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Journal of Substance Abuse Treatment 31 (2006) 385–393

Journal of Substance Abuse Treatment

Regular article

A 12-month controlled trial of methadone medical maintenance integrated into an adaptive treatment model

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Received 16 February 2006; received in revised form 27 April 2006; accepted 14 May 2006

Abstract

Methadone medical maintenance (MMM) reduces the reporting schedule for stable and well-functioning methadone maintenance patients to once a month, with counseling provided by medical staff. We report on the 12-month outcomes of 92 highly stable methadone maintenance patients randomly assigned to one of three study conditions: routine care, MMM at the methadone maintenance program, and MMM at a physician's office. Methadone medical maintenance patients received a 28-day supply of methadone, whereas routine care patients received five or six take-home methadone doses each week. All patients performed a medication recall once a month and submitted two urine samples each month. An adaptive stepped-care system of treatment intensification was used for patients who failed recall or who had drug-positive urine specimens. Seventy-seven patients completed the 12-month study period. Dropout was caused primarily by problems with handling methadone and disliking the recall frequency. There were low rates of drug use or failed medication recall. Treatment satisfaction was high in all groups, but the MMM patients initiated more new employment or family/social activities than did routine care patients over the study period. The stepped-care approach was well tolerated and matched patients to an appropriate step of service within a continuum of treatment intensity.

Keywords: Methadone; Medical maintenance; Stepped care; Adaptive treatment

1. Introduction

Methadone medical maintenance (MMM) is an appropriate intervention for highly rehabilitated methadone maintenance patients who no longer require intensive external monitoring and drug abuse counseling (Des Jarlais, Joseph, Dole, & Nyswander, 1985). Methadone medical maintenance patients report once or twice a month for brief counseling sessions and receive supplies of methadone to last between scheduled contacts. Physicians or other medical staff can provide care either in physician's office settings or in traditional methadone maintenance clinics. Patients can benefit from this intervention in several ways. Two potential benefits involve patients having more time to devote to prorehabilitative activities and reduction in the general level of inconvenience associated with medical care, which is typically more problematic in the management of chronic versus acute health problems. The potential benefits of an MMM intervention also extend to treatment programs. Clinics can benefit because staff resources can be reallocated to the management of less stable patients. The community can also benefit because clinics using the intervention can increase their static census to accommodate new patients who might not otherwise have access to treatment.

Despite positive reports evaluating the use of MMM interventions in patients with long-term stable and positive treatment responses (Fiellin et al., 2001; Novick et al., 1994;

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0740-5472/06/$ – see front matter
doi:10.1016/j.jsat.2006.05.014

Salsitz et al., 2000; Schwartz, Brooner, Montoya, Currans, & Hayes., 1999; Senay et al., 1993), adoption of the intervention has been slow. At least two unresolved issues may be hindering the broader adoption of this intervention in community-based treatment settings: The first issue involves the lack of research on effective management strategies for MMM patients who relapse to drug use. Patients in previous studies who relapsed and could not be adequately treated in an office-based setting were returned to methadone maintenance clinics and not allowed to return to the MMM schedule (Fiellin et al., 2001; Salsitz et al., 2000; Schwartz et al., 1999; Senay et al., 1993). This amounts to a permanent intensification of treatment services that is likely unnecessary in many instances and perhaps to a more punitive versus therapeutic response to otherwise expected lapses to drug use. Another still unresolved issue is how to manage (in programs and in patients) the unavoidable risk of methadone take-home medication misuse. The possibility that some prescribed take-home doses from treatment programs may have contributed to the reported increase in overdose on methadone (Center for Substance Abuse Research, 2003; Center for Substance Abuse Treatment, 2004; Drug Early Warning System [DEWS], 2004) has stimulated increased concern about providing take-home doses of medication, and this concern is a likely source of hesitation in some treatment providers. Studies that address this particular issue by reducing risk of diversion might help lower this apprehension.

The Addiction Treatment Services (ATS) program developed an adaptive stepped-care treatment delivery system (Davison, 2000; Sobell & Sobell, 2000) that provides an effective platform for managing both relapse to drug use and potential methadone misuse by MMM patients (Brooner & Kidorf, 2002; Brooner et al., 2004). This model of care was designed specifically for community-based programs offering methadone or other opioid agonist medications. The core feature of the model is the ability to rapidly increase or decrease the amount of clinic monitoring and counseling based on objective and ongoing indices of a patient's overall clinical status. This expanded continuum of care is particularly well suited for patients with a chronic substance use disorder that is often characterized by a relapsing and remitting course.

King et al. (2002) used the adaptive motivated stepped-care approach to deliver and evaluate treatment response and patient satisfaction with an MMM reporting schedule. Methadone maintenance patients (n = 73) who were drug abstinent and working full time for 12 months were randomly assigned to one of three treatment conditions: (1) MMM in a physician's office setting; (2) MMM in the methadone clinic setting; or (3) routine methadone maintenance treatment. Drug use was assessed using random urinalysis testing, and management of possible medication diversion employed a prerecorded daily telephone recall procedure. Results over the first 6 months of this 12-month evaluation were very encouraging. Patients assigned to the MMM conditions (clinic-based and office-based settings) versus those assigned to routine methadone maintenance reporting schedules reported significant reductions in amount of time spent in clinic-related treatment activities and increased involvement in prorehabilitative activities in the community. The intervention, including the daily prerecorded telephone recall procedure, was extremely well tolerated, associated with low rates of drug use as well as methadone mishandling across study conditions, and associated with high rates of satisfaction for those assigned to the MMM conditions (both clinic-based and office-based settings).

This article reports on the 12-month outcomes from this randomized trial, along with the full and larger sample (N = 98). The longer assessment period evaluates whether the positive findings in the smaller sample over 6 months are sustained in the full sample throughout the year. The larger sample provides additional statistical power to analyze both main effects and potential predictors of good treatment outcome. We hypothesized that patients assigned to MMM schedules would continue to be more satisfied with treatment, spend more time in prorehabilitation activities outside the clinic, and exhibit drug use outcomes similar to those in the routine treatment condition. We also hypothesized that indicators of previous treatment stability, including length of treatment and consecutive months of drug-free urine samples, would correlate with good outcome.

2. Materials and methods

2.1. Study participants and eligibility requirements

Participants were recruited from two community-based methadone maintenance treatment programs in Baltimore, Maryland: ATS at Hopkins Bayview and Man Alive Research. Patients were eligible to participate in the study if they met the following minimal criteria for the previous 12-month period: (1) an uninterrupted episode of methadone maintenance treatment; (2) no urine specimen positive for heroin or other opioids, cocaine, sedatives, or other drugs; (3) verified full-time employment; (4) no failed methadone medication recall or any other problem handling methadone; and (5) desire to remain on methadone maintenance treatment over the 12-month study period. The study was approved by the Johns Hopkins Bayview Medical Center Institutional Review Board.

Approximately 200 of the 380 ATS patients (53%) had received treatment at the ATS over the past 12 months. Approximately half of these patients (n = 98) met all remaining criteria and 68% of them (n = 67) agreed to participate. Only 21% (31/150) of the patients from Man Alive Research who were eligible agreed to participate; thus, a total of 98 patients provided informed written consent. Across programs, patients reported the following