Published in final edited form as:

Contemp Clin Trials. 2012 September ; 33(5): 1074–1079. doi:10.1016/j.cct.2012.06.002.

Pre-Treatment Change in a Randomized Trial with Pregnant Substance-Abusing Women in Community-Based Outpatient Treatment

Steven J. Ondersma,
Wayne State University

Theresa Winhusen, and
University of Cincinnati College of Medicine

Daniel F. Lewis
University of Cincinnati College of Medicine

Abstract

Participants in clinical trials of interventions for substance use frequently show substantial pre-treatment reductions in use. However, pre-treatment change has not been studied among pregnant women, a group with unique motivational characteristics. It is also not clear whether pre-treatment reduction in substance use can be clearly linked to research activities such as pretreatment assessment, or if it is the result of more general factors such as the decision to seek treatment. Using an interrupted longitudinal design, we evaluated pre-treatment change among 148 pregnant women, all of whom had completed a clinical trial comparing motivational enhancement therapy to treatment as usual. When baseline period was compared to the period after randomization and before treatment, the change in substance use was substantial (dropping from an average of substance use on 30.5% of days during baseline to 16.7% of days during the pre-treatment phase; $p < .001$), and was greater in magnitude than change following initiation of study-related treatment. Further, this reduction was significant after controlling for a longitudinal time effect and did not apply to tobacco use. These findings suggest that change following pre-treatment research activities is independent of the decision to seek treatment and is present even among pregnant women, many of whom have already reduced their substance use. These findings also suggest the possible need for re-evaluation of the nature and causes of behavior change, as well as trial design, in clinical trials for substance abuse.

Keywords

substance-related disorders; pregnancy; pregnant women; motivation; clinical trials as topic

© 2012 Elsevier Inc. All rights reserved.

Correspondence regarding this paper should be directed to Steven J. Ondersma, Associate Professor, Department of Psychiatry & Behavioral Neurosciences and Merrill-Palmer Skillman Institute, Wayne State University, 2761 E. Jefferson Ave., Detroit, MI 48207. Phone: 313-444-9797; Fax: 313-993-1372. s.ondersma@wayne.edu.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Introduction

There is substantial evidence that pre-treatment assessment or other elements of clinical trial involvement can themselves result in behavior change [e.g., 1, 2–5]. These effects can be understood in terms of self-regulatory models [6] and Self-Determination Theory [7], a theoretical model that is highly consistent with brief interventions that—much like extended assessment—encourage self-evaluation of the consequences of a given behavior [8].

This phenomenon has yet to be evaluated in pregnant women, a group with unique motivational characteristics [9] that exhibits a pattern of natural substance use reduction during pregnancy [10]. Examination of pre-treatment change in this group could shed important light on methods of intervening with pregnant women, particularly brief interventions. Further, any differences observed could also shed light on motivational processes in other groups.

There is also a need to continue identifying the key factors associated with pre-treatment change. For example, Epstein et al. [5] found that three of five pre-treatment research activities (e.g., telephone screen) were associated with significant reductions in alcohol use, but were unable to disentangle early change associated with an initial intake session from the more basic decision to seek treatment. In doing so, there is also a need to utilize analytic techniques that can detect non-linear change in the context of natural variations in substance use.

Finally, the extent to which pre-treatment change is specific to the behaviors that are targeted by the research study in question (e.g., drug use and abuse) is also unknown. For example, to what extent do changes related to study entry or assessment generalize to other behaviors, such as smoking? Demonstration of specificity could provide important clues in terms of possible explanatory mechanisms for pre-treatment change in behavioral intervention trials.

We therefore evaluated (a) the presence of pre-treatment change; (b) the extent to which that change, if any, could be specifically associated with a baseline assessment and randomization session; and (c) the specificity of any observed change, among a sample of 148 pregnant women from a completed clinical trial. Based on prior findings in non-pregnant samples, and consistent with evidence from the brief intervention literature [11] and Self-Determination Theory [7], we predicted that: (a) pre-treatment change would be present among this sample of pregnant women, despite the likelihood that some natural change had already taken place; (b) substance use would drop during the period between this study's baseline assessment/randomization session and the first treatment session, even after inclusion of a longitudinal time effect and even though all participants had already committed to attending treatment; and (c) this change would be restricted to alcohol and drug use, with no generalization to smoking.

Material and Methods

Participants

Participants in this secondary analysis were 148 of the 200 women recruited during the intake process at substance abuse treatment agencies collaborating with the NIDA Clinical Trials Network on a clinical trial comparing MET to treatment as usual, a study in which no treatment effects were identified [12]. All participants provided written informed consent. To be eligible for the overall study, women had to be (a) at least 18 years of age, (b) pregnant (as confirmed by a pregnancy test) and not planning to terminate the pregnancy, and (c) identified as needing substance abuse treatment via the treatment agency's usual

screening procedure. Exclusion criteria included (a) being more than 32 weeks pregnant, (b) requiring residential or inpatient treatment (other than detoxification), (c) planning to move out of the area within 4 months, (d) being at imminent risk of incarceration, or (e) being a clear risk to self or others. Participants received retail scrip or vouchers worth either \$30 or \$25 for each research-only visit (i.e., not for any treatment sessions), depending on the length of the session. Of the original 200 participants, 148 had their first MET or TAU session at a subsequent visit, after the baseline/randomization session, and so could be included in the present analysis.

Measures

Participant's self-reported use of drugs, alcohol, and tobacco for each day of the study period, beginning with 28 days prior to randomization and continuing through the pre-treatment, during-treatment, and follow-up phases, was assessed using the Timeline Follow-Back (TLFB) procedure [13, 14]. The TLFB data were used to provide a daily use indicator for all analyses.

The Composite International Diagnostic Interview (CIDI; <http://www.crufad.com/index.php/clinician-services/cidi>, archived by WebCite® at <http://www.webcitation.org/5u77EF15S>) was administered during baseline to determine if the participant met DSM-IV criteria for current substance abuse or dependence. Finally, number of days in the past month that the participant experienced psychological problems was assessed by the Addiction Severity Index (ASI)-Lite as administered at baseline. The ASI-Lite, which is derived from the Fifth Edition of the ASI [15], is a structured clinical interview that yields scores for multiple areas of functioning.

Procedure

The study from which these data were derived involved recruitment of pregnant women from pregnant woman-specific programs within community substance abuse treatment agencies in North Carolina, New Mexico, Indiana, and Kentucky. Women were introduced to a research assistant by agency intake staff; those who met the study eligibility criteria described above then completed a baseline research session which in part involved self-report of alcohol, tobacco, and drug use over the past 28 days.

Participants were then (during that same session) randomized into either MET or treatment as usual (TAU) conditions. As noted, in 148 of 200 cases (all cases included in the present analysis), the first MET or TAU session took place at a subsequent visit, after the baseline/randomization session. One hundred and sixteen participants had their first MET / TAU session within the first week after randomization, 20 within the second, 8 within the third, and 4 within the fourth. These sessions took place in the initial phase of treatment, and in the context of a range of other therapeutic activities (See [12] for a full description of study procedures). Notably, all research participants had already completed an administrative intake prior to being recruited into the study.

Statistical analyses

All analyses were completed on the available data from the 148 included participants using SAS, Version 9.1.3 (SAS Institute, Inc). Statistical tests were conducted at a 5% Type I error rate (two-sided) for all measures. For the first hypothesis, improvement from baseline to pretreatment was compared to improvement from pre-treatment to the rest of the active phase using the Wilcoxon signed rank value test.

For hypotheses two and three, the two respective outcomes (daily self-report of drug/alcohol use and daily self-report of cigarette use, both expressed as binary indicators of abstinence

or use) were analyzed using logistic Generalized Estimating Equation models (GEE) with phase (baseline vs. pre-treatment) and time (days since randomization) as covariates. The phase-by-time interaction covariate was evaluated for significance and dropped from the model if non-significant ($p > .10$). The predominant covariate of interest was *phase*, which was treated in GEE analyses as zero for baseline days (the day of randomization plus the 28 days before randomization) and one for pre-treatment days (the days after randomization but before initial MET or TAU treatment). Hypothesis two (a significant drop in substance use following baseline assessment but before treatment) was considered supported if there was a significant phase effect after controlling for the effect of time, with no significant phase-by-time interaction. Hypothesis three (no drop in smoking following the baseline assessment session) was considered supported if there was no significant phase effect or phase-by-time interaction.

Results

Participant characteristics

Of the 148 included participants, 79 (53.4%) were of minority race, 119 (80.4%) were unemployed, and roughly half (82, or 55.4%) had a high school education. Participants averaged 20.7 weeks gestation at randomization and reported, on average, 8.68 days of alcohol / drug use in the past 28 days; 56 (39.4%) tested positive for illicit drugs at study entry (Table 1).

Pre-treatment versus post-treatment change

As seen in Table 2 the weekly percentage of alcohol/drug use days was 30.5% during the baseline period, fell to an average of 16.7% between the baseline and first treatment session, and then averaged 14.5% during the treatment period. Analysis revealed that baseline to pretreatment improvement was significantly greater than during-treatment improvement in this study (Wilcoxon signed rank value = -1140.5, $p < .001$).

Evidence of non-linear post-randomization change

As described earlier, GEE regressions with an interrupted model were used to determine whether alcohol / drug use during pretreatment differed significantly from baseline use. As seen in Figure 1 and Table 3 these regressions demonstrated a significant drop in use in the period between the baseline assessment and first treatment sessions ($\chi^2 = 22.6$; $p < .001$).

Specificity of post-randomization change

The specificity of the association between the baseline assessment/randomization session and alcohol/drug use was examined by applying a similar process to cigarette use, which was also evaluated for each day of study participation using the substance use calendar approach. As also seen in Table 2 and Figure 1 this analysis showed that cigarette use remained unchanged throughout the study period, and more specifically that there was no change from baseline to pretreatment ($\chi^2 = .06$; ns; also see Table 3).

Discussion

We conducted these analyses in order to (a) verify the presence of pre-treatment change among a sample of pregnant women in treatment for substance use; (b) examine the extent to which pre-treatment change, if present, could be associated with a specific baseline research session, among participants who had already decided to enter treatment; and (c) examine whether observed changes were specific to alcohol and drug use or part of a more general trend towards using or reporting less substance use.

These analyses suggest, first, that pre-treatment reductions in drug and alcohol use were clearly present in this sample of pregnant women; that this change eclipsed post-treatment change; and that this change appears to have been non-linear in nature, taking place immediately following the baseline assessment and randomization session. These findings echo those of a other studies showing that (a) substantial change can take place outside of traditional treatment [e.g., 16, 17, 18]; (b) assessment and study enrollment can be associated with reductions in substance use [2, 4, 5]; and (c) change from problem use to abstinence is frequently more sudden than gradual [18, 19].

The present study extends previous work by demonstrating this phenomenon in a sample of pregnant women. Despite (in many cases) already having made spontaneous changes in their substance use, pregnant women nevertheless show reactivity to extended research-related assessment. This study further suggests that this phenomenon may be quite robust, given its presence in a sample that already made the decision to enter treatment and completed an administrative intake before being recruited for the research study. Even brief assessment-based interventions may facilitate change among pregnant women, over and above spontaneous pregnancy-related reductions in use.

Such findings do not in any way call into question the efficacy of traditional treatment approaches. The efficacy of a number of behavioral approaches for problem substance use has been supported in numerous meta-analyses [e.g., 20, 21, 22]. In fact, some have suggested that intensive research-related assessment and other pre-treatment effects may serve to mask the efficacy of interventions in treatment trials [e.g., 2]. However, these findings do suggest that reductions in substance use may be facilitated by a broad range of experiences. Most generally, these experiences all involve the drawing of attention to one's substance use, a process that may itself facilitate change. In this particular instance, the session in question involved overt identification as someone whose substance use is of interest to researchers, an invitation to participate in a treatment study, elicitation of a commitment to participate in that study, agreement to extended monitoring of one's substance use, consideration of the extent and consequences of one's substance use (via extended assessment), and placement into a study condition. Further research should seek to isolate and potentially amplify the key aspects of these elements, keeping in mind the possibility that mere attention to the problem—in perhaps nearly any positive form—may be the most parsimonious explanation for at least part of any subsequent behavior change.

In addition to examining the mechanisms behind pre-treatment change, it is also important to consider how clinical trial methodology might be modified in response to this phenomenon, although of course alternate designs carry their own shortcomings. Minimizing pre-treatment assessment is one possibility, although this step has drawbacks in verification and control of pre-randomization group differences. Alternately, trials could use a washout period to weed out participants exhibiting substantial pre-treatment change, leaving a more recalcitrant sample and thus maximizing the potential to demonstrate differences between active and control conditions. This approach would have the advantage of testing interventions in a context analogous to that of a resource-challenged community agency utilizing a stepped care approach, in which brief motivational interventions act as first-line intervention; it would also be somewhat analogous to an Adaptive Treatment Strategy [23]. Finally, some have argued that single-case designs (such as the multiple baseline design) are under-utilized, given their ability to use each participant as his or her own control [e.g., 24].

Our findings with regard to pre-treatment change also call into question a common method of evaluating linear time-related treatment effects in clinical trial data. As recommended by Liang and Zeiger [25], it is common in longitudinal regressions of clinical trial data to

include the last pre-treatment time point as time-point zero. In trials where treatment begins at randomization, time-point zero would be the point immediately before randomization. In such circumstances, a sudden, non-linear shift at randomization which was not attributed to treatment would make this approach inherently problematic since time-point zero could no longer be modeled as potentially the starting point of a linear trend. This problem could result in hiding linear time-related treatment effects that were actually present.

This study also verified the specificity of the pre-treatment change effect. We found no evidence of reductions in smoking during the pre-treatment phase, whether immediately following the baseline assessment session or at any other time pre-treatment. This suggests that the observed effects with respect to alcohol and drugs may not be solely a function of assessment reactivity, and also that some degree of focused and not incidental attention (perhaps via self-evaluation of consequences or participation in ongoing monitoring) may be necessary for pretreatment change to occur. It is also possible that behaviors with greater stigma and more immediate negative impact are more responsive to attention in the form of assessment.

Limitations

A number of limitations must be highlighted. Perhaps most notably, the number of participants available for analysis was small, limiting the stability and generalizability of the findings. Second, as noted earlier, the data for this secondary analysis were collected as part of a larger clinical trial and not specifically to address the issue of pre-treatment change. A study designed a priori to investigate pre-treatment change may have utilized different measures and/or a different design. For example, randomization into screening only vs. assessment only could allow stronger inferences regarding the causal effect of pre-treatment research assessment [2]. In addition, the need for repeated evaluation of substance use at the daily level necessitated a reliance on self-report, since toxicology testing with this frequency would have been impractical. Finally, the setting of this study necessarily involved limited control over much of participant's treatment. For example, the content of non-study related services received by participants is not known. However, this weakness also lends confidence in the robustness and uniqueness of pretreatment change following research evaluation, which in this study was detectable even in the context of a great degree of variability in treatment experiences.

Conclusions

To our knowledge, this is the first study to demonstrate pre-treatment assessment reactivity among pregnant women. This study also demonstrates that a significant portion of this pre-treatment change was sudden and non-linear, and was observable after controlling for the effect of time and after the decision to begin treatment had already been made. This suggests that the assessment process, in the context of participation in a longitudinal research study, may exert its effects through a mechanism other than by facilitating treatment involvement. It also suggests that these effects may be sudden rather than gradual, and are temporally associated with the introduction of baseline assessment and randomization. Finally, it suggests that these effects may be present even among a sample with a high likelihood of having already undergone significant spontaneous change.

These results suggest that studies of brief interventions may actually be studies of a package of interventions—beginning with identification as a person whose substance use is of interest to investigators, and ending with the final follow-up assessment. This suggestion is supported by the frequency of self-change [16], the inconsistent association between treatment intensity/duration and behavior change [e.g., 26, 27], and the potential power of normative feedback [e.g., 28]. The experiential impact of these small steps may be greater

than previously imagined, making no- or minimal-contact control conditions potentially important in evaluating the true effect of interventions.

Second, these findings underline the necessity of more exploration of the preconditions of pre-treatment change. As important as it is to examine possible preconditions of pre-treatment change, Resnicow and Page [19] suggest that such change may be the result of a highly complex series of interactions between external efforts (such as brief interventions), personal characteristics, substance use severity, state variables, the recency and salience of use-related negative consequences or pro-change messages, etc.; if so, it may suggest that any given precondition may be important only in a relatively rare set of circumstances, making global effects difficult to detect. Despite this likely complexity, such efforts could illuminate factors underlying non-treatment-related change, and in so doing could allow brief intervention efforts to better harness this powerful and efficient phenomenon.

Acknowledgments

This research was supported in part by Joe Young, Sr. funds from the State of Michigan to Wayne State University, and by a series of grants from NIDA as part of the Cooperative Agreement on National Drug Abuse Treatment Clinical Trials Network (CTN) in the Ohio Valley Node (U10DA013732), the North Carolina Node (U10DA013711), and the Southwest Node (U10DA015833). NIDA had no further role in study design or in the collection, analysis and interpretation of data. NIDA Center for the Clinical Trials Network (CCTN) personnel contributed to the design of the original study and CCTN contractors played a role in the collection and analysis of data from the original study. NIDA had no further role in the design of this analysis, in the manuscript writing of the report, or in the decision to submit the paper for publication.

References

1. Carey KB, Carey MP, Maisto SA, Henson JM. Brief motivational interventions for heavy college drinkers: A randomized controlled trial. *Journal of Consulting and Clinical Psychology*. 2006; 74:943–954. [PubMed: 17032098]
2. Kypri K, Langley JD, Saunders JB, Cashell-Smith ML. Assessment may conceal therapeutic benefit: findings from a randomized controlled trial for hazardous drinking. *Addiction*. 2007; 102:62–70. [PubMed: 17207124]
3. McCambridge J, Day M. Randomized controlled trial of the effects of completing the Alcohol Use Disorders Identification Test questionnaire on self-reported hazardous drinking. *Addiction*. 2008; 103:241–248. [PubMed: 18199302]
4. Clifford PR, Maisto SA, Davis CM. Alcohol treatment research assessment exposure subject reactivity effects: part I. Alcohol use and related consequences. *J Stud Alcohol Drugs*. 2007; 68:519–528. [PubMed: 17568955]
5. Epstein EE, Drapkin ML, Yusko DA, Cook SM, McCrady BS, Jensen NK. Is alcohol assessment therapeutic? Pretreatment change in drinking among alcohol-dependent women. *J Stud Alcohol*. 2005; 66:369–378. [PubMed: 16047526]
6. Clifford PR, Maisto SA. Subject reactivity effects and alcohol treatment outcome research. *J Stud Alcohol*. 2000; 61:787–793. [PubMed: 11188483]
7. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *Am Psychol*. 2000; 55:68–78. [PubMed: 11392867]
8. Vansteenkiste M, Sheldon KM. There's nothing more practical than a good theory: integrating motivational interviewing and self-determination theory. *Br J Clin Psychol*. 2006; 45:63–82. [PubMed: 16480567]
9. Ondersma SJ, Winhusen T, Erickson SJ, Stine SM, Wang Y. Motivation Enhancement Therapy with pregnant substance-abusing women: does baseline motivation moderate efficacy? *Drug Alcohol Depend*. 2009; 101:74–79. [PubMed: 19101099]
10. Office of Applied Studies. Substance Use among Women During Pregnancy and Following Childbirth. The NSDUH Report. 2009

11. Burke BL, Arkowitz H, Menchola M. The efficacy of motivational interviewing: a meta-analysis of controlled clinical trials. *J Consult Clin Psychol.* 2003; 71:843–861. [PubMed: 14516234]
12. Winhusen T, Kropp F, Babcock D, Hague D, Erickson SJ, Renz C, et al. Motivational enhancement therapy to improve treatment utilization and outcome in pregnant substance users. *Journal of Substance Abuse Treatment.* 2008; 35:161–173. [PubMed: 18083322]
13. Sobell, LC.; Sobell, MB. *Timeline FollowBack: A Calendar Method for Assessing Alcohol and Drug Use.* Toronto, Ontario: Addiction Research Foundation; 1996.
14. Sobell LC, Agrawal S, Annis H, Ayala-Velazquez H, Echeverria L, Leo GI, et al. Cross-cultural evaluation of two drinking assessment instruments: alcohol timeline followback and inventory of drinking situations. *Subst Use Misuse.* 2001; 36:313–331. [PubMed: 11325169]
15. McLellan AT, Kushner H, Metzger D, Peters R, Smith I, Grissom G, et al. The Fifth Edition of the Addiction Severity Index. *J Subst Abuse Treat.* 1992; 9:199–213. [PubMed: 1334156]
16. Sobell LC, Ellingstad TP, Sobell MB. Natural recovery from alcohol and drug problems: methodological review of the research with suggestions for future directions. *Addiction.* 2000; 95:749–764. [PubMed: 10885050]
17. Sobell LC, Cunningham JA, Sobell MB. Recovery from alcohol problems with and without treatment: prevalence in two population surveys. *Am J Public Health.* 1996; 86:966–972. [PubMed: 8669520]
18. King MP, Tucker JA. Behavior change patterns and strategies distinguishing moderation drinking and abstinence during the natural resolution of alcohol problems without treatment. *Psychol Addict Behav.* 2000; 14:48–55. [PubMed: 10822745]
19. Resnicow K, Page SE. Embracing chaos and complexity: a quantum change for public health. *American Journal of Public Health.* 2008; 98:1382–1389. [PubMed: 18556599]
20. Prendergast ML, Podus D, Chang E, Urada D. The effectiveness of drug abuse treatment: a meta-analysis of comparison group studies. *Drug Alcohol Depend.* 2002; 67:53–72. [PubMed: 12062779]
21. Magill M, Ray LA. Cognitive-behavioral treatment with adult alcohol and illicit drug users: a meta-analysis of randomized controlled trials. *J Stud Alcohol Drugs.* 2009; 70:516–527. [PubMed: 19515291]
22. Dutra L, Stathopoulou G, Basden SL, Leyro TM, Powers MB, Otto MW. A meta-analytic review of psychosocial interventions for substance use disorders. *American Journal of Psychiatry.* 2008; 165:179–187. [PubMed: 18198270]
23. Murphy SA, Collins LM, Rush AJ. Customizing treatment to the patient: adaptive treatment strategies. *Drug Alcohol Depend.* 2007; 88(Suppl 2):S1–S3. [PubMed: 17350181]
24. Kazdin AE. Single-case research designs in clinical child psychiatry. *J Am Acad Child Psychiatry.* 1983; 22:423–432. [PubMed: 6630801]
25. Liang KY, Zeger SL. Longitudinal data analysis of continuous and discrete responses for pre-post designs. *Sankhya: The Indian Journal of Statistics.* 2000; 62:134–148.
26. Moyer A, Finney JW, Swearingen CE, Vergun P. Brief interventions for alcohol problems: a meta-analytic review of controlled investigations in treatment-seeking and non-treatment-seeking populations. *Addiction.* 2002; 97:279–292. [PubMed: 11964101]
27. Lumley J, Oliver SS, Chamberlain C, Oakley L. Interventions for promoting smoking cessation during pregnancy. *Cochrane Database Syst Rev.* 2004;CD001055. [PubMed: 15495004]
28. Riper H, van Straten A, Keuken M, Smit F, Schippers G, Cuijpers P. Curbing problem drinking with personalized-feedback interventions: a meta-analysis. *American Journal of Preventive Medicine.* 2009; 36:247–255. [PubMed: 19215850]

Figure 1.

Mean percentage of substance use days by trial week (number of use days divided by total number of days assessed). The four-week treatment protocol was scheduled to begin during trial week one, and the baseline assessment/ randomization session took place on the first day of trial week one. The four baseline weeks prior to trial week 1 are labeled b1 – b4.

Table 1

Participant Characteristics (N = 148)

Continuous measures	<i>M</i>	<i>SD</i>
Age in years	26.10	5.59
Education in years	11.47	1.58
Weeks pregnant	20.69	7.80
Days of alcohol/drug use at baseline	8.68	10.72
Days (of past 30) with psychological problems	10.53	11.88
Frequencies	<i>n</i>	%
Unemployed	119	80.4 %
Minority Race	79	53.4 %
DSM-IV Abuse/Dependence	58	39.7 %
Depression in the past 6 months	65	43.9 %
Self-report of external pressure to attend treatment	24	16.2%
Primary drug of abuse		
Marijuana	53	35.8%
Cocaine	31	21.0%
Opioids	18	12.2%
Alcohol	13	8.8%
Methamphetamine	10	6.8%
Other	21	14.2%

Table 2
Percentage of Substance Use Days at Baseline, Pre-Treatment, and Post-Treatment Initiation

Time period	Drug / Alcohol Use Days			Cigarette Use Days		
	N	X	SD	X	SD	SD
Baseline	148	30.5%	37.8%	63.1%	45.7%	
Pre-Treatment	148	16.7%	33.6%	63.0%	47.3%	
Post-Treatment Initiation	147	14.5%	29.1%	61.8%	46.2%	

Note. "Baseline" refers to average use during the 4-week period prior to the baseline assessment/randomization session; "Pre-Treatment" refers to average use between the baseline assessment/randomization session and the first treatment session; and "Post-Initial Treatment" refers to average use during treatment.

Table 3
GEE Regressions Testing for the Presence of a Pre-Treatment Phase Shift (Non-Linear Change)

<u>Alcohol / Drugs</u>							
Variable	Estimate	Standard		Z	p	Odds Ratio	
		Error				Upper	Lower
Intercept	-0.644	0.162		-3.99	<.001		
Time	0.013	0.005		2.78	.006	1.01	1.00 1.02
Phase	-0.922	0.175		-5.26	<.001	0.40	0.28 0.56
<u>Cigarettes</u>							
Variable	Estimate	Standard		Z	p	Odds Ratio	
		Error				Upper	Lower
Intercept	0.525	0.164		3.20	.001		
Time	-0.001	0.002		-0.47	.636	1.00	0.99 1.00
Phase	-0.024	0.099		-0.24	.813	0.98	0.81 1.19

Note. Time is measured as the number of days before or after randomization. Phase = 0 indicates the period on or before the day of randomization; Phase = 1 indicates the period after the day of randomization but before the first day of treatment.