



Published in final edited form as:

Addict Disord Their Treat. 2012 September ; 11(3): 150–153. doi:10.1097/ADT.0b013e318264cf6d.

The efficacy of escalating and fixed contingency management reinforcement on illicit drug use in opioid-dependent pregnant women

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Abstract

Objectives—Contingency management (CM), long known to be efficacious in the treatment of substance-dependent men and women, has also been found to be efficacious for substance-dependent pregnant women. However, the specific CM reinforcement parameters in the special population of opioid-dependent pregnant women have been less fully and systematically studied. The Drug Abuse Incentive Systems (DAISY) study, a randomized controlled trial (RCT) of opioid-dependent pregnant patients, found that escalating reinforcement was not superior to a fixed reinforcement CM schedule after a 13-week intervention. To further examine CM's reinforcement parameters in this population, this study aims to test the hypothesis that there is an early treatment response showing an escalating reinforcement schedule to be significantly more efficacious than a fixed schedule after 5 weeks of intervention in opioid-dependent pregnant patients.

Methods—Nine measures of opioid and cocaine abstinence among fixed and escalating CM schedule participants in the DAISY RCT ($N=90$) were compared over the initial 5 weeks of the intervention.

Results—No statistically significant difference in the opioid and cocaine abstinence measures was found between escalating and fixed conditions after 5 weeks (14 opportunities for each participant to leave a urine sample). The mean (SD) number of drug negative urine samples was 8.1 (4.5) and 7.4 (4.3), for escalating and fixed groups, respectively ($p=0.46$).

Conclusions—These results further the scientific knowledge regarding CM treatment in opioid-dependent pregnant women by supporting the finding that the escalating and fixed CM schedules produce similar amounts of drug negatives urine samples early in treatment.

Keywords

contingency management; pregnancy; substance use disorders

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Introduction

Contingency management (CM), awarding vouchers for achieving a targeted behavior, is efficacious for improving adherence to substance use treatment in general populations of men and women (1), including substance-dependent pregnant women (2). CM often results in an immediate cessation of drug use; in a meta-analysis of CM reinforcement therapy for substance use disorders, 3 studies with durations of 2 weeks or less and 4 studies with durations of 3-11 weeks had mean weighted effect sizes of 0.38 and 0.40, respectively (3). Therefore, CM of short duration may be especially useful to use with pregnant women, who have a relatively short and defined time to respond to treatment, in order to quickly reduce fetal drug exposure and optimize the goal of both the mother and neonate being drug-free at delivery.

Cocaine and/or heroin use during pregnancy, especially when taken in the context of poverty and psychological distress, are important risk factors for adverse maternal and child outcomes (4, 5). Systematic evaluation of CM parameters to determine optimal intervention models in special populations, such as in methadone-maintained opioid-dependent pregnant women, is needed (1).

The Drug Abuse Incentive Systems (DAISY) study, a randomized controlled trial (RCT), compared the relative efficacy of 13 weeks of escalating versus fixed CM voucher schedules for reducing opioid and cocaine use in methadone-maintained opioid-dependent pregnant women. Drug abstinence, defined as opioid (excluding methadone) and cocaine-negative urine toxicology laboratory test results, was the behavioral target for the DAISY study. A primary objective of the trial was to evaluate the efficacy of the CM schedules for initiating and sustaining abstinence from opioids and cocaine with the hypothesis that the escalating condition would prove superior to the fixed condition (6).

No significant difference in treatment efficacy by CM schedule was observed at 13 weeks (6), but a review of CM has shown it to be efficacious in as little as 1 week (3). In an effort to more fully examine CM's reinforcement parameters in this special population, this study aims to test the hypothesis that an escalating reinforcement schedule shows a superior outcome early on and is significantly more efficacious than a fixed schedule after only 5 weeks of intervention in opioid-dependent pregnant women. To test the hypothesis that there may have been an early effect that was not sustained throughout the 13-week study in this population of opioid-dependent pregnant women, a secondary data analysis was conducted to examine outcomes from the first 5 weeks of treatment. The primary aim of this study is to compare CM efficacy for the escalating and fixed schedules after 5 weeks of the intervention.

Materials and Methods

Participants

Data were obtained from the DAISY parent study, a 13-week RCT of $N=133$ opioid-dependent, agonist-maintained pregnant women (attendance control, $n=43$; escalating CM, $n=52$; fixed CM, $n=38$) (6). All participants were attending treatment for substance use disorders at the Center for Addiction and Pregnancy (CAP) in Baltimore, Maryland (7, 8). Participation was voluntary and all participants signed an Institutional Review Board approved informed consent form. To complete the analysis comparing the efficacy of the CM schedules, only participants randomized to the escalating reinforcement condition and fixed reinforcement condition were included in this secondary data analysis ($N=90$). Participants randomized to the attendance control condition in the parent study were excluded as this analysis did not include comparing the CM conditions to the control

condition. The escalating and fixed reinforcement treatment conditions are described by Tuten et al. (6).

Outcome measures

During the first 5 weeks of CM intervention there were 14 opportunities for each participant to submit urine samples: 2 urine samples were submitted during the first week of the study and 1 sample 3 days per week (every Monday, Wednesday and Friday) for the following 4 weeks. To evaluate opioid and cocaine abstinence, 9 primary outcome measures were examined. Outcome measures were divided into 3 categories: (1) drug abstinence consisting of (a) number of opioid (excluding methadone) and cocaine negative urine samples, (b) time point of first drug-positive urine sample, and (c) longest number of consecutive drug-negative urine samples; (2) opioid (excluding methadone) abstinence, as in (a) – (c); and (3) cocaine abstinence, as in (a) – (c).

Analyses

Demographics and baseline characteristics were gathered for escalating and fixed CM participants. Continuous variables were analyzed using independent sample *t*-tests and categorical variables were analyzed using Fisher's exact test. Continuous and categorical variables measuring opioid and cocaine abstinence at 5 weeks were analyzed using independent sample *t*-tests and Fisher's exact test, respectively. The 5 week time frame was chosen, as opposed to 1 month, to more fully characterize the early response to the intervention, as the first full week of the intervention required participants to be in a more controlled inpatient setting. Missing urine samples from both CM conditions were imputed as positive for all analyses.

Results

In the total sample, the mean age was 30 years and mean educational level was 11 years. Overall, 72% were African American, 73% were unmarried, and 96% were unemployed. Seventy-three percent of participants reported using cocaine and 94% heroin in the 30 days prior to enrollment. There were no significant differences in demographic and baseline characteristics found between escalating and fixed groups, except for race where there were significantly more black participants in the escalating condition, $p = 0.05$ (Table 1). No statistically significant difference in any of the 9 measures of opioid and cocaine abstinence was found between escalating and fixed conditions after 5 weeks. At the end of 5 weeks, there were 14 opportunities for urine samples to be collected per participant and missing urine samples were imputed as positive. The mean (SD) number of drug negative urines were 8.1 (4.5) and 7.4 (4.3), for escalating and fixed groups, respectively ($p = 0.46$) (Table 2).

Discussion

Although this study comparing escalating and fixed CM schedules found that the groups were similar on all measures of opioid and cocaine abstinence at the end of 5 weeks of intervention, Table 2 reports a pattern of results in favor of the escalating schedule. These results further the scientific knowledge regarding CM treatment parameters in opioid-dependent pregnant women by demonstrating that both the escalating and fixed CM schedule result in some abstinence from opioids and cocaine during early treatment.

The study was powered to detect effect sizes of 0.61 or greater and therefore would have detected any clinically significant effects (9). Several factors may have contributed to the similar opioid and cocaine abstinence rates between CM schedules early in the intervention.

The data for this analysis were collected as part of a trial in which the participants were earning vouchers based on their understanding of the trial and their earning potential lasting 13, not 5, weeks. As described by Tuten et al., the absence of a reset mechanism for missed urine collections in the escalating condition as part of the design of the CM intervention may have contributed to the lack of superiority of the escalating schedule over the fixed schedule(6). These findings suggest that both escalating and fixed CM schedules, for durations of 5 and 13 weeks, have similar utility in assisting pregnant patients in achieving opioid and cocaine abstinence.

Acknowledgments

The funding for this study was provided by the National Institute on Drug Abuse (NIDA) R01-DA 14203. NIDA had no further role in study design; in the collection, analysis, and interpretation of data; or in the writing of the manuscript.

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Table 1

Demographic and Baseline Characteristics for Total Sample, Escalating and Fixed CM Schedules

	Total Sample (N=90)	Escalating Reinforcement Condition (n=52)	Fixed Reinforcement Condition (n=38)
Age (years)	30.0 (5.2)	30.8 (5.0)	28.8 (5.3)
		$t=1.81; df=77.1; p=0.07$	
Black	65 (72.2%)	41 (78.8%)	24 (63.2%)
		$p=0.05$	
Never Married	66 (73.3%)	37 (71.2%)	29 (76.3%)
		$p=0.18$	
Unemployed	86 (95.6%)	49 (94.2%)	37 (97.4%)
		$p=0.33$	
Years of Education	11.2 (1.5)	11.1 (1.4)	11.3 (1.5)
		$t=-0.64; df=76.6; p=0.52$	
Number of women with alcohol use in the last 30-days	21 (23.3%)	12 (23.1%)	9 (23.7%)
		$p=0.20$	
Number of women with cocaine use in the last 30-days	66 (73.3%)	41 (78.9%)	25 (65.8%)
		$p=0.07$	
Number of women with cocaine use in the last 30-days	85 (94.4%)	48 (92.3%)	37 (97.4%)
		$p=0.23$	

Notes: Values are $f(\%)$ or $M(SD)$. p -Values refer to comparisons between the escalating and fixed reinforcement conditions and are derived from an independent sample f -test assuming unequal variances and Welch's approximation for calculation of degrees of freedom or from a Fisher's exact test.

Table 2
Means (SD) for Substance Abuse Treatment Variables and p-Values contrasting the two CM Schedules

	Total Sample (N=90)	Escalating Reinforcement Condition (n=52)	Fixed Reinforcement Condition (n=38)	t	df	p-value
Number of drug-negative urine samples	7.8 (4.4)	8.1 (4.5)	7.4 (4.3)	0.75	81.9	0.46
Time point of first drug-positive urine sample	4.1 (4.9)	4.1 (5.1)	4.2 (4.2)	-0.10	86.7	0.92
Longest number of consecutive drug-negative urine samples	6.0 (4.5)	6.6 (4.6)	5.2 (4.2)	1.50	83.7	0.14
Number of opioid-negative urine samples	8.1 (4.2)	8.3 (4.3)	7.7(4.2)	0.66	80.9	0.51
Time point of first opioid-positive urine sample	4.3 (4.9)	4.3 (5.2)	4.2 (4.5)	0.10	85.4	0.92
Longest number of consecutive opioid-negative urine samples	6.2 (4.5)	6.9 (4.6)	5.3 (4.2)	1.71	83.7	0.09
Number of cocaine-negative urine samples	8.4 (4.3)	8.9 (4.3)	7.8(4.3)	1.20	79.9	0.23
Time point of first cocaine-positive urine sample	5.4 (4.9)	6.0 (5.2)	4.6 (4.4)	1.38	86.0	0.17
Longest number of consecutive cocaine-negative urine samples	6.3 (4.5)	7.0 (4.7)	5.4 (4.1)	1.72	85.2	0.09

Notes: Drug-negative was defined as a urine sample negative for opioids (excluding methadone) and cocaine; opioid-negative was defined as a urine sample negative for opioids excluding methadone. Values are M (SD). P-Values refer to comparisons between the escalating and fixed reinforcement conditions and are derived from an independent sample t-test assuming unequal variances and Welch's approximation for calculation of degrees of freedom.