

Regular article

Targeting HIV-related outcomes with intravenous drug users maintained on methadone: A randomized clinical trial of a harm reduction group therapy

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Abstract

Methadone maintenance programs (MMP) have the potential to play an important role in reducing HIV risk, given the appropriate type and level of ancillary treatments. In this study, we investigated the efficacy of a 12-session harm reduction group intervention for injection drug users, based upon the Information-Motivation-Behavioral skills model of behavior change, that focused on reducing both drug and sex risk. Two hundred and twenty patients entering an MMP were randomized to receive either standard care (SC)—2 hours of counseling per month and a single-session risk reduction intervention—or SC plus the harm reduction group (HRG). Results showed that during treatment, patients receiving HRG were more likely to be abstinent from cocaine and to report fewer unsafe sexual practices. Post-treatment, HRG patients scored higher on a sexual risk quiz and reported increased self-efficacy in high risk sexual situations. Enhancing methadone maintenance with a weekly harm reduction group treatment was somewhat more expensive but can bring about positive changes in behaviors and attitudes that are associated with the transmission of HIV. © 2004 Elsevier Inc. All rights reserved.

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1. Introduction

Maintaining opiate-addicted individuals on methadone provides a number of individual and societal benefits when provided in the context of adequate adjunctive psychosocial services (Ball & Ross, 1991). Therefore, an important research goal has been to determine the optimal level of adjunctive psychosocial treatments in methadone maintenance programs (MMP) for producing a broad range of clinically and socially meaningful outcomes (Avants, 1999; Childress, McLellan, Woody, & O'Brien, 1991; Kraft, Rothbard, Hadley, McLellan, & Asch, 1997; Simpson, Joe, Dansereau, & Chatham, 1997). A pioneering study comparing three levels of psychosocial treatment delivered adjunctive to methadone maintenance concluded that methadone enhanced by the addition of on-site medical/psychi-

atric care, family therapy, and employment counseling provided more benefits than a standard methadone maintenance condition that included daily methadone and individual drug counseling, which in turn provided more benefits than provision of methadone alone (McLellan, Arndt, Metzger, Woody, & O'Brien, 1993). However, a subsequent study, which sought to determine whether the addition of an even higher level of services produced better outcomes, found that an intensive, 25-h per week, manual-guided day treatment program (DTP) was not significantly more effective in reducing illicit drug use than an enhanced standard care condition that included a weekly manual-guided coping skills training group, provided at one third the cost of the DTP (Avants et al., 1999). Furthermore, for certain subgroups of patients, the lower level intensity was significantly more effective than the intensive DTP on a number of outcomes, including HIV risk behavior (Avants, Margolin, Kosten, Rounsaville, & Schottenfeld, 1998). In the absence of a standard care control condition, however, no conclusion could be drawn concerning whether the addition of the weekly group intervention provided

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clinical benefits over and above those of standard care. Therefore, one of the goals of the current study was to investigate the efficacy of the group intervention—modified, as discussed below, in response to the pressing need to evaluate HIV harm reduction treatments—in comparison to standard care.

Determining the optimal type and intensity of psychosocial services to provide in MMPs possesses an increased urgency in view of the high rates of HIV transmission among drug users and their drug and sexual partners (Centers for Disease Control and Prevention [CDC], 2000). By reducing intravenous heroin use and the sharing of drug paraphernalia, methadone maintenance is generally associated with a reduction in HIV transmission (Gossop, Marsden, Stewart, & Treacy, 2002; Hartel & Schoenbaum, 1999; Kwiatkowski & Booth, 2001; Sorensen & Copeland, 2000). However, although it is associated with reduced sex-for-drugs transactions, and with a corresponding reduction in number of sexual partners, there is considerably less evidence that methadone maintenance increases condom use or safer sexual practices (Gibson, Flynn, & McCarthy, 1999; Sees et al., 2000). Nor is it an effective treatment for cocaine abuse (Rhoades, Creson, Elk, Schmitz, & Grabowski, 1998), which is prevalent in MMPs (Kolar, Brown, Weddington, & Ball, 1990; Rawson, McCann, Hasson, & Ling, 1994), and it is associated with increased impulsivity and high risk sexual behavior (Bux, Lamb, & Iguchi, 1995; Grella, Anglin, & Wugalter, 1995; Joe & Simpson, 1995). Thus, adjunctive psychosocial services provided to patients enrolled in MMPs should optimally address cocaine use and high risk sexual behavior, in addition to illicit opiate use. Indeed, in light of recent findings that the strongest predictor of HIV infection among injection drug users is no longer sharing of drug paraphernalia, but rather high risk heterosexual activity (Strathdee et al., 2001), it may be considered essential to include measures of both cocaine use and unsafe sexual practices when evaluating outcomes of adjunctive MMP services.

A number of effective interventions for reducing HIV transmission in various at-risk populations are available (CDC, 1999), yet there is considerable variability in these interventions. Several approaches are based on an Information-Motivation-Behavioral skills (IMB) model of behavior change which posits that information about how HIV is transmitted and motivation to reduce transmission are necessary for the enactment of HIV preventive behavior. However, information and motivation are not sufficient; both work through risk reduction behavioral skills to enact preventive behavior. The IMB model has received empirical support in a number of subpopulations (e.g., Carey et al., 2000; Peipman et al., 2001), including methadone maintained drug users (Bryan, Fisher, Fisher, & Murray, 2000), and has been delivered in both group and individual format. A single session intervention based on the IMB model (Fisher & Fisher, 2000) has also been

described, and has been hypothesized to be potentially as effective for reducing sexual-risk behavior as a multi-session IMB intervention (Kalichman et al., 2001). However, whether a single one-on-one IMB session would be as effective as a more comprehensive multi-session group intervention for reducing drug and sexual risk behavior among inner-city drug users with multiple treatment needs remains an open question (cf. Grella, Etheridge, Joshi, & Anglin, 2000), especially in light of previous findings that standard AIDS education and counseling provided with HIV antibody testing is not effective for injection drug users (Calsyn, Saxon, Freeman, & Whittaker, 1992). Determining the optimal intensity of HIV prevention treatment has therefore been identified as an important research goal (Kalichman et al., 2001; Kamb, Fishbein, & Douglas, 1998).

An inner-city MMP, which can deliver adjunctive psychosocial counseling to patients in both individual and group modalities, provides a relevant, real-world clinical context in which to compare the efficacy of single- and multi-session interventions. To date, there have been relatively few controlled studies comparing different intensities of risk reduction treatments provided adjunctive to methadone maintenance, and most of these have been preliminary in nature or have reported difficulties in the implementation of the interventions (see Baker, Heather, Wodak, Dixon, & Holt, 1993; Grella & Anglin, 1994; Grella, Anglin, & Wugalter, 1997; O'Neill et al., 1996; Schilling, el-Bassel, Hadden, & Gilbert, 1995; Sorensen et al., 1994). Given the outstanding question concerning whether methadone enhanced by a weekly manual-guided group intervention is more effective than standard methadone maintenance in reducing illicit drug use, as well as the important need to assess the efficacy of multi-session format risk reduction interventions in at-risk populations, the current study addressed both of these issues simultaneously, using an additive design. As described in detail below, patients entering an inner-city MMP were randomized to either standard care, which included a single risk reduction session, or to standard care enhanced by a 12-session harm reduction group intervention. The multi-session and the single session risk reduction interventions were both theory-driven, based on the IMB model of behavior change. Within the IMB model of HIV preventive behavior change, an effective harm reduction intervention would be predicted to correct deficits in the information, motivation, and behavioral skills requisite for HIV prevention (Fisher, Misovich, Kimble, & Weinstein, 1999). These treatment process variables were therefore also examined in the current study. Finally, because interventions delivered in community-based MMPs will need to be cost-efficient as well as clinically effective, the current study also calculated the additional cost of the manual-guided group intervention over and above the cost of standard care to the community-based MMP in which it was delivered.

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