

## RESEARCH REPORT

# Pilot randomized controlled study of dexamphetamine substitution for amphetamine dependence

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### Abstract

**Aims.** To test the feasibility of conducting a definitive randomized controlled trial of dexamphetamine substitution for amphetamine dependent people and provide preliminary data. **Design.** An open, two-group pre-post randomized controlled trial. **Participants.** Forty-one long-term, dependent amphetamine users seeking treatment. **Intervention.** Twenty subjects were offered weekly counselling. Twenty-one subjects were, in addition, prescribed up to 60 mg dexamphetamine daily. **Measurements.** Immunoassay and mass spectrometric urinalysis techniques were used to identify the presence of amphetamine and methylamphetamine in urine. The Opiate Treatment Index and Severity of Dependence Scale were used to collect pre- and post-self-report data. Subjects were screened using the Composite International Diagnostic Interview. **Findings.** Reduced street amphetamine use and amphetamine dependence was observed both in subjects prescribed dexamphetamine and subjects receiving counselling only. Treatment subjects appeared more likely to attend counselling. **Conclusions.** A definitive randomized controlled trial of dexamphetamine substitution using the techniques and instruments piloted in this study is feasible. Users appeared to be attracted and retained in substitution treatment. The intervention also appeared to be acceptable to clinicians.

### Introduction

Amphetamine is among the most widely used illicit drugs in Australia. In the most recent National Drug Strategy household survey, 9% of respondents reported amphetamine use at some time in their life and 4% had used amphetamine in the previous 12 months. Among injecting drug users, 70% reported injecting amphetamine in the past year and 51% reported they had initiated injecting drug use with amphetamine

(Australian Institute of Health and Welfare, 1999). Harms associated with regular amphetamine use include psychological morbidity, dependence, medical complications, financial and other social problems (Klee, 1992; Hando, Topp & Hall, 1997; Vincent *et al.*, 1999). Many regular amphetamine users inject the drug and risk infections and complications from unsafe injecting practices (Hall & Hando, 1994; Darke *et al.*, 1994; Hando *et al.*, 1997; Vincent *et al.*,

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1999). Frequent amphetamine injection may also increase the risk of dependence and psychological problems (Hall & Hando, 1994). The number of people presenting to drug and alcohol services with primary amphetamine problems in Australia has increased in recent years, although there are no specific services for amphetamine users (Darke *et al.*, 1996; Torres *et al.*, 1996; Hando & Hall, 1997).

Oral amphetamine substitution may allow some patients to stabilize on a dose which is unaccompanied by either withdrawal or craving. Gradual reduction and eventual cessation of amphetamine use may well follow (Lintzeris, Holgate & Dunlop, 1996). Mattick & Darke (1995) suggest that amphetamine maintenance may be appropriate where amphetamine use is frequent (usually daily), attempts to achieve abstinence have been unsuccessful, dependence is evident, severe adverse complications have occurred and maintenance is likely to cause less harm than continued illicit use. Risks associated with maintenance include psychiatric and cardiovascular complications of high-dose amphetamine, particularly when additional street amphetamine is consumed. However, recent studies of amphetamine substitution programmes in Britain have reported few complications and low levels of psychosis (McBride *et al.*, 1997; Charnaud & Griffiths, 1998; White, 2000). Public health and other community benefits may also outweigh risks associated with prescription of substitution drugs (Fleming & Roberts, 1994; Pates, Coombes & Ford, 1996; Charnaud & Griffiths, 1998). These include a reduction in the transmission of blood-borne viruses (such as HIV and hepatitis C) through shared injecting equipment, improvements in the health and social functioning of drug users, reduced illicit drug use and reductions in crime undertaken to fund drug use (Fleming, 1998).

Evaluations of amphetamine prescription conducted in the 1960s and early 1970s in London concluded that the modest benefits were outweighed by serious negative consequences including psychosis, continuing illicit use and diversion of prescribed amphetamine (Hawks *et al.*, 1969; Gardner & Connell, 1972). More recent evaluations of clinical programmes have suggested that amphetamine users are attracted to services offering amphetamine prescription where they can also be provided with advice, counselling and harm minimization interventions

such as needle and syringe programmes (Fleming & Roberts, 1994; McBride *et al.*, 1997). Reported positive outcomes of amphetamine prescribing included reduced illicit amphetamine use, reduced injecting, reduced sharing of injecting equipment, improved social functioning and retention in treatment (Sherman, 1990; Fleming & Roberts, 1994; Pates *et al.*, 1996; McBride *et al.*, 1997; Charnaud & Griffiths, 1998; White, 2000). Amphetamine prescribing has been found to be widespread in England and Wales; however, there is little scientific evidence to support the efficacy of this intervention (Bradbeer *et al.*, 1998).

The aim of the present pilot study was to evaluate the feasibility of conducting a trial providing dexamphetamine to dependent users under controlled conditions. Issues explored included the feasibility of instruments and laboratory techniques used to assess and monitor subjects and the acceptability of the intervention to users and clinicians. The study did not aim to evaluate definitively the effectiveness of amphetamine substitution. However, between-group analyses were planned for urinalysis results and self-reported street amphetamine use at baseline and follow-up to obtain an indication of the possible impact of this intervention.

## Method

### Subjects

Forty-one treatment-seeking dependent amphetamine users but otherwise in good health provided informed consent and agreed to participate. Amphetamine dependence was diagnosed using the Composite International Diagnostic Interview (CIDI-Auto version 2.1; WHO, 1997). None of the subjects reported a previous diagnosis of attention deficit hyperactivity disorder (ADHD). All subjects were assessed for schizophrenia and other psychotic disorders using the CIDI; however, time constraints precluded assessment of co-morbidity rates for affective and personality disorders. Subjects were recruited from clients attending the Kirketon Road Centre (KRC), a primary health-care centre targeting injecting drug users and other at-risk populations in inner-city Sydney. The study was publicized in other treatment services and advertised in selected media. Twenty-eight amphetamine users were excluded due to histories of major physical or psychiatric illness (36%)

including schizophrenia and other psychotic disorders, or were assessed as not amphetamine-dependent (21%) or were otherwise unwilling or unable to participate. Ethical approval was obtained from relevant institutional ethics committees including that of the South Eastern Sydney Area Health Service. A more detailed description of project procedures is available (Shearer *et al.*, 1999).

### Design

This was an open, two-group pre-post randomized controlled trial. Allocation to treatment (21 subjects) or control (20 subjects) was achieved by 50:50 randomization of prepared Patient Identification Cards identified by group in blocks of 10 and sealed in consecutively numbered opaque envelopes. Enrolling subjects were allocated consecutive case numbers. After study admission and the collection of baseline data, the corresponding envelope was opened in the presence of the subject. All subjects were offered standard care for amphetamine users presenting for treatment. This consisted of weekly counselling sessions provided by the KRC counselling unit. Participants were assessed at baseline and 12 weeks. Urine samples were collected from all subjects at baseline, 6 weeks and 12 weeks. The treatment group were prescribed dexamphetamine to a maximum daily supervised oral dose of 60 mg. Induction began at 20 mg, increasing by 5 mg daily until a maximum dose was achieved. The dose was reduced in the final 2 weeks to a maximum dose of 40 mg at week 12. Symptom checklists were used to monitor adverse events including psychotic symptoms.

### Urinalysis

The presence of amphetamine and methylamphetamine was determined by immunoassay (EMIT™) using a cut-off of 300 ng/ml (Standards Australia, 1995). Presumptive positive samples were confirmed by analysis of the pentafluoropropionic anhydride derivatives using gas chromatography-mass spectrometry operated in the selected ion monitoring mode. Street amphetamine was identified by testing for the presence of methylamphetamine in urine. Methylamphetamine is not a metabolite of dexamphetamine or any other pharmaceutically available drug in Australia.

### Instruments

Baseline demographic data on current drug use, drug use history and previous treatment were collected in a structured interview. The Opiate Treatment Index (OTI) (Darke *et al.*, 1992) was used to measure self-reported amphetamine use and other treatment outcomes. Current dependence on amphetamine was measured using the Severity of Dependence Scale (SDS) described by Gossop *et al.* (1992).

### Data analysis

Data were analysed using SPSS for Windows (version 6.1). An intention-to-treat analysis was used to examine differences between the two study groups at follow-up. The intention-to-treat population was defined as those subjects who were enrolled in the study and randomized. For subjects lost to follow-up, a conservative 'worst case scenario' approach was taken which assumed no changes to baseline data at follow-up. Urine samples missing from subjects lost to follow-up were assumed to be positive for street amphetamine. The Design-Power software package (Bavry, 1987) was used to calculate retrospectively the power of the study sample to reliably detect a difference between the study groups based on independent tests of proportions and an alpha level of 0.05. All statistical tests were two-tailed using a 0.05 level of significance and 95% confidence intervals. *T*-tests were used for continuous variables. Categorical variables were analysed using chi-square tests.

## Results

### Study sample

The forty-one subjects enrolled in the trial had a mean age of 29 years (range 20–48). Most (83%) were male and had used amphetamine a mean of 10 years (range 2–25). Thirty-two per cent of subjects were homosexual or bisexual males. First reported use of amphetamine was at a mean age of 18 years. Regular use and commencement of injecting both started at a mean age of 21 years. Subjects reported currently using amphetamine on average twice a day, usually (95%) by injection. Thirteen per cent of injectors reported sharing injecting equipment with others in the month preceding intake. Subjects reported spending an average of AUD\$56 per

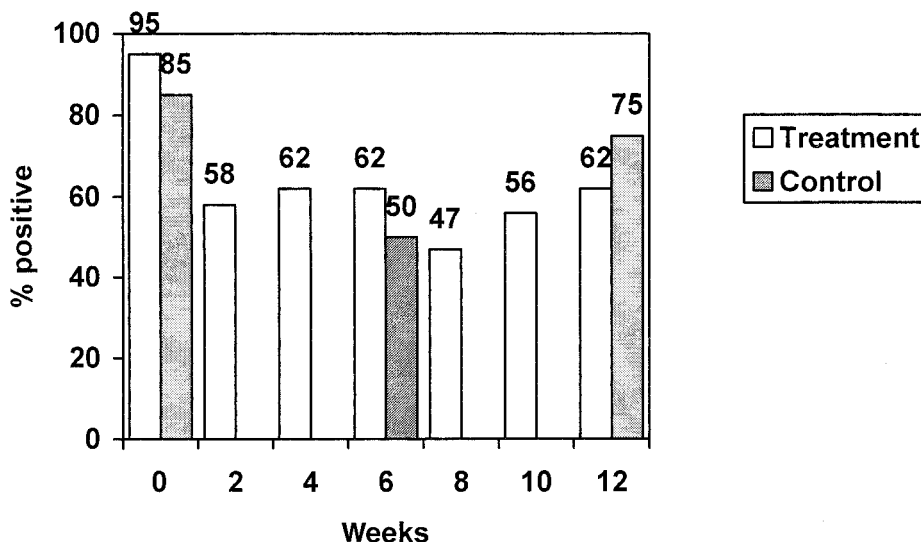


Figure 1. Proportion treatment and control group urine samples positive for methylamphetamine over study period.

day on street amphetamine. Six subjects were enrolled concurrently in methadone maintenance treatment. Study groups were comparable with the exception of gender with females being significantly over-represented in the treatment group (29%) compared to the control group (5%) ( $\chi^2 = 4.4$ ,  $df = 1$ ,  $p = 0.04$ ). Thirty-one subjects completed the study. Losses to follow-up were comparable between treatment (19%) and control (30%) groups ( $\chi^2 = 0.7$ ,  $df = 1$ ,  $p = 0.4$ ).

#### Urinalysis results

Proportions of treatment and control group samples positive for methylamphetamine appear in Fig. 1.

The proportion of urine samples positive for methylamphetamine decreased in both groups at 6 weeks compared to baseline. In the treatment group, the proportion of methylamphetamine positive samples remained stable at 12-week follow-up but increased in the control group. There were no statistically significant differences between the groups at either point (6 weeks:  $\chi^2 = 0.6$ ,  $df = 1$ ,  $p = 0.4$ ; 12 weeks' follow-up:  $\chi^2 = 0.8$ ,  $df = 1$ ,  $p = 0.4$ ). Urine samples were collected from treatment subjects fortnightly allowing a more detailed picture of continued street amphetamine use. The lowest level (47%)

of methylamphetamine positive urine samples in the treatment group was achieved at week 8 after which the proportion steadily increased to 62% at 12 weeks. Note that the 12-week sample was taken after dose reduction to 40 mg.

#### Power calculations

Treatment effect size was estimated at 13% based on the proportion of urine samples positive for methylamphetamine at follow-up (treatment 62%,  $n = 21$ ; control 75%,  $n = 20$ ). The power of the study was calculated as 0.14. This is well below the level (0.8) conventionally accepted as necessary to reliably detect a difference between groups, but the main aim of the study was to determine the feasibility of conducting trials of this kind. The findings are presented because data of this kind are rare, large samples are difficult to obtain, and results can be aggregated in meta-analysis.

#### Self-reported drug use and injecting behaviour

Self-reported street amphetamine use (as measured by the OTI) declined in both groups at 12 weeks though the change was not statistically significant. The number of occasions of use per day declined from 1.8 (SD 1.1) to 1.4 (SD 2.5) in the treatment group and from 2.8 (SD 2.9) to

**Table 1.** Mean OTI and SDS scores at baseline and follow-up

	Treatment (n = 21)		Control (n = 20)		(p) <sup>1</sup>
	Baseline	Follow-up	Baseline	Follow-up	
Amphetamine use	1.8	1.4	2.8	1.9	(0.6)
HIV risk score	12.3	8.9	11.6	9.3	(0.9)
Expenditure	49.7	26.1	64.0	48.5	(0.2)
SDS	10.3	5.3	10.7	7.8	(0.06)
GHQ	7.4	4.8	9.6	6.3	(0.4)
Social	16.0	15.3	13.7	13.4	(0.4)
Crime	0.9	0.6	1.1	1.1	(0.3)
Health	14.9	12.1	13.3	12.0	(0.9)

<sup>1</sup>Independent samples *t*-test for equality of means (two-tailed) between groups at follow-up.

1.9 (SD 2.6) in the control group. Self-reported street amphetamine use was not significantly different between groups at 12 weeks ( $t = -0.58$ ,  $df = 39$ ,  $p = 0.56$ ). At 12 weeks, 23.5% in the treatment group ( $n = 17$ ) reported no street amphetamine use in the past month compared to 7% in the control group ( $n = 14$ ). Estimated daily expenditure on street amphetamine decreased significantly in the treatment group from AUD\$50 (SD AUD\$31) to AUD\$26 (SD AUD\$30) ( $t = -0.233$ ,  $df = 19$ ,  $p = 0.03$ ) but there was no significant difference between treatment and control at follow-up ( $t = -1.43$ ,  $df = 36$ ,  $p = 0.16$ ) (Table 1).

HIV risk-taking behaviour (as measured by the OTI) declined significantly in both groups, primarily due to reductions in drug consumption and injecting (treatment  $t = 3.34$ ,  $df = 20$ ,  $p = 0.003$ ; control  $t = 2.16$ ,  $df = 19$ ,  $p = 0.04$ ) although there was no significant difference between the groups after 12 weeks' follow-up ( $t = -0.17$ ,  $df = 39$ ,  $p = 0.86$ ). At 12 weeks' follow-up, reported daily injecting declined among treatment subjects from 59% to 12% ( $n = 17$ ), and from 35% to 14% among control subjects ( $n = 14$ ). Reduction in SDS scores for both groups was the most marked improvement noted for both groups (treatment  $t = -4.87$ ,  $df = 20$ ,  $p < 0.001$ ; control  $t = -3.85$ ,  $df = 19$ ,  $p = 0.001$ ) although there was no difference between groups at follow-up ( $t = -1.98$ ,  $df = 39$ ,  $p = 0.055$ ). Improvements in psychological adjustment, social adjustment, health and reduction in criminal involvement were apparent in both groups but were not significant either within or between groups.

#### Treatment group data

**Adverse events.** No serious adverse events were reported in the treatment group. No psychotic symptoms were reported for any subjects. Two subjects ceased treatment due to discomfort during the induction phase. One reported agitation and aggressive behaviour. Insomnia was reported by three subjects but these complaints all existed before entry to the trial.

**Compliance.** Twelve treatment group subjects (57%) completed the 12-week course of treatment and nine dropped-out. Among the drop-outs four were lost to follow-up (19%), two terminated treatment due to discomfort (9%) and three to attempt abstinence (14%). Mean days to drop-out was 26 (range 2–63). Treatment retention over study period appears in Fig. 2.

Treatment subjects were dispensed dexamphetamine on a mean of 45 days (range 2–91) over a mean attendance period of 61 days (range 6–98 days). This represented compliance to daily attendance of 74% (range 27–99%). Mean average daily dose of dexamphetamine was 49.4 mg (range 21.6–56.9 mg). At week 6, 14 subjects were dispensed dexamphetamine, of whom 10 received 60.0 mg each day, three received 55.0 mg and one received an average of 22.9 mg. This indicated that most subjects remaining in treatment were stabilized at, or close, to the maximum dose.

**Counselling.** Fifty-seven per cent of treatment subjects attended a mean of 2.6 counselling sessions compared to 25% of control subjects who

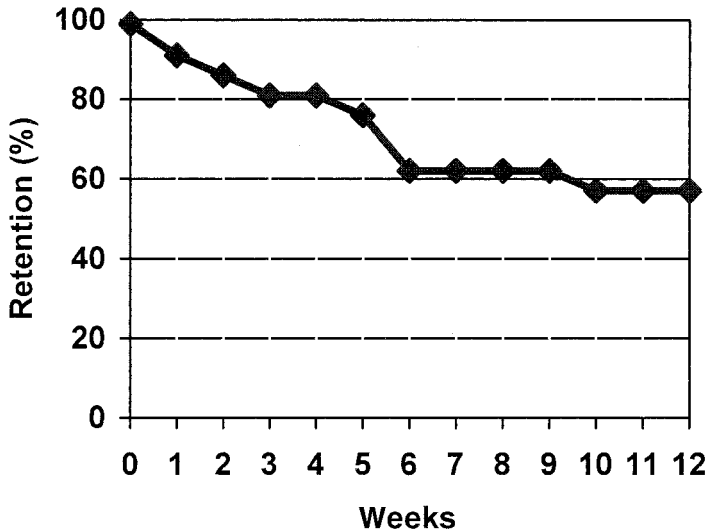


Figure 2. Retention in treatment group over study period ( $n = 21$ ).

attended a mean of 1.4 sessions. Treatment subjects were significantly more likely than control subjects to attend counselling ( $\chi^2 = 4.5$ ,  $df = 1$ ,  $p = 0.03$ ). Females accounted for 68% of counselling sessions attended by treatment group subjects. Forty-three per cent of treatment subjects and 75% of control subjects either declined counselling or failed to attend appointments. No subject attended all regular weekly counselling sessions. Most attended one or two sessions over the course of the study.

### Discussion

The experience in this pilot study supported the general positive impressions reported by recent British observational studies. No serious adverse events or psychotic symptoms were reported during the course of the study. Subjects in treatment were monitored closely for adverse effects by clinical staff with the risk of psychosis carefully explained and repeated over the course of treatment. The risk of psychotic symptoms developing in carefully screened and monitored subjects on this low, oral dose of dexamphetamine appeared to be low. This is consistent with the low rates of psychosis observed in UK studies of dexamphetamine substitution (McBride *et al.*, 1997; Charnaud & Griffiths, 1998; White, 2000). The treatment was acceptable to amphetamine users, as evidenced by satisfactory

levels of study retention and compliance in the experimental group. The majority of treatment subjects were stabilised at the maximum study dosing level. Treatment group subjects were asked at the follow-up interview whether they would continue in treatment if this option were available. Eighty percent expressed a willingness to continue.

As a pilot study, the sample was too small to reliably evaluate the efficacy of dexamphetamine substitution compared to standard care for amphetamine-dependent people. The study group was restricted to subjects who were able to attend an inner-city clinic on a daily basis. The trial could have benefited from a more structured psychosocial intervention tailored towards amphetamine users. However, the counselling offered was representative of usual care for individuals presenting with amphetamine problems. Although attrition was not significantly different between groups, selective attrition bias was possible. Subjects lost to follow-up in the control group were older, had longer histories of amphetamine use, higher SDS scores and higher OTI scores for amphetamine use and expenditure than those lost to follow-up in the treatment group. Thus, an element of 'resentful demoralisation' may have contributed to poorer retention of more problematic users in the control group compared to the treatment group (Cook & Campbell, 1979).

Although the project was conceived as a pilot rather than a definitive study, reduced illicit amphetamine use and injecting drug use at 12 weeks was observed in both groups according to urinalysis and self-report. The reduction was not statistically significant by either measure in either group. The only significant between-group difference was in the uptake of counselling, with treatment group subjects significantly more likely to attend counselling and receiving twice as many sessions as the control group. This outcome may have been affected by the higher proportion of females in the treatment group. Better engagement with treatment services including counselling has been identified previously as a potential benefit of dexamphetamine substitution (McBride *et al.*, 1997). Other statistically significant improvements observed within both groups were reduced HIV risk-taking (due to reduced injecting) and reduced SDS scores. The significant reduction in SDS scores suggested that the compulsive component of amphetamine dependence may have declined over the course of the study. Several subjects at follow-up commented that they felt calmer and more in control of their amphetamine use.

The modest treatment effect observed in the urinalysis results may not be surprising given the episodic nature of problematic amphetamine use. The control group was able to make positive short-term changes in their amphetamine use without substitution therapy and significantly less psychosocial intervention. This may have been due to a 'treatment effect' created by the selection of highly motivated subjects initially committed to daily attendance and the motivational aspects of the assessment process. It is doubtful, however, that many subjects would have presented for treatment without the incentive of substitution therapy.

Whether amphetamine substitution can break the cycle of problematic amphetamine use, prevent relapses and minimize short and long-term harms can only be assessed by a longer period of follow-up in a study with sufficient power. It appeared in this study that problematic amphetamine users could be attracted to, and retained in, substitution therapy. The risks associated with substitution therapy, including adverse events, appeared to be low. Self-reported data and urinalysis results suggested positive changes consistent with the favourable impressions of clinicians in UK substitution pro-

grammes. The serious harms associated with habitual, long-term amphetamine use warrant investigation of all potentially beneficial treatments. Substitution therapy deserves further consideration as one of the range of interventions for problematic amphetamine use. Rigorous controlled trials of amphetamine substitution with adequate sample sizes and follow-up are needed.

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