

A Randomized Clinical Trial of Two Interventions to Reduce HIV Risk and Substance Use Among Highly Vulnerable MSM

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Background

- Men who have sex with men (MSM) account for more than 60% of all new HIV infections in the U.S. and finding ways to identify and lower transmission rates in this group is key to lowering HIV incidence rates.
- Substance-using MSM are among the groups at highest risk for HIV infection and a third of new HIV infections among MSM can be attributed to non-injection substance use.
- Thus, strategies that are specifically designed to lower risks among substance-using MSM must be an essential component of any successful response to the epidemic in this population.
- However, the vast majority of research among MSM substance users has been descriptive in nature and evidence-based risk reduction interventions for not-in-treatment MSM substance users are lacking.
- We tested the efficacy of a novel small group sexual and substance use risk reduction intervention based on psychological empowerment theory compared to an enhanced efficacious HIV risk-reduction counseling condition, based on theories of resilience, among high risk not-in-treatment MSM substance users in the Miami, Florida, USA, metropolitan area.

Purpose and Methods

Purpose: The purpose of this analysis is to present primary outcome measures from a randomized intervention trial that sought to reduce substance use and HIV transmission risk.

Methods: Data from 515 MSM are presented. Participants were recruited through targeted sampling strategies and randomized to a **four-session small group empowerment theory-based intervention (Experimental)** or to a **single session individual resilience theory-based counseling condition (Control)**. To examine the extent of change over time in these outcomes between baseline and 12-month follow-up, Cohen's D (effect size) statistics are reported.

Eligibility:

- Reported unprotected anal intercourse in the past 90 days
- Substance use or alcohol to intoxication at least three times or marijuana use at least 20 days in the past 30 days.
- Between ages of 18-55

Participants were interviewed using a modified version of the Global Appraisal of Individual Needs (Dennis 2002) structured interview, which included measures of:

- Demographics / Environment
- Substance Use
- Mental Health
- Sexual Risk Behaviors

Dennis M.L., Titus J.C., White M.K., Unsicker J.I., Hodgkins D. (2002). Global Appraisal of Individual Needs-Initial (GAIN-I). Bloomington, IL: Chestnut Health Systems.

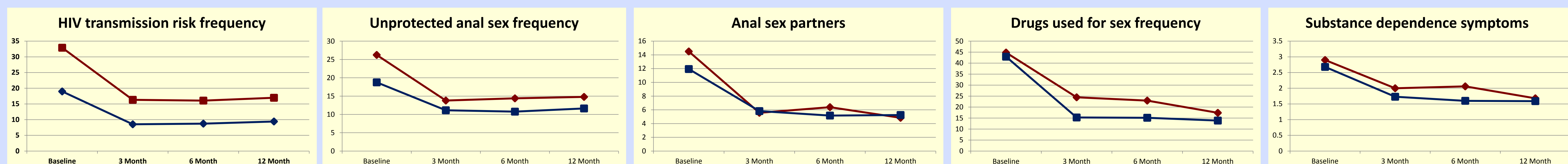
Sample Characteristics

Baseline characteristics of substance-using MSM by intervention condition (N=515)

	Experimental (N=252)		Control (N=263)		P
	N	%	N	%	
Demographics					
Age (mean; SD)	39.21 (9.41)		38.66 (9.88)		0.522
Education in years	13.98 (2.39)		13.71 (2.32)		0.189
Race/ethnicity:					
Hispanic	73	29.0	60	22.8	0.111
African American/Black	51	20.2	57	21.7	0.689
Caucasian/White	117	46.4	133	50.6	0.347
Other	11	4.4	13	4.9	---
HIV-positive	113	44.8	126	47.9	0.485
Substance Use (past 90 days)					
Alcohol (binge drinking)	202	80.2	219	83.3	0.361
Amyl nitrite (poppers)	133	52.8	142	54.0	0.782
Cocaine (powder)	115	45.6	116	44.1	0.727
Crack cocaine	46	18.3	58	22.1	0.283
Methamphetamine	67	26.7	65	24.7	0.627
Rx sedatives	74	29.4	103	39.2	0.019
Rx opioids	54	21.3	75	28.5	0.063
Sexual Behavior (past 90 days)					
Anal intercourse frequency (mean; SD)	29.58 (35.00)		36.55 (50.69)		0.375
HIV transmission risk frequency (mean; SD)	13.92 (25.21)		18.89 (37.03)		0.170
Anal intercourse partners (mean; SD)	11.94 (15.19)		14.50 (21.27)		0.365
Used drugs for sex frequency (mean; SD)	42.94 (68.01)		44.82 (59.84)		0.264
Social/environmental Risk Factors					
Severe mental distress (past year)	149	59.1	149	56.7	0.570
DSM-IVR substance dependence (past 90 days)	152	60.3	168	63.9	0.405
Victimization history (lifetime)	212	84.1	213	81.0	0.348
First abuse before age 18	145	57.5	137	52.1	0.399

Baseline to 12 month change scores for primary and secondary outcomes

		Baseline	3 Month FUA	6 Month FUA	12 Month FUA	BL-12Month Mean Difference	Effect Size	CI for Mean Difference		P
		Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)			Lower	Upper	
HIV transmission risk frequency (excludes UAI between two HIV-positive men)	Control	18.99 (37.03)	8.52 (18.35)	8.73 (20.07)	9.42 (28.76)	9.48	0.71	0.58	0.83	<0.001
	Experimental	13.92 (25.21)	7.80 (16.70)	7.34 (19.13)	7.55 (17.23)	6.38	0.66	0.53	0.78	<0.001
Unprotected anal sex frequency	Control	26.24 (41.79)	13.79 (26.84)	14.39 (26.92)	14.78 (33.24)	11.47	0.74	0.61	0.86	<0.001
	Experimental	18.75 (26.76)	11.14 (18.34)	10.76 (21.47)	11.63 (21.90)	7.12	0.73	0.61	0.85	<0.001
Anal sex partners	Control	14.50 (21.27)	5.57 (9.09)	6.39 (19.51)	4.84 (8.63)	9.66	1.04	0.95	1.12	<0.001
	Experimental	11.94 (15.19)	5.82 (9.81)	5.17 (9.97)	5.25 (12.04)	6.69	0.98	0.89	1.06	<0.001
Drugs used for sex frequency	Control	44.82 (59.84)	24.45 (46.39)	22.96 (42.03)	17.39 (31.70)	27.43	0.94	0.81	1.06	<0.001
	Experimental	42.94 (68.01)	15.28 (33.36)	15.15 (31.08)	13.87 (24.08)	29.08	1.00	0.87	1.13	<0.001
DSM substance dependence symptoms	Control	2.90 (2.42)	2.00 (2.15)	2.06 (2.19)	1.68 (2.04)	1.22	0.49	0.42	0.56	<0.001
	Experimental	2.68 (2.38)	1.95 (1.60)	1.60 (1.97)	1.59 (2.08)	1.09	0.53	0.47	0.60	<0.001



Discussion and Conclusions

Significant effect size for reductions in HIV transmission risk, unprotected anal sex, anal sex partners, drugs used for sex, and substance dependence were all moderate to large. We constructed multilevel linear models for repeated measures, controlling, successively, for age and HIV serostatus. These controls had no effect on rates of behavior change over the course of the study. Although no differences were found by study condition, both interventions addressed substance use and HIV transmission risk, by focusing on individual goals, strengths, motivations, and building positive social support connections and self-efficacy. This suggests that interventions based upon both empowerment theory and resilience theory are efficacious in reducing risk behaviors for MSM.

The results indicate that intervention approaches for substance using MSM that target empowerment and resilience - the identification and achievement of life goals, building positive social relationships, broadening social engagements, and improving coping skills, self-efficacy and self worth - appear to be efficacious based on pre- and post-intervention self reports of behavior change, and may lead to more sustainable behavior change than addressing sexual risk behaviors and drug use with educational or didactic approaches. Further, our findings suggest that substance using MSM can initiate and sustain substantial risk reductions, but that the processes by which these men reduce their risks are poorly understood. Basic research that describes how these reductions occur over time may prove to be the best investment that the field could make in designing interventions for this population.

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