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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.

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Contributors

AWC, JTM, and WJW developed and refined hypotheses for this project. WG, JJ, and JLJ implemented protocols for collection and management of all data elements for this randomized controlled trial. SS provided feedback throughout the randomized controlled trial regarding assessments, contingency management methods, and interpretation of findings. DO co-led efforts to refine the ARTEMIS positive affect intervention protocol and served as the primary clinical supervisor for this randomized controlled trial. MVD and RA led community-based CM at the San Francisco AIDS Foundation as well as assisted with refining the ARTEMIS positive affect intervention protocol. TBN, JLE, and SED were the primary persons responsible for managing and analyzing data from this randomized controlled trial. AWC led this manuscript with feedback from JTM, SS, and WJW. All authors provided feedback on the manuscript and approved of the final manuscript before submission

Conflicts of Interest

No conflict of declared.

Methods: This attention-matched, randomized controlled trial of a positive affect intervention delivered during CM was registered on 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 nonreactive 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. Concurrent decreases paralleled intervention-relate improvements in these psychological processes relevant to affect regulation 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.

Keywords

Contingency Management; HIV; Men who Have Sex with Men; Methamphetamine; Mindfulness; Positive Affect

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 (UNODC, 2017). Agonist therapies and mirtazapine have shown some promise (Coffin et al., 2013; Coffin et al., 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), 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; Bowen et al., 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 2013-2017 (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 inperson 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 Figure 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.

2.1.2. Run-In Period and Randomization.—All eligible participants completed a waiting period prior to randomization (i.e., run-in) that entailed five separate visits: 1) a baseline assessment with a peripheral venous blood sample; 2) three CM urine screening visits (regardless of the toxicology results); and 3) a separately scheduled randomization visit where the first positive affect intervention or attention-control session was delivered. Participants who did not complete the run-in period were not randomized. Of the 136 participants who were eligible and consented to participate in the RCT, 110 (81%) completed the run-in period and were randomized during the first eight weeks of CM. Randomization was accomplished using a computer-generated sequence with randomly permuted block sizes of 2, 4, and 6 to guard against subversion. Only the study data manager had access to the computer-based randomization algorithm.

2.1.3. Baseline Assessment.—Participants completed a baseline assessment during the run-in period that included self-report measures, a urine sample for on-site toxicology screening, and a peripheral venous blood sample to measure T-helper (CD4+) count and HIV viral load (Abbott RealTime HIV-1, Abbott Molecular, Inc, Des Plaines Ill). Self-reported substance use measures were completed by participants using computer-assisted self-interviewing to enhance reliability and validity (Des Jarlais et al., 1999). All participants received a $50 pre-loaded debit card for completing the baseline assessment.

2.1.4. Post-Intervention Assessment.—After the completion of CM, participants completed a 3-month follow-up assessment that included computer-based administration of self-report measures and a urine sample for on-site toxicology screening. To minimize demand characteristics, all post-intervention assessments were administered by a trained interviewer who had not provided intervention or attention-control sessions to the participant. Participants received a pre-loaded $50 debit card for completing this assessment. Of the 110 participants randomized, 98 (89%) completed the post-intervention assessment with no significant differences between the experimental conditions.

2.2. Interventions

2.2.1. Community-Based CM Program.—This RCT was conducted in partnership with a community-based, 3-month CM program for methamphetamine-using sexual minority men that is operated by the San Francisco AIDS Foundation (Gomez et al., 2017). CM was delivered separately from the individual sessions. Urine sample collection is directly observed by CM program staff. The voucher for the initial sample that was non-reactive for methamphetamine and cocaine metabolites was worth $2.00. Vouchers increased in value by 25 cents for each consecutive stimulant-free sample to a maximum of $10.00. Participants earned an $8.50 bonus voucher for every third consecutive stimulant-free sample. Participants who provided a reactive urine toxicology result for stimulants could

return to their place in the escalating reinforcement schedule after producing three consecutive urine samples that were non-reactive for methamphetamine and cocaine (Shoptaw et al., 2006). The total possible reinforcement for providing 36 stimulant-free urine samples over the 12 weeks was $330, and participants could choose to receive incentives earned any time during or after the 3-month intervention period.

2.2.2. Positive Affect Intervention.—Affect regulation treatment to enhance methamphetamine intervention success (ARTEMIS) is a multi-component, individually delivered 5-session intervention targeting positive affect. This intervention was adapted from prior clinical research testing a positive affect intervention for recently diagnosed HIV-positive persons (Moskowitz et al., 2017; Moskowitz et al., 2012). The extant positive affect intervention protocol was adapted, and pilot tested in an RCT with 21 methamphetamine-using sexual minority men receiving CM (Carrico et al., 2015a). The positive affect intervention protocol consists of eight core skills that have been shown to increase positive affect in prior clinical research (Saslow et al., 2014). The ARTEMIS positive affect intervention skills included: 1) positive event noting; 2) positive event capitalizing; 3) gratitude; 4) informal and formal mindfulness; 5) positive reappraisal; 6) personal strengths; 7) attainable goals, and 8) acts of kindness (altruism). A detailed description of the ARTEMIS intervention sessions has been published elsewhere (Carrico et al., 2016a). On average, ARTEMIS interventions sessions were 60 minutes each.

The positive affect intervention protocol was tailored for this population to facilitate greater engagement in the recovery process (e.g., problem-focused coping, values clarification, and referral to community-based services), and the protocol included a stronger focus on mindfulness. Mindfulness is a core affect regulation skill that we hypothesized would promote enhanced awareness, acknowledgment, and tolerance of emotional responses in the present moment. Informal and formal mindfulness exercises during the intervention were designed to sensitize participants to pleasurable experiences in daily life as well as provide a real-time stress reduction through pre-recorded meditation exercises. Informed by prior research examining the efficacy of mindfulness-based relapse prevention (Bowen et al., 2009; Bowen et al., 2014; Witkiewitz et al., 2013), participants completed meditation exercises during ARTEMIS intervention sessions to further enhance mindfulness and assist individuals in coping more effectively with methamphetamine withdrawal. Participants were asked to complete detailed home practice exercises following each session. In order to facilitate home practice, participants received a workbook and an iPod shuffle that was pre-loaded with meditation exercises. Participants received $20 cash for completing each session. Of the 55 participants randomized to receive the ARTEMIS positive affect intervention 49 (89%) completed all five sessions. Home practice completion was relatively low with 38% returning at least three of the four home practice exercises. Approximately 64% of participants reported practicing meditation exercises at least weekly during the intervention.

2.2.3. Attention-Control Condition.—The attention-control consisted of five sessions that included face-to-face administration of psychological measures and neutral writing exercises (Carrico et al., 2015b). We chose an attention-control to provide participants

randomized to this condition with comparable contact time with study staff and identical incentives. Participants were instructed to write as if they were reporting facts without going into any of the thoughts or feelings about the events (e.g., plans for the next 24 hours). All sessions were comparable in length to the intervention sessions but did not include any positive affect skills practice. Participants received $20 cash for completing each attention-control session and an iPod with three pre-loaded pop songs. Of the 55 participants randomized to receive the attention-control condition 49 (89%) completed all five sessions.

2.2.4. Fidelity Monitoring.—Facilitators with master's level training in public health or counseling were provided with a detailed manual that described the procedures for administering the five individual sessions. Audio recordings of positive affect intervention sessions were reviewed by a clinical supervisor during weekly individual supervision with the facilitator to provide feedback on the delivery of intervention content and process-oriented techniques. Monthly group supervision meetings provided opportunities for case presentation and ongoing discussions about optimizing the delivery of the ARTEMIS positive affect intervention skills and attention-control protocol. Audio recordings of intervention sessions were reviewed by an independent fidelity monitor to provide more detailed feedback to facilitators regarding adherence to the positive affect intervention content, interpersonal skills, rapport, and session flow. A total of 71 of the 259 completed positive affect intervention sessions (27%) were coded using fidelity rating checklists with detailed feedback provided to facilitators.

2.3. Secondary Outcomes

The present study focused on examining the efficacy of the ARTEMIS positive affect intervention for improving key secondary outcomes (NCT01926184). We hypothesized that those randomized to receive the ARTEMIS positive affect intervention would report improvements in key psychological processes relevant to affect regulation, reduced methamphetamine craving, and decreased stimulant use during the 3-month CM intervention period. Examining these "training effects" during the 3-month CM intervention period is an important first step to identify plausible mediators of any long-term improvements in HIV disease markers that will be the focus of subsequent analyses. Secondary outcomes examined during the 3-month CM intervention period are briefly described below.

2.3.1. Positive and Negative Affect.—The modified Differential Emotions Scale was administered to assess positive and negative affect (Carrico et al., 2013; Fredrickson et al., 2003). Participants rated how frequently they felt a particular affect in the past week from zero (never) to four (most of the time). The 11 positive affect items (Cronbach's $\alpha = 0.87$) and eight negative affect items (Cronbach's $\alpha = 0.85$) demonstrated adequate internal consistency. We have previously established the predictive validity of this measure in a cross-sectional study with the target population (Carrico et al., 2013). This measure was administered at the screening, baseline, and the 3-month follow up as well as prior to sessions one, three, and five.

2.3.2. Mindfulness.—The Five Facet Mindfulness Questionnaire assesses distinct facets of mindfulness. Participants rated how often each statement was generally true for them

from one (never or very rarely) to five (very often or always). Informed by prior research on Mindfulness-Based Relapse Prevention (Witkiewitz et al., 2013), we selected the 8-item acting with awareness, 8-item non-judgment, and 7-item non-reactivity subscales for analysis. These subscales displayed adequate internal consistency (Cronbach's α range = 0.77 – 0.88). This measure was administered at baseline and the 3-month follow-up.

2.3.3. Methamphetamine Craving.—The Penn Alcohol Craving Scale is a five-item self-report measure that we adapted for assessment of methamphetamine craving (Flannery et al., 1999). Frequency, intensity, and duration of thoughts about using methamphetamine were assessed using the Penn Alcohol Craving Scale at baseline and the 3-month follow-up (Cronbach's alpha = 0.90). Consistent with prior research (Carrico et al., 2015a; Freedman et al., 2006), participants also rated the intensity of their current craving for methamphetamine before each of the five individual sessions using a visual analogue scale from zero (no craving at all) to 100 (some of the worst craving ever). This measure was administered at each of the five individual sessions.

2.3.4. Self-Reported Stimulant Use.—Participants reported how often they used methamphetamine, powder cocaine, and crackcocaine in the past three months. Each stimulant was rated separately on a Likert-type scale from zero (not at all) to seven (daily). Where participants reported using multiple stimulants, the highest frequency rating was selected for the composite outcome. This measure was administered at screening, baseline, and the 3-month follow-up.

2.3.5. Total Non-Reactive Urine Toxicology Results for Stimulants During CM.—During the 3-month CM intervention period, participants could provide up to 36 urine samples that were non-reactive for methamphetamine and cocaine using on-site toxicology testing (i.e., thrice weekly urine screening for 12 weeks). Urine samples were tested at each CM visit using generic single panel dip cards for cocaine and amphetamine (www.drugtestsinbulk.com). We counted the total number of urine samples that were non-reactive for stimulants, which is also referred to as the treatment effectiveness score (Ling et al., 1997). The treatment effectiveness score can best be conceptualized as a measure of stimulant abstinence but not decreasing stimulant use.

2.4. Statistical Analyses

The initial target sample size for this trial was 230 participants (www.clinicaltrials.gov; NCT01926184). At the request of the data safety and monitoring board, power analyses were recalculated to determine whether there was sufficient power to detect reductions in $\log_{10}$ HIV viral load (the primary outcome) with substantially fewer enrolled participants and the addition of a 15-month follow-up assessment (Carrico et al., 2016a). Using NCSS PASS with a total sample size of 150, 80% retention, and four repeated measures of viral load, at varying levels of autocorrelation the minimum detectable effect sizes are in the small-medium range (Cohen's $d = 0.29 – 0.47$). Overall, this RCT had adequate power to detect moderate effects of the ARTEMIS positive affect intervention on the primary outcome over the 15-month follow-up and, a formal power analysis was not conducted for the secondary outcomes examined in the present study.

We began by comparing the ARTEMIS positive affect intervention and attention-control conditions on baseline measures of demographics and health status. We utilized the non-parametric Wilcoxon test of means and chi-squares (Fisher's exact chi-square where cell counts were less than 5) to determine whether the experimental conditions were balanced at baseline with respect to these variables. Intent-to-treat analyses compared the experimental conditions across time by testing the group-by-time interaction effects using mixed effects models. This approach was augmented by planned simple main effects tests comparing the ARTEMIS positive affect intervention and attention-control groups at individual sessions and the 3-month follow-up. Simple effects were examined regardless of the significance of the group-by-time interaction. Intervention-related differences in the total non-reactive urine toxicology results for stimulants during CM were examined using the Wilcoxon rank-sum test.

Continuous, approximately normally-distributed outcomes were analyzed using linear mixed models (LMMs). Non-continuous outcomes were analyzed using generalized linear mixed models (GLMM) fitted via adaptive Gaussian quadrature. Fixed effects included in all models were intervention group assignment, time, and their interaction. For consistency, all mixed effects models were estimated using maximum likelihood and initially were specified to contain random intercepts and slopes and the random intercept-slope covariance. These models were then compared with two reduced models to remove extraneous random effects. The first reduced model contained random intercepts and slopes but omitted the intercept-slope covariance. The second reduced model contained random intercepts only. The Bayesian Information Criterion (BIC) statistic was used to select the best fitting model among these three candidates. Because we conducted intent-to-treat analyses of planned secondary outcomes, statistical significance was set at $p < 0.05$. Stata version 15 was used to perform the analyses.

3. Results

From 2013-2017, 110 participants were randomized to the positive affect intervention (n = 55) or the attention-control condition (n = 55). The 3-month follow-up assessments were completed in June of 2017. Among the 110 randomized participants, age ranged from 24 to 59 years with a mean of 43.2 *(SD* = 8.9). Close to half of the participants were Caucasian (43%), 29% were Hispanic/Latino, 16% were African American, and 12% were other ethnic minorities or multiracial. The majority of participants completed at least some college (75%) and 65% had an income of less than $16,000 per year. The median CD4+ T-cell count was 646 (Interquartile Range = 428 – 816) cells/mm^3 and 73% of participants had an HIV viral load less than 40 copies/mL. Participants had been living with HIV for an average of 12.9 *(SD* = 8.6) years, and most were currently prescribed antiretroviral therapy (ART) at baseline (89%). As shown in Table 1, there were no significant differences in demographics or health status at baseline between the ARTEMIS positive affect intervention and attention-control conditions.

As shown in Table 2, no interaction effects were observed from baseline to 3 months for positive affect ($\chi^2(5) = 9.51$, $p = .090$) or negative affect ($\chi^2(5) = 5.44$, $p = .364$). Although there were no interaction effects for the awareness ($\chi^2(1) = 2.13$, $p = .144$) and

nonjudgement ($\chi^2(1) = 2.32$, $p = .128$) mindfulness subscales, there was a significant interaction effect for the nonreactivity mindfulness subscale ($\chi^2(1) = 3.92$, $p = .048$). Intervention-related increases in positive affect were observed at session 3 (Cohen's $d = .45$, $p = .030$) and session 5 (Cohen's $d = .58$, $p = .010$). Similarly, intervention-related increases in mindfulness were observed at 3 months for the awareness (Cohen's $d = .36$, $p = .034$) and the nonreactivity (Cohen's $d = .48$, $p = .013$) subscales.

No interaction effects on self-reported stimulant use ($\chi^2(2) = 5.25$, $p = .072$) were observed from screening through three months or for methamphetamine craving ($\chi^2(2) = 1.78$, $p = .182$) from baseline to 3 months (see Table 3). There were no interaction effects on the intensity of methamphetamine craving prior to each session ($\chi^2(4) = 8.56$, $p = .073$), and no differences were observed in the total number urine samples that were non-reactive for stimulants during CM ($p = .75$). Intervention-related reductions in self-reported stimulant use (Cohen's $d = -.46$, $p = .030$) and methamphetamine craving (Cohen's $d = -.51$, $p = .026$) were observed at 3 months. Intervention-related reductions in intensity of methamphetamine craving were observed prior to session 3 (Cohen's $d = -.55$, $p = .003$), session 4 (Cohen's $d = -.46$, $p = .021$), and session 5 (Cohen's $d = -.61$, $p = .004$).

4. Discussion

This RCT with HIV-positive, sexual minority men provides preliminary support for the efficacy of a time-limited positive affect intervention for achieving moderate reductions in self-reported stimulant use and methamphetamine craving. The efficacy of the positive affect intervention for achieving decreases in methamphetamine craving during and immediately following CM is meaningful because this is a key symptom of stimulant use disorders that functions as a potent trigger for relapse (APA, 2013; Baker et al., 2004). It is noteworthy, however, that there were no concurrent effects of the positive affect intervention on the total number of urine samples that were non-reactive for stimulants during the community-based CM program. Because urine toxicology screening provides a qualitative biomarker of consistent stimulant abstinence, it cannot detect decreasing frequency of stimulant use. Further clinical research with quantitative biomarkers of stimulants (e.g., hair toxicology screening) is needed to provide more definitive biological confirmation for the efficacy of the ARTEMIS positive affect intervention for decreasing stimulant use during CM.

HIV-positive, sexual minority men, randomized to receive the ARTEMIS positive affect intervention also displayed transient improvements in positive affect and concurrent increases in mindfulness during CM. This provides proof of concept that a positive affect intervention can achieve moderate increases in theory-based psychological processes relevant to affect regulation in methamphetamine users (Carrico, 2014; Carrico et al., 2013). At the same time, intervention-related increases in positive affect were transient such that the positive affect intervention did not report higher positive affect at the post-intervention assessment. Further clinical research is needed to determine which psychological processes mediate the long-term efficacy of the positive affect intervention for decreasing stimulant use and methamphetamine craving.

The scientific rigor of this RCT is consistent with other high-quality RCTs of integrated behavioral and pharmacologic interventions with methamphetamine users (Coffin et al., 2013; Coffin et al., 2018; Colfax et al., 2011). In contrast to other RCTs of behavioral interventions (Carrico et al., 2016b), we required biological confirmation of recent methamphetamine use for enrollment. This maximizes internal validity by ensuring that participants are not merely reporting methamphetamine use to receive CM and research incentives. We also implemented a run-in period to ensure that all randomized participants were sufficiently engaged in the RCT and partnered with a community-based CM program that was intensively engaging participants during the 3-month intervention period. These likely contributed to the robust engagement in both experimental conditions and strong retention rates over the 3-month period. These design features were crucial to the successful implementation of the present RCT.

Findings from this RCT should be interpreted in the context of certain limitations. The sample size was modest, and only HIV-positive sexual minority men were enrolled. RCTs are needed to replicate these findings in larger, more representative samples of methamphetamine users. Difficulties with enrolling the target sample size for this RCT reduced statistical power. This is evidenced by the general pattern of non-significant group-by-time interaction effects for the secondary outcomes. Performing simple effects analyses in the absence of a group-by-time interaction may have inflated the family-wise error rate. It is also noteworthy that changes in positive affect and methamphetamine craving were transient during individual sessions, which underscores the potential benefits of measuring these changes with ecological momentary assessment in future research (Serre et al., 2015). Finally, although findings support the preliminary efficacy of the ARTEMIS positive affect intervention during the 3-month CM intervention period, important questions remain about the maintenance of these treatment gains. Further research should examine the maintenance of treatment effects to inform the development of novel approaches to boost the long-term efficacy of this and other behavioral interventions for substance-using sexual minority men (Carrico et al., 2016b).

Despite these limitations, this RCT provides some of the first evidence that a positive affect intervention can enhance the effectiveness of CM with methamphetamine users. By targeting theory-based psychological processes, positive affect interventions may assist in coping with stimulant withdrawal and sensitize individuals to natural rewards. Positive affect interventions could be a novel approach to optimize the benefits of evidence-based interventions like CM for those living with substance use disorders.

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Highlights

- Tests the efficacy of an integrative intervention for methamphetamine users.
- Increases in positive affect and mindfulness support the theoretical model.
- Promising outcomes highlight the need for further randomized controlled trials.

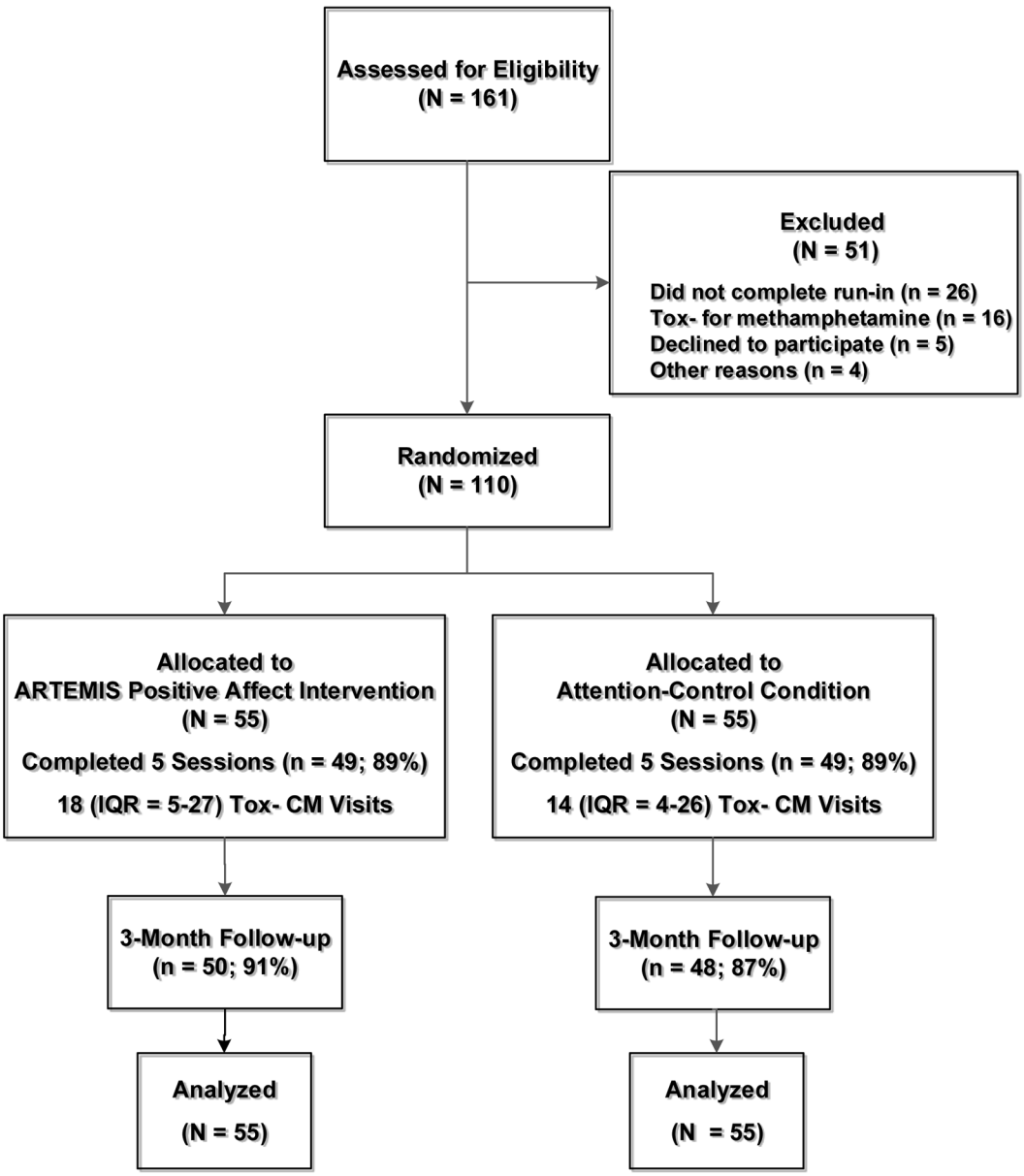

Figure 1.
Screening, randomization, and follow-up for participants.

Table 1.

Baseline characteristics of trial participants (N = 110)

	ARTEMIS (n = 55)	Attention-Control (n = 55)	p-value
	M (SD)	**M (SD)**	
Age	43.2 (9.2)	43.2 (8.5)	0.88
Time since HIV diagnosis (Years)	13.4 (8.9)	12.5 (8.4)	0.62
CD4+ T-cell count (cells/mm^3)	642.9 (272.8)	639.9 (313.6)	0.99
	n (%)	n (%)	
Race/Ethnicity			0.12
Black/African American	9 (8.2)	9 (8.2)	
White	18 (32.7)	29 (52.7)	
Hispanic/Latino	21 (38.2)	11 (20.0)	
Other ethnic minority	7 (12.7)	6 (10.9)	
Education			0.62
Less than high school	5 (9.1)	3 (5.5)	
HS graduate	8 (14.6)	9 (16.4)	
Some college/trade school	25 (45.5)	32 (58.2)	
College graduate	10 (18.2)	7 (12.7)	
Post graduate	7 (12.7)	4 (7.3)	
Income			0.26
< $4,999	8 (14.8)	8 (14.6)	
$5,000-$11,999	9 (16.7)	19 (34.6)	
$12,000-$15,999	14 (25.9)	13 (23.6)	
$16,000-$24,999	6 (11.1)	6 (10.9)	
$25,000-$34,999	4 (7.4)	5 (9.1)	
$35,000-$49,999	7 (13.0)	2 (3.6)	
>$50,000	6 (11.1)	2 (3.6)	
Prescribed anti-retroviral therapy	49 (89.1)	49 (89.1)	1.00
HIV viral load < 40 copies/mL	42 (77.8)	37 (68.5)	0.28

ARTEMIS = affect regulation intervention to enhance methamphetamine intervention success

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Table 2.

Changes in positive affect, negative affect, and mindfulness by treatment arm (N = 110).

	ARTEMIS (n = 55)	Attention-Control (n = 55)	Cohen's *d* (95% CI)	Group x Time p-value
	M (SE)	M (SE)		
Positive Affect				0.090
Screening	26.4 (0.93)	24.9 (0.93)	-	
Baseline	25.9 (0.91)	24.8 (0.91)	-	
Session 1	24.0 (0.91)	23.8 (0.91)	-	
Session 3	26.6 (0.94)*	23.7 (0.93)*	0.45 (0.06, 0.84)	
Session 5	27.4 (1.02)*	23.8 (1.02)*	0.57 (0.17, 0.97)	
3 Months	27.8 (1.06)	26.1 (1.07)	0.31 (−0.08, 0.71)	
Negative Affect				0.364
Screening	14.02 (0.79)	12.82 (0.79)	-	
Baseline	13.02 (0.78)	12.45 (0.78)	-	
Session 1	14.29 (0.77)	13.75 (0.77)	-	
Session 3	12.75 (0.78)	13.57 (0.77)	0.13 (−0.25, 0.52)	
Session 5	11.81 (0.81)	12.61 (0.81)	0.13 (−0.27, 0.52)	
3 Months	10.81 (0.82)	10.73 (0.83)	0.05 (−0.35, 0.44)	
Mindfulness - Awareness				0.144
Baseline	25.04 (0.84)	23.95 (0.84)	-	
3 Months	27.01 (0.86)*	24.41 (0.87)*	0.36 (−0.04, 0.75)	
Mindfulness -Nonjudgment				0.128
Baseline	56.25 (2.00)	56.21 (2.00)	-	
3 Months	62.49 (2.05)	58.66 (2.08)	0.31 (−0.09, 0.71)	
Mindfulness - Nonreactivity				0.048
Baseline	44.03 (1.25)	43.56 (1.25)	-	
3 Months	50.03 (1.31)*	45.42 (1.33)*	0.47 (0.07, 0.87)	

ARTEMIS = affect regulation intervention to enhance methamphetamine intervention success; Between group differences within each time point:

* p < .05;

For interpretability, Cohen's d is computed as the absolute value of the sample means divided by the pooled sample standard deviation

Table 3.

Changes in self-reported stimulant use, urine toxicology screening for stimulants, and methamphetamine craving by treatment arm (N = 110)

	ARTEMIS (n = 55)	Attention-Control (n = 55)	Cohen's *d* (95% CI)	Group x Time p-value
	M (SE)	**M (SE)**		
Pre-Session Methamphetamine Craving				0.073
Session 1	35.98 (3.63)	38.62 (4.21)	-	
Session 2	22.54 (3.51)	30.42 (4.09)	0.29 (−0.09, 0.67)	
Session 3	18.82 (3.45)**	34.57 (4.30)**	0.54 (0.15, 0.93)	
Session 4	16.19 (3.11)*	28.72 (4.22)*	0.46 (0.07, 0.86)	
Session 5	12.58 (2.92)**	28.71 (4.55)**	0.60 (0.20, 1.01)	
Methamphetamine Craving				0.182
Baseline	2.62 (0.18)	2.85 (0.21)	-	
3 Months	1.83 (0.19)*	2.52 (0.24)*	0.50 (0.10, 0.90)	
Self-Reported Stimulant use (past 3 months)				0.072
Screening	4.65 (0.25)	4.51 (0.25)	-	
Baseline	4.16 (0.24)	4.09 (0.24)	-	
3 Months	2.26 (0.31)*	3.22 (0.32)*	0.46 (0.05,0.86)	
	Median (IQR)	**Median (IQR)**		**p-value**
Total Tox- Samples During CM	18 (5–27)	14 (4–26)		0.75

ARTEMIS = affect regulation intervention to enhance methamphetamine intervention success; CM = contingency management; Tox- = non-reactive for methamphetamine and cocaine; Between group differences within each time point:

* p < .05;

** p < .01;

For interpretability, Cohen's d is computed as the absolute value of the sample means divided by the pooled sample standard deviation