Abstract #961

Contingency Management Facilitates PEP Completion among Stimulant-Using MSM

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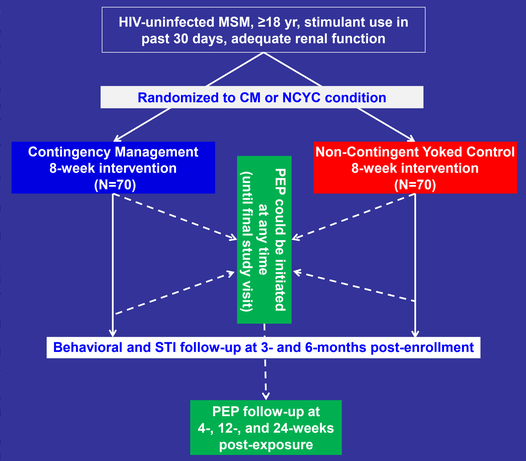
BACKGROUND

- Post-exposure prophylaxis (PEP) after occupational and non-occupational exposures to HIV is recommended by local, state, national and international guidance to reduce the risk of HIV acquisition among uninfected individuals (1,2,3)
- Efficacy data is (and likely will remain) limited to a single case-control study estimating efficacy at 81% reduction in odds of HIV acquisition among PEP users after occupational exposure (4)
- Guidance includes administration of 2 or 3 anti-HIV ART agents as quickly as possible after exposure (outside limits in guidelines range from 36 to 72+ hours; the majority use 72 hours), and a 28-day treatment course with serial follow-up for evidence of seroconversion
- Critical inputs into efficacy are likely viral inoculum, route of inoculation, time from exposure to PEP medication dosing, and course adherence (including course completion)
- MSM represent the majority of incident and prevalent HIV cases in the US and in Los Angeles
- Stimulant-users demonstrate medication non-adherence across a variety of clinical scenarios
- Attributable risk analyses suggest that stimulant use is a major driver of HIV and STD transmission among MSM, likely mediated through a combination of behavioral and biologic factors (6,7)
- "Combination" HIV prevention strategies which would reduce stimulant use, reduce sexual risk behavior, and provide anti-HIV chemoprophylaxis are attractive as they exploit prevention synergies
- Contingency Management (CM) is a behavioral intervention which provides voucher-based incentives for stimulant-use abstinence, and has demonstrated powerful and durable reductions in stimulant use and sexual risk behavior (8,9)
- We previously reported a single-arm uncontrolled trial of a combination of CM with PEP for methamphetamine-using MSM which demonstrated exposure time-to PEP-initiation, adherence, and course completion were not different from historical cohorts of PEP use among non-substance-using populations (10)

OBJECTIVE

- To evaluate the effect of CM, as compared to a control behavioral intervention (a non-contingent yoked control [NCYC]), on substance use, sexual risk behavior, and critical parameters for PEP efficacy (Figure 1).

Figure 1. FriendsCare2 Study Design



METHODS

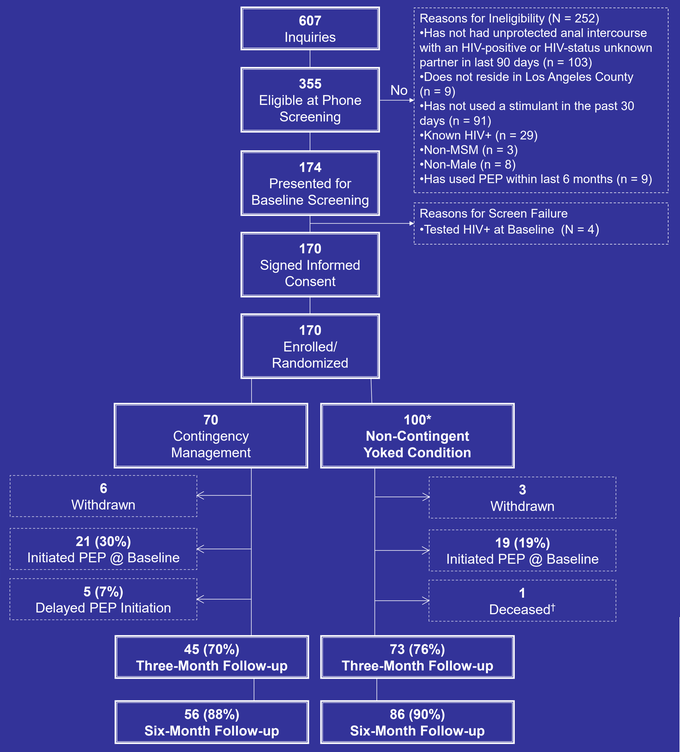
FriendsCare2 was a prospective, randomized controlled clinical trial of CM with PEP among stimulant-using MSM at the Friends Community Center in Los Angeles, California

- Participants were:
  - 18 years or age or older
  - Self-identified MSM
  - HIV-negative on baseline assessment
  - Self-reported stimulant use within the past 30 days
  - Self-report of UAI with an HIV-positive or status-unknown partner within the past 3 months
  - Current resident of LA County, no plans to relocate during the period of study
  - Creatinine clearance > 30 ml/min, not on hemodialysis
  - No previous PEP use in the past 6 months
- Participants were randomized an escalating voucher CM intervention or a NCYC intervention. The intervention lasted 8 weeks, and participants were followed prospectively for a total of 6 months (4 months post-intervention).
- Participants experiencing a high-risk exposure to HIV at any time during the 6 month study period could initiate Truvada-based PEP
- PEP-initiators were followed prospectively on an independent timeline of 6 months of follow-up to assess serial HIV status.

Statistical Analyses:
- Generalized linear model were used to estimate the effect of CM on likelihood of PEP course completion, rates of medication adherence, stimulant use, and self-reported sexual risk behaviors.
- All analyses controlled for participant sexual identity, race/ethnicity, housing status, and income.

RESULTS

Figure 2. Participant recruitment and disposition



*30 participants excluded from analysis due to irregularity in data collection
†Acute heroin overdose; unrelated to study procedures.

Table 1. Baseline demographics

		NCYC (n = 70) N (%) or Mean (SD)	CM (n = 70) N (%) or Mean (SD)	Total (N = 140) N (%) or Mean (SD)	Sig.[a]
Race/Ethnicity					
	Caucasian/white	27 (38.6%)	25 (35.7%)	52 (37.1%)	ns
	African American/black	27 (38.6%)	25 (35.7%)	52 (37.1%)	
	Native American	1 (1.4%)	3 (4.3%)	4 (2.9%)	
	Asian/Pacific Islander	2 (2.9%)	1 (1.4%)	3 (2.1%)	
	Hispanic/Latino	11 (15.7%)	14 (20.0%)	25 (17.9%)	
	Multiracial/Other	2 (2.9%)	2 (2.9%)	4 (2.9%)	
Sexual Identity					
	Gay	28 (40.0%)	37 (52.9%)	65 (46.4%)	ns
	Bisexual	39 (55.7%)	31 (44.3%)	70 (50.0%)	
	Heterosexual	2 (2.9%)	0 (0.0%)	2 (1.4%)	
	Other	1 (1.4%)	2 (2.9%)	3 (2.1%)	
Age	Years	35.8 (10.3)	37.9 (11.8)	36.8 (11.1)	ns
Educational Attainment					
	Less than HS	17 (24.3%)	17 (24.3%)	34 (24.3%)	ns
	HS Diploma/GED	28 (40.0%)	26 (37.1%)	54 (38.6%)	
	More than HS	25 (35.7%)	27 (38.6%)	52 (37.1%)	
Annual Income[b]					
	Less than $15,000	63 (90.0%)	54 (78.3%)	117 (84.2%)	ns
	$15,001 - $30,000	4 (5.7%)	7 (10.1%)	11 (7.9%)	
	$30,001 - $60,000	3 (4.3%)	3 (4.4%)	6 (4.3%)	
	More than $60,000	0 (0.0%)	5 (7.3%)	5 (3.6%)	
Housing Status[c]					
	Own/Rent House/Apt.	14 (20.6%)	26 (37.1%)	40 (29.0%)	*
	Group Housing/Sober Living	2 (2.9%)	6 (8.6%)	8 (5.8%)	
	With Family/Friends	13 (19.1%)	12 (17.1%)	25 (18.1%)	
	No Current Address/Homeless	39 (57.4%)	26 (37.1%)	65 (47.1%)	

[a]* p ≤ 0.05; ns = not significant; All sig tests 2-tailed.
[b]One participant declined to state annual income.
[c]Two participants declined to state housing status.

Table 2. Participant stimulant use and sexual risk behavior outcomes

		NCYC (n = 70) Mean (SD)	CM (n = 70) Mean (SD)	Total (N = 140) Mean (SD)	Sig.[a]
Stimulant Use (# Clean Urine Samples)					
	Methamphetamine	6.8 (6.3)	9.2 (9.1)	8.0 (7.9)	p = 0.06
	Amphetamine	7.0 (6.3)	9.4 (9.2)	8.2 (7.9)	p = 0.08
	Cocaine	7.8 (6.2)	9.7 (9.1)	8.7 (7.8)	ns
	Clean for all Stimulants	6.1 (6.1)	8.9 (9.2)	7.5 (7.9)	*
Sexual Risk Behaviors (Past 30 Days)					
	#Male Sex Partners @ Baseline	3.2 (2.8)	6.8 (12.8)	5.0 (9.4)	*
	#Male Sex Partners @ 6m Follow-Up[b]	1.5 (2.0)	1.7 (2.1)	1.6 (2.0)	ns
	Sig.[a]	***	**	***	
	#Times UAI @ Baseline	10.4 (59.9)	3.9 (6.0)	7.2 (42.5)	ns
	#Times UAI @ 6m Follow-Up[b]	4.3 (26.1)	0.8 (1.8)	2.6 (18.8)	ns
	Sig.[a]	ns	***	ns	

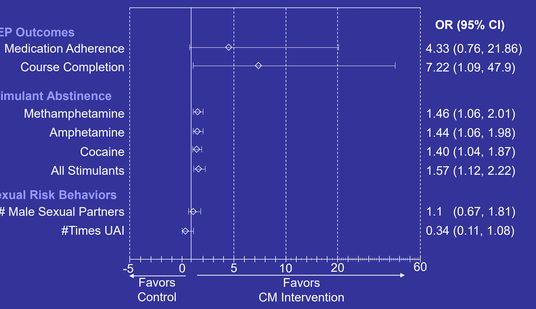
[a]* p ≤ 0.05; ** p ≤ 0.01; *** p ≤ 0.001; ns = not significant; All sig tests 2-tailed.
[b]n = 115 (n_{NCYC} = 59; n_{CM} = 56)

Table 3. Participant intervention- and PEP-related outcomes

		NCYC (n = 70) % or N (%) or Mean (SD)	CM (n = 70) % or N (%) or Mean (SD)	Total (N = 140) % or N (%) or Mean (SD)	Sig.[a]
Attendance	#Visits (out of 24)	6.3 (6.5)	7.8 (8.9)	7.1 (7.8)	ns
Voucher Earnings	#Vouchers (1 = $1)	86.8 (127.7)	112.4 (152.0)	99.6 (140.4)	ns
PEP					
	Initiation	14 (20.0%)	26 (37.2%)	40 (28.6%)	*
	Time from Exposure to Initiation[b]	33.0 (16.1)	32.8 (15.1)	32.9 (15.2)	ns
	Medication Adherence[c]	44.6%	74.7%	61.6%	*
	Course Completion[c]	4 (30.8%)	12 (70.6%)	16 (53.3%)	*

[a]* p ≤ 0.05; ns: non-significant; All sig. tests 2-tailed
[b]Of those that initiated PEP (n = 40)
[c]Of those with valid medication adherence data (n = 30)

Figure 3. Adjusted Odds Ratios (95% CI) for CM vs NCYC (referent) conditions



CONCLUSIONS

- In a randomized controlled trial of stimulant-using MSM, CM facilitated the use of PEP by increasing rates of course completion, and suggesting a trend toward improved adherence
- Reductions in sexual risk afforded by the CM intervention are a prime example of HIV prevention synergy
- Despite small numbers of individuals initiating PEP, findings suggest that CM may be a useful support mechanism for the use of PEP, and potentially other biomedical prophylactic strategies in stimulant-using MSM

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