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Patient-Centered Methadone Treatment: A Randomized Clinical Trial

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Abstract

Background and aims—Methadone patients who discontinue treatment are at high risk of relapse, yet a substantial proportion discontinue treatment within the first year. We investigated whether a patient-centered approach to methadone treatment improved participant outcomes at 12-months following admission, compared with methadone treatment-as-usual.

Design—Two-arm open-label randomized trial.

Setting—Two methadone treatment programs (MTPs) in Baltimore, Maryland, USA.

Participants—300 newly-admitted MTP patients were enrolled between September 13, 2011 and March 26, 2014. Their mean age was 42.7 years ($SD=10.1$) and 59% were males.

Intervention—Newly-admitted MTP patients were randomly assigned to either Patient-centered Methadone Treatment (PCM; $n=149$) which modified the MTP's rules (e.g., counseling attendance was optional) and counselor roles (e.g., counselors were not responsible for enforcing clinic rules) or treatment-as-usual (TAU; $n=151$).

Measurements—The primary outcome was opioid-positive urine test at 12-month follow-up. Other 12-month outcomes included days of heroin and cocaine use, cocaine positive urine tests, meeting DSM-IV opioid and cocaine dependence diagnostic criteria, HIV risk behavior, and quality of life, and retention in treatment.

Findings—There was no significant difference between PCM and TAU conditions on opioid-positive urine screens at 12 months (adjusted odds ratio = 0.98 95% confidence interval (CI) = 0.61,1.56). There were also no significant differences in any of the secondary outcome measures

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Declarations of interest

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(all $P>0.05$) except Quality of Life Global Score ($P=0.04$; 95% CI: 0.01, 0.45). There were no significant differences between conditions in the number of individual or group counseling sessions attended. ($P>0.05$).

Conclusions—Patient-centered methadone treatment (with optional counseling and the counselor not serving as the treatment program disciplinarian) does not appear to be more effective than methadone treatment-as-usual.

Keywords

methadone treatment; opioid substitution therapy; opioid use disorder; patient centered care; therapeutic alliance; treatment retention

Introduction

In the treatment of heroin addiction, longer retention in methadone maintenance is associated with reduced opioid use as measured by urine screens and other positive outcomes (1–12), yet many patients leave methadone treatment within 12 months of admission (13–17). A systematic review of low and middle-income countries found average 12-month retention rates of 56%, and a 50% rate in high-income countries was considered a benchmark for success (14). In the US, methadone treatment is provided solely through specially regulated Methadone Treatment Programs (MTPs) that require some level of counseling. In these programs, some practices can lead to decreased retention, including “administrative” discharge for failure to comply with various program rules, such as fee payment, counseling attendance, repeated positive drug tests, and, loitering (18–20). Typically, prior to actual administrative discharge, conflicts with staff can lead to patients leaving treatment (20). In many MTPs, the counselor functions as the disciplinarian, a role in potential in conflict with maintaining a therapeutic alliance. An additional factor in premature discharge is the lack of continuation of methadone treatment during brief incarcerations (21, 22).

Patient-centered care is “respectful of and responsive to individual patient preferences, needs, and values” (23, 24). It stems from the patient-provider relationship (25) and should permit patients to exercise control over their health-care decisions. The present study tested the effectiveness of an approach to methadone treatment based on these principles. We sought to reduce program-related reasons for premature and administrative discharge (e.g. counseling non-attendance and rule infractions) and hence to reduce opioid use and improve other participant outcomes by changing some of the rules and staff roles. This study addressed whether patient-centered treatment compared to methadone treatment-as-usual (TAU) would be associated with lower rates of opioid-positive urine screens and a variety of secondary outcomes at 12-month follow-up.

Methods

Design

This was a two-parallel-groups clinical trial in which newly-admitted methadone patients were randomly assigned on a 1:1 basis to PCM or TAU. Participants were evaluated at study entry and at 3, 6-, and 12- month follow-up.

Participants

Participants were newly-admitted methadone patients ages 18 and over who provided informed consent, passed an eligibility quiz, and were not pregnant. Follow-up interviews were conducted between December 20, 2011 and April 1, 2015.

Study sites

The study was conducted at two non-profit MTPs in Baltimore, each with a census of approximately 500 patients of lower socio-economic status.

Recruitment

Research assistants (RAs) recruited patients shortly after admission through referral from MTP staff. The RAs screened for eligibility and offered informed consent in a private office at the MTP. Recruitment began on September 13, 2011 and the target of 300 participants was reached on March 26, 2014. The IRBs of Friends Research Institute and the participating programs approved the study, which had a Data and Safety Monitoring Board.

Interventions (Treatment Conditions)

Prior to launch, the participating MTPs each had two treatment teams led by senior counselors. At study initiation, within each MTP, team leaders decided which one would provide PCM for study participants. Some elements of treatment remained common to both Conditions, including: psychosocial and medical intake; dose induction, drug screening and methadone take-home eligibility.

Treatment-as-Usual

TAU was the same treatment offered to patients not enrolled in the study. Participants were required to attend individual and/or group counseling as determined by their counselor. The counselors were both therapists and disciplinarians. Additionally, they served as contact for program services.

Patient-Centered methadone (PCM)

One team at each clinic accepted participants assigned to PCM. In keeping with the definition of patient-centered treatment in which treatment is tailored to the patients' preferences and need, these participants (in contrast to TAU) were encouraged but not required to attend individual and/or group counseling as often or as little as they preferred. In keeping with the goal of enhancing the patient provider relationship, their counselors served solely as therapists. The PCM team leaders would meet with participants as necessary to address rule-related issues. The RA provided a summary of the modified clinic rules to

these participants after random assignment. They were required to have one introductory meeting with their counselor, who would review the modified rules with them. Counselors were able to advocate on their participants' behalf regarding rule violations.

A number of TAU clinic rules were also altered. For example, PCM participants were not to be "administratively" discharged for rule infractions such as: missing counseling; and/or a specified number of consecutive days of treatment; failure to pay fees (which were typically minimal); loitering; verbal conflicts with other patients or staff; or providing adulterated urine specimens. In response to these situations, graduated consequences as an alternative to administrative discharge were sought. For example: counseling was voluntary; participants could be reinstated after missing medication; alternative payment accommodations were encouraged; loitering was to be handled by permitting PCM participants extra leeway to remain in the clinic waiting room; verbal conflicts were handled where possible through remediation by the team leader; and adulterated urine specimens were simply considered a presumptive positive.

Fidelity—A number of steps were taken to enhance fidelity to assigned Treatment Condition. The PI trained each team on their aspects of the protocol separately and held monthly PCM team meetings to review cases for fidelity. Based on counselor reports and RAs review of progress notes, any issues related to possible confounds were discussed and clarified. At the conclusion of the study, the RAs undertook a structured record review of every participant record to determine whether counselors adhered to the study protocol. This review used a checklist that mirrored the items in Table 1.

Study procedures and measures

Randomization—Within each MTP, participants were randomly assigned to either TAU or PCM using block randomization based on successive random permutations of the sequence 1:1:2:2, such that for each successive block of 4 participants, 2 were assigned to each Condition. Numbered, opaque envelopes containing assignments were prepared for each site by the Project Manager. After completing the baseline assessment, RAs opened the next numbered envelope to determine the assigned Condition.

The RA administered the assessments described below at baseline, 3-, 6-, and 12-month follow-up for which the participants were paid \$30 each.

Primary outcome at 12-month follow-up—The primary outcome measure was percentage of opioid-positive urine tests conducted by the RA (using a dip test: DrugCheck® NxStep Onsite Drug Screen Cup) at 12 months. The RA informed participants of the test results prior to commencing their interviews to maximize the likelihood of accurate self-report of recent drug use. Urine specimens were also sent to a laboratory for EMIT testing.

Secondary outcomes at 12-month follow-up

1. Percentage of cocaine-positive urine screens on the dip test.
2. Self-reported number of days of heroin and cocaine use in the 30 days prior to the interview were obtained from the Addiction Severity Index (26).

3. DSM-IV Opioid and Cocaine Dependence Diagnoses were obtained from a modified version of the World Mental Health Composite International Diagnostic Interview illegal substance use section (WMH-CIDI;27). An expanded prior version of that section, (the CIDI Substance Abuse Module) was found to have good reliability in diagnosing both African-American and Caucasian respondents with opioid and cocaine dependence (kappa values: 0.63–0.77 (28).
4. HIV Drug and Sex Risk Scores were obtained from the *HIV Risk Assessment Battery (RAB)*, composed of 45 questions covering substance and needle use and sexual risk behaviors in the past 6 months (7).
5. Quality of Life Global Scores were obtained from the single item of the *World Health Organization Quality of Life Scale–Brief (WHOQOL-BREF)*: “How would you rate your quality of life” rated by participants on a scale of 1 (very dissatisfied) to 5 (very satisfied) (29, 30).
6. Aggregate Physical and Mental Health Quality of Life Score were obtained from the *Short Form-12, version 2* (31), an abbreviated version of the SF-36 which is widely used to measure physical and mental health status. The Aggregate Physical and Mental Health scales are scored using norm-based methods and scores are standardized. Test-retest reliability for the scales were found to be high in US populations (0.89 for Physical and 0.76 for Mental Health).
7. Treatment Retention in the original OTP was measured from program records and in any other OTP or buprenorphine treatment from self-report.

Other measures

Therapeutic Alliance: Therapeutic Alliance was measured using the Helping Alliance Questionnaire (HAQ-II), a 19-item instrument used to measure the therapeutic alliance (32). The HAQ-II responses on its 19 items each have 6 possible responses ranging from 1 (strongly disagree) to 6 (strongly agree) (32). In its validation study, Cronbach’s alpha reliability scores ranged from 0.90–0.93 (32). HAQ-II scores were analyzed for participants who reported attending 3 or more counseling sessions prior to each follow-up interview ($n=190, 156, \text{ and } 151$ at 3, 6, and 12 months, respectively).

Patient Satisfaction with the program and counselor: Patient Satisfaction with the program and counselor was measured with the self-report Client Evaluation Form (CEF), that inquires about the participants’ views of treatment satisfaction, treatment needs, counselor services (33, 34). The CEF consists of 23 self-rated items scored on a 5-point Likert scale with 5 indicating the most positive rating (33, 34). Counselor services scores were analyzed for participants who reported attending 3 or more counseling sessions prior to each follow-up interview.

Number of Counseling Sessions Attended: Number of Counseling Sessions Attended, by individual and group subtype, was collected by RAs from the participant’s MTP record.

Methadone Dose: Methadone Dose was collected from the participant's record at each follow-up due date.

Data analysis

Sample size—Based on findings from our earlier trial of interim methadone maintenance (35) we expected that the TAU group would have a 46% rate of opioid-positive urine screening test results at the 12-month endpoint. We calculated we would need a sample size of 300 participants to yield 80% power to detect a 30% difference in opioid-positive urine screening tests results favoring the PCM group (that is, a 32% opioid-urine positive screening test result in the PCM group), corresponding to an odds ratio of 1.79, using a two-sided Type I error rate of 5%).

Generalized linear mixed models analysis was used to compare the primary outcome of 12-month opioid-positive urine screening between PCM and TAU. The same approach was used to compare the 12-month outcomes for all secondary outcome variables listed above. Days of heroin and cocaine use in the past 30 days and methadone dose were assumed to follow a Poisson distribution; RAB drug- and sex-risk scores, WHOQOL-BREF global question scores, SF-12v2 Aggregate Physical and Mental Health scores, HAQ-II scores, and CEF patient satisfaction scores were assumed to follow a normal distribution; and DSM-IV opioid and cocaine dependence, opioid and cocaine urine screenings, and retention were assumed to follow a binomial distribution. MTP site was treated as a random effect, and missing data for opioid and cocaine urine tests were considered positive. For all other variables (except methadone dose, HAQ-II, and CEF) baseline values were used where 12-month data were missing.

An additional pre-planned analysis examining changes in all above-mentioned outcome variables over time (baseline, 3-, 6-, and 12 month follow-ups) was conducted using a Generalized Estimating Equations (GEE) approach. This analysis was considered important because participant outcomes over the entire course of treatment (not just at a fixed point in time) are of clinical importance.

Results

Participants

As shown in Figure 1, 406 newly-admitted patients were assessed for eligibility, of whom 21 did not meet inclusion criteria and 85 refused participation. Three hundred patients provided informed consent and were randomly assigned (149 to PCM and 151 to TAU). Shortly after randomization, 5 participants were deemed ineligible (2 had transferred from another MTP, 1 with psychosis, 1 with severe benzodiazepine dependence, and 1 was previously enrolled in the study at the other site), leaving 295 evaluable participants (146 in PCM and 149 in TAU). At 3-, 6- and 12-month follow-up assessments, 97.6%, 97.3%, and 96.9% of the 295 participants were located, and 90.2%, 86.4%, and 82.4% were interviewed.

Patient baseline characteristics are shown in Table 2. The sample was 59% male, 58% African-American, and 41% White, with a mean (*SD*) age of 42.7 (10.1) years.

Outcomes

Primary Outcome—As shown in Table 3, there was no significant difference between study condition for the percentage of participants with opioid-positive urine screens at 12-month follow-up (61.0% PCM, 60.4% TAU; difference=0.6%, 95% Confidence Interval (CI) =−0.11 to 0.12%; $P=0.92$).

Secondary Outcomes—No significant differences by study condition were found for secondary outcome variables of cocaine-positive urine screens, self-reported heroin and cocaine use, meeting DSM-IV opioid and cocaine dependence criteria, HIV-risk behaviors, aggregate physical and mental health quality of life, or treatment retention at 12 months (all $P>0.05$; Table 3). For Quality of Life Global Score, PCM participants reported a significantly higher mean score than TAU participants (means=3.70 and 3.47 for PCM and TAU, respectively; difference=0.23, 95% CI=0.01 to 0.45; $P=0.04$).

Other outcomes

Counseling attendance—There were no significant differences found between conditions in the mean number of individual (means=8.69 and 7.77 for PCM and TAU, respectively) and group counseling sessions attended over the 12 months ($P>0.05$), although the PCM condition attended a mean of 3.77 sessions vs. 6.35 for the TAU condition.

Methadone dose—The PCM condition had a significantly lower mean methadone dose than the TAU condition at 12 months (means=70.8 and 76.6 for PCM and TAU, respectively; difference=−5.93, 95% CI=−11.33 to −0.52; $P=0.03$).

Therapeutic alliance and patient satisfaction—There were no significant differences between conditions in therapeutic alliance or patient satisfaction scores at 12 months (all $P>0.05$).

Fidelity to the PCM model—Fidelity to the PCM model is shown in Table 1. The major difference between Treatment Conditions was that TAU counselors noted discussing counseling attendance requirements with 42 participants a total of 94 times, in contrast to the PCM counselors who noted discussing this requirement with only 9 participants a total of 17 times. TAU counselors discussed other rule violations with 7 participants a total of 7 times but there were no such discussion noted by PCM counselors. There were few notes regarding supervisors' discussions with participants. Finally, there were relatively few threats of involuntary discharge in either Treatment Condition.

Deaths and hospitalizations—There were four non-study related deaths in TAU (one each for pneumonia and vascular disease complicated by cocaine use; and two overdoses (one from heroin, methadone, dextromethorphan and cocaine and another from heroin and methadone). The PCM Condition had two non-study related deaths (one from pneumonia and one from methadone overdose). There were 59 non-study related hospitalizations in TAU and 67 in PCM.

Additional planned analyses—Because it is important to examine changes in outcomes over the entire course of 12 month treatment (and not just at one point), as shown in Table 4, we examined the Treatment Condition $\times$ Time interaction effects and found no significant difference between Conditions for the primary outcome of the percentage of participants with opioid-positive urine screens, nor for any of the secondary outcomes.

Discussion

This random assignment study tested the hypothesis that modifying rules associated with patient/staff conflict and relieving counselors of their disciplinary role to increase therapeutic alliance would result in higher rates of retention in treatment and fewer opioid positive urine screens compared to usual care. What we found was surprising. There were no significant differences in opioid positive urine screens, and with the sole exception of global quality of life, no significant differences in any secondary outcomes. Participants in both conditions improved to about the same degree on all measures. Yet, from another perspective, eliminating mandated attendance at counseling sessions did not appear to produce a lesser degree of improvement. This finding supports results from a previous randomized trial conducted in Texas among newly-admitted MTP patients that found no significant between-group differences in 12-month retention or drug use between optional *v.* required counseling groups (36).

It is likely that changes in overall social context of opioid treatment in Baltimore may explain the lack of difference in treatment retention, opioid positive urine screens and other patient outcomes between treatment conditions. During the year prior to participant enrollment and continuing throughout the study, MTP waiting lists largely ceased to exist in Baltimore. This was primarily due to increases in government insurance coverage for many previously uninsured patients which led to the opening of new private MTPs and permitted existing programs to increase their patient census without depending on limited grant funds. In addition, in Baltimore buprenorphine treatment became increasingly available (37), serving as an alternative for patients leaving methadone treatment. Without a long list of people seeking treatment, and with greater dependence on income from insured patients, program management may have become more reluctant to discharge patients who did not meet program expectations about counseling adherence and negative urine screens. This was in sharp contrast to findings from our six clinic study of Baltimore MTPs conducted between 2004 and 2007 that found that 40.5% of the patients discharged from treatment during the first 12 months left due to “program-related reasons,” including missing counseling or medication visits, not paying fees, continued drug use, and providing an adulterated urine specimen (20). While retention in the original MTP in the present study was 47% (140/295), 78% (189/243) of participants interviewed at the 12-month follow-up reported being enrolled in some treatment with methadone or buprenorphine. A reasonable explanation for this finding is that, with no waiting lists, patients with insurance could transfer to other programs that were more convenient or where they could escape from staff-patient conflict at the initial program. Also, unlike many other US jurisdictions (22), prior to the start of the study, the Baltimore City Detention Center began to continue methadone for detainees enrolled in an MTP at the time of arrest. This permitted detained patients to return to their treatment programs following release, without interruption.

The US methadone maintenance regulations formulated in 1972 have remained largely unchanged in terms of requiring counseling and the level of financial support for MTP's became closely linked to the provision of counseling. In addition, in the US, most MTP practitioners came to believe that counseling was such an essential element of the treatment that participation was generally made mandatory. Failure to attend became a point of program-patient conflict and persistent non-participation became a justification for discharge from treatment (20) in contrast to other countries including the UK (38) and Australia (39) where methadone is frequently provided through primary care and counseling is not mandatory.

This study's findings do not support the view that mandated counseling is needed to obtain improvement among MTP patients during the first year of treatment. Patients in PCM afforded the option of attending individual and/or group counseling attended as many individual sessions as participants in TAU. Group counseling was attended less frequently by PCM than TAU participants (although not significantly). The clinical implication is that, although some patients may benefit from mandatory counseling for particular issues, setting rules requiring all patients to receive counseling during the first year of methadone treatment may not be associated with superior outcomes.

Strengths & limitations

This study had a number of strengths, including random assignment, high ascertainment and follow-up rates, use of measures with known psychometric properties, and an objective measure of drug use. Urine drug test results did not differ between the dipstick screenings or laboratory results (the former were presented because when the laboratory changed ownership, it discarded a number of specimens without testing them). It is not known if we would have had different results had we used hair testing rather than urine testing (40). Because participants were predominantly older African-Americans, most of whom were unemployed, it is not clear to what degree findings from this study can be generalized to other MTP populations. Finally, Baltimore, with virtually no waiting lists for entry to opioid treatment at the time of the study may have led to a change in program responses to rule infractions in TAU to more closely resemble PCM (except for optional counseling), and may not be typical of other localities in the US with waiting lists (41).

Our findings suggest that requiring counseling is not demonstrably better than allowing patients to choose how much individual or group counseling they find valuable. Whether these findings can have an influence on the behavior of counseling staff, many of whom believe that patients will not change behavior without some coercion, or on accreditation bodies or regulatory agencies is uncertain. Currently in the US, funding of treatment is intricately entwined in a package of services that includes supervised methadone administration, drug testing, and evidence of counseling attendance. Any changes in this package will require re-thinking the essential elements of MTPs and how these elements should be reimbursed.

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Figure 1. CONSORT Diagram

*Reasons for not meeting inclusion criteria are as follows: transferred from another methadone treatment program ($n=5$); pregnant ($n=4$); not a new admission ($n=1$); unable to pass consent quiz ($n=3$); unable to complete baseline interview ($n=1$); no recent heroin use ($n=5$); re-admitted to program but already in study ($n=2$).

Table 1

Number of participants and number of times topic discussion occurred with participants by Counselors and Counselor Supervisors ($N = 295$)

	PCM ($n = 146$)		TAU ($n = 149$)	
	Participants (n)	Times (n)	Participants (n)	Times (n)
<i>Counselor</i>				
1) required counseling attendance	9	17	42	94
2) required fee payment	1	1	1	1
3) ineligibility for take home doses	5	5	5	13
4) not approving dose changes	2	2	4	4
5) threats of involuntary discharge	6	9	7	12
6) sanctions for threatening behavior/fighting	3	4	0	0
7) sanctions for loitering	0	0	2	2
8) discussions about other rule violations	0	0	7	7
9) sanctions for falsifying urine specimens	0	0	0	0
10) refusing to offer change of counselor	0	0	0	0
<i>Counselor Supervisor</i>				
1) required counseling attendance	0	0	2	2
2) required fee payment	0	0	0	0
3) ineligibility for take home doses	0	0	0	0
4) not approving dose changes	0	0	0	0
5) threats of involuntary discharge	2	2	1	1
6) sanctions for threatening behavior/fighting	1	1	0	0
7) sanctions for loitering	0	0	0	0
8) discussions about other rule violations	1	1	0	0
9) sanctions for falsifying urine specimens	0	0	0	0
10) refusing to offer change of counselor	1	1	0	0

Note: Data obtained from MTP records. PCM = Patient Centered Methadone; TAU = Treatment as Usual.

Table 2Participant characteristics at baseline ($N=295$)

	Total Sample ($N = 295$)	Patient Centered Methadone (PCM) ($n = 146$)	Treatment as Usual (TAU) ($n = 149$)
<i>Demographics</i>			
% Male (n)	59.0 (174)	63.0 (92)	55.0 (82)
Age, mean (SD)	42.7 (10.1)	43.5 (10.3)	42.0 (9.8)
Race			
% Black (n)	58.0 (171)	61.6 (90)	54.4 (81)
% White (n)	41.4 (122)	38.4 (56)	44.3 (66)
% Hispanic (n)	0.7 (2)	0.0 (0)	1.3 (2)
% Married (n)	19.7 (58)	19.2 (28)	20.1 (30)
% Employed in last 30 days (n)	37.3 (110)	33.6 (49)	40.9 (61)
Years of education, mean (SD)	11.3 (2.0)	11.3 (2.0)	11.4 (2.0)
<i>Drug use and treatment</i>			
Age of first heroin use, mean (SD)	21.4 (6.8)	20.9 (6.7)	21.9 (6.9)
Age of first cocaine use, mean (SD)	22.5 (7.9)	22.2 (7.7)	22.9 (8.1)
% With prior MTP episode (n)	53.6 (158)	55.5 (81)	51.7 (77)
<i>Criminal justice involvement</i>			
Age of first crime, mean (SD)	17.5 (6.5)	17.3 (6.9)	17.7 (6.0)
Lifetime number of arrests, mean (SD)	12.4 (12.9)	10.4 (10.0)	14.3 (15.0)
Lifetime months of incarceration, mean (SD)	51.0 (68.3)	53.1 (75.1)	49.0 (61.1)

Note: MTP = methadone treatment program. There were no statistically significant differences between Treatment Conditions on any variables (all P s > 0.05), except for lifetime number of arrests ($P = 0.01$). $N=291$ (145 PCM, 146 TAU) rather than 295 for age of first heroin use due to 4 participants who reported never having used heroin. $N=249$ (122 PCM, 127 TAU) for age of first cocaine use due to 46 participants who reported never having used cocaine. $N=272$ (136 PCM, 136 TAU) for age of first crime due to 23 participants who reported never having committed a crime.

Patient Centered Methadone (PCM) and Treatment As Usual (TAU) outcomes at 12 months

Table 3

	Patient Centered Methadone (PCM) [n = 146]	Treatment as Usual (TAU) [n = 149]	Odds ratio (95% CI)	Risk difference (95% CI)	P
<i>Primary outcome</i>					
Opioid-positive screen, % (n)	61.0 (89)	60.4 (90)	0.98 (0.61, 1.56)	0.006 (−0.11, 0.12)	0.92
<i>Secondary outcomes</i>					
Cocaine-positive screen, % (n)	45.9 (67)	57.0 (85)	1.57 (0.99, 2.49)	−0.11 (−0.23, 0.00)	0.06
Drug Risk score (RAB), mean (SD)	0.72 (2.56)	1.36 (3.63)		−0.64 (−1.36, 0.08)	0.08
Sex Risk score (RAB), mean (SD)	2.75 (2.35)	3.03 (2.33)		−0.29 (−0.82, 0.25)	0.29
Quality of Life Global score (WHOQOL-BREF), mean (SD)	3.70 (0.91)	3.47 (1.00)		0.23 (0.01, 0.45)	0.04
DSM-IV Opioid Dependence, % (n)	60.3 (88)	69.1 (103)	1.48 (0.91, 2.39)	−0.09 (−0.20, 0.02)	0.11
DSM-IV Cocaine Dependence, % (n)	28.1 (41)	34.9 (52)	1.37 (0.84, 2.26)	−0.07 (−0.18, 0.04)	0.21
Days of heroin use/last 30 days, mean (SD)	9.43 (12.05)	9.84 (12.31)		−0.74 (−4.93, 3.44)	0.73
Days of cocaine use/last 30 days, mean (SD)	4.59 (8.74)	5.30 (9.68)		−0.89 (−2.67, 0.88)	0.32
Aggregate Physical Health score (SF-12v2), mean (SD)	40.14 (7.47)	41.51 (7.40)		−1.37 (−3.07, 0.34)	0.12
Aggregate Mental Health score (SF-12v2), mean (SD)	45.38 (13.27)	43.14 (13.44)		2.23 (−0.83, 5.29)	0.15
Retained in original MTP 12 months (MTP records), % (n)	48.6 (71)	46.3 (69)	0.91 (0.58, 1.44)	0.02 (−0.09, 0.14)	0.69
Enrolled in any OTP or buprenorphine treatment at 12 months (self-report; N=243), % (n)	78.9 (97)	76.7 (92)	0.88 (0.48, 1.62)	0.02 (−0.08, 0.13)	0.68

Notes: As noted in methods sections, missing 12 month urine screen data were considered positive. For all other variables (except methadone dose, HAQ-II, and CEF) baseline values were used where 12-month data were missing

RAB=Risk Assessment Battery

For outcome “Enrolled in any OTP or buprenorphine treatment at 12 months,” data were obtained from 12-month interviews (N=243; 123 PCM and 120 TAU).

Scale score ranges are as follows:

- Drug Risk score range: 0–22, with higher scores indicating greater risk.
- Sex Risk score range: 0–18, with higher scores indicating greater risk.
- WHOQOL-BREF global question (How would you rate your quality of life?) score range: 1 (very poor) – 5 (very good)
- SF-12v2 Aggregate Physical Health and Mental Health scale scores are T-scores (Mean=50, SD=10) based on 1998 general U.S. population norms (N = 7,837).

Table 4

Tests of significance, *P* values, and estimated marginal means (95% confidence intervals [CIs]) for outcome variables at baseline, 3-, 6-, and 12-month follow-up for Treatment Condition $\times$ Time interaction (*N* = 295)

	Patient Centered Methadone (PCM) [<i>n</i> = 146]	Treatment as Usual (TAU) [<i>n</i> = 149]	Treatment Condition $\times$ Time Interaction Test Statistic	<i>P</i>
<i>Primary outcome</i>				
Opioid-positive screen, mean (95% CI)			$\chi^2(3) = 1.92$	0.59
Baseline	0.78 (0.72, 0.85)	0.80 (0.73, 0.87)		
3-month	0.45 (0.37, 0.54)	0.50 (0.42, 0.59)		
6-Month	0.51 (0.42, 0.59)	0.56 (0.48, 0.65)		
12-Month	0.53 (0.44, 0.61)	0.50 (0.41, 0.59)		
<i>Secondary outcomes</i>				
Cocaine-positive screen, mean (95% CI)			$\chi^2(3) = 0.85$	0.84
Baseline	0.43 (0.35, 0.51)	0.51 (0.43, 0.59)		
3-month	0.38 (0.30, 0.47)	0.51 (0.42, 0.59)		
6-Month	0.41 (0.33, 0.50)	0.48 (0.40, 0.57)		
12-Month	0.37 (0.29, 0.45)	0.46 (0.37, 0.55)		
Drug Risk score (RAB), mean (95% CI)			$\chi^2(3) = 4.85$	0.18
Baseline	1.68 (1.06, 2.29)	2.97 (2.09, 3.84)		
3-month	0.47 (0.25, 0.69)	0.90 (0.50, 1.29)		
6-Month	0.36 (0.20, 0.51)	1.01 (0.58, 1.43)		
12-Month	0.51 (0.20, 0.82)	0.85 (0.43, 1.28)		
Sex Risk score (RAB), mean (95% CI)			$\chi^2(3) = 3.86$	0.28
Baseline	3.31 (2.96, 3.66)	3.22 (2.85, 3.60)		
3-month	2.80 (2.43, 3.18)	2.79 (2.45, 3.14)		
6-Month	2.62 (2.25, 2.99)	2.96 (2.57, 3.35)		
12-Month	2.70 (2.28, 3.12)	3.00 (2.59, 3.41)		
Quality of Life Global score (WHOQOL-BREF), mean (95% CI)			$\chi^2(3) = 3.82$	0.28
Baseline	3.06 (2.91, 3.22)	2.95 (2.78, 3.11)		
3-month	3.64 (3.49, 3.80)	3.68 (3.54, 3.82)		
6-Month	3.64 (3.47, 3.80)	3.67 (3.52, 3.82)		
12-Month	3.77 (3.63, 3.92)	3.63 (3.48, 3.79)		
DSM-IV Opioid Dep., mean (95% CI)			$\chi^2(1) = 0.40$	0.53
Baseline	0.95 (0.91, 0.99)	0.95 (0.91, 0.98)		
3-month	N/A	N/A		
6-Month	N/A	N/A		
12-Month	0.54 (0.45, 0.63)	0.63 (0.54, 0.72)		
DSM-IV Cocaine Dep., mean (95% CI)			$\chi^2(1) = 0.08$	0.77
Baseline	0.27 (0.20, 0.34)	0.33 (0.26, 0.41)		
3-month	N/A	N/A		

	Patient Centered Methadone (PCM) [<i>n</i> = 146]	Treatment as Usual (TAU) [<i>n</i> = 149]	Treatment Condition × Time Interaction Test Statistic	<i>P</i>
6-Month	N/A	N/A		
12-Month	0.28 (0.20, 0.35)	0.36 (0.28, 0.45)		
Days of heroin use/last 30 days, mean (95% <i>CI</i>)			$\chi^2(3) = 1.98$	0.58
Baseline	24.84 (23.37, 26.31)	24.98 (23.54, 26.41)		
3-month	6.05 (4.50, 7.59)	6.23 (4.61, 7.84)		
6-Month	6.39 (4.64, 8.14)	7.54 (5.69, 9.39)		
12-Month	6.33 (4.55, 8.10)	5.48 (3.85, 7.11)		
Days of cocaine use/last 30 days, mean (95% <i>CI</i>)			$\chi^2(3) = 0.88$	0.83
Baseline	6.84 (5.03, 8.66)	8.52 (6.75, 10.29)		
3-month	3.77 (2.61, 4.93)	5.11 (3.75, 6.47)		
6-Month	3.98 (2.65, 5.31)	4.50 (3.11, 5.89)		
12-Month	3.78 (2.50, 5.06)	4.22 (2.70, 5.75)		
Aggregate Physical Health score (SF-12v2), mean (95% <i>CI</i>)			$\chi^2(3) = 4.25$	0.24
Baseline	41.83 (40.57, 43.09)	41.51 (40.32, 42.69)		
3-month	40.49 (39.36, 41.63)	41.49 (40.25, 42.72)		
6-Month	40.51 (39.23, 41.79)	42.03 (40.87, 43.20)		
12-Month	39.77 (38.52, 41.02)	41.27 (40.00, 42.54)		
Aggregate Mental Health score (SF-12v2), mean (95% <i>CI</i>)			$\chi^2(3) = 0.30$	0.96
Baseline	44.47 (42.60, 46.33)	42.48 (40.42, 44.55)		
3-month	47.08 (44.96, 49.19)	44.62 (42.45, 46.78)		
6-Month	46.62 (44.31, 48.94)	43.85 (41.72, 45.99)		
12-Month	45.37 (43.14, 47.60)	43.16 (40.87, 45.46)		

Notes: 12-month means do not correspond to means in Table 3 because means in Table 4 are estimated marginal means from GEE analyses.

DSM-IV Opioid and Cocaine Dependence were analyzed at baseline and 12 months only because their criteria are measured over a 12-month period. The relatively high rate of meeting these criteria at 12-month follow-up could have been influenced by meeting criteria in the first few months of treatment.

Due to missing urine samples, the *ns* for opioid and cocaine urine screens are as follows: At baseline, *n* = 292 (3 missing); at 3-month follow-up, *n* = 254 (12 missing); at 6-month follow-up, *n* = 244 (11 missing) for opioid and 245 (10 missing) for cocaine, and at 12-month follow-up, *n* = 238 (5 missing).

RAB=Risk Assessment Battery.

Scale score ranges are as follows:

- Drug Risk score range: 0–22, with higher scores indicating greater risk.
- Sex Risk score range: 0–18, with higher scores indicating greater risk.
- WHOQOL-BREF global question (How would you rate your quality of life?) score range: 1 (very poor) – 5 (very good)
- SF-12v2 Aggregate Physical Health and Mental Health scale scores are *T* scores (*Mean*=50, *SD*=10) based on 1998 general U.S. population norms (*N*= 7,837).

The number of days in original MTP obtained from MTP program data (maximum 365 days) means (*SE*) are as follows: TAU: 239.90 (12.62); PCM: 256.50 (13.19); $\chi^2(1) = 0.83$, *P* = 0.36.

OTP = Opioid Treatment Program (methadone or buprenorphine).

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