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A randomised controlled trial of methadone maintenance treatment versus wait list control in an Australian prison system

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Abstract

Objectives: The aim was to determine whether methadone maintenance treatment reduced heroin use, syringe sharing and HIV or hepatitis C incidence among prisoners. *Methods:* All eligible prisoners seeking drug treatment were randomised to methadone or a waitlist control group from 1997 to 1998 and followed up after 4 months. Heroin use was measured by hair analysis and self report; drugs used and injected and syringe sharing were measured by self report. Hepatitis C and HIV incidence was measured by serology. *Results:* Of 593 eligible prisoners, 382 (64%) were randomised to MMT ($n = 191$) or control ($n = 191$). 129 treated and 124 control subjects were followed up at 5 months. Heroin use was significantly lower among treated than control subjects at follow up. Treated subjects reported lower levels of drug injection and syringe sharing at follow up. There was no difference in HIV or hepatitis C incidence. *Conclusions:* Consideration should be given to the introduction of prison methadone programs particular where community based programs exist.

Keywords: Randomised controlled trial; Methadone; Prisoner; Injections; Hepatitis C; HIV

1. Introduction

Estimates of injecting drug use in prison have ranged from 11 (Correctional Service Canada, 1996) to 53% (Gore et al., 1995). The frequency of injecting in prison may be considerably lower than in the community but the risks of HIV and hepatitis C transmission are magnified through the sharing of limited injecting equipment among large numbers of inmates of unknown HIV or hepatitis C status (Dolan et al., 1996a). Drug injection with shared equipment is likely to be the main route for HIV (Taylor et al., 1995; Stark et al., 1997; Dolan and Wodak, 1999; Choopanya et al., 2002; Buavrit et al., 2003) and hepatitis C (Vlahov et al., 1993; Christensen et al., 2000) transmission among prisoners. Tattooing has also been shown to be a route for hepatitis C transmission in prison (Post et al., 2001). Hepatitis C prevalence among prisoners has ranged from 30 (Hedouin et al., 1998) to 58% (Malliori et al., 1998). Reports of hepatitis C incidence have ranged from 1.1 per 100 person years (Vlahov et al., 1993) among general prisoners to 25 (Christensen et al., 2000) and 38 per 100 person years (Crofts et al., 1995) among drug injectors who have been released from prison and re-incarcerated.

Methadone maintenance treatment (MMT) reduces mortality (Caplehorn et al., 1994), heroin consumption

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(Gottheil et al., 1993; Sees et al., 2000), criminality (Newman et al., 1973), HIV transmission (Metzger et al., 1993), and re-incarceration (Dole et al., 1969) among injecting drug users (IDUs) in community settings, yet MMT is rarely provided to prisoners (Dolan and Wodak, 1996). Prison-based methadone programs have been documented in New York (Magura et al., 1993) and New South Wales (NSW) (Hall et al., 1993), however, prospective evaluations of effectiveness have not been previously published.

In 1997, there were 7957 inmates in NSW prisons (Corben, 1997) and 685 inmates received MMT (Corrections Health Service, 1998). The prevalence of HIV and HCV among NSW male inmates was less than 1% (NCHECR, 2001) and approximately 30% (Butler et al., 1997), respectively. In one NSW study, IDUs in MMT reported lower levels of injecting in prison than non-treated peers (Dolan et al., 1996b). The aims of the Prison Methadone Program were to reduce drug injecting and prevent HIV and hepatitis transmission in prison (Corrections Health Service, 1998). This study examined whether the Methadone Maintenance Program was achieving its aims.

2. Methods

The primary aims of the study were to determine whether prison based MMT reduced (a) heroin injection and (b) syringe sharing. A secondary aim was to determine whether prison based MMT reduced (c) HIV and (d) HCV seroincidence (Dolan et al., 2003).

In 1997, the waiting time for methadone treatment in NSW prisons was approximately 6 months. All inmates on the waiting list were asked to enter the study and, if assessed as suitable, they were either randomised into methadone treatment immediately or had a 4-month delay with guaranteed access after that period.

Male inmates were eligible to participate if they: (1) were assessed as suitable for MMT by a detailed interview with medical staff which confirmed they had a heroin problem; (2) were serving prison sentences longer than 4 months at time of interview; and (3) were able to provide signed informed consent. Group allocation was based on block randomisation. A sequential list of case numbers was matched to group allocations in blocks of ten by randomly drawing five cards labelled 'control' and five cards labelled 'treatment' from an envelope. This procedure was repeated for each block of ten sequential case numbers. The list of case numbers and group allocation was held by a researcher not involved in recruiting or interviewing inmates. The trial nurses responsible for assessing, recruiting and interviewing inmates had no access to these lists. Once an inmate had been recruited and interviewed, the trial nurse contacted the Central Randomisation System via a mobile telephone to ascertain the inmate's group allocation.

Subjects were interviewed at study entry (baseline) and approximately 4 months later (follow up). Hair and blood samples were collected at both interviews. All interviews were carried out with subjects while in custody.

Hair analysis offers the longest window of detection (7–100+ days) of all drug tests (United Nations International Drug Control Programme, 1998). Quantitative results for hair analysis (nanograms per mg of hair) were analysed. Over 50 hairs were cut approximately 2 mm from the scalp at the vertex. Hair samples were tested for morphine by Tricho-Tech Limited, Wales, UK. At baseline, one cm of hair cut from the root was analysed for morphine to assess heroin use in the previous month. At follow-up, a 3 cm segment of hair cut from the root was divided into three, one cm sections and analysed for morphine to assess heroin use in each of the 3 months preceding the follow-up interview.

Finger prick blood samples were collected and tested for antibodies to HIV and hepatitis C by the Centre for Immunology, St. Vincent's Hospital, Sydney. The samples were assayed using an algorithm that has a high correlation with assays of venous blood samples (NCCLS, 1988). HIV antibody was detected using Genetic Systems HIV-1 ELISA tests, and if reactive twice, underwent Western blot confirmatory testing. Specimens were tested for HCV antibody using a modified third generation enzyme immunoassay (Abbott HCV 3.0, Chicago II). A modified cut-off value for optical density was calculated to capture greater than 95% of the seronegative population. Specimens were considered positive for anti-HCV if the optical density cut-off ratio was greater or equal to 1.0 on initial and subsequent testing. The date of seroconversion was taken as the midpoint between the last negative and first positive antibody tests.

Subjects were asked about their drug use, injecting and the shared use of injecting equipment in the month preceding prison entry and the previous month or less in prison (baseline). Subjects were re-interviewed approximately 4 months after their first interview and were asked about drug use, injecting and syringe sharing during the past 3 months, that is second, third and fourth months. These periods, 1 month before baseline and 3 months before follow up approximated the time periods for which hair samples were analysed. Heroin use was not measured by self-report or hair analysis in the first month after recruitment to allow treated subjects to achieve an adequate dose of methadone.

Subjects allocated to MMT commenced on 30 mg of methadone and were increased by five mg every 3 days until 60 mg was achieved. Data on duration in treatment were obtained from the NSW Department of Health.

Data on methadone dose at follow up were based on self-report.

Sample size was calculated to detect a difference in heroin use, but not in HIV or HCV incidence. The prevalence of HIV was too low and the prevalence of HCV was too high to detect a difference within a feasible sample size. The calculated sample size provided power of 0.9 with a value of 0.01 for a 23% difference in proportions in heroin use in pilot data (Dolan et al., 1996b). Data were analysed using SPSS for WINDOWS (version 9.0). An intention-to-treat model was used to examine differences between study groups at baseline and follow-up. All statistical tests used a 0.05 level of significance. *T*-tests were used for continuous and the χ^2-test for categorical data to assess the differences between groups for the primary outcome variables. Group and time variations in concentrations of morphine in hair were tested using a General Linear Model for Repeated Measures. HCV incidence was calculated using the person years method with 95% confidence intervals calculated using an exponential error factor for incidence rates (Breslow and Day, 1987).

The study was approved by the four relevant Ethics Committees. Subjects were not remunerated for their participation.

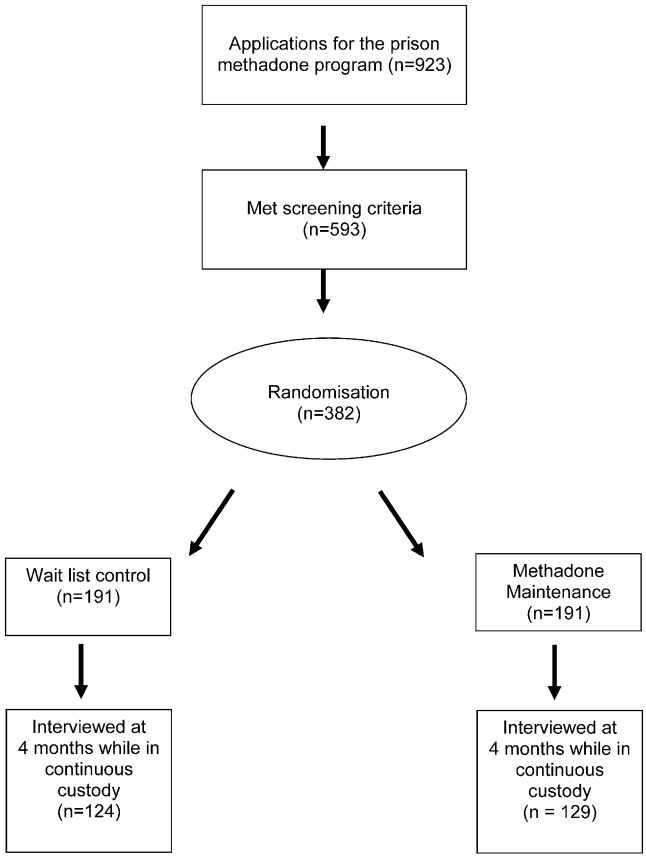

Fig. 1. Subject flow chart.

3. Results

Between August 1997 and October 1998, 923 consecutive applicants for the prison methadone program were assessed for the study; 330 (36%) applicants did not meet study criteria. Of the remaining 593 eligible applicants, 382 (64%) were randomly allocated to methadone maintenance ($n = 191$, treated) or routine care ($n = 191$, control) (Fig. 1). At follow-up, 129 (68%) treated and 124 (65%) control subjects who had been in continuous custody were re-interviewed. The mean duration to follow up interview were; 156 days (range: 86–641 days) for treated and 136 days (range: 55–530 days) for control subjects. A further 29 treated and 33 control subjects were followed up but had been released from prison between interviews and are, therefore, excluded from these results.

Baseline characteristics were similar among treated and control groups except for a small difference in sentence length and time in prison (Table 1). No subject was in methadone treatment at baseline. A majority of subjects reported a history of sharing syringes in the community (64%, $n = 124$; 74%, $n = 129$) or in prison (79%, $n = 117$; 76%, $n = 119$) at some time. Similar reports of Most Serious Offences were made by both treated and control groups; robbery (38 vs. 32%), assault (16 vs. 25%) and break and enter (23 vs. 22%).

3.1. Heroin use

Over 80% of subjects in both groups either reported heroin use in the month prior to baseline interview or had morphine positive hair results at baseline (Fig. 2). There were no between-group differences in hair analysis results measured either by nanograms (group × month; $F = 0.57$, $P = 0.45$) or in the between-group proportions of morphine positive hair results (Table 2). Some control subjects received methadone treatment prior to follow-up interview while some treatment subjects were not offered methadone due to operational reasons specific to one prison. When these subjects were removed from the analysis, the between-group difference in proportions of hair results positive for morphine was significant at month 4 (27% treated; 42% control $\chi^2 = 4.3$ $P = 0.05$). Self reported heroin use declined significantly in the treated group ($P < 0.001$) in each of the 3 months prior to follow-up interview (Table 3).

3.2. Heroin injection and injection of other drugs as measured by self report

Nearly all treated and control subjects reported drug use (100 vs. 99%) and drug injection (98 vs. 93%) in the month before prison entry. Most often this was heroin

Table 1
Baseline characteristics of treated and control subjects

Baseline characteristics	Sample followed up		
	Treated ($n = 129$)	Controls ($n = 124$)	P
Mean years of age (S.D.)	27 (6)	27 (6)	0.8
Mean age (years) at first imprisonment (S.D.)	20 (3)	20 (4)	0.5
Mean number of times in prison (S.D.)	4 (3)	5 (7)	0.4
Security classification			
Maximum%	16	21	
Medium%	14	12	
Minimum%	14	16	
Escapee%	22	13	
Unclassified%	33	37	
Not reported%	1	1	0.4
Mean weeks of sentence (S.D.)	134 (166)	166 (207)	0.3
Mean weeks in prison at baseline (S.D.)	30 (63)	39 (116)	0.4
Mean age (years) at first injection (S.D.)	17 (3)	17 (4)	0.8
Mean age (years) daily injection began (S.D.)	18 (4)	18 (4)	0.7
Started injecting in prison (%)	9	15	0.2

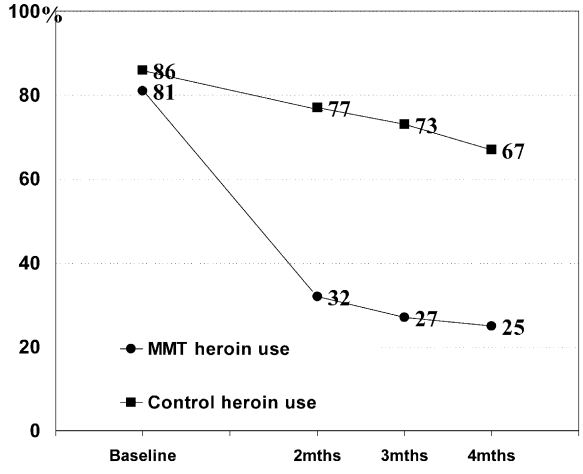

Fig. 2. Percentage of subjects who either reported heroin use or hair test positive for morphine.

(96 vs. 90%) rather than amphetamine (40 vs. 40%) injection. During the study period, reports of injection of any drug decreased among treated subjects (64–34%) but not among control subjects (70–75%) (Table 3). Likewise reports of heroin injections decreased among treated (60–32%) but not among control subjects (68–74%). The mean number of heroin injections reported per month was also significantly lower among treated subjects at Month 2, 3 and 4 compared with control subjects (Table 3).

3.3. Syringe sharing

Approximately half the subjects in each group reported syringe sharing in the month before baseline (Table 3). At follow up, treated subjects were significantly less likely to report syringe sharing than control subjects ($P < 0.001$). There was no difference between groups in the number of sharing partners among those who shared at baseline or at follow up.

Table 2
Percent positive for morphine and mean nanograms in hair at baseline and follow up months 2, 3 and 4

	Treated	Control	P
Baseline	($n = 128$)	($n = 123$)	
Positive%	82	83	ns
Mean (ng morphine/mg hair)	3.5	4.1	ns
Range	0.0–40	0.0–47.6	
Month 2	($n = 87$)	($n = 82$)	
Positive%	33	43	ns
Mean (ng morphine/mg hair)	0.27	0.77	ns
Range	0.0–4.4	0.0–16.6	
Month 3	($n = 106$)	($n = 95$)	
Positive%	31	41	ns
Mean (ng morphine/mg hair)	0.20	0.80	ns
Range	0.0–3.9	0.0–13.9	
Month 4	($n = 125$)	($n = 117$)	
Positive%	31	37	ns
Mean (ng morphine/mg hair)	0.24	0.30	ns
Range	0.0–5.8	0.0–8.8	

3.4. HIV and HCV seroincidence

HIV prevalence was zero at both baseline and follow up for all subjects. Baseline HCV antibody seroprevalence was 76% ($n = 129$) and 72% ($n = 124$) for treated and control subjects, respectively. Of 32 treated and 35 control subjects who were hepatitis C antibody negative at baseline, four subjects in each group had seroconverted by follow up. Hepatitis C incidence was lower

Table 3
Self reported heroin injection and syringe sharing, baseline follow up

	Treated ($n = 129$)	Controls ($n = 124$)	P-value
Any injection%			
Baseline	64	70	
Follow-up	34	75	< 0.001, $\chi^2 = 42.5$, df = 1
Heroin injection%			
Baseline	60	68	
Follow-up	32	74	< 0.001, $\chi^2 = 50.87$, df = 1
Mean number of times heroin injected			
Baseline	9	15	ns
Follow-up			
Month 2	1.4	7.7	< 0.001, $t = -5.0$
Month 3	1.1	8.8	< 0.001, $t = -5.3$
Month 4	1.3	8.5	< 0.001, $t = -4.1$
Shared syringes%			
Baseline	53	45	ns
Follow-up	20	54	< 0.001

among the treated than control group, but the difference was not statistically significant (Table 4).

Among *all* subjects, seroconversion to hepatitis C antibody during follow-up was associated with older age (25 years or more, $P = 0.02$), being tattooed in prison during the study period ($P = 0.01$) and reporting recent heroin injection at follow-up ($P < 0.05$).

3.5. Tattooing and sexual risk behaviour

At follow up, 12% of each group reported being tattooed during the study. Three percent of controls and 4% of treated subjects reported sharing a tattoo needle. Five percent of controls and 4% of treated subjects

Table 4
HCV incidence and predictors of HCV incidence among treated and control subjects[a]

Variable	Treated			Control		
	Number of cases/risk	Rate per 100 py	95% CI	Number of cases/risk	Rate per 100 py	95% CI
Incidence	4/32	24.3	7–62	4/35	31.7	9–81
Age group						
< 25 years	2/18	17.4	2.1–63	1/24	10.6	0.3–59
25+ years	2/14	40.0	4.8–144	3/11	96.0	19.7–280
Aboriginal						
Yes	1/9	19.5	0.5–109	0/8	0	–
No	3/23	26.0	5.4–76	4/27	41	11–105
Inject heroin at FU						
Yes	1/5	32.9	0.8–183.3	3/21	36.5	7.5–107
No	3/23	21.9	4.5–63.9	1/7	29.2	0.7–163
Shared at FU						
Yes	1/5	32.9	0.8–183.3	2/15	32.9	4.0–118.8
No	3/23	21.9	4.5–63.9	1/7	36.5	0.92–203
Tattoo at FU						
Yes	1/3	58.4	1.5–325.3	1/4	54.8	1.4–305
No	3/25	18.3	3.8–53.4	3/27	25.6	5.3–74.8
Any inject at FU						
Yes	1/5	32.9	0.8–183.3	3/21	36.5	7.5–106.5
No	3/23	21.9	4.5–63.9	1/10	18.3	0.5–102

[a] Note all P values > 0.05.

reported cleaning the tattoo needle. No subject reported having sex with another prisoner at follow up.

3.6. Methadone treatment

Over two thirds (68%) of the treated group remained in treatment, with an average duration of 144 days (range 72–530). Their mean dose of methadone was 61 mg (range: 1–150), with most (60%) reporting a stable dose of methadone at follow up. Methadone treatment was discontinued for 29 subjects in the treated group (23%) during the study, after an average of 51 days in treatment (range 5–133). Twelve treatment subjects (9%) did not start treatment. Approximately half the treated subjects reported that other inmates suggested they leave methadone treatment. A similar proportion of control subjects (58%) also reported other inmates suggested that they not enter treatment.

Nineteen percent of control subjects commenced methadone treatment during the study period. The mean dose of methadone prescribed for the 24 controls at follow up was 84 mg (range: 10–120). Nine percent of control subjects received methadone for the entire duration of the study period (mean duration 209 days, range 95–530). A further 11% of controls received methadone for part of the study period (mean duration 67 days, range: 2–146).

4. Discussion

This randomised controlled trial found that prison based MMT reduced heroin injection when measured by either hair analysis or self-report. Self-reported data appeared to be more sensitive than hair analysis in detecting between group differences in this low frequency heroin using population. However, when analysis was based on treatment exposure, there was a significant between group difference in the proportions of morphine positive hair samples at month 4.

No subject was found to be HIV positive at baseline or follow up, reflecting the very low HIV prevalence ($\sim$ 1%) among IDUs in Australia (NCHECR, 2001). Approximately 70% of subjects were hepatitis C antibody positive at baseline, reflecting the high HCV prevalence ($>50\%$) among IDUs in Australia (NCHECR, 2001). Predictors of hepatitis C seroconversion were being tattooed in prison, being older than 25 years and recent heroin injection. Efforts need to be directed at reducing the prevalence of tattooing in prison or making it safer.

One limitation of this study was the short duration of follow up. This coupled with the high prevalence of hepatitis C infection precluded the possibility of detecting a difference in hepatitis C incidence between groups. The duration of follow up was shorter than the usual time taken to access MMT in prison. Prolonging the duration of follow up would have seriously compromised the recruitment of subjects. In retrospect, hepatitis C negative inmates should have been over sampled.

Another limitation of the study was that only two thirds of treated subjects remained in treatment. Subjects reported that other inmates and staff discouraged them from remaining in or entering methadone treatment. Inmates and staff should be educated about the benefits of MMT. Also subjects in this study were on moderate doses of methadone (61 mg) and outcomes may have improved with higher doses, our previous work found a relationship between methadone dose and reduction in injecting in prison (Dolan et al., 1996b). There was potential for contamination through control subjects starting methadone before the follow-up interview. Analyses were stratified to test for this bias by removing these subjects. This did not change outcomes with the exception of proportions of morphine positive hair samples, which were significantly higher in the control group in the final month of follow-up (month 4).

Methadone treatment reduced drug use and injection in prison. The implications from this study are far reaching as very few countries provide MMT to prisoners. This study suggests that prison based methadone programs should be provided in countries where community based programs operate (Dolan, 2001).

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