is to assess if reinforcing job-related activities reduces time to job attainment and increases % days working. Contrast weights of +1 will be assigned to Groups C and D and -1 to Groups A and B. Aim #3 is to examine if reinforcing both negative BrACs and job activities produces synergistic effects in terms of primary drinking and employment outcomes. To test this hypothesis, we will assign contrast weights of +2 to Group D, +1 to Groups B and C and -3 to Group A.

Power analyses. Our studies reinforcing drug abstinence find Cohen's *d* effect sizes of 0.5 to ≥1.0 for substance use outcomes (Petry et al, 2000,2004,2005abc,2006b,2007a,2010b,2011a,2012abc), and our pilot trial using cell phone recorded BrACs yielded an effect size of *d*=0.52 for LDNS and *d*=0.62 for % negative BrACs (Alessi & Petry, 2013). Our study reinforcing job activities and abstinence (Drebing et al., 2007) had an effect size of 0.47 in terms of increasing job acquisition and 0.49 for abstinence. We conservatively powered this study to detect the smallest of these effect sizes. Using a Type I error rate of α=.05, a Type II error rate of β=.20, and power=0.80 (Cohen, 1988), 62 participants are needed to detect

an effect size of *d*=0.47 between conditions reinforcing a target behavior and conditions not reinforcing that behavior.

We expect a smaller, but still clinically meaningful, effect size of *f*=.22 when comparing across reinforcer conditions. With power 0.80, 64 participants/group can detect *f*=.22 using the 3-group contrast in Aim 3 (Cohen, 1988). To accommodate for missing data, we will randomize 280 participants in total (70/group).

With 70 participants/group in a 2x2 design, we will be overpowered to detect main effects of reinforcing negative BrACs on alcohol outcomes, and main effects of reinforcing job-related activities on employment outcomes. Nevertheless, this sample size provides power to ascertain if the combined reinforcement intervention is most effective. It also allows detection of a small to medium effect size in determining if reinforcing one behavior can improve both alcohol and employment outcomes (e.g., Group B > A, and Group C > A) to isolate the simplest efficacious reinforcement approach. Moreover, it permits evaluation of secondary outcomes and exploratory analyses of moderators and mediation effects.

Secondary aims are to evaluate the impact of interventions on other drug use, and mental and physical health indices. These are continuous measures, with missing data likely. If no systematic differences in missing data are noted, hierarchial linear models (HLM; Gibbons et al., 1993) using MIXREG (Hedeker, 1993) will analyze differences between groups over time. These analyses have advantages over repeated measures ANOVA as they estimate missing data via model parameter estimates and use real time, rather than scheduled time, of assessments. The same contrasts outlined above will be used to evaluate the aims. Analyses will be conducted for both short-term (e.g., BL to M3, with up to 3 data points/participant: BL,M1,M3) and long-term effects (BL through M12, with up to 6 data points: BL,M1,3,6,9,12). Models will include factors for group (using contrasts above), time, and interaction of group by time. Analyses will ascertain whether the interventions impact areas of functioning beyond alcohol use and employment indices. For example, reinforcement interventions can reduce psychiatric symptoms and improve quality of life (Petry et al., 2007b, in press c).

To determine if patient factors predict outcome, multiple regression analyses will be used to identify predictors of continuous measures (longest duration of negative samples, % negative BrACs, % working days), and logistic regressions for dichotomous variables (e.g., job attainment or not). Cox regression analyses may also be used to determine what factors predict time to event outcomes, such as time to job attainment, or first job interview. Independent variables will include treatment condition, substance use and psychiatric symptom severity (e.g., AUDIT, BSI scores), duration of unemployment and occupational class, work indices (e.g., work ability, involvement, self-efficacy), criminal justice system involvement, and demographics (e.g., gender and race). Analyses will be conducted for the entire sample and with interactions of predictors with condition to assess if certain characteristics are more predictive of outcomes in the different treatment conditions.

Latent growth models using structural equation modeling will examine if changes in drinking (or self efficacy which previously have been shown to mediate intervention effects; e.g., Litt et al., 2008; Petry et al., 2007c), mediate employment outcomes. Models can be built sequentially, starting with a basic latent growth model comprising, for example, days employed over time, modeled linearly as slope and intercept. A bootstrapping resampling procedure will estimate model test statistic *p* values and parameter standard errors (Arbuckle, 2006). Models will be considered to fit if Comparative Fit Index (CFI) and root mean square error of approximation (RMSEA) are adequate, e.g., >.90 and <.10 (Bollen & Long, 1993). We will use an iterative basis to establish the best fitting growth model (e.g., linear, quadratic) based on modification indices (Jöreskog & Sörbom, 1984). Once a basic latent growth model is determined, effect of treatment condition will be added as a predictor of slope and intercept. Then, drinking days (or self efficacy scores) will be included, using pre-, during- and post-treatment indices. Beta weights of the full model can be tested using a product of coefficients test to determine if mediation is significant (MacKinnon 2007ab). Although we expect that drinking days (and/or self efficacy scores) may mediate effects of finding and retaining employment, we can also test the converse relationship and examine whether changes in employment, for example, mediate changes in drinking.

Economic Evaluation. If primary aims are supported, we will conduct cost-effectiveness analyses.

These interventions can be costly, and not only must costs of reinforcers be included, but so must administration costs, which include staff time for managing and delivering reinforcers. Despite costs, these interventions may provide benefits to society in terms of increased productivity and reduced healthcare service utilization (hospitalizations, ER visits). This study will estimate costs of these reinforcement interventions and determine their net benefit in terms of improving both drinking and employment outcomes.

a. Comprehensive administrative costs of interventions will be quantified (Olmstead et al, 2007abc; Rosenheck et al, 1995; Sindelar et al. 2007ab), including costs of prizes, mileage for purchasing them, BrAC testing and management (personnel time to arrange and review videos, and cell phones costs in Groups B and D), and setting and verifying job-related activities (Groups C and D only). Costs related exclusively to data collection will not be included (i.e., cell phones and staff salary for collection and viewing BrAC videos when not reinforced in Groups A and C). Costs for usual employment and clinical services, and reimbursement for same when applicable, will be ascertained.

b. General healthcare costs will be estimated by multiplying service units used by average unit costs. In- and out-patient, day hospital, aftercare and emergency room services will be estimated from CT claims data, and nationally from the Market Scan database, which estimates service costs.

c. Societal costs will be obtained on productivity (days worked, earnings, and workdays affected by substance use), automobile crashes (including property damage, injuries, and fatalities), and criminal justice system costs. Participants receiving reinforcement interventions may have reduced societal costs, and the SU collects data on these variables, police contacts, court hearings, and incarceration, along with timing of events that resulted in criminal justice service use so acts occurring before study participation can be separated from those occurring during it in terms of resource utilization. Unit costs of services will be estimated from national reports (Pastore & Maguire, 2003; US Dept. of Justice 2006).

Net benefits. Resource utilization and cost data will be used to estimate mean net benefit (benefits – costs) per patient in each group from agency and societal perspectives (Drummond et al, 2005; Zarkin et al., 2008). Mean net benefits, and confidence intervals around estimates, then will be calculated by subtracting mean net benefit of reinforcement conditions from standard care. Finally, sensitivity analyses (Olmstead et al., 2007a; Drummond et al., 2005) will determine the robustness of the net benefit to alternative assumptions about a variety of cost parameters (e.g., unit costs of services, reimbursements received).

Cost-effectiveness ratios. If the interventions engender net benefits (as they have been shown to in the context of substance abuse treatment; Lott & Jencius, 2009), then they ought to be adopted. Even in the absence of a net benefit, the incremental cost-effectiveness ratio (ICER) is critical to policy decisions. The ICER is calculated as: (i) incremental costs to (ii) incremental effectiveness (difference between average effectiveness of treatments in terms of days abstinent or employed). Using expert panel recommendations (Gold, 1996; Johanneson, 1996; Weinstein, 1996), we will present traditional ICERs and uncertainty of the ratios (Gold, 1996; O'Brien et al., 1994) and derive a single synthetic measure of multiple indicators of effectiveness, including quality of life (Hargreaves et al., 1997; Rosenheck et al., 1998). We will also conduct acceptability curve analysis to provide policy relevant interpretations (Fenwick et al, 2001,2004; Lothgren & Zethraeus, 2000; Polsky et al., 1997; vanHout et al., 1994). Multiple samples are selected randomly (bootstrapped), with replacement, from the original sample to approximate the larger population. Incremental cost and effectiveness values and ICERs can be calculated for each new sample and compared with theoretical "willingness to pay" values for an outcome, such as days without drinking or days employed. Such analyses inform policy makers in decision-making (Olmstead et al, 2007ab; Sindelar et al, 2007b) and can be conducted with samples even smaller than those herein (Olmstead et al., 2007c,2009; Sindelar et al., 2007a).

This study allows for rigorous determination of costs and benefits of interventions that accrue to unemployment service agencies and society more generally. A provider perspective is crucial because, at least in the immediate future, agencies are unlikely to fund expanded services unless they are cost beneficial. Societal perspectives (ICER analyses) are critical for future policy that might allocate state and federal funding to support reinforcement interventions, as is now being done for substance abuse services (Petry et al., in press b) as well as in other health care arenas (National Business Group on Health, 2013). Only a comprehensive study such as this can address multiple perspectives and extend

them to clinically and socially relevant settings and populations.

Future directions: If the dual reinforcement intervention yields the best outcomes and is cost-effective, then that approach should be adopted clinically. If reinforcing job-related activities alone increases job attainment even without reducing drinking, this approach may be expanded to other unemployed groups, including those without drinking problems; if it fails to improve outcomes, other approaches are needed to improve transition to re-employment. Likewise, reinforcing negative BrACs may only reduce drinking but not improve employment outcomes; this BrAC reinforcement approach then may be useful for other populations with hazardous drinking (e.g., college students, patients in medication trials), but not specifically the unemployed. Regardless of outcomes, this study is likely to guide future research and practice in assisting unemployed persons and hazardous drinkers. Importantly, these groups, both independently and collectively, represent a sizeable proportion of US society, and they experience significant—yet preventable— morbidity and mortality.

Human Subjects

1. RISKS TO THE SUBJECTS
   a. Human Subjects Involvement and Characteristics.
      i. Inclusion Criteria.

Subjects will be 280 men and women, age 18-65 years, who have not worked for pay for >4 weeks in the formal economy and are willing to participate in an employment agency training programs and accept part- or full-time work. Study subjects must also be hazardous drinkers defined by AUDIT scores ≥8 (Saunders et al., 1993), self-report drinking a mean of >2 drinks/drinking day or ≥14 drinks/week in men (≥1 drink/drinking day or ≥7 drinks/week in women) in the past 2 months, or submission of a positive breath (≥0.02 g/dl) alcohol or urine EtG sample. They must be English or Spanish speaking and able to read at 5th grade level, have a valid photo ID, and willing and able to use study equipment and sign an off-campus property transfer form.

Regarding the inclusion criteria, the age criteria will encompass the vast majority of individuals seeking services at an employment agency, with an upper age limit imposed to avoid inclusion of individuals eligible for social security benefits. We recognize that the definition of unemployment is controversial and complex, given that many individuals are under-employed or employed in non-permanent positions. Because patterns of work participation are difficult to capture, we have elected to use the absence of formal and "reportable" employment within the past 4 weeks as a hard entry criterion. To appraise potential confounding influences, a short survey instrument based on the Labor Utilization Framework (Lichter et al., 1991) categorical approach to employment status will be included to distinguish between any work and formal vs informal work (Creed & Machin, 2002). We further note that the criteria we are proposing purposefully exclude seasonal and part-time laborers from the study during periods in which they are able to secure at least some employment. Nevertheless, individuals who go for 4 weeks or more without working for pay are study eligible. In this manner, the study focuses on recruiting individuals into the study who have ample time to dedicate toward finding a job, as we would not want individuals to have difficulty completing study activities because of their part-time or seasonal jobs. The criteria we are proposing are likely to encompass a broad range of unemployed individuals, and those most likely to seek services at CTULA; further, the interventions designed are best suited toward this group. The vast majority of individuals seeking services at employment agencies will meet this inclusion criterion related to unemployment.

Criteria related to drinking are consistent with heavy or hazardous drinking guidelines (NIAAA, 1995). They represent levels of alcohol consumption that are likely to be associated with difficulties in obtaining or maintaining employment and that result in adverse health consequences. The minimal weekly drinking criteria are sufficient to ensure that such levels will be captured via our alcohol monitoring procedures, and similar to the frequency/quantity criteria used in our cell phone and breathalyzer pilot trial that showed successful reductions in drinking (Alessi & Petry, 2013). Because persons who were recently in a controlled environment may not yet have had the opportunity to meet these drinking criteria, the timeframe of assessment may include the period before entering the controlled environment. In addition to criteria for hazardous drinking, persons with an alcohol positive breath or urine EtG test will be included, because recruiting participants from a labor agency may set conditions for nondisclosure of drinking and limit generalization of results. Submission of a breath or urine EtG sample positive for alcohol is indicative of recent drinking to ensure inclusion of persons who may deny extent of their drinking but who likely are hazardous drinkers.

The vast majority of individuals seeking services at CTULA and other employment agencies are English or Spanish speaking. We expect that very few persons will be excluded by the language requirement. A fifth grade reading level is required to operate phones, as we found previously that persons with very low reading abilities encountered difficulties sending videos via text messaging systems.

Subjects must have a valid state-issued ID because we are lending equipment (phones and breathalyzers), and the State of Connecticut requires signatures for use of such equipment. We have employed similar procedures before without difficulties.

All subjects must be willing to sign informed consent

ii. Exclusion criteria are: (1) have begun receiving unemployment benefits within the past 4 weeks; (2) worked full-time or part-time <3 months in the past 3 years in the formal or informal (i.e., under-the-table) economy; (3) physiological alcohol withdrawal symptoms (scores $\geq$ 10 on the Clinical Institute Withdrawal Assessment for Alcohol-revised; Sullivan et al., 1989); (4) physiological withdrawal symptoms from an illicit drug use disorder; (5) serious untreated psychiatric illness (schizophrenia, bipolar disorder, or suicide risk); or (6) in recovery from gambling disorder (Petry & Alessi, 2010; Petry et al., 2006a).

Individuals who have recently been awarded unemployment benefits will not be recruited into the study, because working for pay in the imminent future can be a financial disincentive in these cases. The course of unemployment benefits is nowadays variable and often unpredictable, so we will only exclude persons with recent onset of unemployment benefits, as these are the only cases likely to have financial disincentives associated with finding a job. After expending some time on unemployment benefits (e.g., 4 or more weeks), persons are generally very interested and motivated to find employment, as it typically takes at least 4-8 weeks to apply for jobs, attend interviews, and begin working.

In terms of employment histories, we are excluding long-term unemployed persons (i.e., those who have not worked for pay for >3 years) as these individuals are likely to have more severe employment difficulties and obstacles related to re-employment.

Any individual who is seeking alcohol treatment will be referred for it, and participation in this study will provide supplemental services; many alcohol treatment outpatients continue drinking while in treatment (Alessi et al., 2016). However, individuals with physiological withdrawal symptoms from alcohol or an illicit drug use disorder require more intensive substance abuse treatment services than those provided in the context of this study and

will be referred to such. They may participate in the study after receiving treatment for other substance use disorders.

Those with severe untreated psychiatric disorders will also require psychiatric treatment before the services in this study would likely benefit them. However, individuals with bipolar disorder, schizophrenia, or other psychiatric histories who are stable (e.g., taking medications and no recent psychiatric hospitalizations) may benefit from this study and can participate in it. We and others have shown that reinforcement interventions can be particularly efficacious in individuals with severe and persistent mental health problems (Drebing et al., 2007; McDonnell et al., 20130; Petry, Alessi, & Rash, 2013).

Individuals who are in recovery from gambling disorder, or who currently meet DSM-5 gambling disorder criteria and are desiring to stop or reduce gambling, will be excluded from this study because of potential concerns of similarity of prize reinforcers with gambling. Although this precautionary measure is taken, the prize intervention is not gambling because participants risk nothing of monetary value. Further, no increases in gambling behaviors or problems have been reported among participants in any of our prior trials (Petry & Alessi, 2010; Petry et al., 2006a; Petry et al., 2008).

For the pilot component we expect that about 10 patients will participate as pilot subjects, and they will be informed (via the pilot consent form) that the purpose of their participation is to monitor staff's performance in administration of study procedures, therefore they may not meet all inclusion/exclusion criteria. Pilot participants will only have a 3-month post treatment interview and no long term follow-up.

iii. Ineligible Patients.
Some participants will choose not to enroll in or will not qualify for the study. These individuals may continue receiving standard services at the employment agency, and they may also be referred to other providers or facilities (e.g., other substance abuse treatment clinics, mental health treatment facilities, or to a gambling treatment clinic such as Problem Gambling Services in CT) as appropriate.

iv. Treatment Clinics, Services, and Patient Population.
Participants will be recruited from individuals seeking services at the John J. Driscoll United Labor Agency in Connecticut (CTULA), a non-profit 501 (c) 3 community service agency that assists displaced workers throughout the state, and other employment agencies. It provides assessments, career counseling, vocational rehabilitation, client advocacy and referrals. It also assists with providing basic needs such as food and shelter, crisis counseling, and free workshops, including basic computer literacy. The agency specializes in hard to place clients with multiple barriers to employment. It serves over 7,000 clients per year, an estimated 15-20% of whom would be eligible for the study, providing ample flow for study recruitment.

b. Sources of Materials. Research material includes interviews, questionnaires, audiorecordings of interviews and interventions, recorded breathalyzer tests, cell phone texts, abstraction of data from employment agency records, and observation of participants by study staff. Breath samples and urine samples will be tested for evidence of alcohol and illicit drugs, e.g., stimulants (cocaine, amphetamine and methamphetamine), opioids, benzodiazepines and THC. None of these materials will be available to legal, educational, or employer representatives. Data obtained for research purposes will be at no cost to participants. Urine and breath samples obtained for study purposes will not be shared with employment agency staff except in the case of an emergency (participant deemed a threat to himself or others).

c. Potential Risks. Risks associated with participation in this research study include the following:
   i. Disappointment if not assigned to one's preferred treatment group;

ii. Discomfort from being asked questions about employment histories and problems, alcohol and drug use, medical problems and histories, psychosocial problems, and submitting breath and urine samples;
iii. Difficulties that may arise from discontinuation of study cellular phone service if participants fail to submit requested breath alcohol samples.
iv. Potential breach of confidentiality, including those associated with lost or stolen cell phones.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent.

Study participants will be recruited from individuals seeking services at The Village, InterCommunity, Inc. or CTULA and other employment agencies via posted flyers and direct referrals there and posted at other social service agencies, and from employment agency staff. We may also advertise the study in newspapers, online and on pens, notepads, calendars, mugs, small candies, etc. using IRB-approved language. All potential participants will receive an explanation of the study protocol, its potential risks and benefits, and alternative treatment available. Following resolution of any questions, participants will be asked to sign the study consent form and HIPAA document. Electronic consent forms will be used. PDFs of the signed consent and HIPAA will be printed from REDCap and provided to the subject. Paper forms will be available for use to participants who prefer that option. As noted above, participants who choose not to enroll in the study or who are deemed ineligible for it will receive standard services at an employment agency and may also be referred elsewhere for services if indicated.

An opt-in statement regarding audiorecording in the consent form will be utilized for recording of the interactions between research assistants and study participants, including baseline and follow-up interviews and intervention sessions. These audiorecordings are utilized for quality insurance procedures, to rate research assistants according to set standards in interview and treatment administration. Individuals may enroll in the study even if they do not choose to allow audiorecording (in our prior studies, less than 10% of partcipants refuse audiorecording). The consent form will explain that the purpose is to rate the research assistants' interviewing and intervention administration skills.

Separate consent forms will be utilized for pilot subjects (est. 10, depending on staff training and turnover), and pilot subjects may be included to train research staff in study procedures. Pilot consent forms (unlike those used for the randomized phase) will not allow patients to participate without audiorecording, and they will clearly indicate that staff are being trained to administer assessments and study procedures.

b. Protection Against Risks. The following will protect against potential risks:

i. Random group assignment is used, and participants have about a 75% chance (210 of 280) of being assigned to a reinforcement group (70 are in the standard care condition; see power analyses). Participants may voluntarily end study participation if they are dissatisfied with their assignment.
ii. The interviews and sample collections are brief, participants may skip questions or take a break if uncomfortable, and the particular sample assays chosen are intended to minimize discomfort.
iii. All participants will be informed (in the informed consent form, at clinic visits, and via phone and text reminders) that they will be expected to submit breathalyzer samples within 1 hour of requests. Missing more than 50% of BrAC tests in a week will result in cell phone discontinuation (or cessation of $35/month payment for cell phone service if using one's own study-compatible phone). The consent form will state explicitly that all study participants will be asked to submit between 7 and 21 samples per week in weeks 1-12 to maintain cellular service (or the $35 payment), and that failure to submit

at least 50% of requested samples in a week may disqualify them from further participation in the breathalyzer component of the study. Participants will be informed of how to reinstate cellular service (or their $35/month cell phone payments) in the consent form (i.e., they need to submit an unprompted breathalyzer test). If cellular service is discontinued, they will also be contacted to inform them of the process about how to restore it (i.e., submit a test). While cellular service will be reinstated once during the course of the 12-week study, participants will no longer be eligible for cellular service (or the $35/month payment of their cell plan) and the BrAC payments for sample submission if they fail to submit 50% of samples for two weeks during the study period.

Participants will be informed that if they get a job in which they work evenings and/or weekends, their BrAC testing schedule can be altered so as not to interfere with their work hours. Participants who successfully obtain jobs during the course of the 12-week intervention period will be required to show proof of their working hours (e.g., paystubs, work schedules) if they are requesting a change from the typical BrAC prompt schedule, designed to request samples primarily during evening and weekend times.

iv. All data will be coded by number, not name, and a "key" form will be kept in a separate locked file cabinet. No information will be provided about the participants enrolled in this study to anyone outside of the clinical and research teams, except in emergency situations (e.g., severe intoxication, participant deemed a threat to him/herself or others) or as required by law. Locators (identified by participants to assist in finding them if needed for follow-ups) will not be given <u>any</u> information regarding the participant's treatment statu*s,* only that we are trying to reach them regarding their participation in a health study.

Digital audio recordings of interviews and sessions will be stored as .wma or similar files. All recordings will be labeled by number, not name, and the "key" form will be kept separate in a locked file cabinet. These files will be transferred from the digital recorder to a secured folder on the UCHC network drive after the recording is completed. This folder will only be accessible to research staff. Once files are transferred to the secure folder, they will be deleted from the recorder itself. When not in use, recorders will be stored in locked cabinets with data. Subjects will not be identified by name on recordings. Only study personnel will review the recordings for training, supervision, and adherence monitoring purposes. We will obtain consent to audiorecord, and patients may participate in the study without allowing audiorecording. The files will be permanently deleted at the end of the study.

Participants will be informed that using facial recognition software to validate breath test results is a procedure associated with this study. The device uses a multi-tier security scheme for data transmission and reception including a 128-bit encryption enhanced with a rotating encryption key on activation so every device has a unique encryption signature, encryption for data in motion over Verizon's CDMA cellular network, and 256-bit encryption over Verizon's Hosted Private Network. Servers hold the following certifications: SSAE 16 Type II SOC 1, Type II SOC 2, and SOC 3 provider; SO 27001 certified. Physical servers are protected using keycard, biometric, and surveillance, and the network segmented to protect access using best security practices and standards, with access only available over 256 bit encrypted virtual private network connection. The monitoring portal security is enforced using token authentication over 256 –bit SSL, with a hashing scheme implemented for authentication and does not store passwords for user security. Methods to submit results in a private location will be encouraged, e.g., at home or in a quiet, lockable room (e.g., private restroom). Participants may lose their cell phones (or they may be stolen). In such cases, there may be text messages between study staff and

participants stored on the phones, and these may be viewed by others who find or steal phones. During the cell phone training procedure, research staff will encourage participants to: (1) password protect their phones; (2) keep their cell phones in their possession at all times; and (3) delete study messages after viewing them. Similar procedures have been approved by two different IRBs (Yale University and University of Connecticut Health Center) in four of our ongoing or completed studies, and we have not encountered any difficulties.

Research staff's study phones will likewise be password protected, and the research desktop computer will be password protected, physically locked down and not networked, with access limited to research staff.

Any study participant who arrives at a study visit grossly intoxicated is not provided any services that day. This project will strictly adhere to these rules, and individuals who appear to be intoxicated or smell strongly of alcohol will not be allowed to participate in study procedures, including intervention sessions or follow-up evaluations. Such participants will be immediately referred to clinic staff (e.g., clinic director) and/or asked to leave the center. If the participant is deemed a threat to him/herself or others, police or emergency personnel will be contact to assist in the situation as required by law. Any participant who may have driven to the center will be requested to provide their keys to clinic personnel. If they refuse, police or emergency services may be contacted, as required by law.

c. Potential Benefits of the Proposed Research to the Subjects and Others. The anticipated benefits to participants in the study include careful evaluation of their employment, alcohol and substance use, medical and psychiatric status, and a potential for reducing alcohol use and improving their employment problems. Participants in all groups will receive $25 in gift cards for the baseline assessment, and $50 for all others. They will receive $2 per BrAC sample provided plus bonuses (estimated $184/month) and a study-paid cell phone (or $35 per month if they choose to use their own phone) so long as they provide study-requested samples when prompted, average 10 per week. Return of study equipment results in a $50 payment at Month 3, and $25 at Month 12. Depending on group assignment, participants may also receive prizes for submitting negative BrACs and/or completing employment-related activities.

Benefits to society include a potential improvement in the effectiveness of interventions for unemployed hazardous drinkers.

d. Importance of the Knowledge to be Gained. The potential risks of these treatments are minor compared to the risks incurred by unemployed individuals with hazardous drinking, which includes significant morbidity and mortality. The risk/benefit ratio appears favorable.

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