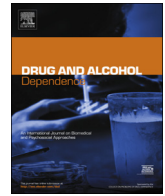




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## Randomized controlled trial of a positive affect intervention for methamphetamine users



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## ABSTRACT

**Background:** Contingency management (CM) is an evidence-based intervention providing rewards in exchange for biomarkers that confirm abstinence from stimulants such as methamphetamine. We tested the efficacy of a positive affect intervention designed to boost the effectiveness of CM with HIV-positive, methamphetamine-using sexual minority men.

**Methods:** This attention-matched, randomized controlled trial of a positive affect intervention delivered during CM was registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT01926184). In total, 110 HIV-positive sexual minority men with biologically confirmed, recent methamphetamine use were enrolled. Five individual sessions of a positive affect intervention (n = 55) or an attention-control condition (n = 55) were delivered during three months of CM. Secondary outcomes examined over the 3-month intervention period included: 1) psychological processes relevant to affect regulation (i.e., positive affect, negative affect, and mindfulness); 2) methamphetamine craving; 3) self-reported stimulant use (past 3 months); and 4) cumulative number of urine samples that were non-reactive for stimulants (i.e., methamphetamine and cocaine) during CM.

**Results:** Those randomized to the positive affect intervention reported significant increases in positive affect during individual sessions and increases in mindfulness over the 3-month intervention period. Intervention-related improvements in these psychological processes relevant to affect regulation were paralleled by concurrent decreases in methamphetamine craving and self-reported stimulant use over the 3-month intervention period.

**Conclusions:** Delivering a positive affect intervention may improve affect regulation as well as reduce methamphetamine craving and stimulant use during CM with HIV-positive, methamphetamine-using sexual minority men.

## 1. Introduction

Amphetamine-type stimulants such as methamphetamine are the second most commonly used illicit substances with an estimated 19.3–54.8 million users worldwide (United Nations Office on Drugs and Crime, 2017). Agonist therapies and mirtazapine have shown some promise (Coffin et al., 2013, 2018; Colfax et al., 2011; Karila et al.,

2010), but there is currently no widely approved pharmacotherapy for the treatment of stimulant use disorders. Although behavioral interventions have demonstrated modest effectiveness (Carrico et al., 2016b; Colfax et al., 2010), novel approaches are needed to achieve greater reductions in stimulant use. Because stimulant use fuels the HIV/AIDS epidemic in high priority populations like gay, bisexual, and other men who have sex with men (referred to here as sexual minority men),

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boosting the effectiveness of behavioral interventions for stimulant users may also have important implications for both HIV prevention and care (Bourne et al., 2015; Carrico et al., 2014; Colfax et al., 2010; Koblin et al., 2006; Ostrow et al., 2009).

Contingency management (CM) with thrice-weekly urine screening is an evidence-based, behavioral intervention that provides rewards in exchange for biological confirmation of abstinence from stimulants such as methamphetamine (Prendergast et al., 2006; Roll et al., 2006). CM has demonstrated effectiveness as a stand-alone therapy, and it has been shown to enhance the effectiveness of substance use disorder treatment with methamphetamine users (Roll et al., 2006; Shoptaw et al., 2005). Although randomized controlled trials (RCTs) provide support for the effectiveness of CM for decreasing stimulant use in methamphetamine-dependent sexual minority men (Reback et al., 2010; Shoptaw et al., 2005), some individuals can experience difficulties with achieving consistent abstinence during CM (Menza et al., 2010). This underscores the need for integrative approaches that target fundamental neurobehavioral processes such as withdrawal and anhedonia that may undermine the benefits of CM (Baker et al., 2004; Goldstein and Volkow, 2011).

The experience of positive affect such as happiness or gratitude could assist with managing symptoms of stimulant withdrawal during CM and sensitize individuals to natural sources of reward (Carrico, 2014). Positive affect is theorized to reinvigorate coping efforts in the midst of chronic stress (Folkman and Moskowitz, 2000), and this could assist individuals with avoiding the stimulant use and changing other important health behaviors (Carrico and Moskowitz, 2014; Carrico et al., 2013; Pressman and Cohen, 2005). Positive affect is associated with neuropsychological changes that may partially reflect dopamine reward system activation (Ashby et al., 1999). In addition, trait positive emotionality is associated with greater resting metabolism in the orbitofrontal and cingulate regions of the brain (Volkow et al., 2011) and greater left prefrontal, as well as anterior cingulate cortex activation, has been consistently observed during the experience of positive affect (Lindquist et al., 2016). Because these brain regions are thought to underlie emotional processing, and executive functioning, the experience of positive affect could promote greater self-regulation (Fredrickson and Branigan, 2005).

Given growing evidence that positive affect has unique beneficial psychological and physical health effects, researchers have begun testing interventions that target positive affect and found emerging evidence of efficacy in various populations (Boutin-Foster et al., 2016; Cohn et al., 2014; Huffman et al., 2015; Moskowitz et al., 2017; Ogedegbe et al., 2012; Peterson et al., 2012; Seligman et al., 2005), including those living with alcohol and substance use disorders (Carrico et al., 2015a; Krentzman et al., 2015). Meta-analyses demonstrate that these interventions increase not only positive affect but also reduce negative affect (Bolier et al., 2013). Positive affect interventions are generally multi-component, and some include mindfulness training, consistent with the present RCT. Mindfulness components are hypothesized to increase acknowledgment, awareness, and tolerance of strong emotions (Bowen et al., 2009, 2014; Brown et al., 2007; Witkiewitz et al., 2013). Despite the fact that it does not explicitly target positive affect, mindfulness training has been found to increase positive affect and decrease negative affect (Grossman et al., 2007).

Although brief positive affect interventions are feasible and acceptable for those living with alcohol and substance use disorders (Carrico et al., 2015a; Krentzman et al., 2015), the efficacy of positive affect interventions for reducing stimulant use has not been rigorously tested. Positive affect interventions provide coping skills training and sensitize individuals to natural sources of reward, which could lead to improvements in psychological processes relevant to affect regulation such as greater positive affect, reduced negative affect, and increased mindfulness. The overarching scientific premise of the present RCT is that intervention-related improvements in these psychological processes relevant to affect regulation will boost the capacity of individuals

to manage withdrawal symptoms and craving to achieve greater reductions in stimulant use during CM.

The present study examined the efficacy of the positive affect intervention for improving key secondary outcomes during three months of CM. Relative to an attention-control condition, we hypothesized that those randomized to receive the positive affect intervention would report greater increases in positive affect and mindfulness as well as reductions in negative affect during three months of CM. We also examined whether participants randomized to the positive affect intervention experienced greater concurrent decreases in methamphetamine craving and stimulant use compared to those receiving an attention-control condition.

## 2. Methods

This RCT was conducted in San Francisco, CA USA in collaboration with a community-based CM program from 2013 to 2017 ([www.clinicaltrials.gov](http://www.clinicaltrials.gov); NCT01926184). A detailed description of the protocol for this RCT has been published elsewhere (Carrico et al., 2016a). CM visits were completed at the San Francisco AIDS Foundation, and all other trial-related activities occurred at a separate field site at the Alliance Health Project. All relevant procedures were approved by the Institutional Review Boards for the University of California, San Francisco, University of Miami, and Northwestern University. This RCT received a certificate of confidentiality from the National Institute on Drug Abuse. The University of California, Los Angeles Data Safety and Monitoring Board for Addiction Medicine held annual meetings to review participant-related events and overall progress for this RCT. There were no adverse events or serious adverse events.

### 2.1. Design

#### 2.1.1. Recruitment, screening, and enrollment

A total of 184 individuals were recruited for this RCT from a community-based CM program, using flyers and palm cards distributed in the community and implementing an incentivized snowball sampling method where eligible participants received up to \$30 for referring other eligible participants. Recruitment and enrollment occurred for 41 months. To be eligible for this RCT, participants were required to meet the following inclusion criteria: 1) 18 years of age or older; 2) report anal sex with a man in the past 12 months; 3) speak English; 4) provide documentation of HIV-positive serostatus (i.e., letter of diagnosis or ART medications other than Truvada that are matched to their photo identification); and 5) provide a urine or hair sample that was reactive for methamphetamine. Participants completed a brief telephone screen and those judged potentially eligible were scheduled for an in-person screening visit. After the telephone screen, nine participants were not invited to attend an in-person screening visit because they did not meet the inclusion criteria, 10 potentially eligible individuals did not attend an in-person screening visit, and three declined to participate. One potentially eligible participant died prior to completing a screening visit.

At the screening visit, 161 participants completed a signed informed consent and a Health Insurance Portability and Accountability Act (HIPAA) release to access treatment records at the community-based CM program. Those without evidence of recent methamphetamine use from urine screening provided a hair sample for toxicology testing. Participants were excluded after the screening visit for the following reasons: 1) inability to provide informed consent; 2) negative urine and hair toxicology results for methamphetamine; and 3) inability to follow the study protocol. All participants received a \$50 pre-loaded debit card for completing the screening visit. As shown in Fig. 1, 161 participants completed a screening visit. Of these, 16 (10%) were excluded because they did not provide a urine or hair sample that was reactive for methamphetamine, five (3%) declined to participate, and four (2%) did not meet the inclusion criteria.

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