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A Randomized Trial of a Behavioral Intervention for High Risk Substance-Using MSM

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Abstract Substance-using men who have sex with men (MSM) are among the groups at highest risk for HIV infection in the United States. We report the results of a randomized trial testing the efficacy of a small group sexual and substance use risk reduction intervention based on empowerment theory compared to an enhanced efficacious control condition among 515 high risk not-in-treatment MSM substance users. Effect sizes for sexual risk and substance use outcomes were moderate to large: HIV transmission risk frequency, $d = 0.71$ in the control versus 0.66 in the experimental group; number of anal sex partners, $d = 1.04$ versus 0.98; substance dependence symptoms, $d = 0.49$ versus 0.53; significant differences were not observed between conditions. Black MSM reduced their risks at a greater rate than White or Latino men. The findings point to a critically important research agenda to reduce HIV transmission among MSM substance users.

Introduction

According to recent CDC estimates, men who have sex with men (MSM) account for more than 60 % of all new infections in the United States [1]. Given that the majority of all new infections in the United States occur among MSM, finding ways to identify and lower transmission rates in this group is key to lowering HIV incidence rates in the United States. We now have evidence, compiled over the past 30 years, to show that substance-using MSM are among the groups at highest risk for HIV infection in the United States [2–5]. Furthermore, two independent analyses using HIV seroconversion end-points found that about a third of new HIV infections among MSM can be attributed to non-injection substance use [6, 7]. This body of epidemiological and behavioral research makes it clear that if we are to reduce rates of HIV transmission among MSM in the United States, 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.

Despite widespread agreement that substance-using MSM suffer a large proportion of new HIV infections in the United States, the vast majority of research among MSM substance users has been descriptive in nature. As such, evidenced-based risk reduction interventions for not-in-treatment MSM substance users are lacking [8–11]. To date, there have been only four randomized controlled trials (RCTs) to reduce HIV risk among MSM substance users [12–14], the most recent of which is the subject of this report. The earlier RCTs testing new interventions for

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MSM substance users all demonstrated high levels of risk reduction in both the experimental and control conditions, but differences in behavior change reached statistical significance between conditions in only one of these studies, which was implemented among men in substance abuse treatment [13].

We tested the efficacy of a novel small group sexual and substance use risk reduction intervention based on psychological empowerment theory [15] compared to an enhanced efficacious [16] HIV risk-reduction counseling condition among high risk not-in-treatment MSM substance users in South Florida (Miami/Ft. Lauderdale). The small group intervention approach, and to a somewhat lesser extent the control condition, conceptualized sexual risk behaviors and substance use primarily as *symptoms* of underlying life problems related to the substance use, violence, and AIDS syndemic [17] present in this population. This paper presents outcome data comparing an enhanced efficacious intervention that is already part of standard HIV risk-reduction public health practice to a new intervention specifically designed for substance using MSM.

Methods

Site

South Florida (Miami/Ft. Lauderdale) is a well-known migration destination for MSM, with the second highest proportion of same-sex households among large cities in the nation [18]. The Miami metropolitan area reports the highest HIV and AIDS incidence rates in the U.S. [19]. A recent Miami study found that almost half (45 %) of HIV-positive MSM were unaware of their infection [20]. Baseline data from the present study indicated that almost one-third of HIV-negative men who migrated to South Florida after the age of 18 seroconverted within 5 years of doing so [21], making the study site one of the highest risk settings for HIV seroconversion among MSM in the United States.

Study Sample

The study was designed to recruit a sample of 500 participants, in order to achieve 0.85 power to detect a 0.25 effect size reduction in HIV transmission risk events, assuming 20 % attrition over 12 months.

Participants ($N = 515$) were recruited between November 2008 and October 2010 through multiple methods, including direct outreach, participant referral, and internet and print media. Eligible men were between the ages of 18 and 55; reported multiple anal sex partners and at least one

unprotected anal intercourse (UAI) event with a non-monogamous partner in the past 90 days; met one or more of three substance use inclusion criteria: binge drinking (five or more drinks) at least three times, drug use (excluding marijuana) at least three times, and/or marijuana use at least 20 days, in the past month; resided in South Florida and intended to remain there through the term of study participation; and provided a mailing address and personal telephone number. Men were ineligible if they were newly diagnosed with HIV infection in the prior 6 months (including tests at study enrollment) or if they participated in an HIV or substance use prevention intervention or substance abuse treatment program in the prior 12 months. Follow-up interviews were completed in December 2011.

Procedures

The study was conducted at two field offices, one in Wilton Manors (a suburb of Ft. Lauderdale) and one in Miami Beach. The offices were located in standard business office buildings; the Wilton Manors office building was located on the site of a community based organization. Both of these neighborhoods serve as the dominant residential, gathering and recreational centers for MSM in South Florida, are located in adjoining counties, and are situated close enough to each other that there is substantial movement by MSM between the two neighborhoods. Men responding to recruitment messages called the nearest field office and were screened to determine eligibility over the telephone. Those who were eligible and expressed interest in participating were asked to visit the field office, where staff members rescreened for eligibility and administered informed consent using procedures approved by the University of Delaware's Institutional Review Board (predecessor institution for the project). Following consent, locator data were collected, men reporting HIV-negative serostatus were offered confidential testing, and all enrollees were scheduled for a second appointment for baseline assessment. Enrollees were paid a $20 stipend for their time and travel expenses.

At the second appointment, all respondents completed a standardized baseline assessment based on the Global Appraisal of Individual Needs (GAIN, v. 5.4) [22]. Private offices were used for all assessments using computer-assisted face-to-face interviewing procedures. These interviews lasted approximately an hour and a half. Following completion of the baseline assessment, participants were randomized to the small group or control intervention conditions using a computer-generated random number table. In order to make sure that the experimental intervention small groups ($N = 5$–10) could be formed within a short period of time after participants' baseline assessments

were completed, randomization proceeded in blocks of 20. Field office staff and participants were blinded to randomization until immediately after the baseline interview. Participants were aware that some were assigned to a small group discussion condition and others to an individual counseling format. Follow-up interviews at 3, 6, and 12 months after intervention completion (1 week for the control arm and 5 weeks for the experimental arm) included the same items as the baseline instrument, exclusive of life history items, and lasted about 1 h. Participants were offered HIV education literature, condoms, and a $50 stipend upon completing each assessment.

Staff

The field offices were staffed by MSM age-peers with a minimum of a Bachelor's degree, 1 year of prior research experience, and demonstrated commitment to MSM health. In addition to being trained in the recruitment procedures, data collection instruments, and intervention protocols, all staff completed requirements for State of Florida certification as HIV test counselors. Field staff also completed 20 h of motivational interviewing (MI) training conducted by a professional MI trainer. Experimental and control arm intervention protocols were delivered by the same staff members. The dissimilarities of the intervention formats and intensities, together with regular monitoring of all

intervention delivery components for fidelity, minimized risk of contamination across arms.

Interventions

The design of the 4-session small group experimental arm of the study was grounded in psychological empowerment, the process by which people gain mastery of issues of concern to them [23]. In an individual context, empowerment is a process through which individuals come to perceive a connection between their goals and the means to achieve them, and between their efforts and the desired results [24]. Psychological empowerment theory asserts that goals can be achieved based on one's efforts to fulfill those goals, but achievement is also subject to interactions among current risk factors (social isolation, substance use), strengths (perceived control, coping skills, critical awareness), and awareness of resources [23]. The conceptual model guiding the intervention approach, which was developed during extensive pilot qualitative research and a small preliminary efficacy trial [25, 26], is shown in Fig. 1.

Given this background, the experimental intervention focused on assisting high risk MSM substance users in: (1) strengthening the skills needed to exercise control over their lives; and (2) taking a third person view of the interactions of drugs and sex among gay men, and examining the
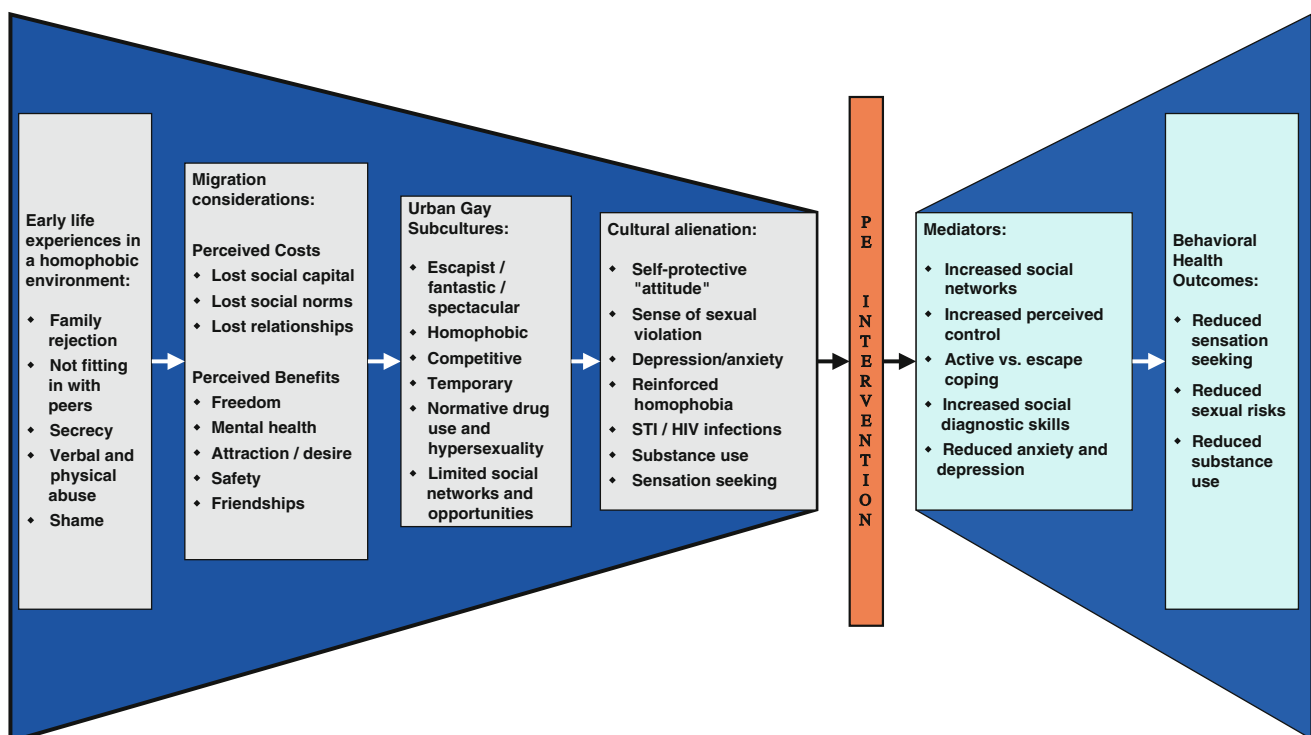

Fig. 1 Conceptual model of MSM health risks and theorized psychological empowerment intervention effects

good and bad experiences associated with them; (3) broadening their spheres of social engagement; and, (4) identifying achievable life goals and action plans to move toward them.

The intervention employed two main tools to help men achieve these aims: (1) guided group discussions that emphasized the building of trust and intimacy with other men, and the sharing of men's diverse experiences, strengths, and approaches to problem solving; and, (2) individual take home exercises that promoted self-awareness, social diagnostic skills, and social connectedness. The primary group intervention components by session are outlined in Fig. 2.

In accordance with psychological empowerment theory, goals were entirely participant-identified, and included a wide diversity of efforts, such as: educational, vocational,

hobby and volunteering pursuits; substance abuse treatment entry; changing friendship networks; and exiting abusive relationships. Intervention sessions were scheduled 1 week apart. Each group session lasted about 2 h, and was facilitated by two staff members. Participants who missed a group session were invited to attend the other sessions for their group, but they were not permitted to attend other groups for the session(s) they missed.

One week after completion of the four group sessions, men in the experimental arm of the study attended an individual goal achievement counseling session with a staff member. In keeping with the psychological empowerment framework, staff used an extensive compendium of resources, including health and social services and opportunities for employment, education and social engagement

Fig. 2 Group intervention session content

Session 1

Icebreaker

Discussion:
  A. Coming out; experiences of secrecy and social support. Identify strengths (e.g., self-reliance, self-awareness, cultural resistance) used to take control of problems.

  B. Managing gay/bi life in South Florida: dating and sex; community; friendships; competition; homophobia. Identify strengths we can use to exercise control and make changes.

Homework: Gay venue observation - social behaviors; quality time with a friend; sexual intimacy.

Session 2

Icebreaker

Discussion:
  HIV serostatus, disclosure and safer sex: HIV-based identities; stigma and segregation; diversity of perspectives and behaviors; sensation seeking; intimacy; barriers to safer sex. Identify strengths we can use to exercise control and make changes.

Homework: Gay venue observation - drug use; quality time with a friend; sexual intimacy.

Session 3

Discussion:
  A. Alcohol and drugs: meanings and motivations; benefits and drawbacks; relationship to sex, boredom and loneliness; risk reduction measures. Identify strengths we can use to exercise control and make changes.

  B. Taking control and managing stress: creating a social safety net; setting and achieving goals; new stress relief techniques.

Homework: Goal setting; joining an organization; stress reduction.

Session 4

Discussion:
  A. Taking control of your place in the gay scene.

  B. Pairs exercise: setting goals and making changes.

Homework: goal setting; social participation; friendship; sexual intimacy.

Session 5 (individual)

Goal achievement plan
  -   Action steps
  -   Identifying barriers and ways to overcome them
  -   Resource identification and referrals

Comprehensive referrals for health and social services

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to assist men in identifying action plans to initiate the achievement of the goals they identified for themselves during the group sessions. Potential barriers to goal achievement were also discussed, as well as possible ways these might be overcome. Comprehensive referrals were made for any health and social service needs. Individual counseling sessions lasted about 1 h.

The single session individual control condition included sexual and substance use risk assessment and risk reduction counseling using the RESPECT model [16]. Because of the high levels of vulnerability and need of the target population, and guided by a resilience theoretical framework that focuses on assets and resources to overcome risk [27], we enhanced the control condition based on key domains of resilience that emphasize understanding and separating oneself from risk, strengthening positive relationships, and fostering initiative, creativity and morality [28]. Examples of the implementation of these approaches included re-forming friendship networks to reduce substance use, using humor to negotiate condom use, and taking the initiative to develop alternative social engagements to drugs-sex involvement. Each session lasted 30–45 min, and concluded with a written individualized risk reduction plan. Staff used the same compendium of resources as for the experimental arm to assist with referrals to needed health and social services.

All intervention sessions were audio recorded; transcripts of all group discussions were reviewed for fidelity to the intervention protocols, as were 20 % of all individual counseling sessions. Participants in both study arms were offered condoms and a $30 stipend to cover time and travel costs at the completion of each intervention session.

Measures

Sexual Risk Behaviors

Sexual behavior measures at each assessment included counts of past 90 day receptive and insertive anal intercourse events, with or without a condom, with a casual or primary partner, and with a seroconcordant, serodiscordant, or unknown serostatus partner. Study eligibility requirements excluded men in monogamous relationships, so that unprotected sex with both primary and casual partners was considered risk behavior. Participants answered interviewers' questions about these behaviors by completing a chart of responses such that parent items (e.g., "how many times did you have receptive anal sex without a condom") were followed by sub-items (e.g. how many times with an HIV+, HIV− and HIV-unknown partner), and the totaled sub-items were equal to the related parent item frequency. The sexual risk inventory included a total of 21 items and took about 10 min to administer. Because uptake of HIV testing at study enrollment was low (many participants said

they already had another preferred testing venue), participant HIV status was assessed by self report, and seropositivity was verified with a notice of diagnosis or ARV prescription.

Substance Use

Substance use measures at each assessment included past 90 day frequency of use of each substance, including binge drinking (five or more drinks at one sitting) and the non-medical use of prescription medications. We also inquired how often each substance was used before or during sex in the past 90 days. DSM-IVR substance dependence was determined by the endorsement of three or more of seven dependence symptoms (e.g. needing more drug to get the same effect, experiencing withdrawal symptoms, being unable to quit or cut down) in the past 90 days.

Syndemic Symptoms

We report several measures of syndemic factors to more comprehensively describe the sample. *The General Mental Distress Scale (GMDS)* is comprised of past year DSM-IVR symptom counts for depression (nine items), anxiety (12 items), and somatic disorders (four items). This scale is reducible to classifications indicating clinical significance (subclinical, moderate and severe) [22] and was further dichotomized in the analyses presented here into "severe" and "not severe." Alpha reliability coefficients for the depression, anxiety, and somaticism subscales in this study were 0.822, 0.829, and 0.706, respectively. *Victimization* was assessed by affirmative responses to the following events: being attacked with a weapon or being beaten so as to cause bruises, cuts or broken bones (physical abuse); being forced to participate in sexual acts against one's will (sexual abuse); or being made to feel very bad about oneself or one's life (emotional abuse). For analysis, we used a summary measure: any lifetime abuse vs. no abuse. We constructed a separate variable to identify participants whose first experience of abuse occurred when they were minors.

Outcome Measures

The primary outcome measure is frequency of unprotected anal intercourse (UAI) involving HIV transmission risk (i.e. excluding UAI where both partners were HIV-positive). We selected this measure, which includes UAI between men who believe they are HIV-negative, because of the large number of HIV-positive men in South Florida who are unaware of their status [20], and because the high rates of UAI and partner change reported by the HIV-negative men in our sample render serosorting an

ineffective risk reduction strategy for them [29]. We note, however, that the intervention effects on the primary outcome measure did not substantially differ if other definitions of sex risk were used, neither the broader measure of any UAI, nor the narrower measure of UAI with serodiscordant or unknown serostatus partners. We report mean outcome data for any UAI to show the similarity of results across the two measures. Secondary outcome measures, using past 90 day recall periods, include: (1) receptive and insertive HIV transmission risk frequencies, (2) numbers of anal sex partners, (3) frequency of binge drinking or using drugs before or during sex, and (4) DSM-IVR substance dependence symptoms.

Data Analyses

The level of significance was set at $p < 0.05$ for all tests. Data from the interview questionnaires were analyzed using *Stata/SE* 12.1 for Windows. There were no missing data from any completed assessments. Descriptive statistics were calculated to describe the sample by intervention condition in terms of demographics; HIV serostatus; past 90 day substance use and sexual risk behaviors; mental distress; substance dependence; and victimization history.

All outcomes were examined on an intent-to-treat basis, and included all of the data available for each follow-up wave. For the baseline to 3 month outcomes, there were 467 cases available for analysis; for baseline to 6 months, 459 cases; and for baseline to 12 months, 453 cases. Because the outcome measures—had positively skewed distributions, we used log transformations of these measures for the longitudinal analyses (although the substance dependence measure was not highly skewed, we report the log transformed measure for consistency). The transformations not only reduced the rightward skew of the data, but they also reduced the effect of right side outliers that were predominant in the control group. Baseline differences and longitudinal effect sizes for these measures are reported for the log-transformed measures.

To examine change over time in the primary and secondary outcomes, we constructed multilevel non-linear growth models (MLM) for repeated measures, controlling for age, age * time interaction, race/ethnicity, race/ethnicity * time interaction, HIV serostatus, HIV serostatus * time interaction, arm, and arm * time interaction. These models take all available measurement points into account, and quantify the slope and shape of the behavior change curves over the three follow-up points. In addition to differences in behavior change by intervention condition, the models indicate whether there were significant differences in baseline outcome measures and rates of behavior change by demographic variables (e.g. Black race, HIV serostatus). In accordance with the Consolidated Standards of Reporting

Trials statement, we also report a summary of outcome results by study condition, including Cohen's *d* effect size statistics and related 95 % confidence intervals. Effect sizes and confidence intervals are reported for the log-transformed measures.

Results

Sample Characteristics

Sample characteristics at baseline by study condition are shown in Table 1. The sample was diverse as to age, race/ethnicity, and serostatus, and averaged almost 2 years of college education. Substance use was also diverse, with the large majority (81.2 %) reporting binge drinking. About two-thirds (62.3 %) reported illicit stimulant (cocaine, crack, and/or methamphetamine) use, 53.4 % amyl nitrites, 34.4 % prescription sedatives and 25 % prescription opioids. Numerous other substances were reported but did not exceed 20 % prevalence.

By any measure, the study participants reported extraordinarily high rates of HIV risk behaviors and related psychosocial/syndemic health conditions. Participants reported an average of more than 13 anal sex partners and 16 HIV transmission risk events in the past 90 days, for an average of about one new anal sex partner and high risk HIV transmission event each week. Majorities met criteria for severe mental distress (57.9 %) and substance dependence (62.1 %), and had been victimized as minors (54.8 %). The intervention groups were not significantly different on any of these measures, except that the control group reported more frequent use of sedatives at baseline.

The control group also reported higher frequencies on most sexual risk measures, but these did not approach the 0.05 level of significance. As noted in the "Methods" section, the log transformations substantially attenuated the effect of right side outliers that predominated in the control group. Skewness in the sexual risk variables ranged from 3.37 to 5.55, and was reduced in the log-transformed variables to a range of 0.28 to 0.99.

Enrollment, Retention and Adverse Events

The participant flow chart is shown in Fig. 3. The most common reasons for failing the initial eligibility screen were: sexual risk threshold (64.5 %); substance use threshold (20.8 %); both sexual risk and substance use thresholds (13.5 %); and recent enrollment in a drug treatment or HIV prevention program (13.7 %). In total, 515 men were randomized into the study. Four hundred-twenty participants (81.6 %) completed all four assessments, 47

Table 1 Baseline characteristics of substance-using MSM by intervention condition $N =$ (515)

	Experiment ($N = 252$)		Control ($N = 263$)		Chi square or t statistic	p
	N	%	N	%		
Demographics						
Age[a]	39.21	(9.41)	38.66	(9.88)	0.640	0.522
Education in years[a]	13.98	(2.39)	13.71	(2.32)	1.314	0.189
Ethnicity:						
Hispanic	73	29.0	60	22.8	2.545	0.111
African American/Caribbean	51	20.2	57	21.7	0.160	0.689
White	117	46.4	133	50.6	0.884	0.347
Other	11	4.4	13	4.9	–	–
HIV-positive	113	44.8	126	47.9	0.487	0.485
Substance use (past 90 days)						
Alcohol (binge drinking)	202	80.2	219	83.3	0.835	0.361
Amyl nitrites (poppers)	133	52.8	142	54.0	0.076	0.782
Cocaine (powder)	115	45.6	116	44.1	0.122	0.727
Methamphetamine	67	26.7	65	24.7	0.237	0.627
Crack cocaine	46	18.3	58	22.1	1.153	0.283
Rx sedatives	74	29.4	103	39.2	5.478	0.019*
Rx opioids	54	21.4	75	28.5	3.444	0.063
Sexual behaviors (past 90 days)						
Anal intercourse frequency[a,b]	29.58	(35.00)	36.55	(50.69)	0.888	0.375
HIV transmission risk frequency[a,b]	13.92	(25.21)	18.89	(37.03)	1.373	0.170
Anal intercourse partners[a,b]	11.94	(15.19)	14.50	(21.27)	0.907	0.365
Used drugs for sex frequency[a,b]	42.94	(68.01)	44.82	(59.84)	1.119	0.264
Syndemic factors						
Severe mental distress	149	59.1	149	56.7	0.323	0.570
DSM-IVR substance dependence	152	60.3	168	63.9	0.694	0.405
Victimization history (lifetime)	212	84.1	213	81.0	0.879	0.348
First abuse before age 18	145	57.5	137	52.1	0.712	0.399

[a] Mean (SD)

[b] t statistics and p-values obtained after log transformation

* Significant difference between groups

(9.1 %) completed baseline plus two follow-ups, 25 (4.9 %) completed baseline plus one follow-up, and 23 (4.5 %) completed only the baseline assessment. Participants lost to all follow-up and those who did not complete the 12-month assessment did not differ from other participants on measures of race/ethnicity, income, mental distress, victimization history, substance use, substance dependence, or sex risk. Men lost to all follow-up and to the 12 month assessment were about 5 years younger, on average, than other participants. Although a number of participants experienced drug overdose, medical problems and/or victimization over the course of the study, no adverse events were attributable to study participation.

Study Outcomes

Table 2 displays the results of the MLMs of longitudinal changes in the frequencies of the log transformed primary and secondary outcome measures, controlling for age, race/ethnicity, HIV serostatus, and arm, and their interactions with time. Results for the primary outcome measure, HIV transmission risk frequency, are shown in the first column. The observed decrease in HIV transmission risk events was significant at the $p < 0.001$ level for the entire sample. Time^2, the quadratic term indicating rate of change, is also significant and indicates a nonlinear and decreasing rate of reduction in the outcome variable over time. There
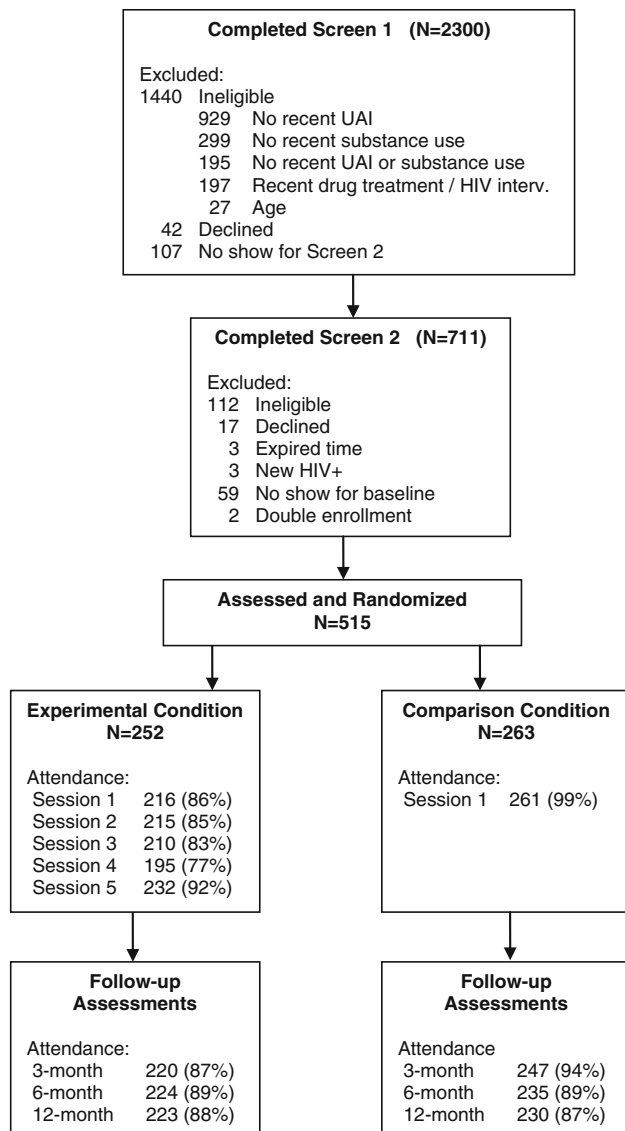
Completed Screen 1   (N=2300)

Excluded:
1440 Ineligible
     929   No recent UAI
     299   No recent substance use
     195   No recent UAI or substance use
     197   Recent drug treatment / HIV interv.
     27   Age
  42 Declined
 107 No show for Screen 2

Completed Screen 2   (N=711)

Excluded:
 112 Ineligible
  17 Declined
   3 Expired time
   3 New HIV+
  59 No show for baseline
   2 Double enrollment

Assessed and Randomized
N=515

Experimental Condition
N=252

Attendance:
Session 1   216 (86%)
Session 2   215 (85%)
Session 3   210 (83%)
Session 4   195 (77%)
Session 5   232 (92%)

Comparison Condition
N=263

Attendance:
 Session 1   261 (99%)

Follow-up
Assessments

Attendance:
3-month   220 (87%)
6-month   224 (89%)
12-month   223 (88%)

Follow-up
Assessments

Attendance
3-month   247 (94%)
6-month   235 (89%)
12-month   230 (87%)

Fig. 3 Study flow chart

are no age or racial/ethnic differences at baseline, but Black men reduced their HIV transmission risk frequency at a 17 % greater rate over time than Hispanic men ($p < 0.01$) and 18 % greater than White men ($p < 0.01$). HIV positive men had much lower rates of HIV transmission risk events than HIV-negative men at baseline ($p < 0.001$), because the outcome variable excluded UAI events where both partners were HIV-positive. There was no difference by serostatus in rate of change in HIV transmission risk frequency over time. No significant differences in outcome between the experimental and control conditions were observed.

The results are similar for receptive and insertive HIV transmission risk frequencies, shown in the second and third columns of Table 2. There were two differences in the receptive transmission risk model: there was no significant

difference between Black and Hispanic men in rate of behavior change; and there were no significant differences in baseline receptive transmission risk frequencies by serostatus. Change in numbers of anal sex partners is shown in column 4. The patterns are similar to those for HIV transmission risk frequency, except that HIV-positive participants reported 29 % ($p < 0.001$) more partners at baseline compared to HIV-negative men. No significant differences in outcome between the experimental and control conditions were observed.

Change in frequency of using drugs/binge drinking before or during sex is shown in column 5 of Table 2. Patterns of behavior change are similar to those observed for number of anal sex partners, except that Black men reported 37 % higher frequency of binge drinking before or during sex than Hispanic men ($p < 0.05$) and 44 % higher frequency than white men ($p < 0.01$) at baseline. Similar to the other outcome measures, however, black men reduced their use of drugs/binge drinking for sex at a faster rate than White and Hispanic men over the course of the study. No significant differences in outcome between the experimental and control conditions were observed.

Change in substance dependence symptoms is shown in column 6. As for the other outcome measures, the observed decrease in symptoms was significant at the $p < 0.001$ level for the entire sample. Time^2, the quadratic term indicating rate of change, is also significant and indicates a nonlinear and decreasing rate of reduction in the substance dependence symptoms over time. Black men reported more symptoms than White men at baseline ($p < 0.01$). HIV positive men reported more symptoms than HIV-negative at baseline ($p < 0.01$). No differences in rates of change by demographics were observed, and there were no significant differences in outcome between the experimental and control conditions.

Wave by wave changes in the mean values of primary and secondary outcome measures are shown in Table 3 (total UAI frequency is also shown to demonstrate the similar result to HIV transmission risk frequency). As indicated by the results of the multilevel models in Table 2, reductions in sexual risk behaviors, substance use, and substance dependence symptoms were greatest between baseline and 3 month follow-up, with rather modest changes thereafter.

Effect sizes for the changes in the log transformed primary and secondary outcome measures between baseline and 12 month follow-up by study arm are also shown in Table 3. Effect sizes were moderate to large across all outcomes, and no significant differences were observed between study conditions. The effect size for the reduction in substance dependence symptoms was moderate (0.49 in the control group vs. 0.53 in the experimental group). Effect sizes for all main sexual risk outcomes were large:

Table 2 Multilevel model of longitudinal change in past 90 day outcomes (log-transformed) ($N = 515$)

Column	1		2		3		4		5		6	
Variable	HIV trans. risk frequency		Receptive trans. risk frequency		Insertive trans. risk frequency		Anal sex partners		Used drugs for sex frequency		Subst. depend. symptoms	
	Estimate	S.E.	Estimate	S.E.	Estimate	S.E.	Estimate	S.E.	Estimate	S.E.	Estimate	S.E.
Fixed effects :												
Intercept	2.45[†]	0.26	1.60[†]	0.25	1.62[†]	0.24	1.98[†]	0.19	2.82[†]	0.27	1.41[†]	0.14
Time	−1.07[†]	0.12	−0.63[†]	0.10	−0.72[†]	0.11	−0.88[†]	0.09	−1.14[†]	0.14	−0.34[†]	0.07
Time^2	0.19[†]	0.02	0.13[†]	0.02	0.11[†]	0.02	0.17[†]	0.01	0.24[†]	0.02	0.05[†]	0.01
Age	−0.003	0.006	−0.01	0.006	0.004	0.006	−0.000	0.004	0.01	0.006	−0.006	0.003
Age*Time	0.001	0.002	0.00	0.002	0.000	0.002	−0.001	0.002	−0.003	0.003	0.001	0.002
Race (ref. Black)												
Hispanic	−0.07	0.16	0.08	0.15	−0.20	0.15	0.02	0.12	−0.37*	0.16	−0.08	0.09
White	0.003	0.14	0.11	0.13	−0.12	0.13	0.06	0.10	−0.44**	0.14	−0.23**	0.08
Other	−0.06	0.27	0.07	0.26	−0.18	0.25	0.19	0.19	0.17	0.27	−0.10	0.15
Hispanic*Time	0.17**	0.06	0.07	0.05	0.16**	0.06	0.11*	0.05	0.18*	0.07	0.02	0.04
White*Time	0.18**	0.06	0.10*	0.05	0.12*	0.05	0.13**	0.04	0.27[†]	0.06	0.04	0.03
Other*Time	0.10	0.10	0.05	0.09	0.03	0.09	0.12	0.08	0.01	0.12	0.005	0.06
HIV status (ref. neg)	−0.66[†]	0.11	−0.12	0.11	−0.77[†]	0.10	0.29[†]	0.08	0.28*	0.11	0.18**	0.06
HIV status*Time	0.01	0.04	0.05	0.04	0.08*	0.04	−0.03	0.03	−0.03	0.05	−0.004	0.03
Arm (ref. Control)	−0.17	0.11	−0.14	0.10	−0.08	0.10	−0.06	0.08	−0.19	0.11	−0.08	0.06
Arm*Time	0.04	0.04	0.02	0.03	0.03	0.04	0.02	0.03	−0.03	0.05	−0.01	0.03
Random variance:												
Intercept	0.90[†]	0.09	0.96[†]	0.08	0.86[†]	0.08	0.49[†]	0.05	0.82[†]	0.10	0.25[†]	0.03
Linear slope (Time)	0.06[†]	0.02	0.05[†]	0.01	0.07[†]	0.01	0.04[†]	0.01	0.09[†]	0.02	0.03[†]	0.01
Residual	0.74[†]	0.03	0.49[†]	0.02	0.50[†]	0.02	0.35[†]	0.02	0.89[†]	0.04	0.25[†]	0.01

SE = standard error

[a] All parameter entries are restricted maximum likelihood estimates fitted using Stata/SE12.1 xtmixed

* $p < 0.05$; ** $p < 0.01$; [†] $p < 0.001$

HIV transmission risk frequency, 0.71–0.66; number of anal sex partners, 1.04–0.984; and frequency of using alcohol and/or drugs for sex, 0.94–1.00. Effect sizes for receptive and insertive HIV transmission risk frequencies separately were moderate.

Discussion

The risk reductions reported by the high risk MSM substance users in this study are as large or larger than those achieved by other efficacious interventions for MSM now being diffused as tools in standard public health practice [10, 30], and are particularly impressive given their achievement in such a high risk population. 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. Moreover, resilience-based interventions have demonstrated efficacy in reducing substance use and mental distress in other populations [31–34].

Although in designing the study we strongly believed that group process would be an important element in assisting high risk substance using men to legitimize, embrace and enact the proficiencies targeted by empowerment theory, men in the single-session individual counseling arm reported reductions in their sexual and substance use risk behaviors to the same extent as the men in the four-session group condition. Although a finding of no difference between arms of an RCT study is often interpreted as evidence of a failed trial of an innovative intervention, it is important to point out that in this case the comparisons were between an intervention with proven efficacy, which we enhanced based on resilience theory, and a novel

Table 3 Baseline to 12 month change scores for primary and secondary outcomes

	BL (N = 515)		3 Mo FUA (N = 467)		6 Mo. FUA (N = 459)		12 Mo. FUA (N = 453)		BL-12 Mo Mean	Effect	CI for E.S. difference		p
	Mean (sd)		Mean (sd)		Mean (sd)		Mean (sd)		Difference	Size[a]	Lower	Upper	
HIV trans. risk frequency													
Control group:	18.89	37.03	8.52	18.35	8.73	20.7	9.42	28.76	9.48	0.71	0.58	0.83	<0.001
Experimental group:	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 group:	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 group:	18.75	26.76	11.14	18.34	10.76	21.47	11.63	21.9	7.12	0.73	0.61	0.85	<0.001
Receptive trans. risk frequency													
Control group:	8.79	22.11	3.67	8.62	3.92	11.3	4.02	11.15	4.77	0.46	0.35	0.57	<0.001
Experimental group:	7.22	17.49	3.62	11.11	3.30	13.79	3.50	10.49	3.72	0.43	0.32	0.54	<0.001
Insertive trans. risk frequency													
Control group:	10.11	26.33	4.85	13.54	4.80	13.91	5.40	22.14	4.71	0.54	0.43	0.65	<0.001
Experimental group:	6.70	12.70	4.18	11.54	4.04	12.02	4.05	11.61	2.65	0.52	0.42	0.63	<0.001
Anal sex partners													
Control group:	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 group:	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/drunk for sex frequency													
Control group:	44.82	59.84	24.45	46.39	22.96	42.03	17.39	31.7	27.43	0.94	0.81	1.06	<0.001
Experimental group:	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 dependence symptoms													
Control group:	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 group:	2.68	2.38	1.73	1.95	1.60	1.97	1.59	2.08	1.09	0.53	0.47	0.60	<0.001

[a] Effect size (Cohen's *d*) and related 95 % confidence intervals are for log-transformed measures

intervention specifically designed for substance using MSM. As such, the new intervention did not perform at levels above and beyond one of the more powerful evidence-based risk-reduction interventions available to the field. However, the similarity of effects between study arms also suggests that brief interventions—delivered in the context of a friendly and comfortable field office staffed by MSM age peers—enable even very high risk MSM to access mechanisms to reduce risk. In this study, the brief intervention condition took ~40 min to complete, and had higher uptake than the group condition. The logistics of implementing the brief individual resilience counseling condition were much simpler, and this intervention format would be much more easily implemented, scalable and sustainable in community settings.

Our finding that Black men reduced their sexual risk behaviors to a greater extent than White and Hispanic men, despite exhibiting no higher levels of risk at baseline, bears further investigation. Black men reported higher frequencies of using drugs/binge drinking for sex, as well as higher levels of substance dependence symptoms, than other men at baseline, but they also reduced their drugs/binge drinking—sex frequencies at a faster rate than White and Hispanic men. As reported elsewhere [35], African American/

Black men in the study commonly reported the importance of social support to their health and health behaviors, including the unique support they found through their contact with project staff. Moreover, they perceived their baseline levels of social support outside of the project staff—as a group—to be much lower than among White and Hispanic men. It is possible that the supportive environment offered by the field office, including regular contact from staff and extensive referrals to health and social services, had a stronger effect on helping Black men reduce risk compared to White and Latino men. We acknowledge that a small proportion of our sample was Black MSM, potentially reducing the generalizability of this finding.

Limitations

Although the recruitment procedures resulted in a sample of a wide age range and broadly inclusive of the racial/ethnic makeup of South Florida, our ability to generalize the findings to other MSM is limited by the study eligibility requirements, including regular substance use and recent UAI. Syndemic characteristics are likely much more prevalent among high risk substance users than among MSM

in general, and the study interventions may have been particularly well-suited to men with high levels of mental distress, social isolation, and victimization histories. We also note that all data are based on self-report, potentially leading to underreporting of socially undesirable behaviors. Given the high levels of substance use and sexual risk behaviors we found, however, underreporting of these and other stigmatized behaviors would appear to be uncommon. Moreover, men reported reductions in substance dependence symptoms over time that accompanied their reported reductions in substance use.

Another limitation of the study is that the RESPECT model was enhanced to include resilience-based approaches to risk reduction, and as such was perhaps more robust than a true standard of care. As such, the efficacy of the experimental condition compared to a true standard of care cannot be measured.

Implications for Future Research

Our study results are similar in some ways to other behavioral intervention trials for substance-using MSM [12–14]. Stall et al. reported no differences in sexual risk outcomes among substance abuse treatment clients assigned in a modified random design to a standard recovery group format or a recovery group enhanced to include sexual risk reduction protocols. In a four-arm randomized trial for MSM treatment enrollees, Shoptaw and colleagues found that contingency management, with or without cognitive behavioral therapy (CBT), was more efficacious for client retention, duration and continuity of clean urines, and reducing unprotected receptive anal intercourse than CBT alone, although changes in drug use were not different across conditions. In a two-armed RCT of a group-based CBT intervention compared to a time-matched control, that also included a non-randomized third group receiving HIV testing and counseling alone, Mansergh et al. reported no statistical differences in sexual risk or substance use reduction across study arms. As the latter and the present studies are the only two of the four to target not-in-treatment MSM, clearly new behavioral approaches are needed for non-treatment populations of MSM substance users.

However, each of these studies demonstrated high and sustained levels of risk reduction in both the experimental and control conditions. In all of four studies, the reductions were evident at the first follow-up and sustained through the final assessment. These similarities are striking and 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. A more comprehensive

understanding of the factors that contribute to risk reductions among high risk MSM substance users in control arms is needed to inform the design of low threshold interventions that could be broadly disseminated.

In the present study, one possible explanation is that both intervention conditions, despite varying significantly in dose and mode of delivery, were focused on participants' self-identification of strengths and needs, and provided high levels of social support and extensive referrals to health and social services. Other possible explanations include the experience of study enrollment alone, self-selection into research studies of participants who are ready to change, and/or reactive effects to study assessments [36–39]. Although several HIV RCT outcome reports have suggested such potentially confounding effects [14, 16, 40–43], their measurement in the HIV prevention research literature is scant (see [39, 42, 44]), and is not apparent in studies of high risk MSM substance users.

So-called reactive effects of research and/or clinical assessments among substance users have been recognized in the literature since at least the mid-1970s [37]. Researchers studying both substance abuse and sexual risk behaviors have attributed these behavioral responses to assessments to consciousness raising, focused attention, self-monitoring, self-efficacy, and similar phenomena [36, 37, 40, 42, 45]. Indeed, qualitative data from young adult multidrug users who recently completed a large-scale natural history study conducted by the investigators attributed their extensive reductions in substance use to increased self-awareness that emerged in response to the comprehensive health and social risk assessments [46]. Largely missing from this literature is systematic empirical evidence for how and why study assessments might produce behavior change [36, 45].

This analysis points to several potentially important strategies for future research designs of RCTs of interventions to assist high risk MSM reduce their health risk behaviors: (1) the inclusion of wait list and assessment-only conditions, so that enrollment, assessment and intervention effects can be clearly evaluated; and (2) more extensive qualitative data collection from study completers to contextualize motivations and mechanisms of behavior change. The overarching aim should be to identify the least intensive and most effective behavioral interventions that can be scaled up in community settings, as well as provide the necessary and complementary support for treatment as prevention [47], pre-exposure prophylaxis [48], and other emerging biological prevention approaches to be effective [49].

Conclusion

MSM suffer the majority of new HIV infections in the United States, and a substantial proportion of these new

infections occur among substance-using MSM. The men sampled for this trial not only reside in a region characterized by one of the highest HIV incidence rates for MSM in the United States, but are men who also reported exceptionally high levels of sexual risk-taking. Given that these men reside in an area that attracts enormous numbers of gay male tourists, it is likely that the sexual risk-taking behaviors of substance-using MSM in South Florida have epidemiological repercussions not only locally but far beyond Florida's borders. We now have data from four separate studies to show that rates of sexual risk-taking among MSM substance users can be reduced to an impressive degree, and that these risk reductions are stable for relatively long periods of time. These findings—and the larger epidemiological contexts of HIV risk among substance-using MSM—suggest that interventions can be designed to reduce HIV transmission risk in this population, and, moreover, that continued attempts to lower HIV infection rates among MSM substance users could prove to be an essential tool to reduce HIV-related health disparities among the broad population of MSM in the United States.

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