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## Primary Outcomes in Two Randomized Controlled Trials of Treatments for Cannabis Use Disorders

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### Abstract

**Background**—While several randomized controlled trials evaluating a range of treatments for cannabis use disorders have appeared in recent years, these have been marked by inconsistency in selection of primary outcomes, making it difficult to compare outcomes across studies.

**Method**—With the aim of identifying meaningful and reliable outcome domains in treatment studies of cannabis use disorders, we evaluated multiple indicators of marijuana use, marijuana problems, and psychosocial functioning from two independent randomized controlled trials of behavioral treatments for cannabis use disorders ( $Ns = 450$  and  $136$ ).

**Results**—Confirmatory factor analysis indicated that the best-fitting model of outcomes in both trials encompassed three distinct factors: frequency of marijuana use, severity of marijuana use, and psychosocial functioning. In both trials, frequency of marijuana use and longest period of abstinence during treatment were most strongly associated with outcome during follow-up. Using two categorical definitions of “clinically-significant improvement,” individuals who demonstrated improvement differed on most end-of-treatment and long-term outcomes from those who did not improve.

**Conclusions**—Results may guide future randomized controlled trials of treatments for cannabis use disorders in the collection of relevant end-of-treatment outcomes and encourage consistency in the reporting of outcomes across trials.

### Keywords

cannabis use disorder; marijuana; treatment; primary outcome

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## 1. Introduction

Cannabis dependence has been recognized as the most common illicit drug use disorder in the United States for many years (Anthony et al., 1994; Kandel et al., 1997; Substance Abuse and Mental Health Services Administration, 2009), and there has been a two-fold increase in treatment admissions for cannabis use disorders in the past decade (Substance Abuse and Mental Health Services Administration, 2008). Until recently, however, there were relatively few trials evaluating treatments for cannabis dependence. To date, 13 randomized controlled trials evaluating behavioral and pharmacologic treatments for cannabis use disorders have been conducted, most of which have appeared in the past five years (Budney et al., 2000; Budney et al., 2006; Carpenter et al., 2009; Carroll et al., 2006; Copeland et al., 2001; Kadden et al., 2007; Levin et al., 2004; Levin et al., in press; McRae-Clark et al., 2009; Stephens et al., 2000; Stephens et al., 2007; Stephens et al., 1994; The Marijuana Treatment Project Research Group [MTP], 2004).

Selection of appropriate outcomes in trials of treatments for substance use disorders is a complex area where there is still controversy as to treatment goals (e.g., total abstinence vs. reduction in use), as well as the number and type of domains that should be evaluated (e.g., drug use vs. consequences of use vs. psychosocial functioning) (Carroll and Rounsaville, 2002; Donovan and Marlatt, 2005). Thus, as would be expected for any emerging field, there is no clear consensus regarding domains that describe primary outcomes in clinical trials for cannabis use disorders. Table 1 indicates the wide variety of outcomes that have been reported in the existing randomized trials. The most commonly reported outcomes were duration of abstinence and frequency of marijuana use, and most trials collected outcomes based on both self-report and urine toxicology data. There is a great deal of variability across studies in number (e.g., the range of outcomes reported was 6-11) and type of outcomes (e.g., psychosocial functioning was assessed with nine different self-report measures).

With an expanding focus on developing new treatments and making existing treatments more powerful (Vandrey and Haney, 2009), greater consistency in selection and reporting of outcome domains for marijuana treatment trials is desirable for several reasons. First, consistent reporting of outcomes would clarify patterns and magnitude of treatment effects, thereby facilitating comparisons across studies that differ in setting, sample characteristics, and comorbid problems. Second, greater uniformity in indicators of outcome is important for meta-analytic examination of the efficacy of treatments for cannabis use disorders and for comparative effectiveness studies (Jones et al., 1996; Lauer and Collins, 2010). Finally, consistent use of outcomes is important for “benchmarking,” i.e., comparing outcomes from well-controlled randomized trials to clinical practice (McLellan et al., 2007).

Standards for the reporting of outcomes exist in the treatment of other substances of abuse, including tobacco (College of Problems of Drug Dependence, 1999; Hughes et al., 2003) and alcohol (Allen, 2003; Babor et al., 1994; College on Problems of Drug Dependence, 1999; Kadden and Litt, 2004), and have greatly facilitated comparative evaluations in their fields (e.g., The Cochrane Reviews). In general, the process for developing greater standardization in measuring and reporting outcomes has been guided by expert consensus. An alternative strategy for developing a consistent standard for outcome reporting is via empirical analysis of different outcome indicators. An empirically-driven approach has several potential advantages, including using psychometric analyses of patterns within and across studies and maximizing the possibility of identifying meaningful behavioral changes that can be attributed to the effects of treatment. One example of an empirical approach is McKay and colleagues' evaluation of outcomes in cocaine treatment (McKay et al., 2001). Using confirmatory factor analysis, McKay et al. found that two factors of frequency and

severity of use best represented cocaine treatment outcomes. More recently, Falk and colleagues evaluated outcomes in alcohol treatment by computing effect sizes and assessing the long-term predictive power of end-of-treatment outcomes (Falk et al., 2010).

In this report we describe an empirical analysis of outcomes in two independent randomized controlled trials of treatments for cannabis use disorders (Carroll et al., 2006; MTP, 2004). We address the following four questions:

(1) What are the key end-of-treatment outcome domains? Based on previous research (McKay et al., 2001), we hypothesized that outcomes would encompass two domains of frequency and severity of marijuana use. Because treatments for cannabis use disorders may ameliorate psychosocial problems (e.g., Budney et al., 2000; Budney et al., 2006; Carroll et al., 2006; Copeland et al., 2001; Kadden et al., 2007; MTP, 2004; McRae-Clark et al., 2009; Stephens et al., 1994; Stephens et al., 2000), we hypothesized that outcomes would also include a third domain of psychosocial functioning.

(2) What is the relation between indicators of end-of-treatment outcome domains and a proxy for longer-term outcomes? Based on existing literature (Budney et al., 2000; Budney et al., 2006; Carroll et al., 1994; Higgins et al., 2000; McKay et al., 1999), we hypothesized that frequency of marijuana use and duration of continuous abstinence during treatment would be strongly related to longer-term outcome.

(3) What is the effect size associated with these outcomes? Few prior randomized controlled trials of treatments for cannabis use disorders have provided effect sizes associated with end-of-treatment outcomes (Budney et al., 2000; Carroll et al., 2006; Stephens et al., 2007); thus, there is a need for more information regarding which outcomes may be most sensitive to the effects of treatment.

(4) How can we assess clinically-significant improvement? Most of the prior trials of treatments for cannabis use disorders have reported that reduction of marijuana use is a more common outcome than complete abstinence (Budney et al., 2006; Carpenter et al., 2009; Copeland et al., 2001; Levin et al., 2004; Stephens et al., 1994); however, there is no agreement about how to determine clinically-significant reduction of marijuana use. Three prior studies (Stephens et al., 1994; MTP, 2004; Carroll et al., 2006) have offered possible definitions of clinically-significant improvement, and with the two trials in this analysis we were able to examine two of these definitions (Carroll et al., 2006; Stephens et al., 1994). With each definition of improvement, we examine whether the prevalence of individuals who were classified as “improved” differed between treatment groups and whether “improved” individuals reported better end-of-treatment and long-term outcomes than those who were classified as “not improved.”

## 2. Method

### 2.1 Trials

Data were drawn from two independent randomized controlled trials of behavioral therapies for adults with cannabis use disorders. As described below, the studies shared a number of outcome measures, although their sample, design, and interventions varied.

**2.1.1 Marijuana Treatment Project (MTP)**—MTP (2004) was a large multisite randomized clinical trial conducted between 1996 and 1999. Participants were 450 individuals who were 18 years of age or older and were seeking treatment for their marijuana use at outpatient facilities in Farmington, Connecticut; Miami, Florida; and Seattle, Washington. Individuals who met criteria for a cannabis use disorder were randomly

assigned to one of three individual treatments: (1) a 2-session motivational enhancement therapy (MET); (2) a 9-session multicomponent treatment that added cognitive-behavioral therapy and case management to MET sessions; or (3) a delayed treatment control condition in which participants could choose to receive either of the two treatments after a 4-month waiting period (Steinberg et al., 2005; Stephens et al., 2002). Participants (mean age = 36 years) were predominantly male, European-American, single, and employed full-time.

MTP participants were assessed at baseline and at 4-, 9-, and 15-months after the start of treatment. Self-reports of substance use were collected via the Timeline Follow-back (TLFB) method (Sobell and Sobell, 1992), and urinalysis verified self-reports of marijuana abstinence collected at each assessment. Problems associated with marijuana use were assessed with the Marijuana Problems Scale (MPS; Stephens et al., 2000). Psychosocial functioning was assessed with the Addiction Severity Index (ASI; McLellan et al., 1992), the Beck Depression Inventory (BDI; Beck et al., 1961), and the state portion of the State-Trait Anxiety Inventory (STAI; Spielberger et al., 1983).

**2.1.2 Marijuana Yale Study (MJ Yale)**—Participants in the MJ Yale study (Carroll et al., 2006) were 136 individuals between the ages of 18 and 25 years who were referred for treatment for cannabis dependence in New Haven, Connecticut. They were randomly assigned to one of four individual weekly treatments: (1) a motivational/skills-building approach (MET/CBT; MTP, 2004; Steinberg et al., 2005) plus voucher-based contingency management in which participants received vouchers contingent on session attendance or submission of marijuana-free urine specimens (CM; Budney and Higgins, 1998; Higgins et al., 1991); (2) MET/CBT without CM; (3) manualized drug counseling (DC; Baker, 1998; Mercer and Woody, 1999) plus CM; and (4) DC without CM. Participants (mean age = 21 years) were predominantly male, minority, single, and unemployed.

MJ Yale participants were assessed at baseline, weekly during treatment, and at 6-month follow-up. Self-reports of substance use were collected via the TLFB method (Sobell and Sobell, 1992), and urinalysis verified self-reports of marijuana abstinence. Problems associated with marijuana use were assessed with the MPS (Stephens et al., 2000). Psychosocial functioning was assessed with the ASI (McLellan et al., 1992) and the Brief Symptom Inventory (BSI; Derogatis, 1993). Because ASI items on drug use were revised to gather information for marijuana use specifically, outcomes of ASI Marijuana, rather than Drug, composite scores are reported.

## 2.2 Outcomes

Because the two trials assessed end-of-treatment outcomes at different time points (i.e., 16 weeks after the start of treatment in MTP and 8 weeks after the start of treatment in MJ Yale), outcomes were examined separately. Descriptive data on treatment outcomes are available in previous reports (Carroll et al., 2006; MTP, 2004).

**2.2.1 MTP**—The following outcome variables were computed for each participant: (a) number of self-reported days of marijuana use in week 16 (TLFB); (b) percent days of self-reported marijuana abstinence in the prior 90 days (TLFB); (c) maximum number of consecutive days of marijuana abstinence during treatment (TLFB); (d) Drug composite scores (ASI); (e) Psychological composite scores (ASI); (f) number of marijuana problems (MPS); (g) sum of state anxiety symptoms (STAI); and (h) sum of depression items (BDI).

**2.2.2 MJ Yale**—The following outcome variables were computed for each participant: (a) number of self-reported days of marijuana use in week 8 (TLFB); (b) percent days of marijuana abstinence during treatment (TLFB); (c) maximum number of consecutive days of

marijuana abstinence during treatment (TLFB); (d) Marijuana composite scores (ASI); (e) Psychological composite scores (ASI); (f) number of marijuana problems (MPS); (g) scale score of anxiety symptoms (BSI); and (h) scale score of depression symptoms (BSI). Outcomes of (i) percent of marijuana-negative urine specimens during treatment, and (j) maximum number of consecutive marijuana-negative urine specimens during treatment were computed from urinalysis data.

### 2.3 Data Analysis

Pearson correlations examined the relations between the end-of-treatment outcomes in each trial. Confirmatory factor analysis (CFA) with AMOS 19 tested the relative fit of competing factor models of outcomes in each trial, testing the hypothesized 3-factor solution [(1) frequency of marijuana use, (2) severity of marijuana use, and (3) psychosocial functioning] against an alternative model of a 1-factor solution of all outcomes. Multiple fit statistics were estimated for each model. A nonsignificant chi-square statistic in the chi-square goodness-of-fit test for a model suggested that the model provided an adequate representation of the data. The goodness-of-fit indices (i.e., goodness-of-fit index [GFI; Joreskog and Sorbom, 1989], normed comparative fit index [CFI; Bentler, 1990], incremental fit index [IFI; Bollen, 1989]) ranged from zero to one, with higher values indicating better fit; indices with values of 0.90 and above were considered acceptable. Root mean square of approximation (RMSEA) values less than 0.05 suggested that models had good fit and values less than 0.11 suggested they had acceptable fit. A model with all outcomes as indicators of three independent constructs was then compared to an alternative model with all outcomes as indicators of one construct in order to assess the incremental fit of the models of marijuana outcomes. The comparison of models was tested by subtracting the chi-square value for the 1-factor model from the chi-square value for the 3-factor model and then subtracting the degrees of freedom for the 1-factor model from the degrees of freedom for the 3-factor model. If the difference in chi-square values evaluated at the difference in degrees of freedom was significant, then the model with the smaller individual chi-square was considered to provide a relative improvement in fit over the other (Bryant and Yarnold, 1995). Both maximum likelihood and full information maximum likelihood models were conducted and provided similar results; results from maximum likelihood models are presented.

Separate linear regression models tested the ability of end-of-treatment outcomes to predict the long-term outcome of percent days of marijuana abstinence from the end of treatment to the last follow-up in each study (at 15 months after the start of treatment in MTP and at six months after the start of treatment in MJ Yale). We selected percent days of marijuana abstinence during follow-up as the long-term outcome because this outcome was reported in both studies and is less sensitive to different lengths of follow-up. Because there were between-group differences in treatment success in both studies (Carroll et al., 2006; MTP, 2004), each model entered treatment group on the first regression step. Prior research has shown that pretreatment characteristics predict outcomes (Stephens et al., 1993), so each model also entered pretreatment characteristics related to demographics (age, gender, race, education, marital status, and employment status) and marijuana use history (percent days of marijuana use in the 90 days [MTP] or 28 days [MJ Yale] prior to treatment entry) on the first regression step. To examine the ability of end-of-treatment outcomes to predict long-term outcome, over and above the effects of treatment group and pretreatment characteristics, each model entered all end-of-treatment outcomes on the second step. Standardized betas estimated the strength of each end-of-treatment outcome to predict long-term outcome.

To support interpretation of the utility of end-of-treatment outcomes, effect sizes (i.e., Cohen's *d* for independent means; Cohen, 1992) were computed for each outcome. To

compare the effect of treatment on each outcome, between-treatment group effect sizes (Cohen's  $d = [\mu_{\text{experimental}} - \mu_{\text{control}}]/\sigma$ , where  $\mu_{\text{experimental}} - \mu_{\text{control}}$  is the difference between the means for the treatment and placebo groups and  $\sigma$  is the pooled standard deviation) were computed; in MTP, the 9-session extended treatment was the experimental group ( $n = 156$ ) and the 2-session brief treatment was the control group ( $n = 146$ ), and in MJ Yale, the MET/CBT + CM treatment was the experimental group and the DC without CM treatment was the control group. To evaluate which outcome was most sensitive to change, effect sizes were also computed for those outcomes that were assessed pre- and post-treatment (Cohen's  $d = [\mu_{\text{posttreatment}} - \mu_{\text{pretreatment}}]/\sigma$ ). According to Cohen (1992), effect sizes of 0.2 were considered small, 0.5 medium, and 0.8 large.

To classify individuals as showing “clinically-significant improvement” we used two different definitions that have been reported in the literature. According to the Stephens et al. (1994) definition, individuals were “improved” if their end-of-treatment frequency of marijuana use was 50% or less of pretreatment levels and they reported a score of 0 on the MPS. According to the Carroll et al. (2006) definition, individuals were “improved” if they completed treatment and submitted at least one marijuana-free urine specimen during treatment (indicative of at least 14 days of marijuana abstinence). For each definition, chi-square tests compared the prevalence of individuals classified as “improved” vs. “not improved” between treatment groups, and independent-samples  $t$ -tests compared those who improved vs. did not improve on all end-of-treatment and long-term outcomes.

### 3. Results

#### 3.1 Correlations among End-of-Treatment Outcomes

Correlations among the outcomes are presented separately for each trial in Table 2. In both MTP and MJ Yale, outcomes related to frequency of marijuana use (i.e., number of days of marijuana use in the last week, percent days of marijuana abstinence, maximum period of marijuana abstinence) strongly correlated with each other and with ASI Drug/Marijuana Composite scores (i.e., most  $r$  values  $> .6$ ) but not with outcomes related to ASI Psychological composite scores and anxiety and depression symptoms. Outcomes related to frequency of marijuana use strongly correlated with MPS scores in MTP but not in MJ Yale. In MJ Yale, outcomes related to urinary confirmation of marijuana use were strongly correlated with outcomes related to self-reported frequency of using marijuana and to ASI Marijuana composite scores but not to MPS scores nor to outcomes related to psychosocial functioning.

#### 3.2 Factor Structure of End-of-Treatment Outcomes

In a comparison of fit indices for the 3-factor vs. 1-factor models of outcomes, the chi-square values were smaller, the goodness-of-fit indices were greater, and the RMSEA values were smaller for the 3-factor model vs. the 1-factor model in MTP ( $\chi^2$ : 26.15 vs. 152.02; GFI: 0.97 vs. 0.86; CFI: 0.99 vs. 0.87; IFI: 0.99 vs. 0.87; RMSEA: 0.07 vs. 0.19) and in MJ Yale ( $\chi^2$ : 243.39 vs. 350.92; GFI: 0.71 vs. 0.64; CFI: 0.84 vs. 0.69; IFI: 0.84 vs. 0.71; RMSEA: 0.14 vs. 0.19). In an assessment of the incremental fit of the competing models, the difference in chi-square values was significant in MTP ( $\Delta\chi^2 = 125.87$ ,  $\Delta df = 3$ ,  $p = .000$ ) and in MJ Yale ( $\Delta\chi^2 = 107.53$ ,  $\Delta df = 1$ ,  $p = .000$ ), indicating that the 1-factor and 3-factor models did not have comparable fit to the data. Because the chi-square values for the 3-factor models were smaller than those for the 1-factor model, the 3-factor model provided a relative improvement in fit over the 1-factor model. Therefore, in both trials, the model with three factors of frequency of marijuana use, severity of marijuana use, and psychosocial functioning provided the better fit of the data than the model with one factor of marijuana use. Factor loadings for each outcome in each study are presented in Table 3.

### 3.3 Relations between End-of-Treatment and Follow-up Outcomes

After accounting for variance attributable to treatment group and pretreatment characteristics, end-of-treatment outcomes were significantly associated with percent days of marijuana abstinence from the end of treatment to the last follow-up in both studies (MTP:  $F(16, 207) = 16.51, p = .000$ ; MJ Yale:  $F(18, 27) = 4.03, p = .001$ ). However, the relative predictive strength of each outcome differed between the two studies (Table 4). In MTP, the end-of-treatment outcome of percent days of marijuana abstinence during treatment was the strongest predictor of long-term outcome, and the outcome of maximum period of marijuana abstinence during treatment was also a significant predictor of long-term success. In MJ Yale, the outcome of number of days of marijuana use in the last week of treatment was the strongest predictor of long-term outcome, and MPS score was also a strong predictor ( $p = .04$ ) of long-term outcome. The standardized beta for the outcome of maximum period of marijuana abstinence during treatment to predict long-term outcome in MJ Yale was large ( $\beta = 0.51$ ) but did not achieve statistical significance ( $p = .08$ ).

### 3.4 Effect Sizes of End-of-Treatment Outcomes

Effect sizes (Cohen's  $d$ ) for end-of-treatment outcome measures are shown in Table 5. The effect sizes of between-treatment groups outcomes ranged from small to medium in both studies (MTP: 0.13 – 0.53; MJ Yale: 0.15 – 0.59). The effect sizes of pre- vs. posttreatment outcomes ranged from small to large (0.05 – 1.08) in MTP but were all characterized as small in MJ Yale (0.33 – 0.35). There was no outcome measure with a medium or large effect size across both trials.

### 3.5 Identification of Individuals with Clinically-Significant Improvement

According to the definition of clinically-significant improvement described by Stephens et al. (1994), 27 individuals (9%) in MTP and 12 (9%) in MJ Yale were classified as “improved.” The prevalence of improved individuals differed at a statistically significant level across treatment groups in MTP (14% in the extended treatment group vs. 3% in the brief treatment group;  $\chi^2(1) = 10.56, p < .01$ ) but not in MJ Yale (11% across the 3 active treatment groups vs. 3% in the control group;  $\chi^2(1) = 1.82, p = .18$ ). In MTP, the individuals who were improved reported significantly better outcomes related to all end-of-treatment and follow-up indicators than those who did not improve (Table 6). In MJ Yale, improved individuals reported significantly better end-of-treatment outcomes related to frequency and severity of marijuana use but not in the three outcomes related to psychosocial functioning nor in the long-term outcome. It should be noted that the lack of difference in long-term outcome in MJ Yale may be due to a relatively small number of participants classified as “improved.”

According to the definition of clinically-significant improvement described by Carroll et al. (2006), 105 individuals (35%) in MTP and 58 individuals (43%) in MJ Yale were classified as “improved.” The prevalence of improved individuals differed across treatment groups in MJ Yale (48% across the 3 active treatment groups vs. 27% in the control group;  $\chi^2(1) = 4.21, p = .04$ ) but not in MTP (33% in the extended treatment group vs. 36% in the brief treatment group,  $\chi^2(1) = 0.29, p = 0.59$ ). In both trials, improved individuals reported significantly better end-of-treatment outcomes related to frequency and severity of marijuana use than those who did not improve; the one exception was that there was no difference in MPS scores in the MJ Yale trial. Those who were improved reported lower end-of-treatment depression scores in MTP, but there were no other between-group differences in outcomes related to psychosocial functioning in either study. In both studies, those who were improved reported a significantly greater percentage of marijuana-abstinent days during follow-up than those who were not improved.

## 4. Discussion

This evaluation of end-of-treatment outcomes in two randomized controlled trials of treatments for cannabis use disorders indicated the following: First, in both trials the best-fitting model of end-of-treatment outcomes encompassed three domains: frequency of marijuana use, severity of marijuana use, and psychosocial functioning. Second, end-of-treatment outcomes significantly predicted long-term outcome, although the strength of association of specific end-of-treatment indicators differed between studies. Third, effect sizes for end-of-treatment outcome indicators were modest. Fourth, individuals who demonstrated alternate definitions of clinically-significant improvement reported better end-of-treatment and long-term outcomes than those who did not improve.

To our knowledge, this is the first report to utilize confirmatory factor analytic techniques to understand the empirical structure of end-of-treatment outcomes from trials of treatments for cannabis use disorders. Our results suggest that end-of-treatment outcomes related to frequency of marijuana use, severity of marijuana use, and psychosocial functioning represent distinct domains of change associated with the effects of treatment and that these domains were consistent across two independent treatment trials. In light of these results, future randomized controlled trials of treatments for cannabis use disorders should collect and report end-of-treatment outcomes related to all three domains. Additionally, these data suggest that outcomes related to frequency and severity of marijuana use can be considered primary outcomes, and those related to psychosocial functioning can be considered secondary outcomes, for three reasons: (1) outcomes related to frequency and severity of marijuana use strongly correlated with one another; (2) several of the outcomes related to frequency and severity of marijuana use predicted long-term treatment success; and (3) several of these outcomes showed medium effect sizes. Conversely, outcomes related to psychosocial functioning did not strongly correlate to marijuana frequency and severity outcomes, did not predict long-term treatment success, and showed mostly small effect sizes. Existing treatments for cannabis use disorders have beneficial effects on psychosocial characteristics (Budney et al., 2000; Budney et al., 2006; Carroll et al., 2006; Copeland et al., 2001; Kadden et al., 2007; MTP, 2004; McRae-Clark et al., 2009; Stephens et al., 1994; Stephens et al., 2000), and current data suggest outcomes related to psychosocial functioning should still be included in future trials but should be considered secondary to outcomes related to frequency and severity of marijuana use.

Not only did we detect consistency in the domains represented by end-of-treatment outcomes across two studies of behavioral treatments for cannabis use disorders, we found consistency in the ability of end-of-treatment outcomes to predict long-term outcome. Although there was some discrepancy across the two studies in which specific end-of-treatment outcomes predicted long-term outcome, the prognostic significance of outcomes related to percent days of marijuana use and continuous abstinence from marijuana is consistent with the broader substance abuse literature (Budney et al., 2000; Budney et al., 2006; Carroll et al., 1994; Higgins et al., 2000; McKay et al., 1999; McKay and Weiss, 2001). The majority of prior marijuana treatment trials have reported these two outcomes (Table 1), and, given preliminary evidence for their long-term significance, future treatment trials should consider these for use as primary outcome measures. Further evaluation may indicate which of these two outcomes may serve as a “sentinel outcome” (Allen, 2003) to be consistently reported in future trials.

The effect sizes associated with most end-of-treatment outcomes fell within the small to medium range, indicating modest effects attributable to behavioral treatments for cannabis use disorders. This finding of modest effect sizes is consistent with effect sizes associated with psychosocial interventions for other substance use disorders (Dutra et al., 2008) and

with prior studies that have noted that complete abstinence from marijuana is difficult to attain (Budney et al., 2006; Carpenter et al., 2009; Copeland et al., 2001; Levin et al., 2004; Stephens et al., 1994). Thus, there exists a need to further develop behavioral treatments for individuals with cannabis use disorders and to demonstrate more robust effects of these treatments.

Because it highlighted meaningful changes in end-of-treatment and long-term marijuana use outcomes, clinically-significant improvement can be a viable outcome for individuals with cannabis use disorders. The definition of improvement provided by Stephens et al. (1994) was more stringent than the definition used by Carroll et al. (2006) in that it categorized far fewer individuals as “improved” and detected more differences in end-of-treatment outcomes related to psychosocial functioning. On the other hand, the definition provided by Carroll et al. (2006) captured more “improved” individuals, while still demonstrating better end-of-treatment outcomes related to frequency and severity of marijuana use for those who were improved vs. not improved. Although these definitions of what constitutes clinically-significant improvement should be regarded as preliminary, future work needs to be done to derive a standard definition of clinically-significant improvement that takes into account a meaningful reduction in marijuana consumption, a decrease in marijuana-related problems, and improvement in psychosocial functioning.

Strengths of this study include its utilization of two independent randomized controlled trials of behavioral treatments for cannabis use disorders and its empirical analysis of outcomes. Limitations of this study include: (1) selection of outcomes that were, to a large extent, limited to those included in the two trials and in the existing literature (McKay et al., 2001); (2) small sample size, notably in the MJ Yale trial; and (3) between-study differences in designs (e.g., type of sample, interventions delivered). However, the differences in design may make our findings more generalizable to future trials testing new treatments in diverse samples.

The most commonly-reported indicators in randomized controlled trials of treatments for cannabis use disorders: (1) capture meaningful outcome domains, (2) are reasonably sensitive, (3) predict longer-term outcome, and (4) relate to clinically-significant improvement. Our findings represent an important first step in understanding primary efficacy endpoints within the burgeoning literature of treatment for adults with cannabis use disorders. With consistency in the reporting of outcomes in future studies, meta-analyses and comparative outcome studies can be conducted to understand how efficacious current treatments for cannabis use disorders are and to suggest ways to improve our interventions. Future studies might examine whether there are early indicators that treatment is likely to be successful, how important other psychosocial outcomes might be, how to best biochemically validate outcomes, when to gather outcomes and with what assessment instruments, how to best assess clinically-significant improvement, and whether improvement in marijuana use at the end of treatment promotes future cessation.

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Outcomes in Randomized Controlled Trials for Cannabis Use Disorders.

Table 1

First Author, Year	Marijuana Outcomes								
	Self-Report Only	Self-Report & Urinalysis	Continuous Abstinence	% Days Abstinent	Frequency Marijuana Use	% Marijuana (-) Urine Specimens	Marijuana Problems/Craving	ASI Scores	Psychosocial Functioning
Budney, 2000		X	X		X		X	X	X
Budney, 2006		X	X	X	X	X	X	X	X
Carpenter, 2009		X	X						X
Carroll, 2006		X	X	X		X		X	
Copeland, 2001		X	X	X	X		X		X
Kadden, 2007		X	X	X	X		X	X	
Levin, 2004		X	X		X	X	X	X	X
Levin, in press		X	X		X				
MTP, 2004		X	X	X	X		X	X	X
McRae-Clark, 2009		X		X	X	X	X		X
Stephens, 1994		X	X		X		X		
Stephens, 2000	X		X	X	X		X		
Stephens, 2007		X		X	X		X		
% Studies	8	92	85	62	85	31	77	46	54

Note. An “X” denotes that a study reported the outcome. ASI = Addiction Severity Index, MTP = Marijuana Treatment Project.

Correlations Among End-of-Treatment Outcomes.

Table 2

MTP Outcome	1	2	3	4	5	6	7
1. # Days of MJ Use in Last Week of Treatment							
2. % Days of MJ Abstinence in Prior 90 Days	-.86*						
3. Max # Consecutive Days of MJ Abstinence during Treatment	-.66*	.76*					
4. ASI Drug Composite Score <sup>a</sup>	.69*	-.74*	-.57*				
5. MPS Score	.42*	-.50*	-.49*	.57*			
6. ASI Psychological Composite Score	.19*	-.19*	-.12	.32*	.33*		
7. Anxiety Score (STAI)	.26*	-.31*	-.23*	.45*	.38*	.44*	
8. Depression Score (BDI)	.27*	-.33*	-.27*	.42*	.44*	.49*	.66*
MJ Yale Outcome	1	2	3	4	5	6	7
1. # Days of MJ Use in Last Week of Treatment							
2. % Days of MJ Abstinence during Treatment	-.73*						
3. Max # Consecutive Days of MJ Abstinence during Treatment	-.59*	.76*					
4. % MJ-Negative Urines during Treatment	-.51*	.59*	.80*				
5. Max # Consecutive MJ-Negative Urines during Treatment	-.48*	.58*	.84*	.92*			
6. ASI MJ Composite Score <sup>a</sup>	.48*	-.68*	-.60*	-.60*	-.57*		
7. MPS Score	.27	-.25	-.20	-.21	-.21	.36*	
8. ASI Psychological Composite Score	.22	-.13	-.25	-.12	-.19	.07	-.05
9. Anxiety Score (BSI)	.23	-.06	-.08	-.08	-.05	.05	.13
10. Depression Score (BSI)	.28	-.03	-.08	-.13	-.13	.08	.19
							.33
							.61*

Note. Pearson correlations are presented for end-of-treatment (16 weeks after the start of treatment in MTP, 8 weeks after the start of treatment in MJ Yale) outcomes. Participants with available data on all outcomes were included ( $N = 234$  for MTP,  $N = 55$  for MJ Yale). MJ = marijuana. MTP = Marijuana Treatment Project. MJ Yale = Contingency Management/MET/CBT Study. ASI = Addiction Severity Index. MPS = Marijuana Problems Scale. STAI = State Trait Anxiety Inventory; BDI = Beck Depression Inventory – Second Edition, BSI = Brief Symptom Inventory.

\*  $p < .01$ .

<sup>a</sup> In the MJ Yale study, the ASI was revised to gather composite scores for marijuana use only. In MTP, the ASI gathered composite scores for all drug use.

**Table 3**

Factor Loadings for End-of-Treatment Outcomes.

Outcome	Factor		
	Frequency of Marijuana Use	Severity of Marijuana Use	Psychosocial Functioning
MTP			
% Days MJ Abstinence in Prior 90 Days	.90		
# Days Used MJ in Last Treatment Week	.77		
Max # Consecutive Days of MJ Abstinence during Treatment	.58		
ASI Drug Composite Score		.79	
MPS Score		.44	
Anxiety Score (STAI)			.58
Depression Score (BDI)			.56
ASI Psychological Composite Score			.36
MJ Yale			
Max # Consecutive Days of MJ Abstinence	.93		
% Days MJ Abstinence during Treatment	.71		
Max # Consecutive MJ-Negative Urine Specimens during Treatment	.69		
% MJ-Negative Urine Specimens during Treatment	.65		
# Days Used MJ in Last Treatment Week	.45		
ASI MJ Composite Score		.97	
MPS Score		.13	
ASI Psychological Composite Score			1.75
Anxiety Score (BSI)			.16
Depression Score (BSI)			.06

*Note.* MJ = marijuana, MTP = Marijuana Treatment Project, MJ Yale = Contingency Management/MET/CBT Study, ASI = Addiction Severity Index, MPS = Marijuana Problems Scale, STAI = State Trait Anxiety Inventory, BDI = Beck Depression Inventory, BSI = Brief Symptom Inventory. *N* = 227 for MTP, *N* = 55 for MJ Yale.

**Table 4**

End-of-Treatment Predictors of Long-Term Outcome.

End-of-Treatment Outcome	MTP			MJ Yale		
	$\beta$	$t$	$p$	$\beta$	$t$	$p$
# Days Used MJ Last Week of Treatment	-.06	-0.60	.55	-.73	-3.54	.00
% Days of MJ Abstinence	.42	3.75	.00	-.11	-0.47	.65
Max # Consecutive Days MJ Abstinence during Treatment	.19	2.47	.01	.51	1.83	.08
% MJ-Negative Urines during Treatment	N/A	N/A	N/A	.03	0.11	.92
Max # Consecutive MJ-Negative Urines during Treatment	N/A	N/A	N/A	-.31	-0.91	.36
ASI MJ / Drug Composite Score <sup>a</sup>	-.10	-1.23	.22	-.14	-0.79	.44
MPS Score	-.02	-0.31	.75	.35	2.13	.04
ASI Psychological Composite Score	-.01	-.15	.88	.17	1.35	.19
Anxiety Score	.06	0.97	.33	.13	0.76	.45
Depression Score	.05	0.72	.47	.11	0.60	.55

*Note.* Standardized betas from multiple linear regression models are presented. Outcome in each model was percent days of marijuana abstinence during the follow-up period (15 months after the start of treatment in MTP, 6 months after the start of treatment in MJ Yale). Each model entered treatment group and pretreatment characteristics on the first regression step, with all end-of-treatment predictors on the next regression step. MJ = marijuana, MTP = Marijuana Treatment Project, MJ Yale = Contingency Management/MET/CBT Study, ASI = Addiction Severity Index, MPS = Marijuana Problems Scale.  $N = 224$  for MTP,  $N = 46$  for MJ Yale.

**Table 5**

Effect Sizes for End-of-Treatment Outcomes.

Outcome	<i>d</i>	
	Between-Treatment Groups	Pre- vs. Post-Treatment
# Days Used MJ Last Week of Treatment		
MTP	.46	
MJ Yale	.18	
% Days of MJ Abstinence		
MTP	.53	
MJ Yale	.31	
Max # Consecutive Days MJ Abstinence during Treatment		
MTP	.45	
MJ Yale	.35	
% MJ-Negative Urines during Treatment (MJ Yale)	.29	
Max # Consecutive MJ-Negative Urines during Treatment (MJ Yale)	.57	
ASI MJ / Drug Composite Score <sup>a</sup>		
MTP	.52	1.08
MJ Yale	.31	.35
MPS Score		
MTP	.52	.56
MJ Yale	.15	.33
ASI Psychological Composite Score		
MTP	.13	.05
MJ Yale	.23	.33
Anxiety Score		
MTP (STAI)	.38	.37
MJ Yale (BSI)	.59	--
Depression Score		
MTP (BDI)	.34	.36
MJ Yale (BSI)	.37	--

*Note.* MJ = marijuana, MTP = Marijuana Treatment Project, MJ Yale = Contingency Management/MET/CBT Study, ASI = Addiction Severity Index, MPS = Marijuana Problems Scale, STAI = State Trait Anxiety Inventory, BDI = Beck Depression Inventory, BSI = Brief Symptom Inventory. The sample size ranged from 240 to 261 for MTP and from 31 to 66 for MJ Yale.

**Table 6**  
Differences in End-of-Treatment and Long-Term Outcomes for Two Definitions of Clinically-Significant Improvement.

MTP Outcome	Carroll Definition of Improvement		Stephens Definition of Improvement	
	Improved (n = 105)	Not Improved (n = 197)	Improved (n = 27)	Not Improved (n = 275)
# Days of MJ Use in Last Week of Treatment	1.33 (2.22)	4.42 (2.88) *	0.19 (0.48)	3.54 (3.02) *
% Days of MJ Abstinence (Prior 90 Days)	81 (24)	31 (34) *	98 (4)	49 (38) *
Max # Consecutive Days of MJ Abstinence during Treatment	70.74 (46.62)	21.09 (36.71) *	113.19 (34.48)	35.73 (43.49) *
ASI Drug Composite Score <sup>a</sup>	0.08 (0.09)	0.19 (0.09) *	0.01 (0.04)	0.15 (0.10) *
MPS Score	5.25 (4.50)	8.13 (4.09) *	0 (0)	8.03 (4.11) *
ASI Psychological Composite Score	0.12 (0.17)	0.14 (0.19)	0.07 (0.11)	0.15 (0.19) *
Anxiety Score (STAI)	33.75 (10.96)	35.97 (11.09)	30.37 (10.10)	35.96 (11.03) *
Depression Score (BDI)	7.29 (8.27)	9.18 (7.44) *	3.81 (4.39)	9.62 (8.28) *
% Days of MJ Abstinence (Follow-Up)	66 (32)	36 (36) *	86 (21)	44 (37) *
MJ Yale Outcome				
	Improved (n = 58)	Not Improved (n = 80)	Improved (n = 12)	Not Improved (n = 126)
# Days of MJ Use in Last Week of Treatment	0.68 (1.67)	2.89 (2.85) *	0.08 (0.29)	2.06 (2.68) *
% Days of MJ Abstinence (Prior 90 Days)	89 (17)	56 (36) *	98 (2)	68 (34) *
Max # Consecutive Days of MJ Abstinence during Treatment	39.05 (17.89)	10.20 (12.04) *	48.75 (10.06)	20.55 (19.74) *
% MJ-Negative Urines during Treatment	55 (39)	14 (33) *	63 (37)	29 (40) *
Max # Consecutive Days of MJ-Negative Urines during Treatment	2.86 (3.50)	0.47 (1.22) *	3.58 (2.19)	1.32 (1.97) *
ASI MJ Composite Score <sup>a</sup>	0.11 (0.18)	0.31 (0.28) *	0.02 (0.08)	0.24 (0.26) *
MPS Score	2.94 (3.50)	4.32 (3.81)	0 (0)	4.36 (3.62) *
ASI Psychological Composite Score	0.04 (0.12)	0.08 (0.16)	0.01 (0.03)	0.07 (0.15) *
Anxiety Score (BSI)	0.20 (0.41)	0.17 (0.31)	0.15 (0.30)	0.19 (0.38)
Depression Score (BSI)	0.26 (0.43)	0.21 (0.32)	0.12 (0.26)	0.26 (0.40)
% Days of MJ Abstinence (Follow-Up)	86 (19)	53 (33) *	82 (27)	66 (33)

*Note.* Means (standard deviations) are presented. Asterisks indicate significant differences in independent-samples *t*-tests between “improved” and “not improved” groups within each definition. MJ = marijuana, MTP = Marijuana Treatment Project, MJ Yale = Contingency Management/MET/CBT Study, ASI = Addiction Severity Index, MPS = Marijuana Problems Scale, STAI = State Trait Anxiety Inventory, BDI = Beck Depression Inventory, BSI = Brief Symptom Inventory.

\*  $p < .01$ .