

A Preliminary Trial of Twelve-Step Facilitation
and Acceptance and Commitment Therapy With
Polysubstance-Abusing Methadone-Maintained
Opiate Addicts

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The present study compared methadone maintenance alone to methadone maintenance in combination with 16 weeks of either Intensive Twelve-Step Facilitation (ITSF) or Acceptance and Commitment Therapy (ACT) in a preliminary efficacy trial with polysubstance-abusing opiate addicts who were continuing to use drugs while on methadone maintenance. Results showed that the addition of ACT was associated

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with lower objectively assessed opiate and total drug use during follow-up than methadone maintenance alone, and lower subjective measures of total drug use at follow-up. An intent-to-treat analysis which assumed that missing drug data indicated drug use also provided support for the reliability of objectively assessed total drug use decreases in the ACT condition. ITSF reduced objective measures of total drug use during follow-up but not in the intent-to-treat analyses. Most measures of adjustment and psychological distress improved in all conditions, but there was no evidence of differential improvement across conditions in these areas. Both ACT and ITSF merit further exploration as a means of reducing severe drug abuse.

Opiate dependence constitutes a particularly important subset of substance abuse problems. Relative to other substance abusing subgroups, opiate addicts have greater employment problems, greater medical problems, more legal problems, and incur greater costs of society (Deschenes, Anglin, & Speckart, 1991). Methadone maintenance is a well-validated empirically supported treatment for opiate dependence (Gossop, Marsden, Stewart, & Treacy, 2001) with effects that meet or exceed other available medications (Barnett, Rodgers, & Bloch, 2001). The impact of methadone is poorer for polysubstance abusing clients, however (e.g., Darke, Swift, Hall, & Ross, 1993).

A variety of approaches have been tried to increase the impact of methadone treatment. The results of adding psychotherapy to the drug counseling normally received as part of methadone maintenance have been mixed. Some studies have shown improved outcomes (e.g., Rawson, Huber, et al., 2002; Woody, McLellan, Luborsky, & O'Brien, 1995) while others have not (e.g., Magura, Rosenblum, Fong, Villano, & Richman, 2002; Rounsaville, Glazer, Wilber, Weissman, & Kleber, 1983; Rounsaville, Kosten, Weissman, & Kleber, 1987; Woody, Luborsky, McLellan, & O'Brien, 1988). There is a need for the evaluation of additional types of psychosocial interventions for those clients who are not receiving maximal benefit from methadone maintenance (Carroll, 1997).

Psychosocial methods with substance abuse populations present particular challenges given the practice base in the area, however. Many treatment providers are paraprofessionals who are themselves in recovery, and some have strong opinions about the methods that are most helpful, creating a particularly wide gap between research and practice in substance abuse treatment (Rawson, Marinelli-Casey, et al., 2002). For example, while approximately 80% of substance abuse treatment providers report that they are open to research-based interventions, a similarly large percentage are interested primarily in research on treatments that emphasize spirituality and 12-step program participation (Forman, Bovasso, & Woody, 2001).

A number of researchers have begun to research such methods. Twelve-step facilitation (TSF) is the most prominent example (Project MATCH Research Group, 1997). TSF is a structured, manualized psychosocial intervention designed to both parallel and facilitate a 12-step perspective. The treatment emphasizes acceptance of the addiction problem, surrender of control, and active participation in 12-step meetings and a program of recovery. Several studies have shown a positive relationship between drug outcomes

and participation in 12-step activities (Carroll et al., 2000; Fiorentine, 1999; Humphreys, 1999) or adoption of 12-step consistent beliefs during treatment (e.g., Fiorentine & Hillhouse, 2000). While TSF has been shown to improve participation in 12-step activities (Humphreys, 1999), the experimental evidence on actual improved outcomes is still limited. The largest study examining these outcomes was Project MATCH (Project MATCH Research Group, 1997). In that study, three methods were compared (Carroll et al., 1998): TSF, motivational enhancement therapy (MET), and cognitive behavioral therapy (CBT). In general, no differences in outcome were found, but since CBT and MET have more extensive outcome support, the utility of TSF was indirectly supported. Other studies have used somewhat similar designs and evidence on the effectiveness of TSF is still limited (e.g., Carroll et al., 2000; Donovan, 1999).

The recent empirical interest in behavior therapy in acceptance and mindfulness interventions may provide another way to provide empirically supported treatments that fit more readily with the existing practice base. Several empirically based treatments of this kind are available (see Hayes, Follette, & Linehan, 2004; Hayes, Jacobson, Follette, & Dougher, 1994) but they have only recently begun to be applied to substance abuse disorders. For example, Dialectical Behavior Therapy has a growing base of support in the substance abuse area (Linehan et al., 1999; Linehan et al., 2002). These treatments are relatively friendly to the basic beliefs of many substance abuse providers (e.g., Linehan et al., 2002). For example, while the emphasis on God in 12-step programs is a known barrier to participation by nonbelievers (Tonigan, Miller, & Schermer, 2002), mindfulness meditation provides an alternative, more experiential approach to issues of spirituality that seems to be yielding positive outcomes in the substance abuse area (Groves & Farmer, 1994; Linehan et al., 1999; Marlatt, 2002; Simpson et al., 1998).

Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 1999), with its emphasis on acceptance, spirituality, mindfulness, and behavior change, also seems fairly friendly to 12-step sensibilities (Wilson, Hayes, & Byrd, 2000). At the level of its underlying model, there is also evidence that “experiential avoidance” (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996)—the attempt to regulate thoughts, feelings, or other private experiences even when attempts to do so cause significant behavioral harm—applies to this clinical area. Substance abuse seems to be frequently motivated by an attempt to regulate negative private experiences (e.g., Shoal & Giancola, 2001)—indeed, the subjective effectiveness of its utility in that regard predicts relapse (Litman, Stapleton, Oppenheim, Peleg, & Jackson, 1984). Even if substance abuse was initially motivated by other factors, however, as it evolves a variety of drug-related responses emerge (e.g., cravings; withdrawal symptoms) that themselves become the target of experiential avoidance and subsequent drug use (e.g., Nathan, 1997; Toneatto, 1999). Over time, these sources of influence begin to combine and negative affect or cognitions begin to trigger drug-related responses that are then regulated by drug use (Childress et al., 1994). Thus, substance dependences can readily serve

an experiential avoidance function for both preexisting problems as well as those precipitated by the drug use itself.

The purpose of the present project is to examine the preliminary efficacy of TSF and ACT when combined with methadone maintenance as compared to methadone maintenance alone for polysubstance-abusing opiate addicts. While both of these treatments seem to fit with the 12-step focus of the practice base (Forman et al., 2001), it should be acknowledged that there is a widespread dislike of the use of methadone maintenance or any agonist treatment within the 12-step community. In fact, this dislike is not based directly in Alcoholics Anonymous, the 12-step traditions, or the “big book,” but reflects in part the intrusion of Synanon-style confrontation into 12-step thinking (Kurtz, 1999). Alcoholics Anonymous canonical texts embrace the possibility of a harm reduction approach suggesting that moderation may be possible if individuals are not “too alcoholic” (Alcoholics Anonymous, 1976, p. 92) and noting that “some will moderate . . . and some will not” (Alcoholics Anonymous, 1976, p. 109). Medications are similarly not eschewed formally by Alcoholics Anonymous—indeed, Alcoholics Anonymous prints and distributes a pamphlet on how to work with physicians and the prescription of psychoactive drugs in the context of 12-step programs. By staying linked to the core model and its canonical writings, in this project we were able to recruit and train effective 12-step counselors who would work with methadone maintenance clients using a 12-step model and would refer clients to 12-step groups that were accepting of methadone maintenance participants. Clients were also educated in these details so that they could quote core 12-step writings if individuals challenged their use of prescribed medications during 12-step meetings outside of the project.

Method

Participants

Participants ($N = 138$) who had received methadone for at least the last 60 days and who had used opiates during that time were recruited from one of the three community-based methadone clinics in the Reno, Nevada, area. Ninety-seven percent had relapsed within the past 30 days; 3% had relapsed within the past 60 days. Study participants met *DSM-IV* criteria for substance abuse or dependence for at least one other substance and had relapsed to that substance during the last 30 days.

Consensus conferences organized by the National Institute on Drug Abuse have recommended that early treatment development studies deliberately keep populations broad unless there are theoretical reasons not to do so (see Hayes, Barlow, & Nelson-Gray, 1999, pp. 88–89). Exclusion criteria accordingly were minimal. Participants receiving psychopharmacological treatment other than methadone (e.g., antidepressants) had to be on a stable dose for at least 8 weeks prior to study inception and were asked to remain on their current dose for the study’s duration (none were excluded on that basis). Participants

were excluded due to a current *DSM-IV* diagnosis of schizophrenia, schizoaffective disorder, psychosis NOS, or bipolar affective disorder (1 was excluded on that basis), or due to imminent criminal justice proceedings that might result in incarceration during treatment (1 was excluded on that basis). Participants agreed to complete assessments (10 were excluded because they did not complete the intake); then to be randomly assigned to a treatment condition (1 refused); to comply with the requirements of that condition; to continue with the project for the full 16 weeks; and to not seek additional psychiatric, psychological, or substance abuse treatment during the duration of the study, unless recommended by study personnel or the methadone clinic. One additional participant was excluded due to a close friendship with treatment staff. One hundred twenty-four actual participants were thus randomly assigned.

Treatment Conditions and Setting

Participants were randomly assigned in sequential waves of three to Methadone Maintenance alone (MM), to Acceptance and Commitment Therapy Plus Methadone Maintenance (ACT), or to Intensive Twelve Step Facilitation Therapy Plus Methadone Maintenance (ITSF). Participants were seen in a community-based clinical facility dedicated to the project, housed separately from the methadone clinics.

MM. Methadone maintenance was supplied in the same fashion as it was before entering treatment, in accord with the policies of the responsible methadone clinic. Generic drug counseling was also provided in all three methadone clinics utilized in this study as required by law. This monthly counseling session consisted of monitoring problem behaviors; ensuring compliance with clinic rules, especially with respect to drug use; offering necessary referrals to medical, social, and legal services; and responding to personal crises.

ACT. In addition to the same methadone maintenance regimen received by participants in the MM condition, each participant in the ACT condition was treated using a 16-week treatment protocol, consisting of 48 sessions: 32 individual 1-hour sessions and 16 group 90-minute sessions. Therapists carried out treatment according to a written therapy manual (modified from Hayes, Strosahl, et al., 1999), which consisted of a detailed description of the ACT therapy components and the suggested order in which they are to be covered. Group sessions were facilitated by one of the therapists providing the individual treatment. Sessions proceeded according to a separate written protocol. Group sessions were designed to apply ACT concepts to concrete life domains such as financial issues and relationships. An HIV education module was also included. Participants entered the group in their first week of treatment.

ITSF. In addition to the same methadone maintenance regimen received by participants in the MM condition, each participant in the ITSF condition was treated using a 16-week treatment protocol, consisting of 48 sessions: 32 individual 1-hour sessions (16 weekly sessions with their therapist, and 16 with a sponsor, who was a member of a 12-step organization such as AA, NA, or CA) and sixteen 90-minute group sessions. The treatment was dubbed

ITSF rather than TSF because the original Project MATCH protocol involved only 12 sessions rather than the 48 used here. Therapists carried out treatment according to a written therapy manual used in Project MATCH (Carroll et al., 1998), consisting of a description of 12-step therapy components and the suggested order in which they are to be covered. Therapists monitored the weekly client attendance at the sponsor meetings. Missed meetings were addressed as a clinical issue during the following individual therapy session. Group sessions were facilitated by one of the two therapists providing the individual treatment. The group meetings consisted of readings from and discussion of *Twelve Steps and Twelve Traditions* (Alcoholics Anonymous World Services, 1986). Group attendees were encouraged to relate the readings to their own life experiences. An HIV education module was also included. The objective of the group meetings was to provide clients with a deeper understanding of the 12 Steps and 12 Traditions. Participants entered the group the first week they entered treatment.

Therapists

ACT therapists ($N = 4$) were trained at the master's level or higher in clinical psychology, and had at least 2 years of experience in the treatment of substance abuse and in the delivery of behavior therapy. Since part of the 12-step philosophy is that "one addict can best understand and help another addict" (Narcotics Anonymous World Service Office, 1988, p. 18), 12-step therapists ($N = 3$) had themselves recovered through the 12-step model. ITSF therapists had at least 5 years of experience in the treatment of substance abuse. Both ITSF and ACT therapists were trained through a clinical workshop and supervised clinical work using their respective models.

Adherence

All individual and group therapy sessions were recorded on videotape. Treatment integrity was evaluated using a rating scale developed for ACT (The ACT Tape Rating Scale; Gifford & Hayes, 1998), intermixed with the adherence subscale for Twelve Step Facilitation developed for Project MATCH (Carroll et al., 1998). The ACT and TSF subscales showed good internal consistency (coefficient alpha, ACT = .82, TSF = .85). A team of three raters trained to reliability (mean intraclass correlation coefficients = .73; Shrout & Fleiss, 1979, model [2,1]) and blind to treatment assignment rated a random sample of 69 tapes, approximately half ACT and half ITSF. The ACT tapes had significantly higher ACT scores, $t(69) = 10.06$, $p < .001$, than did ITSF tapes. ITSF tapes had significantly higher 12-step scores, $t(69) = 12.50$, $p < .001$, than did ACT tapes (Gifford, Hubbert, Karnahrens, & Hayes, 1999). Eighty-two percent of the ACT tapes and 81% of the ITSF tapes were rated as adherent using criteria similar to those used in Project MATCH (Carroll et al., 1998). Overall, this pattern of results shows that ACT and ITSF conditions were distinct and implemented in accord with their respective treatment manuals.

Assessment

Administration of assessments. All assessments were carried out by a team of assessors blind to the treatment condition of the participants. Full assessment batteries were administered at baseline, midtreatment (8 weeks), post-treatment (16 weeks), and at follow-up (6 months after end of treatment). Partial assessments were also taken more frequently, but these data go beyond the purposes of the present report and will be reported elsewhere. Participants gave urine samples twice before treatment began and twice weekly during treatment. To improve subject retention and assessment compliance, participants were reimbursed for their participation and for submission of urinalyses (UAs) and assessments (\$45 per week for the 16 weeks of treatment). Participants could receive these funds through payments sent directly to their methadone clinics to cover the expense of their methadone or through merchandise credits at a local department store (nationwide chain). In addition, participants received \$75 (as a payment to their methadone clinic for methadone or, if subject was no longer on methadone, in merchandise credit) for completion of the 6-month follow-up battery.

Screening and diagnostic assessments. The following clinical interviews were utilized in determining if participants met the diagnostic criteria for study entry. The Mini-SCID and Auto-SCID-II were used to diagnose major Axis I and Axis II *DSM-III-R* diagnoses, respectively. These instruments were utilized in determining if participants met the diagnostic criteria for study entry.

The Mini-SCID is a microcomputer version of the Structured Clinical Interview for *DSM-III-R* (SCID; Spitzer, Williams, Gibbon, & First, 1992). The SCID is a semistructured interview for making major Axis I *DSM-III-R* diagnoses, including mood disorders, anxiety disorders, psychoactive substance use disorders, somatoform disorders, eating disorders, and psychotic symptoms. The SCID has been extensively demonstrated to be a reliable and valid instrument both in the assessment of substance-abusing (Kosten, Bryant, & Rounsaville, 1991) and non-substance-abusing individuals (Skre, Onstad, Torgersen, & Kringlen, 1991).

The Auto-SCID-II is a computerized version of the widely used version of the Structured Clinical Interview for *DSM-III-R* Axis II disorders (SCID-II; Spitzer, Williams, Gibbon, & First, 1990). The SCID-II is utilized to diagnose personality disorders. Interrater (Maffei et al., 1997), test-retest reliability (First et al., 1995) and internal consistency coefficients (for both diagnoses and items; Maffei et al., 1997) are satisfactory.

Primary outcome assessments. The primary outcome target of the study was drug use. This was assessed objectively by UAs and subjectively by relevant portions of the Addiction Severity Index (ASI; McLellan, Luborsky, Woody, & O'Brien, 1980), corroborated where possible by objective data. If negative self-reports were directly contradicted by available UA data for the time period in question, use was coded as positive.

UAs were obtained from all participants at their regularly scheduled individual and group counseling sessions (for a total of two per week). Specimens

were collected in temperature-sensitive cups to avoid urine substitution and under constant direct staff observation to ensure authenticity. Participants who failed to give urine on scheduled days were required to submit the following day. One sample from each subject per week was randomly selected and sent to an outside lab for assay. Participants had their urine screened for polydrug use, including opiates, cocaine, benzodiazepines, barbiturates, amphetamines, and methadone. Overall, 20.6% of scheduled samples were missing during the 16-week intervention. Subjects averaged 12.7 weeks of completed urines and 3.3 weeks of missed urines.

The 155-item Addiction Severity Index (ASI; McLellan et al., 1980) is a 45- to 60-minute structured interview that measures patterns of drug use and lifetime and recent (past 30 days) severity of problems in seven areas (medical, employment, alcohol, drugs, legal, family/social, and psychiatric/psychological). In each of these areas, items are combined into a composite or factor score (from 0 = *no significant problem* to 1.0 = *extreme problem*). Participants were administered the ASI by trained research technicians, who met regularly to compare assessment-related problems and reduce differences in administering this scale. A briefer (15 to 20 minutes) version of the ASI, exclusive of historical and lifetime items, was utilized for all assessments following baseline. The ASI has been demonstrated to be a reliable and valid measure (Kosten, Rounsaville, & Kleber, 1983; McLellan et al., 1985; McLellan et al., 1992).

Secondary outcome measures. Non-drug-related psychopathology was assessed by the Social Adjustment Scale–Self Report (SAS-SR; Weissman & Bothwell, 1976), Beck Depression Inventory (BDI; Beck, Rush, Shaw & Emery, 1979), Symptom Checklist-90-R (SCL-90-R; Derogatis, Lipman, & Covi, 1973), and a portion of the ASI (for the medical, employment, legal, family/social, and psychiatric components). Additional process and outcome measures were collected that will be reported elsewhere.

Results

The sample was 49% male, 13% ethnic minorities, and 42.2 years old on average (range: 23–64). On average, participants had already been through 6.5 residential or outpatient professional substance abuse treatment programs ($SD = 7.3$; range: 0–36). Subjects were dominantly single (72%), and unemployed or partially employed (60%). More than half had an Axis II disorder (52%); 40% had a mood disorder; 42% an anxiety disorder. The average score on the BDI (18.8; $SD = 11.0$) placed participants in the moderately depressed range (14–20; Robinson, Shaver, & Wrightsman, 1991); the average global severity index (GSI) on the SCL-90-R was elevated at 1.05 ($SD = .67$), placing them somewhat below the published norm for psychiatric outpatients (1.26; $SD = .68$) but well above that for nonpatients (.31; $SD = .31$; Derogatis, 1975). Participants abused a wide variety of other substances, meeting dependence criteria for alcohol (35%), cocaine (46%), sedatives

(10%), and other drugs (35%), in addition to opiates. Means and standard deviations for major study variables are shown in Table 1.

Retention, Dose, and Satisfaction

The randomization process resulted in the assignment of 42 participants to ACT, 44 to ITSF, and 38 to MM. Dropouts after that time are shown in Figure 1, organized by week. Fourteen percent of each active treatment group never attended a single session after random assignment, and an additional 20% dropped out after a single week of treatment. At post, drug outcome data were available on 24 (57%), 26 (59%), and 28 (74%) of these participants, respectively, a nonsignificant difference, Pearson $\chi^2(2, N = 124) = 2.76, ns$. At follow-up, drug outcome data were available on 18 (43%), 25 (57%), and 26 (68%) of these participants, respectively, which is also nonsignificant, but barely so: Pearson $\chi^2(2, N = 124) = 5.49, p < .07$.

On average (including all dropouts) ACT participants attended 19.5 therapy sessions; ITSF participants attended 19.7 sessions. Of these sessions, 6.9 and 6.3 sessions were therapy groups, respectively. A completer was defined as an ACT or 12-step subject who attended at least 50% of the group and individual sessions. MM control subjects were not required to attend therapy and were considered to have "completed" if they gave urine samples for at least half (i.e., 8 weeks) the duration of the intervention (i.e., 16 weeks). By that criterion, 55% of both psychosocial groups were completers; 76% of the MM participants were completers. There were no differences between any of the groups at any time period in methadone dose, so any differential effects seen were not due to changes in methadone maintenance per se.

Based on the Client Satisfaction Questionnaire (Larsen, Attkisson, Hargreaves, & Nguyen, 1979), there was no significant difference between groups in client satisfaction posttreatment, indicating that any differences in outcome were probably not due to global differences in treatment acceptability.

Analytic Approach

No data currently exist comparing ACT or ITSF to the standard empirically supported treatment (methadone maintenance) used with this population. The present study was designed to make these comparisons using an additive design. The original sample size is sufficient to reveal significant outcome differences assuming a large effect size (Cohen's d of .8), but attrition led to lower numbers for posttreatment and follow-up comparisons, and thus the power fell below .6 even for large effect sizes in some comparisons (Cohen, 1988, pp. 36–37). The comparisons *between* ITSF and ACT could be assumed to involve smaller effect sizes and the present trial is underpowered for these comparisons.

Thus, in the results below we compare ACT and ITSF each to the MM alone condition either in the primary analysis or through the post hoc comparison tests chosen. Direct comparisons between ACT and ITSF were not

TABLE 1
MEANS, STANDARD DEVIATIONS, AND N FOR STUDY VARIABLES

	ACT			ITSF			MM			Total		
	Intake	Post	F Up									
SAS												
Mean	2.39	2.31	2.24	2.39	2.25	2.32	2.47	2.31	2.19	2.41	2.29	2.25
SD	0.53	0.64	0.43	0.51	0.65	0.55	0.63	0.53	0.54	0.55	0.60	0.51
N	41	28	20	44	28	26	38	32	26	123	88	72
BDI												
Mean	18.76	17.04	14.65	19.16	16.71	15.73	18.26	13.56	13.54	18.75	15.67	14.64
SD	9.16	10.94	8.00	12.33	12.23	13.48	11.53	10.93	10.89	11.01	11.34	11.13
N	42	28	20	44	28	26	38	32	26	124	88	72
SCL 90												
Mean	1.10	1.02	0.92	1.04	0.97	0.90	1.00	0.80	0.77	1.05	0.92	0.86
SD	0.62	0.64	0.54	0.74	0.64	0.68	0.65	0.73	0.71	0.67	0.67	0.65
N	42	28	20	44	28	26	38	32	26	124	88	72
ASI Medical												
Mean	0.38	0.31	0.30	0.37	0.37	0.38	0.37	0.35	0.35	0.38	0.34	0.35
SD	0.39	0.36	0.39	0.39	0.39	0.41	0.38	0.40	0.39	0.38	0.38	0.39
N	42	27	19	44	28	26	38	32	26	124	87	71
ASI Employment												
Mean	0.61	0.63	0.53	0.62	0.64	0.65	0.68	0.70	0.56	0.64	0.66	0.59
SD	0.26	0.28	0.26	0.25	0.30	0.27	0.29	0.29	0.32	0.27	0.29	0.29
N	42	27	19	44	28	26	38	32	26	124	87	71
ASI Legal												
Mean	0.14	0.09	0.04	0.13	0.14	0.03	0.14	0.08	0.02	0.14	0.10	0.03
SD	0.16	0.15	0.11	0.14	0.15	0.11	0.18	0.11	0.07	0.16	0.14	0.10
N	42	27	19	44	28	26	38	32	26	124	87	71

ASI Family/Social												
Mean	0.30	0.17	0.15	0.22	0.22	0.14	0.23	0.10	0.17	0.25	0.16	0.15
SD	0.26	0.24	0.19	0.23	0.28	0.21	0.21	0.14	0.19	0.23	0.23	0.20
N	42	27	19	44	28	26	38	32	26	124	87	71
ASI Psychiatric												
Mean	0.31	0.26	0.34	0.30	0.29	0.26	0.26	0.18	0.18	0.29	0.24	0.25
SD	0.22	0.27	0.23	0.22	0.23	0.26	0.21	0.23	0.20	0.22	0.24	0.24
N	42	27	19	44	28	26	38	32	26	124	87	71
Opiates Objective												
N clean	20	13	11	18	12	13	18	10	7	56	35	31
Total N	42	23	18	44	22	26	38	28	25	124	73	69
Total Drug Objective												
N clean	17	12	9	15	11	10	16	9	3	48	32	22
Total N	42	23	18	44	22	26	38	28	25	124	73	69
Opiates Self-Report												
N clean	8	9	10	8	11	9	7	10	8	23	30	27
Total N	42	24	19	44	24	26	38	30	26	124	78	71
Total Drug Self-Report												
N clean	6	8	8	6	9	5	4	8	4	16	25	17
Total N	42	24	19	44	24	26	38	30	26	124	78	71

Note. SAS = Social Adjustment Scale; BDI = Beck Depression Inventory; SCL 90 = Symptom Checklist 90; ASI = Addiction Severity Index.

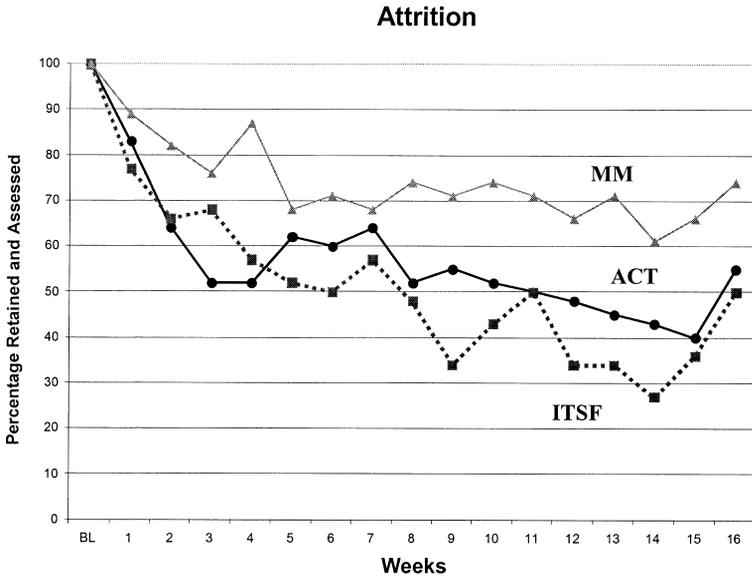


FIG. 1. Percentage of participants retained and assessed week by week during the 16-week treatment.

made except for occasions in which one of the additional treatments produced results that differed significantly from the MM alone condition, and the other did not. In all but one case, however, comparisons between ACT and ITSF were not even marginally significant, and thus no space will be taken reporting these comparisons except for that one situation.

Analyses were conducted on the obtained data and, when significant, on all randomized subjects using an intent-to-treat analysis. All missing drug data were assumed to be positive. Parametric intent-to-treat analyses were based on multiple imputation (Schafer, 1997; Schafer & Graham, 2002), using NORM (Schafer, 1999). Based on parameters from maximum-likelihood estimation, seven imputations were calculated and analyzed. Analyses were combined using the mean differences and standard errors for each condition, using Rubin's (1987) rules for scalar estimands.

Two caveats emerge from these numbers. First, these numbers are fairly small and any significant effects reported should be viewed with caution until these results can be replicated in a larger study. Second, even though no statistically significant differences in the percentage of participants assessed at post or follow-up were found, assessment rates were generally lower in the two added treatments at post, and particularly so in the ACT condition at follow-up, where differences approached conventional levels of significance. The higher retention rate in the MM alone condition is not surprising given the high financial incentives for minimal involvement (assessment only). The

follow-up assessment rates are more difficult to interpret. All participants in follow-up had the same incentives for maintaining contact. Since all of the methadone clinics in the region participated in the study, we were able to contact virtually all subjects who had not moved away, deliberately dropped out of the study, or stopped receiving methadone. Several apparently successful participants were known to have left the area to pursue positive social goals during follow-up (e.g., new jobs); others were probably no longer reachable because they had relapsed and dropped out of methadone maintenance altogether. Because any combination of such negative and positive factors could have been involved, a more general sense of caution is particularly warranted with follow-up data.

Drug Outcomes

The primary focus of the present study is on drug outcomes. Objective drug outcomes as assessed by monitored urinalysis at pre, post, and 6-month follow-up are shown in Figure 2. All drug results are charted in terms of the percentage of participants testing negative for the substance.

ACT Versus MM Alone

Participants began the study with a similar likelihood of UAs negative for opiates (Figure 2). At post, 57% of the ACT group and 36% of the MM alone group produced UAs negative for opiates, a nonsignificant difference. At the 6-month follow-up, 61% of ACT participants and 28% of MM alone subjects produced UAs negative for opiates, a statistically significant difference: Pearson $\chi^2(1, N = 43) = 4.71, p = .03$. The intent-to-treat analysis was not significant.

The objective results for total drug use were similar (Figure 2). At post-treatment, 52% of the ACT group and 32% of the MM alone group tested negative, a nonsignificant difference. At the 6-month follow-up, 50% of the ACT participants and 12% of the MM alone participants tested negative for any drug, a statistically significant difference, Pearson $\chi^2(1, N = 43) = 7.51, p = .006$. The intent-to-treat analysis was marginally significant, Pearson $\chi^2(1, N = 80) = 2.87, p = .09$.

Self-reported opiate use showed patterns broadly similar to the objective data (Figure 2), but none of the differences reached statistical significance. Self-reported total drug use also showed patterns similar to the UA data (Figure 2). The differences were not significant at posttreatment but at the 6-month follow-up, 42% of the ACT subjects and 15% of MM subjects reported no drug use, a significant difference, Pearson $\chi^2(1, N = 45) = 4.0, p = .045$. The intent-to-treat analysis was not significant.

ITSF Versus MM Alone

Objective opiate use outcomes are shown in Figure 2. There were no significant differences. Objective total drug use data are also shown in Figure 2.

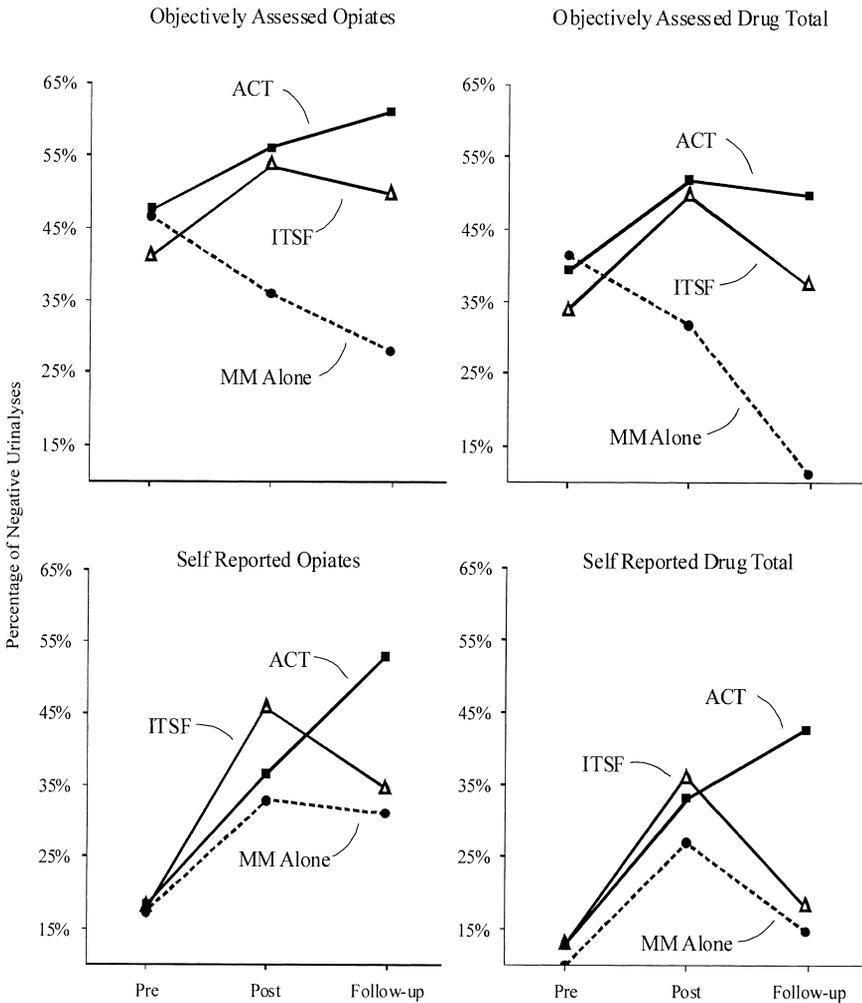


FIG. 2. Percentage of participants actually assessed (for *N*s, see text) who were negative for opiates or total drugs in the three conditions at pre, post, and 6-month follow-up, as assessed through UAs, and corroborated self-report.

At posttreatment 50% of ITSF participants tested negative for any drug as compared to 32% of the MM alone participants, a nonsignificant difference. At 6-month follow-up, 38% of the ITSF participants tested negative as compared to 12% of the MM only participants, a significant difference, Pearson $\chi^2(1, N = 51) = 4.70, p = .03$. The intent-to-treat analysis was not significant.

Self-report data are shown for opiate and total drug data in Figure 2, respectively. There were no significant differences.

ACT Versus ITSF

Comparisons between ACT and ITSF were made only if one differed from the MM condition and one did not. The only such comparison that was even marginally significant was self-reported total drug use at follow-up, in which 42% of the ACT group and 19% of the ITSF group reported no drug use, Pearson $\chi^2(1, N = 45) = 2.80, p < .10$.

Psychological Distress and Social Adjustment

Psychological distress and social adjustment data were analyzed using a repeated measures multivariate analysis of variance for all three group (using pre, post, and follow-up scores) based on both the obtained data and intent-to-treat data sets. Contrast tests were used to compare post and follow-up phases to baseline, using a Bonferroni correction. Between-group effects were evaluated using Dunnett's test comparing the ACT and ITSF conditions to MM alone.

The multivariate analysis showed a significant effect for phase (Pillai's trace: $F[16, 228] = 2.71, p = .001$; partial eta squared = .16, observed power assuming $p = .05, .995$). There was no effect for group or the Group \times Phase interaction in the multivariate or any of the univariate tests, indicating that the phase effect found was due to an improvement for all groups on these measures. Table 2 presents the contrast analyses comparing post and follow-up scores to baseline in the univariate tests. All of the distress and adjustment variables showed significant or marginally significant improvement in at least one of the change comparisons except the ASI Medical score, which did not improve, and the ASI Employment score, which worsened from baseline to the post phase. The same basic pattern was shown in the intent-to-treat analyses using multiple imputation (see Table 2), except that the ASI Medical score now did improve, the ASI Psychiatric score did not, and the worsening of the ASI Employment score was no longer significant.

Analyses of differences between completers and noncompleters are available in Bissett (2002). These analyses will not be repeated here as there were no significant baseline differences between completers and noncompleters, nor any differences in outcomes for the subset of noncompleters for whom post ($n = 10$) or follow-up ($n = 17$) data were available.

Discussion

The present study was, in essence, two studies designed to gather preliminary evidence of the efficacy of these approaches when added to the most widely available empirically supported treatment for opiate dependence. The results suggest that both ACT and ITSF may add to the benefits of methadone maintenance in the reduction of drug use in polysubstance-abusing opiate addicts. ACT participants showed lower rates of objectively assessed opiate and total drug use at follow-up as compared to the methadone maintenance participants; the latter was supported by an intent-to-treat analysis. ITSF

TABLE 2
 CONTRAST TESTS OF WITHIN-SUBJECT EFFECTS FOR SECONDARY OUTCOMES,
 OBSERVED DATA, AND INTENT TO TREAT

Measure/Phase	<i>F</i>	<i>p</i>	Partial Eta Squared	Observed Power ^a	<i>t</i> on Intent to Treat	<i>p</i> Intent to Treat
BDI						
Post versus baseline	2.66	.11	.042	.361	2.49	.02
Follow-up versus baseline	8.10	.006	.119	.800	2.73	.01
SAS						
Post versus baseline	1.85	.18	.030	.268	2.53	.02
Follow-up versus baseline	3.39	.07	.053	.441	1.98	.056
SCL 90						
Post versus baseline	2.29	.14	.037	.320	1.96	.058
Follow-up versus baseline	7.08	.01	.107	.745	1.63	.11
ASI Medical						
Post versus baseline	0.02	.88	.000	.053	2.20	.03
Follow-up versus baseline	0.28	.60	.005	.082	1.50	.14
ASI Legal						
Post versus baseline	1.21	.28	.020	.191	2.42	.02
Follow-up versus baseline	9.72	.003	.139	.866	4.35	.000
ASI Psych						
Post versus baseline	3.98	.05	.062	.501	1.61	.13
Follow-up versus baseline	1.77	.19	.029	.259	.90	.39
ASI Employment						
Post versus baseline	3.57	.06 ^b	.056	.460	-.73	.47
Follow-up versus baseline	0.00	1.00	.000	.050	-.81	.42
ASI Family and Social						
Post versus baseline	10.61	.002	.150	.893	3.08	.002
Follow-up versus baseline	19.10	.000	.242	.990	1.59	.12

Note. Two-tailed tests are used throughout. SAS = Social Adjustment Scale; BDI = Beck Depression Inventory; SCL 90 = Symptom Checklist 90; ASI = Addiction Severity Index.

^a Computed using alpha = .05

^b Marginally significant worsening.

participants showed the same effects for total drug use and ACT subjects also showed significantly lower rates of self-reported total drug use at follow-up, but neither were significant if all missing data was assumed to be indicative of drug use. Only in the area of self-reported total drug abuse at follow-up was there any indication of differential effects between ACT and ITSF.

There is nothing in the outcome data reported here that indicates why participants improved when they did. Processes of change data were collected, however, and can be found in Bissett (2002). These results were complex, and thus will be reported in other outlets, but there were differences in processes

of change between ACT and ITSF that fit with their treatment models, suggesting that the outcome effects seen were not due simply to nonspecific characteristics of treatment. Larger, better controlled studies will be needed to explore these questions adequately.

There are many limitations to this study. The reasons for dropout were not systematically assessed and monitoring of client experiences during the follow-up period was limited. The rates of attrition found in this study interfered with its power. It is difficult to tell yet if the attrition rates in either ACT or ITSF indicate there is a problem with client acceptability. In the present study, participants were paid \$45 a week for participation—a significant amount for this poor and largely unemployed or partially employed sample. That factor seemed to draw a particular kind of participant. It was common, for example, for participants in this study to cheer out loud if they were assigned to the control condition. Even there, however, where assessment alone produced a relatively large financial benefit, attrition was notable (see Figure 1). Various factors in this sample may have produced significant dropout above and beyond the acceptability of psychotherapy, such as poor motivation for treatment, poor psychosocial adjustment, drug use patterns themselves, access (the clinic was a few miles from the methadone maintenance clinics—free bus passes were provided but travel was required), and the like. Whatever the reason, dropout occurred quickly and then tended to stabilize. Virtually the entire dropout in the ACT condition, for example, occurred after only 2 weeks of treatment (see Figure 1)—during a part of the protocol that was designed primarily to establish a positive therapeutic relationship.

Methadone maintenance itself often has significant dropout rates. A recent large double-blind randomized controlled trial found that only 52% of methadone subjects were retained after 13 weeks (Mattick et al., 2003). Meta-analyses of psychotherapy studies that exclude those purely with substance abuse have found average dropout rates of about 50% across the treatment outcome literature (Wierzbicki & Pekarik, 1993). These rates are known to be higher for heroin addicts in particular (Stanton, 1997), and especially in the context of individual therapy (Stanton & Shadish, 1997). Considering all of these factors, we cannot yet say if the attrition in the ACT or ITSF conditions was large because it is not yet clear which benchmark to use. Only future research will resolve this question.

In addition to the drug outcomes, all three conditions improved on several measures of psychological or social outcomes, but there was no significant difference between these treatments. Although drug outcomes were not good for methadone maintenance alone, particularly by follow-up, the other outcomes were generally positive, at least over the period examined. This may not be surprising given that methadone maintenance is an empirically supported treatment known to result in significantly improved social functioning of opiate-addicted individuals. Furthermore, while the current study did not formally alter the ongoing methadone maintenance program, participation in the study essentially meant that methadone could now be free to participants,

since payments for assessment offset those costs. Free methadone removes economic barriers to treatment and can lead to more consistent medication, and thus to more positive outcomes (Anglin, Speckart, Booth, & Ryan, 1989). In addition, the regular assessments (especially UAs, which were taken every week) may have helped structure the lives of some participants in the MM alone group and kept their attention on their methadone treatment participation. Once again, further research will be needed to disentangle these issues.

This is the first study to have experimentally examined ITSF with a multi-problem polysubstance-abusing population. While the results indicate that ITSF may be worth additional development, there are problems to overcome. Given the widespread nature of 12-step programs, and the extensive treatment histories of the participants in this study, some individuals come into treatment predisposed to avoid further 12-step intervention. It was not difficult to find excellent 12-step counselors accepting of methadone maintenance for this study, but in actual clinics this might be an issue. As mentioned earlier, we have had good results by arguing the issue from the canonical texts of the 12-step movement itself. It can be difficult to find 12-step meetings accepting of methadone maintenance, but this was not impossible in Reno, Nevada, which is not a large city (population of about a quarter of a million in the metropolitan area). Additional things might also be done to link 12-step facilitation to the client's involvement with the 12-step community. For example, systematic use of sponsors with a severe drug abuse history and experience with methadone maintenance might be useful.

Drug abuse presents a daunting challenge to empirical clinical approaches. In addition to the inherent difficulty of the problem itself, the drug abuse treatment delivery system is in disarray (McLellan, Carise, & Kleber, 2003), and there is a large divide between the average counselor's attitudes and many research-based approaches (Rawson, Marinelli-Casey, et al., 2002). Both of the treatment approaches examined in the present study hope to cross that divide, either by connecting directly to 12-step approaches, or by complementing the core 12-step philosophy.

The present results suggest that a variety of more contextual treatments focused on mindfulness, acceptance, cognitive defusion, and the like might be helpful with substance abusing populations (e.g., Linehan et al., 1999; Linehan et al., 2002). Because such treatments deal seriously with issues first raised in the context of the 12-step tradition, but do so in a new way (Wilson et al., 2000), there may be a number of new paths for behavioral and cognitive therapists to explore that might both produce positive outcomes and offer hope of crossing the divide between empirically based approaches to substance abuse and the attitudes of many existing treatment providers.

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