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# Treatment process, alliance and outcome in brief versus extended treatments for marijuana dependence

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# Abstract

**Aims**—The Marijuana Treatment Project, a large multi-site randomized clinical trial, compared a delayed treatment control condition with a brief (two-session) and extended (nine-session) multi-component treatment among 450 marijuana-dependent participants. In this report we present treatment process data, including the fidelity of treatment delivery in the three community-based treatment settings as well as the relationships between treatment process and outcome.

**Design**—Independent evaluations of clinician adherence and competence ratings were made based on 633 videotaped sessions from 163 participants. Relationships between clinician adherence and competence, ratings of the working alliance and marijuana treatment outcomes were evaluated.

**Findings**—Protocol treatments were implemented with strong fidelity to manual specifications and with few significant differences in adherence and competence ratings across sites. In the brief two-session treatment condition, only the working alliance was associated significantly with frequency of marijuana use, but in the extended treatment therapist ratings of working alliance predicted outcomes, as did the interaction of alliance and curvilinear adherence.

**Conclusions**—Behavioral treatments for marijuana use were delivered in community settings with good fidelity. Participant and therapist working alliance scores were associated significantly with improved marijuana use outcomes in a brief behavioral treatment for adults with marijuana dependence. In extended treatment the therapist ratings of working alliance were associated with more positive outcome. However, in that treatment there was also a significant interaction between alliance and curvilinear adherence.

# Keywords

Alliance; behavioral treatment; brief treatment; marijuana dependence; Marijuana Treatment Project; treatment process

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Declarations of interest None.

# INTRODUCTION

Marijuana is the most commonly used illicit substance in the United States and accounts for more substance use disorders than any other drug [1–4]. Marijuana use accounts for an increasingly large number of treatment admissions in the United States [5]. Nevertheless, comparatively little is known regarding the efficacy of treatment for marijuana use disorders. Reports from randomized clinical trials evaluating behavioral interventions for marijuana use disorders have begun to appear within the past 15 years [6–9], and generally support the efficacy of those behavioral approaches demonstrated previously to be efficacious for other substance use disorders, including motivational interviewing, cognitive–behavioral approaches and contingency management [10–12].

The Marijuana Treatment Project (MTP) [13] was a large, multi-site randomized controlled trial evaluating the efficacy of brief approaches [9] to marijuana treatment in a diverse patient population. Four hundred and fifty marijuana-dependent individuals were assigned randomly to: (1) a delayed treatment control condition; (2) a two-session brief intervention emphasizing motivational interventions; or (3) a nine-session intervention that integrated motivational enhancement therapy (MET), cognitive-behavioral therapy (CBT) and case management (CM). Regarding treatment outcomes, the group assigned to the nine-session treatment reduced marijuana use significantly more than the group assigned to the twosession treatment, and both groups improved significantly more than those assigned to the delayed treatment control group [13]. Although MTP was a rigorous multi-site trial of manual-guided treatments for marijuana dependence, it was significant in that it also included several design elements intended to enhance the real-world applicability of findings, including the use of community-based settings with diverse patient populations, and study clinicians drawn from the staff at those clinics [14]. This study thus provides an opportunity to address important questions regarding whether treatment integrity can be protected in the context of trials that place greater emphasis on external validity [14]. The first aim of this report is to evaluate the extent to which study treatments were implemented in accordance with manual guidelines and with sufficient fidelity and skill. We anticipated that, as defined in the treatment manuals, there would be a high degree of MET-consistent interventions applied in both the two- and nine-session treatments (i.e. high MET adherence), and that the degree of CBT consistent interventions would increase over time for the nine-session treatment. We also anticipated that using a centralized training strategy would result in limited variability in treatment implementation (mean adherence and skill levels) across sites.

The second aim of this report is to examine process–outcome relationships in these treatments. There has been little investigation to date of the relationship between treatment adherence, therapist competence and the working alliance in predicting drug use outcomes. When adherence has been assessed, in general there has been inconsistent evidence of strong relationships between treatment adherence and outcome [15,16]. However, in a recent evaluation of process–outcome relationships in cocaine treatment, Barber and colleagues [17] reported an interaction effect between alliance and adherence, suggesting a curvilinear relationship between adherence and alliance on treatment outcome. When the working alliance was strong, therapist adherence appeared to have little impact on treatment outcome. Thus, using data from the MTP, we aimed to evaluate the extent to which therapist adherence and competence in delivering treatment, ratings of the working alliance and their interactions were associated with marijuana use outcomes.

# METHODS

#### **Overview of design**

Detailed information about the study design, methods, treatments and main treatment outcomes have been provided in previous reports [13,18–20]. The study was conducted at three out-patient community-based sites. At each site, 150 participants were assigned randomly to one of three treatment conditions. The study treatments were manual-guided [19] and implemented over a 12-week (for extended treatment) or 5-week (for brief treatment) period.

#### **Participants**

Individuals were eligible for the study if they were 18 years of age or older, had a DSM-IV diagnosis of current marijuana dependence and used marijuana on at least 40 of the 90 days prior to screening. Participants were excluded if they had a current DSM-IV diagnosis of dependence on another drug or alcohol. Demographic information for the 450 participants who were randomized to treatment can be found in a previous report [15].

#### Treatments

**Two-session intervention**—The two-session intervention was delivered 1 week and 4 weeks following randomization, with a primary emphasis on MET and secondary emphasis on introducing coping skills.

**Nine-session intervention**—The nine-session intervention was delivered over a 12week period. The first two sessions were intended to be similar to the first two sessions of the two-session intervention. These were followed by seven additional sessions that integrated elements of CBT and CM. Clinicians were encouraged to use a MET interactional style throughout treatment. The CM interventions were intended to broaden the treatment's capacity to meet the needs of a diverse population by helping participants with psychosocial problems to recognize practical barriers to stopping marijuana use, and to develop strategies to reduce those problems.

#### **Clinicians and training**

Clinician training and monitoring was based on methods used in previous multi-site trials for addiction [21,22]. As described in the main outcome paper [15], clinicians participated in a 2<sup>1</sup>/<sub>2</sub>-day didactic seminar, and were assigned four training cases (two nine-session and two two-session). Training sessions were videotaped for review, process ratings and supervision. During the main phase of the trial, all treatment sessions were videotaped for ongoing supervision.

Eleven clinicians were trained and certified to perform both study treatments. Ninety-one percent had master's degrees; 9% had bachelor's degrees. Six (55%) were female, all were Caucasian, and their average age was 44 years. Clinicians reported an average of 8.7 years of clinical experience, and most reported that they had had some previous exposure to motivational interviewing (73%), cognitive–behavioral therapy (82%) or case management (82%). Thus, these clinicians are similar to clinicians in other community-based settings participating in clinical research in the United States [23,24].

#### Assessments

**Participant assessments**—Diagnoses of substance abuse and dependence were determined by means of the Structured Clinical Interview for DSM-IV (SCID) [25]. The baseline and follow-up interviews also included the Addiction Severity Index (ASI) [26] and

the Time-Line Follow-Back (TLFB) interview [27] was used to measure the frequency and pattern of marijuana use.

**Process assessments**—The Yale Adherence and Competence Rating Scale (YACS) [28] was used to assess therapist adherence (levels of delivery of manual-specified interventions) and competence (skill in delivering intervention). The YACS has been validated, refined and used in multiple studies and shown be highly sensitive to variations in process and its ability to detect differences across treatment settings and treatment approaches [11,29–33]. The YACS is comprised of multiple scales; several scales assess interventions common to many behavioral treatments for substance use disorders (e.g. assessment of substance use and general functioning, provision of support), while other scales are treatment-specific (e.g. interventions associated with treatments such as CBT, MET, Twelve-Step facilitation).

For each item, raters use two seven-point Likert-type scales: first, they rate the extent to which the intervention was present in the session (adherence rating), with scores ranging from [1] 'intervention did not occur' to [7] 'present to a very high degree/dominated the session'. Secondly, they rate the skill with which the clinician delivered the intervention (competence rating), with scores ranging from 'very poor' [1] to 'excellent' [7]. The YACS has been found to be reliable in previous studies, with a mean intraclass correlation coefficient (ICC) estimate of 0.87 for the adherence dimension and a mean ICC estimate of 0.86 for the competence dimension across scales [28,34,35]. For the present study, five YACS scales were used; three treatment-specific (MET, CBT, CM) and two general (structure and facilitative conditions) scales.

Independent YACS ratings were completed using session tapes from one-half of the randomized sample (77 of the 146 participants assigned to the two-session treatment; 86 of the 156 participants assigned to the nine-session treatment). All available sessions for these participants were rated, resulting in a process evaluation sample of 633 sessions from 163 participants. Process raters were eight master's level clinicians who had participated in the original psychometric evaluations of the YACS and multiple process evaluation studies in the past. Raters were blind to the participants' treatment assignment and were trained through review of the rating manual and several practice ratings to achieve consensus.

The working alliance was evaluated using the client and therapist versions of the Working Alliance Inventory (WAI), administered after session 2 [36]. The WAI has been shown to have good factor structure, reliability, concurrent and predictive validity in several studies, including those with substance users [37–39]. Session 2 is a commonly used time-point for measuring the alliance, and scores collected at this time-point have been shown previously to predict treatment outcome [29].

#### Data analysis

To evaluate the psychometric properties of the adapted YACS, inter-rater reliability was evaluated using intraclass correlation coefficients (ICCs) on nine randomly selected sessions that were rated by all eight raters (e.g. a complete block design). With eight raters and an expected ICC of 0.85, we calculated the approximate number of subjects required with an alpha of 0.05 and a confidence interval width of 0.3 using the Bonett formula for ICC sample size estimation [40]. The sample size approximation came to 8. Simple correlations were used to evaluate relationships among and between the adherence and competence scales of the YACS. Simple correlations and analysis of variance (ANOVA) models were used to evaluate relationships of specific process variables (e.g. YACS and WAI scores) with treatment outcome (e.g. frequency of marijuana use, operationalized as percentage of days of marijuana use). Random regression models [41] were used to evaluate change in

YACS scores over time and relationships between YACS, WAI, and marijuana use outcome measures.

# RESULTS

#### Psychometric evaluation of the adherence/competence scale

Using the Shrout & Fleiss [42] fixed-effects model to estimate inter-rater reliabilities for independent samples, the five YACS scales were found to be reliable. Intraclass correlation coefficients ranged from 0.75 to 0.95 for the adherence dimension and from 0.85 to 0.91 for the competence dimension across the scales. Confirmatory factor analyses using the adherence dimension indicated that the hypothesized structure of the scales resulted in good-fitting models for all scales. The five adherence scales satisfied the criteria for evaluating goodness of fit GFI) [e.g.  $\chi^2$ /degrees of freedom ratio of less than 2, all had GFI and comparative fit (CFI) indices of 0.9 or above] [43].

#### Fidelity: clinician adherence and competence

In order to compare directly session content for the two treatments, Table 1 presents YACS ratings for the two-and nine-session treatments for both the adherence and competence dimensions. For session 1, mean CBT adherence scores were significantly higher in the two-session treatment than the nine-session treatment and structure (STR) scores were significantly higher in the nine-session treatment than the two-session treatment. MET, CM and facilitative condition (FC) scores were not significantly different by condition. On the competence dimension for session 1, both MET and STR scores were higher for the nine-session treatment, and there were no differences in CBT, FC or CM competence by treatment. There were no significant differences in session 2 scores by condition for either the competence or adherence dimensions of any of the scales. Overall, these ratings compare favorably with ratings obtained by previous multi-site trials of CBT and MET involving doctoral-level therapists [28,34,44].

Random effect regression analyses were used to evaluate change in adherence scores over time for the 86 participants in the nine-session treatment (raw data are presented in Fig. 1). There were significant effects for time for the MET ( $t_{(484)} = -8.32$ , P < 0.01), CBT ( $t_{(478)} = 6.4$ , P < 0.01) and STR scales ( $t_{(487)} = -3.34$ , P < 0.01), suggesting significant decreases in MET and STR scores over time and increases in CBT scores over time, which was consistent with manual guidelines and our hypotheses. Effects of time for the CM and FC scales were not significant, indicating that delivery of these elements was comparatively stable across time.

Mean CM scores were comparatively low across time (although they peaked early in treatment, as prescribed in the manual). Exploratory analyses suggested that these interventions were used as intended, and there was a strong relationship between pretreatment ASI composite scores and delivery of CM, where participants who had a mean CM score of 2 or more had significantly higher baseline ASI psychological composite scores than those with lower mean CM scores (mean baseline ASI psychological composite 0.30 versus 0.12, F = 11.58, P = 0.001) and ASI employment composite scores (mean 0.44 versus 0.24, F = 9.20, P = 0.003). That is, there appears to have been a relationship between baseline severity and therapist application of CM whereby participants who had more severe symptoms at baseline were treated with more CM.

In terms of YACS ratings for the two-session treatment, CM, structure (STR) and facilitative conditions (FC) adherence scores increased from session 1 to session 2 (n = 44, P = 0.05) and, as anticipated, MET scores decreased between the two sessions (3.6 to 2.9, F = 11.70, P = 0.00, df = 1,43).

#### Site differences

Site differences were evaluated using ANOVA models and are presented in Table 2. For the adherence scales, there were no significant site effects in the two-session treatment. There were two statistically significant site effects for the nine-session treatment, where mean MET and FC

scores differed by site. Regarding competence ratings, there were no significant site differences in the two-session treatment. For the nine-session treatment, CBT and STR scores were significantly higher in site 3 versus site 2. Overall, however, the comparatively few site effects seen, given the number of comparisons (three sites  $\times$  two dimensions  $\times$  five scales), suggests that the training and monitoring protocol in this trial was associated with consistent delivery of the protocol treatments. Similarly, ANOVA models were used to evaluate whether there were significant differences across the 11 clinicians in adherence and competence ratings, or outcome (percentage of days using marijuana). Overall, even using liberal *P*-values (<0.20) as suggested by Crits-Christoph & Mintz [45] to evaluate therapist effects, few differences were found.

#### **Process-outcome relationships**

Table 3 provides simple correlations between adherence and competence ratings and the main outcome measure, percentage of days of marijuana use. For the two-session treatment, only the FC scale was associated significantly with outcome, where higher mean FC adherence and competence scores were associated with fewer days of marijuana use. In the nine-session treatment, higher mean MET adherence and competence scores were correlated significantly with more days of marijuana use. Similarly, higher mean CM scores were correlated significantly with more days of marijuana use.

#### Relationships between adherence, competence and outcome

In order to explore further the relationships between adherence and competence and outcome, general linear regression models were used to predict drug treatment outcome (percentage of days in treatment that marijuana was used) from YACS adherence and competence ratings. Baseline marijuana was included as a covariate all these analyses. For these analyses, only MET adherence and competence were considered, because MET was the primary active intervention in both the brief and extended treatments.

**Does adherence predict outcome in a linear or curvilinear fashion?**—In both the two-session and nine-session treatments, linear adherence (e.g. mean MET adherence score) did not predict outcome (two-session: t = 0.40, P = 0.69, nine-session: t = 1.44, P = 0.15). Similarly, adherence was not a curvilinear predictor of outcome in either treatment (two-session: t = 0.21, P = 0.83, nine-session: t = 1.73, P = 0.09).

**Does competent delivery of treatment predict outcome?**—Competence in delivering MET did not predict treatment outcome in either treatment (two-session: t = 1.12, P = 0.27, nine-session: t = 1.19, P = 0.24).

**Do adherence and competence together predict outcome?**—We investigated whether competence had an additive effect with adherence in predicting outcome. In a model predicting outcome from both adherence and competence, the inclusion of both terms again failed to predict outcome (two-session: adherence: t = -0.71, P = 0.48, competence: t = 1.26, P = 0.21; nine-session: adherence: t = 1.83, P = 0.07, competence: t = -1.06, P = 0.29).

**Does the interaction of adherence and competence predict outcome?**—In both treatments, the interaction between adherence and competence was not a significant predictor of treatment outcome (two-session: t = -0.46, P = 0.65, nine-session: t = 0.69, P = 0.49).

# Working alliance ratings

Overall, participant rated WAI-C scores were high across the bond, task and goal subscales (mean scores for the nine-session treatment were, respectively, 6.0, 6.1 and 6.1 on the sevenpoint Likert scale). There were no significance differences between the two-session and nine-session treatments from the participant perspective (bond F = 0.85, task F = 0.05, goal F = 0.09). However, WAI-T scores indicated that from the clinicians' perspective, bonds (F = 4.6, P = 0.04), tasks (F = 6.1, P = 0.02) and goals (F = 4.5, P = 0.04) were all rated more positively after the second session in the nine-session versus the two-session treatment. In both treatments, ratings from the clinicians' perspective (WAI-T scores) were somewhat lower than the participant ratings (WAI-C scores) and, as in previous evaluations [37,38], correlations of participant and therapist from the same sessions were only moderate (0.28 for the two-session treatment and 0.34 for the nine-session treatment).

The relationship of the working alliance and outcome was examined using general linear models. In the two-session treatment, participant-rated alliance predicted outcome (t = -2.97, P < 0.001) significantly, with better alliance predicting fewer days of marijuana use. Therapist-rated alliance was also related significantly to outcome (t = -3.68, P < 0.001). In the nine-session treatment, however, patient-rated alliance did not predict days of marijuana use (t = -0.81, P = 0.41), but therapist-rated alliance predicted significantly fewer days of marijuana use (t = -2.25, P = 0.03).

Finally, we examined the interaction between adherence and alliance. In both treatments, the interaction of linear adherence and alliance failed to predict treatment outcome (two-session: t = 1.74, P = 0.09, nine-session: t = -0.21, P = 0.84). We also examined the interaction of curvilinear adherence and alliance in predicting outcome, as hypothesized above. In the two-session treatment this interaction did not predict treatment outcome significantly (t = 1.68, P = 0.10). However, in the nine-session treatment this interaction predicted outcome significantly (t = 2.77, P = 0.01).

### DISCUSSION

Several aspects of treatment process were evaluated in a large multi-site trial of brief (twosession MET/CBT) and extended (nine-session MET/CBT/CM) behavioral treatments for marijuana dependence. In general, the multi-component treatments appeared to be implemented with good fidelity to manual specifications. Mean scale scores for the MET and CBT scales, as well as the general, non-specific scores (structure and facilitative conditions), were comparable to those in previous studies which used more highly trained and closely supervised clinicians [28,34]. There were very few significant differences in adherence, competence and working alliance ratings across the three treatment sites and little evidence of meaningful variability due to therapist effects.

As one of the first multi-site clinical trials for marijuana dependence using an effectiveness model, MTP is notable in several respects. In particular, it was implemented in three community-based treatment settings, recruited a more diverse sample of participants than seen in previous studies of marijuana users, and the treatments were implemented by predominantly master's-level counselors drawn from community-based programs. The data suggest that the treatments were delivered largely as defined in the manual, site effects were minimal and treatments were well accepted by participants. These findings suggest that

studies that emphasize external validity need not necessarily do so at the expense of internal validity. One limitation of the current study was that complete adherence and competence ratings were completed for only half the study sample. However, this sample was relatively large, was selected randomly and included all participating clinicians, and a comparable proportion of participants from the three sites. MTP is also notable in its implementation of an integrated multi-component treatment. When we examined the relationship between treatment fidelity and treatment outcome, the data suggested that adherence, competence and their combination were not associated strongly with marijuana use outcomes. This may reflect, in part, the limited range of variability in adherence and competence scores (that is, fairly high adherence and competence were found across the board) that may result in limited impact on treatment outcome [46] in controlled trials.

One treatment dimension that has been associated consistently with better outcomes is the working alliance [47,48]. In this study, both participants' and therapists' working alliance scores were associated significantly with marijuana use outcomes in the two-session intervention. In the nine-session treatment participant-rated alliance did not predict outcome, but higher therapist-rated alliance was associated significantly with fewer days of marijuana use. However, in the nine-session treatment, there was a significant interaction effect between alliance and curvilinear adherence. When alliance was high adherence had less impact on outcome, but when alliance was weaker, therapist adherence to treatment was substantially more influential. This replicates that seen in psychosocial treatment for cocaine [49].

One possibility for the differential findings in the two forms of treatment is that, in the twosession treatment, clinicians had little time to work with participants and implement interventions, so the quality of the relationship played a comparatively large role in outcome. However, in the nine-session treatment the working alliance was only part of a larger array of interventions and processes. In effect, these data suggest that alliance was, to some extent, a 'necessary but not entirely sufficient' treatment component in this trial. That is, the MTP data suggest that there may be a certain minimal level of alliance, below which specific interventions may be of limited use in fostering positive change. Given a sufficient level of alliance, however, use of specific, empirically grounded interventions may be able to exert their effects. At the other end of the continuum, at very high levels of alliance, the effect of those interventions may be more difficult to determine.

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# Figure 1.

Mean adherence scores across time, extended (nine-session) treatment; n = 86. MET: motivational enhancement therapy scale; CBT: cognitive-behavioral therapy scale; CM: case management scale; STR: structure scale; FC: facilitative conditions scale.

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Table 1

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Table 2

Mean adherence and competence ratings by site.

	Site 1		Site 2		Site 3				
	Mean	SD	Mean	SD	Mean	SD	F	df	Р
2-session	n treatmen	t, adhere	ence dime	ension					
CBT	2.29	0.59	2.45	0.84	2.61	0.84	1.22	2,74	0.30
MET	3.31	0.76	3.33	0.57	3.33	0.67	0.01	2,74	0.99
CM	1.32	0.40	1.25	0.34	1.35	0.55	0.34	2,74	0.72
FC	3.57	0.78	3.22	0.74	3.36	0.67	1.42	2,74	0.25
STR	3.00	0.53	2.73	0.35	3.10	0.74	2.73	2,74	0.07
9-session	n treatmen	t, adhere	ence dime	ension					
CBT	2.19	0.51	2.38	0.56	2.51	0.59	2.34	2,83	0.10
MET	2.50	0.78	2.87	0.70	2.90	0.53	3.05	2,83	0.05
CM	1.53	0.47	1.56	0.46	1.56	0.39	0.04	2,83	0.96
FC	3.42	0.45	3.19	0.46	3.51	0.56	3.11	2,83	0.05
STR	3.07	0.50	3.08	0.36	3.26	0.31	1.75	2,83	0.18
2-session	treatmen	t, compe	etence dir	nension					
CBT	2.20	0.78	2.33	1.12	2.70	06.0	2.11	2,74	0.13
MET	3.67	0.82	3.58	0.70	3.57	0.85	0.12	2,74	0.88
CM	1.38	0.77	1.22	0.47	1.33	0.48	0.25	2,40	0.78
FC	3.61	0.92	3.28	0.69	3.49	0.65	1.12	2,74	0.33
STR	2.83	0.59	2.60	0.56	2.96	0.85	1.78	2,74	0.18
9-session	treatmen	t, compe	etence dir	nension					
CBT	2.07	0.55	2.12	0.66	2.48	0.64	3.29	2,83	0.04
MET	2.91	0.80	3.15	0.73	3.32	0.67	2.12	2,82	0.13
CM	1.44	0.56	1.28	0.42	1.49	0.49	1.31	2,79	0.28
FC	3.57	0.58	3.34	0.52	3.72	0.68	2.70	2,83	0.07
STR	3.18	0.52	3.07	0.44	3.45	0.43	4.29	2,83	0.02

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CBT: cognitive-behavioral therapy scale; MET: motivational enhancement therapy scale; CM: case management scale; FC: facilitative conditions scale; STR: structure scale.

#### Table 3

Relationship between mean adherence and competence scores and outcome (percentage days of marijuana use), simple correlations.

Scale	r	
2-session treatment ( $n = 77$ )		
Adherence sco	ores	
Mean CBT	-0.082	
Mean MET	0.069	
Mean CM	-0.075	
Mean STR	-0.145	
Mean FC	-0.283*	
Competence s	scores	
Mean CBT	-0.12	
Mean MET	-0.04	
Mean CM	-0.186	
Mean STR	-0.0073	
Mean FC	-0.256	
9-session treatment ( $n = 86$ )		
Adherence scores		
Mean CBT	-0.182	
Mean MET	0.415 **	
Mean CM	0.322 **	
Mean STR	0.198	
Mean FC	0.006	
Competence scores		
Mean CBT	-0.112	
Mean MET	0.273 **	
Mean CM	0.133	
Mean STR	0.089	
Mean FC	0.04	

CBT: cognitive-behavioral therapy scale; MET: motivational enhancement therapy scale; CM: case management scale; FC: facilitative conditions scale; STR: structure scale.

 $^{*}P < 0.05;$ 

\*\* P<0.01.