Randomized Controlled Trial of a Positive Affect Intervention to Reduce HIV Viral Load in Methamphetamine-Using Sexual Minority Men

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Introduction

Contingency management (CM) is an evidence-based intervention where individuals receive incentives for toxicologically confirmed stimulant abstinence.

CM achieves moderate reductions in stimulant use and short-term decreases in viral load, but important concerns remain about durability of treatment gains.

Novel interventions are needed to address fundamental neurobehavioral processes such as withdrawal and anhedonia that undermine the benefits of CM.

We demonstrated that an individually delivered positive affect intervention with recently diagnosed HIV-positive persons improves psychological adjustment.[1]

The scientific premise of this randomized controlled trial (RCT) is that a positive affect intervention will boost the effectiveness of CM.

Those randomized to receive the positive affect intervention reported improvements in multiple secondary outcomes during the 3-month CM intervention period: enhanced psychological adjustment, reduced methamphetamine craving, and decreased stimulant use.[2]

We examined the efficacy of the positive affect intervention delivered during CM for achieving durable reductions in the primary outcome, $\log_{10}$ HIV viral load.

Methods

This Phase II RCT was registered on www.clinicaltrials.gov (NCT01926184) and annual reviews were conducted by the University of California, Los Angeles Data Safety and Monitoring Board in Addiction Medicine (DSMB-AM).

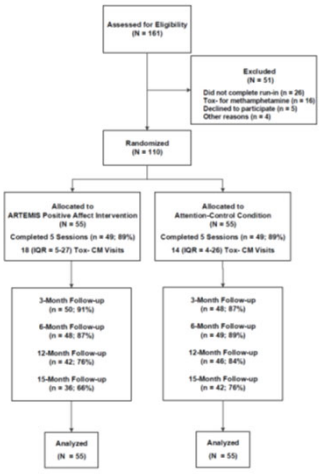
Recruitment and Screening. From 2013-2017, a total of 184 individuals were recruited for this RCT from a community-based CM program, using flyers in the community, and via an incentivized snowball sampling method.

Inclusion Criteria. 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; and 5) provide a urine or hair sample that was reactive for methamphetamine.

Run-in Period and Randomization. Eligible participants completed a waiting period prior to randomization (i.e., run-in) that entailed five separate visits: 1) a baseline assessment; 2) three CM urine screening visits (regardless of the toxicology results); and 3) a separately scheduled randomization visit.

Assessments. 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. Peripheral venous blood samples to measure HIV disease markers were collected at baseline, six, 12, and 15 months. As shown in the Figure, follow-up rates at six (88%), 12 (80%), and 15 (71%) months were acceptable with no significant differences by arm.

Figure. CONSORT: Screening, Randomization, and Follow-up



Community-Based CM Program. CM was provided for three months by the San Francisco AIDS Foundation through the Positive Reinforcement Opportunity Project (PROP). The total possible reinforcement of stimulant abstinence during thrice-weekly urine screening over the three months was $330.

Positive Affect Intervention. Affect Regulation Treatment to Enhance Methamphetamine Intervention Success (ARTEMIS) is a multi-component, individually delivered 5-session intervention designed to increase positive affect. The ARTEMIS intervention protocol consists of eight core skills that have been shown to increase positive affect.

ARTEMIS

Attention-Control Condition. Attention-control sessions consisted of face-to-face administration of psychological measures and neutral writing exercises. Participants had comparable contact time and identical incentives.

Statistical Analyses. Intent-to-treat analyses compared the experimental conditions across time by testing the group-by-time interaction effects using repeated measures models with correlated residuals estimated via maximum likelihood using the Stata -mixed- command. Planned simple main effects tests compared the ARTEMIS intervention and attention-control conditions at each follow-up assessment using the Stata -contrast- post-estimation command.

Results

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 participants were Caucasian (43%), 29% were Hispanic/Latino, 16% were African American, and 12% were other ethnic minorities or multiracial.

At baseline the median CD4+ T-cell count was 646 (Interquartile Range = 428 – 816) cells/mm^3 and 14% had an unsuppressed viral load ($\geq$ 200 copies/mL).

As shown in the Table, we observed a significant group-by-time interaction for the primary outcome of $\log_{10}$ HIV viral load ($\chi^2(3) = 7.83$, $p = 0.0496$).

Table. Primary and Secondary Outcomes by Treatment Arm (N = 110)

	N	ARTEMIS (n = 55)	Attention-Control (n = 55)		Group x Time p-value
		M (SD)	M (SD)	Cohen's *d* (95% CI)	
HIV Viral Load (Log$_{10}$)					0.0496
Baseline	108	1.04 (1.23)	1.42 (1.40)	-	
6 Months	87	0.69 (0.75)**	1.82 (1.61)**	0.89 (0.45, 1.33)	
12 Months	84	0.93 (1.21)*	1.52 (1.51)*	0.43 (-0.01, 0.86)	
15 Months	74	0.88 (1.03)*	1.49 (1.38)*	0.50 (0.04,0 .96)	
CD4+ T-Cell Count (Square Root)					0.584
Baseline	108	24.68 (5.86)	24.18 (7.50)	-	
6 Months	85	25.28 (6.08)	23.06 (7.83)	0.32 (-0.11, 0.74)	
12 Months	78	24.10 (6.41)	23.93 (8.31)	0.02 (-0.42, 0.47)	
15 Months	70	25.13 (5.61)	23.80 (7.29)	0.20 (-0.27, 0.67)	
Positive affect					0.051
Screening	110	33.27 (7.63)	31.25 (8.76)	-	
Baseline	110	32.38 (8.64)	31.40 (9.41)	0.11 (-0.27, 0.48)	
Session 1	110	30.24 (8.97)	30.02 (10.11)	0.02 (-0.35, 0.40)	
Session 3	104	33.33 (8.00)	29.75 (9.85)	0.40 (0.01, 0.79)	
Session 5	98	35.06 (9.23)**	29.57 (10.34)**	0.56 (0.16, 0.96)	
3 Months	98	34.82 (8.42)	32.27 (9.47)	0.28 (-0.11, 0.68)	
6 Months	96	35.45 (8.12)**	30.96 (8.84)**	0.53 (0.12, 0.93)	
12 Months	88	35.17 (10.11)*	30.74 (11.19)*	0.41 (-0.01, 0.84)	
15 Months	78	32.86 (10.11)	32.26 (12.07)	0.05 (-0.39, 0.50)	

Planned comparisons demonstrated that the ARTEMIS intervention displayed significantly lower $\log_{10}$ HIV viral load at six ($z = 4.11$; $p < 0.001$), 12 ($z = 2.60$; $p = 0.009$), and 15 months ($z = 2.41$; $p = 0.016$).

We also observed via logistic regression that ARTEMIS intervention participants had significantly lower risk of at least one unsuppressed HIV viral load over the 15-month follow-up period (RR = 0.33; 95% CI = 0.15 – 0.69; $p < 0.001$).

There were no significant differences in CD4+ T-cell count by treatment arm ($\chi^2(3) = 1.95$, $p = .584$).

In a sensitivity analyses excluding the 15-month time point there was a significant group-by-time interaction for positive affect ($\chi^2(6) = 12.96$, $p = 0.044$).

ARTEMIS intervention participants reported significantly higher positive affect in planned comparisons at session 5 ($z = 2.63$; $p = 0.009$) as well as at six ($z = 2.67$; $p = 0.008$) and 12 ($z = 2.10$; $p = 0.036$) months.

Conclusions

This RCT is the first to demonstrate that a behavioral intervention for can achieve **durable and clinically meaningful reductions in HIV viral load** among substance users living with HIV.

The fact that only 14% of participants presented with unsuppressed viral load at baseline highlights the need for integrative, behavioral interventions to **mitigate risk of HIV viral rebound**.

The efficacy of the ARTEMIS intervention for increasing positive affect provides important proof-of-concept and corroborates prior findings from our team.[1]

These results should be interpreted with caution given the relatively modest sample size, which underscores the need for a Phase III RCT of ARTEMIS.

References

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