



## Use of continuous transdermal alcohol monitoring during a contingency management procedure to reduce excessive alcohol use



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### ABSTRACT

**Background:** Research on contingency management to treat excessive alcohol use is limited due to feasibility issues with monitoring adherence. This study examined the effectiveness of using transdermal alcohol monitoring as a continuous measure of alcohol use to implement financial contingencies to reduce heavy drinking.

**Methods:** Twenty-six male and female drinkers (from 21 to 39 years old) were recruited from the community. Participants were randomly assigned to one of the two treatment sequences. Sequence 1 received 4 weeks of no financial contingency (i.e., \$0) drinking followed by 4 weeks each of \$25 and then \$50 contingency management; Sequence 2 received 4 weeks of \$25 contingency management followed by 4 weeks each of no contingency (i.e., \$0) and then \$50 contingency management. During the \$25 and \$50 contingency management conditions, participants were paid each week when the Secure Continuous Remote Alcohol Monitor (SCRAM-II™) identified no heavy drinking days.

**Results:** Participants in both contingency management conditions had fewer drinking episodes and reduced frequencies of heavy drinking compared to the \$0 condition. Participants randomized to Sequence 2 (receiving \$25 contingency before the \$0 condition) exhibited less frequent drinking and less heavy drinking in the \$0 condition compared to participants from Sequence 1.

**Conclusions:** Transdermal alcohol monitoring can be used to implement contingency management programs to reduce excessive alcohol consumption.

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## 1 Introduction

Contingency management provides financial incentives to clients to achieve targeted behaviors, such as moderation or elimination of substance use (Griffith et al., 2000; Higgins and Silverman, 2008; Lussier et al., 2006; Prendergast et al., 2006; Roll et al., 2013; Stitzer and Petry, 2006). Incentives typically depend on objective measures (e.g., blood or urine testing) to verify compliance, by measuring the presence of metabolites of drugs of abuse (e.g., marijuana, cocaine, opiates) that remain in the body for days after use (e.g., Budney et al., 2000; Higgins et al., 2000; Petry et al., 2005a).

In contrast to other drugs of abuse, biological markers for identifying alcohol use are not as straightforward for the use of financial contingencies. Biological markers for alcohol use are either direct

(i.e., ethanol itself or analytes of ethanol metabolism) or indirect (i.e., toxic or nontoxic effects of alcohol). Direct biological markers of alcohol have short half-lives, so without excessive monitoring, verification of true abstinence is difficult. For example, breath alcohol concentration (BrAC) or blood alcohol concentration (BAC) is present only for a few hours, whereas urinary ethyl glucuronide and urinary ethyl sulfate are present for a few days (Maenhout et al., 2013; McDonnell et al., 2011). While there is a more promising direct marker, phosphatidylethanol, that may better detect alcohol consumption over longer periods of time, its pharmacokinetics require more study before assessing its utility (Hahn et al., 2011; Helander et al., 2012). Indirect markers of alcohol use have longer half-lives, measured in weeks or months (e.g., liver enzymes such as  $\gamma$ -glutamyltransferase or carbohydrate-deficient transferrin), but they are not specific to alcohol use and may result in false positives (Helander et al., 2014; Maenhout et al., 2013; Marques et al., 2010; Marques, 2012). In short, implementation of biomarkers in contingency management procedures for alcohol use is difficult.

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Nonetheless, several studies indicate that contingency management procedures may effectively reduce excessive alcohol use (e.g., Alessi et al., 2007; Alessi and Petry, 2013; Barnett et al., 2011; Hagedorn et al., 2013; Hunt and Azrin, 1973; Koffarnus et al., 2011; McDonell et al., 2012; Miller, 1975; Miller et al., 1974a,b; Petry et al., 2000, 2005b). However, to verify abstinence, most studies measured overt signs of intoxication, BAC, and/or BrAC at intervals ranging from daily to once a week. Because alcohol remains in the body only for several hours after the last use, BAC or BrAC readings ideally would be measured multiple times daily; even this may not ensure adherence to contingency management programs (Alessi and Petry, 2013). McDonell et al. (2012) verified abstinence by measuring urinary ethyl glucuronide twice weekly during a four-week contingency management procedure. However, urinary ethyl glucuronide is present only for up to two days (Maenhout et al., 2013; McDonell et al., 2011) and would need to be measured every other day to ensure adherence. With infrequent monitoring, a drinker can time alcohol consumption to prevent a positive screening; with frequent monitoring, procedures become burdensome and invasive.

Accurate transdermal alcohol monitoring devices create new opportunities for both research and treatment, including use in contingency management procedures. They detect alcohol excreted through the skin (Swift, 2003) and provide a continuous measure of transdermal alcohol concentration (TAC) over time (Swift, 2000, 2003). Recent methods for converting TAC data to more clinically meaningful outcomes (i.e., peak BrAC and number of standardized units of alcohol consumed; Dougherty et al., 2012, 2014; Hill-Kapturczak et al., 2014) make their use even more compelling.

To our knowledge, only one study (Barnett et al., 2011) examined the feasibility of using transdermal alcohol monitoring devices in a contingency management procedure. This study included 13 heavy drinkers (men who consumed  $\geq 15$  drinks and women who consumed  $\geq 8$  drinks per week, including 2 or more heavy drinking episodes per week) who expressed interest in reducing or stopping drinking. Most had either a lifetime diagnosis of alcohol dependence or alcohol abuse. Participants wore a transdermal alcohol monitor for three weeks. In the first week, participants were told to drink as usual. During the subsequent two weeks, participants were told not to drink and received financial reinforcement (on an escalating scale) if their TAC reading did not exceed 0.02 g/dl. Average TAC readings (compared to baseline) were reduced by 72%, and 63% self-reported that they reduced drinking to below the national recommended weekly limit. Nonetheless, participants did not reduce the number of drinks they consumed when they did drink.

The present study sought to determine whether transdermal alcohol monitors could be used effectively to implement contingency management in non-treatment seeking drinkers, with different drinking patterns, for a longer intervention period. Our goals were to: (1) reduce problematic patterns of drinking (not abstinence); (2) determine whether incentive magnitude affected drinking outcomes; and (3) determine any carryover effect of contingency management after the incentive was removed.

## 2. Methods

### 2.1 Participants and criteria

We recruited 29 healthy participants from the community ( $n = 20$  men and  $n = 9$  women) aged 21–39 years who reported patterns of drinking episodes that met National Institute on Alcohol Abuse and Alcoholism (2010) “at-risk” drinking criteria (daily limits of  $>3$  drinks for women and  $>4$  drinks for men) on 3 or more days within the prior 28 days. Individuals responded to newspaper, radio, and flyer advertisements. They underwent an initial phone screening about psychiatric/medical health and current drinking behavior to determine eligibility. Those who passed this initial prescreen were invited to the laboratory to complete a more extensive 3-h screening. Exclusion criteria included an IQ less than 70, a current Axis I psychiatric disorder, pregnancy, current serious medical condition (e.g., diabetes, uncontrolled

hypertension), history of substance dependence, and a positive urine drug test for the metabolites of drugs of abuse (cocaine, opiates, methamphetamines, barbiturates, benzodiazepines, or THC).

Additional screening included a detailed substance abuse history, review of alcohol consumption patterns during the prior 28 days using the Timeline Followback procedure (Sobell and Sobell, 1992), psychiatric screening using the Structured Clinical Interview for DSM-IV-TR Axis I Disorders: Research Version, Non-Patient Edition (SCID-I/NP; First et al., 2001), intelligence screening using the Wechsler Abbreviated Scale of Intelligence (WASI; Wechsler, 1999), urine drug and pregnancy tests, and a medical history and physical examination by a physician or physician’s assistant. The Institutional Review Board at The University of Texas Health Science Center at San Antonio reviewed and approved the protocol.

### 2.2 Procedures

**2.2.1 Study design.** The study was divided into three 4-week experimental conditions: where \$0 (no contingency; drinking as usual), \$25, or \$50 was provided when TAC readings did not exceed 0.03 g/dl on any day during the experimental week. Based on our earlier work (Dougherty et al., 2012; Hill-Kapturczak et al., 2014), this TAC level corresponded to light to moderate drinking (1–2 beers), but was generally exceeded with drinking 3 or more beers. Participants exceeded the criteria if three or more consecutive TAC readings achieved or exceeded 0.03 g/dl during a positive TAC event confirmed by Alcohol Monitoring Systems (AMS, Littleton, CO). Participants were randomly assigned to Sequence 1–4 weeks of \$0 (no contingency) followed by 4 weeks of \$25 contingency management, or Sequence 2–4 weeks of \$25 contingency management followed by 4 weeks each of \$0 (no contingency). During the \$0 contingency conditions, participants received no directions regarding alcohol consumption. Conditions were counterbalanced to explore whether reductions in drinking during the \$25 incentive condition persisted after the incentive was removed. After completing either sequence, the weekly incentive was increased to \$50 for 4 weeks to determine whether increased payment resulted in further suppression of drinking. Weekly \$25 or \$50 incentive payments were delivered only when the TAC level criterion was not exceeded on any day that week. Weekly incentives were used to reduce burden on participants visiting the laboratory, and to parallel usual treatment. All participants received \$10 per day for wearing the monitor and an additional \$15 for each weekly clinic visit.

**2.2.2 Transdermal alcohol monitoring.** TAC was measured continuously using a tamper-resistant Secure Continuous Remote Alcohol Monitor (SCRAM-II™, Alcohol Monitoring Systems Inc., Highlands Ranch, CO). Each participant was fitted with a device and wore it for 12 weeks. The SCRAM-II measured TAC approximately every 30 min until removal of the device. Infrared signals and temperature were also recorded to ensure that no tampering or device disruption occurred. Data were retrieved weekly in our clinic using SCRAM Direct Connect™, which connects the transdermal alcohol monitor to a computer via a USB cable. Data were then uploaded to a web-based application for download and export.

**2.2.3 Timeline Followback (TLFB; Sobell and Sobell, 1992).** Incentives were delivered based solely on TAC monitoring data to prevent bias. A TLFB assessment was completed only after the incentive was (or was not) delivered. The quantity of alcohol consumed each day during the 7 days before each laboratory visit was recorded. Following standard convention (National Institute on Alcohol Abuse and Alcoholism, 2010), heavy drinking on any given day was defined as  $\geq 4$  standard units for women and  $\geq 5$  for men. These data were used to determine the level of correspondence between the TAC monitoring criteria and participants’ self-reported alcohol use.

### 2.3 Data analysis

The characteristics of the participants were summarized using descriptive statistics. Differences between men and women and between the two treatment sequences were examined using *t*-tests or chi-squared tests for continuous and categorical variables, respectively.

The analysis for this 3-treatment 2-sequence crossover design utilized a simple first-order carryover effect model (Hedayat and Stufken, 2003), which is a special case of a mixed-effect model to account for all three phases of the contingency and the four weeks within a phase. The analytic model considered fixed effects such as the direct treatment effect (i.e., \$0 vs. \$25 vs. \$50) while simultaneously examining the treatment sequence/group effect (i.e., whether participants were in the group that received \$25 contingency first or second, an inter-subjects factor), period effect (i.e., 12 weeks over 3 different contingencies), and simple first-order carryover effect (i.e., the treatment effect from the previous period that does not interact with the direct treatment effect in the current period), along with random subject effects and random measurement errors. Analyses considering the period, sequence, direct treatment, and first-order carryover effects were conducted for the percent of participants exceeding criteria, proportion of days with any drinking, and the proportion of days with heavy drinking (i.e., using TAC data to estimate peak BrAC, see below). These analyses yielded significant findings only for the proportion of days with heavy drinking. Sensitivity analyses of this measure examined the difference between \$25 contingency vs. \$0 contingency using the first 4 weeks of data (i.e., before crossover) and from the weeks 5 to 8 (i.e., after crossover) separately.

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