Brief cognitive behavioural interventions for regular amphetamine users: a step in the right direction

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ABSTRACT

Aims The present study sought to replicate and extend a small pilot study conducted by Baker, Boggs & Lewin (2001) which demonstrated that brief interventions consisting of motivational interviewing and cognitive-behaviour therapy (CBT) were feasible and associated with better outcomes compared with a control condition.

Design Randomized controlled trial (RCT).

Setting Greater Brisbane Region of Queensland and Newcastle, NSW, Australia.

Participants The study was conducted among 214 regular amphetamine users.

Measurements Demographic characteristics, past and present alcohol and other drug use and mental health, treatment, amphetamine-related harms and severity of dependence.

Findings The main finding of this study was that there was a significant increase in the likelihood of abstinence from amphetamines among those receiving two or more treatment sessions. In addition, the number of treatment sessions attended had a significant short-term beneficial effect on level of depression. There were no intervention effects on any other variables (HIV risk-taking, crime, social functioning and health). Overall, there was a marked reduction in amphetamine use among this sample over time and, apart from abstinence rates and short-term effects on depression level, this was not differential by treatment group. Reduction in amphetamine use was accompanied by significant improvements in stage of change, benzodiazepine use, tobacco smoking, polydrug use, injecting risk-taking behaviour, criminal activity level, and psychiatric distress and depression level.

Conclusions A stepped-care approach is recommended. The first step in providing an effective intervention among many regular amphetamine users, particularly those attending non-treatment settings, may include provision of: a structured assessment of amphetamine use and related problems; self-help material; and regular monitoring of amphetamine use and related harms. Regular amphetamine users who present to treatment settings could be offered two sessions of CBT, while people with moderate to severe levels of depression may best be offered four sessions of CBT for amphetamine use from the outset, with further treatment for amphetamine use and/or depression depending on response. Pharmacotherapy and/or longer-term psychotherapy may be suitable for non-responders. An RCT of a stepped-care approach among regular amphetamine users is suggested.

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KEYWORDS Amphetamines, brief intervention, cognitive-behaviour therapy, methamphetamine, motivational interviewing, polydrug, psychostimulants, stepped care, treatment.

INTRODUCTION

There has been a world-wide increase in the use of amphetamines, particularly methamphetamine (United Nations Office on Drugs and Crime 2003). In Australia, there are many indications that the increase in amphetamine use over the last several years will continue, including an increase in the availability, use and injection of methamphetamine and more demand for treatment and emergency services (Jenner & McKetin 2004).

Regular amphetamine use can be associated with a range of adverse outcomes, including psychological problems such as depression, anxiety, irritability, paranoia, difficulty concentrating, aggression, hallucinations and psychosis (Topp, Day & Degenhardt 2003). In a previous report (Baker *et al.* 2004b), we noted that almost half (49.1%) of the current sample of amphetamine users reported that they had been diagnosed or treated for a mental health problem and that these problems occurred commonly after the commencement of regular amphetamine use.

Despite the increasing prevalence of amphetamine use and associated adverse consequences and calls for specific treatment (Hando, Topp & Hall 1997), as far as the authors are aware, a small pilot study (Baker, Boggs & Lewin 2001) of cognitive–behaviour therapy (CBT) among regular amphetamine users remains the only randomized controlled trial (RCT) of a psychological intervention among a sample of regular amphetamine users conducted to date. Recent reviews of controlled trials of psychosocial interventions among psychostimulant users (Baker & Lee 2003; Baker *et al.* 2004a) have concluded that motivational interviewing and CBT may be a promising approach among amphetamine users. Miller, Yahne & Tonigan (2003) have recently reviewed RCTs of motivational interviewing among drug-abusing or -dependent samples. Fourteen of the 17 trials identified reported positive treatment effects. More recently, Rohsenow *et al.* (2004) found two sessions of motivational interviewing to be beneficial among cocaine users with low initial motivation to change.

The initial pilot study conducted by Baker *et al.* (2001) was designed to test the feasibility of conducting and evaluating brief CBT among regular amphetamine users. In that study, a pilot sample of 64 regular users of amphetamines was recruited in the Newcastle region of New South Wales (NSW), Australia and participants were assigned randomly to either a control condition, two or four sessions of counselling. The main findings were that brief CBT appeared feasible among regular users of amphetamines and that significantly more people in the CBT condition abstained from amphetamines at 6-month follow-up compared to the control condition.

The present study sought to replicate and extend the small pilot study among a larger sample of regular amphetamine users in Newcastle and the Greater Brisbane Region, Queensland, Australia. It was hypothesized that a four-session intervention would be associated with a greater reduction in amphetamine use and related harms (including psychological problems) compared to a two-session intervention and that both interventions would be more efficacious than a control condition.

METHOD

Design

Participants were assigned randomly to either an active treatment (two or four sessions of CBT in addition to a self-help booklet) or control condition (self-help booklet alone). The self-help booklet was developed by the National Drug and Alcohol Research Centre (NDARC 2001). A nine-block randomization schedule was used, which was coordinated by an independent clinical trials researcher. The sample was stratified by location, gender and maintenance pharmacotherapy status for heroin dependence. Assessments were scheduled at pre-treatment, post-treatment (5 weeks following pre-treatment assessment) and 6 months following the post-treatment assessment. Assessments were conducted by trained interviewers who were blind to participants' treatment allocation.

Participants and procedure

Participants were 214 regular users of amphetamines recruited from the Newcastle region ($n = 98$) of NSW and from the Greater Brisbane Region of South-East Queensland ($n = 116$), Australia. Regular use of amphetamines was defined as at least weekly use (a score of 0.14 or more for amphetamine use on the Opiate Treatment Index, OTI). Enrolment in maintenance pharmacotherapy for heroin dependence (i.e. methadone maintenance treatment (MMT) or buprenorphine maintenance) and/or

polydrug use did not exclude participants from taking part in the study, an approach taken in other recent studies of amphetamine users (e.g. Gossop, Marsden & Stewart 2000; Baker *et al.* 2001; Shearer *et al.* 2001). Exclusion criteria were suicidality or acute psychosis, acquired cognitive impairment and current enrolment in treatment for amphetamine use.

Participants were recruited between October 2001 and September 2002 by means of notices placed within various agencies and treatment centres, media releases and via word of mouth. Notices stated that university researchers were conducting a project to help people regularly using amphetamines to reduce their use. Just over half the sample (115 of 214, 53.7%) was referred by an alcohol and other drug service (including needle and syringe programmes) but less than a third were engaged in treatment for alcohol and drug problems other than amphetamines (68 of 214, 31.8%). The remaining participants were recruited via word of mouth (30, 14.0%), media advertisements (27, 12.6%), general practitioners (21, 9.8%), a youth service (10, 4.7%) and other community agencies (11, 5.1%). All participants were reimbursed $20 for each assessment interview they completed, an amount comparable to similar research in the area. Initial interviews took place either in the location from which they were recruited or participants were asked to attend research centres or other local health facilities. Post-treatment and follow-up interviews were conducted at the same locations where possible. However, in order to maximize retention, some follow-up interviews were conducted at the person's home or by telephone.

Volunteers were screened to determine their suitability for the study. The purpose and design of the study was described to eligible volunteers. Participants were assured that all information was strictly confidential to the research team who were independent of any treatment agency and that refusal to participate would not affect their relationship with the agency in any way. Participants were asked to provide written consent to take part in the study, and if aged under 18 years consent was sought from their parent/guardian.

Participants were interviewed and then assigned randomly to a study condition. Interviews took approximately 1 hour to complete. The interviewer then undertook the first session if the participant was allocated to a treatment condition, or gave them a self-help booklet and made a time for follow-up if allocated to the control condition.

Measures

Pre-treatment measures have been documented in an earlier paper (Baker *et al.* 2004b) and are described here only briefly. Data were collected on demographic characteristics, past and present alcohol and other drug use and mental health, treatment history, amphetamine-related harm and severity of dependence. Diagnosis of amphetamine abuse or dependence during the 6 and 12 months preceding interview was determined using the Non-Alcohol Psychoactive Substance Use Disorders sections of the Structured Clinical Interview for the *Diagnostic and Statistical Manual* (DSM)-IV—research version (SCID-I/NP; First *et al.* 1998). Severity of dependence was assessed via the amphetamine version of the Severity of Dependence Scale (SDS) (Gossop *et al.* 1995). Three scales of the Opiate Treatment Index (OTI, Darke *et al.* 1992) were administered: the Drug Use Scale, the HIV Risk-taking Behaviour Scale and the Crime Scale. A speed use ladder adapted from Biener & Abrams (1991) was used to assess self-rated stage of change for amphetamine use. Mental health was assessed via the Brief Symptom Inventory (BSI) (Derogatis & Melisaratos 1983); the Beck Depression Inventory II (BDI-II) (Beck, Steer & Garbin 1988); and the International Personality Disorder Examination Questionnaire (IPDEQ) (Loranger *et al.* 1997). All instruments were administered at pre-treatment, post-treatment and 6-month follow-up, except for the SCID-I/NP (pre-treatment only), SDS (pre-treatment and 6-month follow-up) and the IPDEQ (a measure of relatively stable personality characteristics, which was administered at post-treatment).

It was planned to conduct urine-screening tests for amphetamine use on a random sample of 20% of participants at 6-month follow-up.

Four-session cognitive behaviour therapy condition

A therapist manual (Baker *et al.* 2003), revised and expanded from that used in the pilot study (Baker *et al.* 2001) and a self-help booklet (NDARC 2001) guided treatment sessions, which focused on developing skills to reduce amphetamine use. Sessions were conducted individually and lasted 45–60 minutes. Session content included role-plays and take-home exercises for practising skills. The first session involved a motivational interview (Miller *et al.* 1992; Miller & Rollnick 2002) to increase motivation to reduce amphetamine use. The following sessions focused on cognitive–behavioural coping strategies and relapse prevention, using techniques developed by Marlatt & Gordon (1985). In the second session, participants were taught how to reduce craving with progressive muscular relaxation and coping self-talk. The third session focused on controlling thoughts about using amphetamine. The fourth session focused on coping with lapses and developing a coping drill to use in high-risk situations following any future lapses.

Two-session cognitive behaviour therapy condition

The procedure and content of the first two sessions was the same as described above for the longer intervention. Participants were also given the same self-help booklet as the intervention group (NDARC 2001) which details amphetamine-related harms and suggestions for reducing amphetamine use.

Control group

Participants allocated to the control condition were given the same self-help booklet as the intervention conditions (NDARC 2001).

Therapists

Therapists were university graduates with relevant clinical experience in the substance abuse field (three psychologists and one social worker). A week-long training session was held at the commencement of the project. This covered research procedures and role-plays of assessment instrument administration and treatment sessions. Videotaped feedback was used to enhance training. Session checklists were employed to guide weekly supervision provided by the chief investigators (A.B., N.K.L.).

Data analysis

As in the pilot study (Baker *et al.* 2001), due to treatment attendance patterns among the intervention group (detailed below), participants were reassigned according to the number of treatment sessions they attended (one, two or three–four). Data were analysed using SPSS for Windows (version 11). χ^2 analyses or logistic regressions were performed on categorical outcome variables (e.g. abstinence versus continued use). Repeated-measures analyses of covariance (ANCOVA) were performed to examine the impact of treatment on key variables including amphetamine and other drug use, level of amphetamine dependence, stage of change for amphetamine use, injecting and sexual risk-taking behaviour, mental health (depression and psychopathology) and criminal activity. Because of the patterns of follow-up assessments completed (detailed below), these ANCOVAs were conducted for each pair of time-points. As a partial control for the number of statistical tests, the threshold for significance was set at $P < 0.01$.

RESULTS

Sample characteristics and patterns of participation

Overall recruitment and attrition profiles for the current RCT are presented in Fig. 1. Approximately one-quarter (68 of 282, 24.1%) of those who were screened were excluded, primarily because they failed to meet the amphetamine threshold of weekly consumption (27) or were suicidal or acutely psychotic (16).

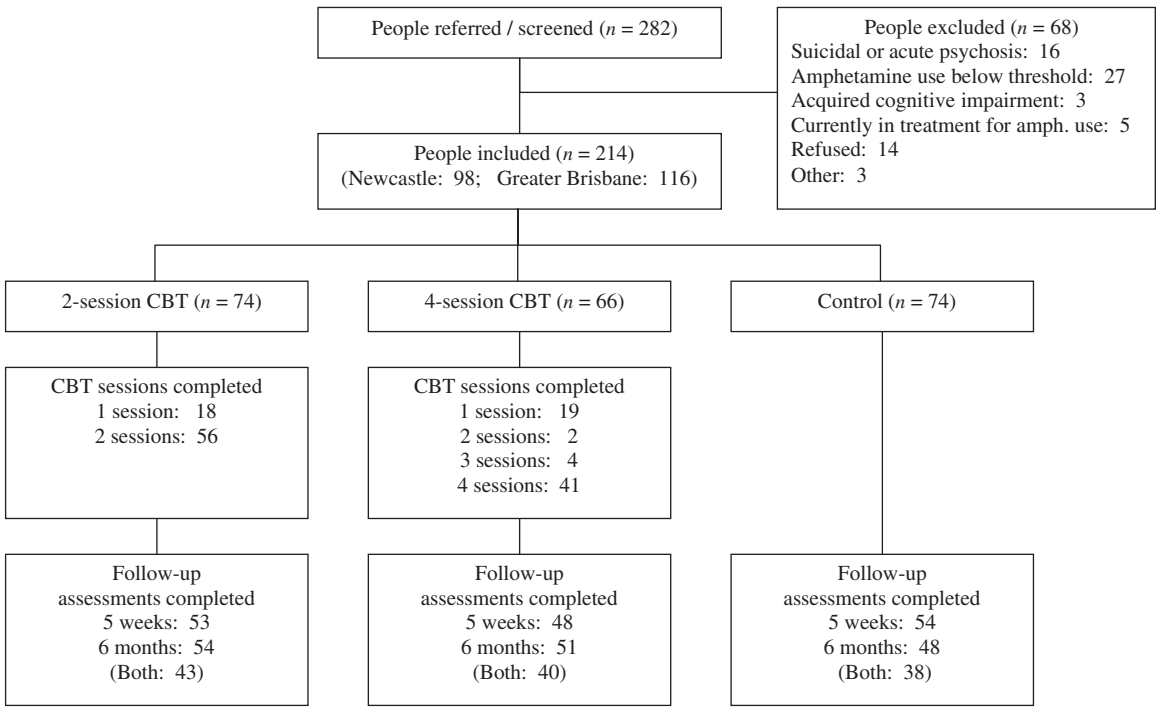

Figure 1 Recruitment and attrition profiles

Treatment sessions completed

A total of 214 participants were recruited into the study, of whom approximately one-third (74) were assigned to the control condition. Of the 74 participants allocated to two sessions of treatment, 56 (75.7%) completed both sessions. Of the 66 assigned to four sessions of treatment, 45 (68.2%) completed three or four sessions of treatment.

Preliminary analyses of data on key prognostic variables of age, location (Brisbane versus Newcastle), enrolment in pharmacotherapy treatment, amphetamine use, polydrug use and severity of amphetamine dependence indicated that there were no significant differences on these variables between participants who completed the number of sessions to which they were allocated ($n = 97$) and those who did not ($n = 43$). Comparisons within the treatment allocation groups (two versus four sessions) also revealed similar proportions completing all treatment sessions (56 of 74, 75.7%; 41 of 66, 62.1%, respectively). However, females (45 of 54; 83.3%) were significantly more likely than males (52 of 86; 60.5%) to complete all treatment sessions allocated ($\chi^2_{(1)} = 8.15$, $P < 0.01$). Therefore, the primary analyses were based on the number of sessions actually attended (i.e. B1, one session; B2, two sessions; or B3, three–four sessions), which were unlikely to be influenced by treatment participation biases, with the exception of gender, which was consequently retained as a covariate.

Assessment sessions completed

At post-treatment, 155 (72.4%) participants completed the assessment, including 2.6% (four of 155) as home visits and 9.7% (15 of 155) as telephone interviews. At 6-month follow-up, 153 (71.5%) participants were assessed, including 5.2% (eight of 153) as home visits and 28.8% (44 of 153) as telephone interviews. One hundred and twenty-one (56.5%) participants completed all three assessments. The pattern of assessments completed was categorized as follows: pre-treatment assessment only; pre-treatment and post-treatment assessment; pre-treatment and 6-month follow-up; and all three assessments. There were no significant differences on the descriptive variables listed above by the pattern of assessments completed, except for location ($\chi^2_{(3)} = 16.51$, $P < 0.001$). The majority of Newcastle participants (70.4%) completed all three assessments compared with less than half (44.8%) in Brisbane. Most of those who completed all of the treatment sessions to which they were allocated (81 of 97, 83.5%) completed the 6-month follow-up compared with only half (24 of 43, 55.8%) of those who did not complete all of the sessions to which they were allocated.

Sample characteristics by subgroups

Overall pre-treatment sample characteristics and patterns of drug use have been reported elsewhere (Baker *et al.* 2004b). The main pre-treatment characteristics of the control and attendance-based intervention groups are shown in Table 1. Most participants were born in Australia and almost two-thirds of the sample was male, with a significant history of amphetamine use. Levels of amphetamine use were high and mental health problems were common. One-third of the sample was currently in treatment for other substance use, mainly maintenance pharmacotherapy for heroin dependence. Participants enrolled in maintenance pharmacotherapy for heroin dependence had a significantly lower mean level of amphetamine use at pre-treatment (mean 0.81, SD 0.89) compared to those not enrolled in pharmacotherapy (mean 1.60, SD 1.59) ($F_{1,149} = 8.75$, $P < 0.01$).

As there was a gender bias in treatment completion, a location effect for assessment completion, and level of amphetamine use was influenced by pharmacotherapy status, the main analyses included gender, location and pharmacotherapy status as covariates.

Changes in amphetamine use

Mean pre-treatment, post-treatment, 6-month follow-up and change scores for amphetamine and polydrug use are displayed in Table 2. Standardized change scores and abstinence rates for these outcome measures are also reported in Table 2; the former facilitate 'effect size' comparisons with other intervention studies. A series of repeated-measures ANCOVAs (with gender, location and pharmacotherapy status as covariates) was conducted to examine relationships between the number of treatment sessions attended and changes in drug use scores over time (with separate analyses for: pre-treatment versus post-treatment, post-treatment versus 6-month follow-up and pre-treatment versus 6-month follow-up). Overall, the repeated-measures ANCOVAs revealed significant main effects for time, but no significant group × time interactions.

Amphetamine use fell significantly for the sample as a whole between pre-treatment (mean 1.41, SD 1.51) and post-treatment (mean 0.70, SD 1.01) ($F_{1,148} = 22.64$, $P < 0.001$) and between pre-treatment (mean 1.38, SD 1.47) and 6-month follow-up (mean 0.62, SD 1.09) ($F_{1,146} = 22.11$, $P < 0.001$), with no difference between post-treatment (mean 0.58, SD 0.79) and 6-month follow-up scores (mean 0.53, SD 0.99) ($F_{1,114} = 0.00$, NS). As shown in Table 2, the largest differential reduction in amphetamine use was between the control group and those attending three or four sessions. The mean daily occasions of use of amphetamine

Table 1 Pre-treatment sample characteristics by number of sessions attended.[a]

		Brief intervention				
	C: Control group (n = 74)	*B: Any sessions (n = 140)*	*B1: 1 session (n = 37)*	*B2: 2 sessions (n = 58)*	*B3: 3–4 sessions (n = 45)*	*Overall (n = 214)*
Demographic characteristics						
% Male	64.9% (48)	61.4% (86)	78.4% (29)	55.2% (32)	55.6% (25)	62.6% (134)
Mean age (years)	30.19 (8.13)	30.23 (7.70)	30.67 (7.51)	29.81 (8.50)	30.42 (6.88)	30.22 (7.83)
Age left school (years)	15.84 (1.61)	16.30 (6.28)	15.41 (1.48)	15.66 (1.51)	17.87 (10.77)	16.14 (5.16)
Amphetamine use						
Mean duration of regular use	8.49 (7.07)	9.25 (6.87)	11.45 (7.11)	9.30 (6.76)	7.38 (6.40)	8.98 (6.99)
Mean daily level of amphetamine use (OTI)	1.55 (1.61)	1.48 (1.67)	1.32 (1.87)	1.43 (1.27)	1.67 (1.96)	1.50 (1.65)
Mean stage of change for amphetamine use (1–5)	3.28 (1.33)	3.17 (1.11)	3.24 (1.26)	3.26 (1.13)	3.00 (0.93)	3.21 (1.19)
% Enrolled in methadone maintenance treatment (MMT)	23.0% (17)	27.9% (39)	35.1% (13)	26.0% (15)	24.4% (11)	26.2% (56)
Mental health						
% Ever diagnosed/treated	48.7% (36)	47.1% (66)	35.1% (13)	41.4% (24)	64.4% (29)	47.7% (102)
% Currently taking medication for mental health	43.2% (32)	40.7% (57)	37.8% (14)	39.7% (23)	44.4% (20)	41.6% (89)

[a]Tabled values are percentages (and frequencies) or mean scores (with standard deviations).

Table 2 Selected OTI[a] pre-treatment, follow-up, change and abstinence indices by treatment group (as-treated, with no missing data substitutions).

		Mean OTI score (SD)					
OTI drug use category	*Treatment group (as-treated)*	*Pre-treatment (n = 214)*	*5 weeks post-treatment (n = 155)*	*6-month follow-up (n = 153)*	*Standardized Change from pre-treatment (n = 153)*	*% Abstinent change from pre-treatment (effect size units)*	*at 6-month follow-up (n = 153)*
Amphetamine	C: Control	1.55 (1.61)	0.81 (0.93)	0.78 (1.18)	0.76 (1.70)	0.54	51.1%
	Brief intervention						
	B1: 1 session	1.32 (1.87)	0.41 (0.51)	0.58 (0.80)	0.25 (0.93)	0.55	27.1%
	B2: 2 sessions	1.43 (1.27)	0.67 (1.11)	0.50 (1.20)	0.75 (1.55)	0.18	40.0%
	B3: 3–4 sessions	1.66 (1.95)	0.68 (1.13)	0.57 (0.98)	1.04 (2.16)	0.75	47.5%
	Overall	1.50 (1.65)	0.70 (1.01)	0.62 (1.09)	0.76 (1.71)	0.55	41.2%
Polydrug use (of 11)	C: Control	4.35 (1.29)	4.00 (1.27)	3.50 (1.29)	0.64 (1.53)	0.46	0.0%
	Brief intervention						
	B1: 1 session	4.35 (1.62)	3.94 (1.56)	4.00 (1.71)	0.60 (2.37)	0.43	0.0%
	B2: 2 sessions	4.45 (1.57)	3.83 (1.24)	3.51 (1.51)	0.95 (1.60)	0.68	0.0%
	B3: 3–4 sessions	4.04 (1.48)	3.51 (1.39)	3.03 (1.37)	1.00 (1.53)	0.71	2.5%
	Overall	4.31 (1.46)	3.83 (1.33)	3.44 (1.46)	0.82 (1.68)	0.59	0.6%

[a]OTI = Opiate Treatment Index.

fell 0.76 units among the control condition compared to 1.04 units among the three- or four-session intervention group. Expressed in effect size units (0.55 versus 0.75), this represents a difference of 0.20 of a standard deviation, a small effect size. At the 6-month follow-up, half (82 of 153, 53.6%) of the sample were still above the amphetamine recruitment threshold (i.e. weekly use).

The analyses reported above, and the associated data in Table 2, represent a conventional treatment efficacy analysis. That is, group assignment was based of the treatment sessions actually attended (i.e. as-treated) and there were no missing data substitutions. RCTs are often viewed from a broader, programme effectiveness perspective, with associated intention-to-treat (ITT) analyses (Wright & Sim 2003), although this was not the primary

focus of the current study. However, to facilitate comparisons with other RCTs, we conducted a parallel series of amphetamine analyses in which group assignment was based on the treatment groups to which participants were initially randomized (i.e. as-allocated). The upper half of Table 3 reports OTI amphetamine scores for the treatment groups as-allocated, including means for each occasion and change scores and standardized change scores from pre-treatment to 6-month follow-up. The lower half of Table 3 reports the corresponding values after substitutions for missing outcome data, a common practice in ITT analyses. In this instance, missing follow-up data were imputed by carrying forward the last available observation. Similar repeated-measures ANCOVAs to those described earlier were conducted for each of these data sets (i.e. with gender, location and pharmacotherapy status as covariates, and pairwise comparisons between occasions). Once again, there were no significant treatment group effects, or group × time interactions. In both analyses (i.e. with and without substitutions for missing outcome data) overall amphetamine use fell significantly between pre-treatment and post-treatment and between pre-treatment and 6-month follow-up, but there were no significant differences between post-treatment and 6-month follow-up scores (analyses available from the authors upon request). Thus, the original amphetamine analyses and the ITT-based analyses produced comparable results, although the magnitude of the change between pre-treatment and 6-month follow-up was smaller in the ITT analyses (0.41 versus 0.55 effect size units).

Abstinence from amphetamines was also analysed in several ways (see Table 4), reflecting different methodological approaches to group assignment and missing data. For these analyses, group assignment was either on an as-treated basis (i.e. the number of treatment sessions actually attended) or an as-allocated basis (i.e. the groups to which participants were randomized initially), while missing outcome data were either ignored (i.e. no substitutions for missing outcome data) or coded as non-abstinent. For convenience, the various combinations of these methodological approaches are referred to as different data sets in Table 4 (i.e. D1–D4). Data set D1 (i.e. as-treated, with no missing data substitutions) represents a conventional treatment efficacy analysis, while data set D4 (i.e. as-allocated, with missing outcome data coded as non-abstinent) is consistent with a traditional ITT analysis. Logistic regression analyses were conducted for each data set, with amphetamine abstinence status at the 6-month follow-up as the outcome variable and treatment group as the key predictor variable. Table 4 reports three models for each data set: unadjusted analyses (Model 1, with no covariates); analyses controlling for gender, location and pharmacotherapy status (Model 2); and an additional model (Model 3), which also controls for duration of regular amphetamine use.

As shown in Table 4, the abstinence analyses were similar for Models 1 and 2, with the inclusion of covariates having little effect. For these models, the odds ratios (OR) reached statistical significance only when missing outcome data were coded as non-abstinent, in which case, higher rates of abstinence were reported by those who attended two or more sessions (40.8% abstinent, as-treated analysis, data set D3) or who were allocated to the four-session intervention (37.9% abstinent, as-allocated analysis, data set D4), relative to the control group (17.6% abstinent). Arguably, the analyses in which duration of regular amphetamine use was also controlled (Model 3) produced a more coherent set of findings. First, with respect to treatment efficacy, attendance at two or more treatment sessions was associated with a higher likelihood of abstinence at 6 months, relative to the control group, whether or not missing outcome data were substituted (27.1% versus 49.4% abstinent, as-treated analysis, data set D1, adjusted odds ratio (AOR) = 3.07, $P < 0.01$; and 17.6% versus 40.8%

Table 3 OTI[a] amphetamine profiles by treatment group (as-allocated, with and without missing data substitutions).

		Mean OTI amphetamine score (SD)				
Missing data status	*Treatment group (as-allocated)*	*Pre-treatment*	*5 weeks post-treatment*	*6-month follow-up*	*Change from pre-treatment*	*Standardized change from pre-treatment (effect size units)*
No substitutions for missing outcome data		($n = 214$)	($n = 155$)	($n = 153$)	($n = 153$)	
	C: Control	1.55 (1.61)	0.81 (0.93)	0.78 (1.18)	0.76 (1.70)	0.55
	2 sessions	1.43 (1.63)	0.63 (1.06)	0.59 (1.18)	0.56 (1.46)	0.40
	4 sessions	1.53 (1.73)	0.64 (1.03)	0.50 (0.88)	0.99 (1.97)	0.71
Data substitutions: last available observation carried forward		($n = 214$)	($n = 214$)	($n = 214$)	($n = 214$)	
	C: Control	1.55 (1.61)	1.10 (1.39)	1.00 (1.37)	0.56 (1.69)	0.36
	2 sessions	1.43 (1.63)	0.96 (1.64)	0.94 (1.78)	0.50 (1.49)	0.33
	4 sessions	1.53 (1.73)	0.88 (1.16)	0.68 (1.09)	0.85 (1.79)	0.55

[a]OTI = Opiate Treatment Index.

Table 4 Analysis of amphetamine abstinence rates at 6-month follow-up for selected group assignment and missing data strategies.[a]

Data set (D): Group assignment and missing data status	*Treatment group*	*% Abstinent at 6-month follow-up*	*Model 1*		*Model 2*		*Model 3*	
			OR	*(99% CI)*	*AOR*	*(99% CI)*	*AOR*	*(99% CI)*
D1. As-treated and no substitutions for missing outcome data	C: Control	27.1% (13/48)	1.00	1.00	1.00		1.00	
	B1: 1 session	40.0% (8/20)	1.80	(0.42, 7.60)	1.69	(0.39, 7.40)	2.22	(0.46, 10.62)
	B2/3: > 1 session	49.4% (42/85)	2.63	(0.96, 7.19)	2.62	(0.94, 7.30)	3.07*	(1.06, 8.88)
D2. As-allocated and no substitutions for missing outcome data	2 sessions	46.3% (25/54)	2.32	(0.78, 6.92)	2.32	(0.76, 7.07)	2.95	(0.92, 9.50)
	4 sessions	49.0% (25/51)	2.59	(0.86, 7.81)	2.50	(0.82, 7.63)	2.86	(0.91, 9.00)
D3. As-treated and missing outcome data coded non-abstinent	C: Control	17.6% (13/74)	1.00	1.00				
	B1: 1 session	21.6% (8/37)	1.29	(0.35, 4.73)	1.23	(0.33, 4.61)	1.57	(0.40, 6.22)
	B2/3: > 1 session	40.8% (42/103)	3.23**	(1.26, 8.28)	3.22*	(1.24, 8.36)	3.61**	(1.35, 9.63)
D4. As-allocated and missing outcome data coded non-abstinent[b]	2 sessions	33.8% (25/74)	2.39	(0.87, 6.57)	2.35	(0.85, 6.51)	2.94*	(1.01, 8.55)
	4 sessions	37.9% (25/66)	2.86*	(1.03, 7.96)	2.82*	(1.01, 7.91)	3.08*	(1.07, 8.88)

[a]Logistic regression analyses were used to examine differences in abstinence rates between the treatment groups. Odds ratios (OR) are reported for Model 1 (the basic, unadjusted model), while adjusted odds ratios (AOR) are reported for Model 2 (controlling for gender, location and pharmacotherapy status) and Model 3 (controlling for Model 2 effects and duration of regular amphetamine use). Associated 99% confidence intervals (99%CI) are also reported: *$P < 0.01$; ** $P < 0.001$ (based on Wald statistics). The reference group for each analysis is indicated by an OR/AOR of 1.00. [b]This strategy is consistent with a traditional intention-to-treat (or programme effectiveness) analysis.

abstinent, as-treated analysis, data set D3, AOR = 3.61, $P < 0.001$). Secondly, from an ITT or programme effectiveness perspective (data set D4), participants allocated to either of the initial treatment groups were more likely to be abstinent at 6 months (control group: 17.6% abstinent; two sessions: 33.8% abstinent, AOR = 2.94, $P < 0.01$; and four sessions: 37.9% abstinent, AOR = 3.08, $P < 0.01$).

Urine samples were collected from 17.4% (19 of 109) of the participants who attended face-to-face interviews at the 6-month follow-up. All were consistent with self-reported use of amphetamines (on 10 occasions use was reported and detected, on five occasions no use was reported and nil was detected, and on four occasions use in the past month was reported but not detected).

Severity of dependence on amphetamines decreased significantly over time between pre-treatment (mean 8.10, SD 3.73) and 6-month follow-up (mean 6.24, SD 4.25) ($F_{1,146} = 43.60$, $P < 0.001$), with no significant difference between intervention conditions (pre-treatment mean versus 6-month follow-up mean – control group: 8.52, SD 3.76 versus 6.15, SD 4.13; group B1: 8.05, SD 3.85 versus 6.75, SD 4.05; group B2: 6.91, SD 3.85 versus 5.58, SD 4.60; group B3: 8.10, SD 3.73 versus 6.85, SD 4.25).

There was a significant overall increase in stage of change from pre-treatment (mean 3.16, SD 1.15) to post-treatment (mean 3.80, SD 1.18) ($F_{1,148} = 23.39$, $P < 0.001$), and from pre-treatment (mean 3.19, SD 1.19) to 6-month follow-up (mean 4.08, SD 1.21) ($F_{1,146} = 42.56$, $P < 0.001$). There was no significant overall improvement in stage of change between post-treatment (mean 3.83, SD 1.18) and 6-month follow-up (mean 4.16, SD 1.11) ($F_{1,114} = 2.98$, NS). There were no significant differences in stage of change between intervention conditions.

Changes in other drug use

There were significant reductions over time for the sample as a whole in use of benzodiazepines among participants who had used benzodiazepines at least weekly at initial assessment. Pre-treatment (mean 3.34, SD 3.97) and post-treatment (mean 1.03, SD 2.05) daily use scores were significantly different ($F_{1,36} = 15.28$, $P < 0.001$), as were pre-treatment (mean 3.57, SD 4.40) and 6-month follow-up (mean 0.57, SD 1.43) ($F_{1,33} = 10.45$, $P < 0.01$), with no difference between post-treatment (mean 1.18, SD 2.26) and 6-month follow-up (mean 0.64, SD 1.55) ($F_{1,23} = 0.27$, NS).

There was a significant overall reduction in tobacco use between pre-treatment and 6-month follow-up (with no significant differences between pre-treatment and post-treatment or between post-treatment and follow-up) for the sample as a whole, with no differences between intervention conditions. The number of cigarettes smoked fell from a mean of 17.81 (SD 12.47) at pre-treatment to a mean of 14.68 (SD 11.57) cigarettes per day at 6-month follow-up ($F_{1,146} = 15.58$, $P < 0.001$), a relatively modest reduction.

There were no other significant differences between intervention groups on use of other individual drug

classes among participants who were using them at least weekly at pre-treatment.

There was a significant overall reduction in polydrug use, from pre-treatment (mean 4.30, SD 1.47) to post-treatment (mean 3.83, SD 1.33) ($F_{1,148} = 10.96$, $P < 0.001$) and from pre-treatment (mean 4.27, SD 1.47) to 6-month follow-up (mean 3.44, SD 1.46) ($F_{1,146} = 30.04$, $P < 0.001$), with no significant difference between post-treatment (mean 3.70, SD 1.36) and 6-month follow-up scores (mean 3.44, SD 1.41) ($F_{1,114} = 1.14$, NS). While there were no significant differences between the intervention conditions, mean number of substances used fell 0.64 units among the control group versus 1.00 unit among the three- or four-session group. Expressed in effect size units (0.46 versus 0.71), this represents a difference of a quarter of a standard deviation (see Table 2).

Changes in drug-related harm

Among participants who injected any drugs at pre-treatment, there was a significant overall reduction in injecting risk-taking behaviour from pre-treatment (mean 7.33, SD 5.28) to post-treatment (mean 4.53, SD 4.44) ($F_{1,138} = 25.65$, $P < 0.001$) and from pre-treatment (mean 6.71, SD 5.04) to 6-month follow-up (mean 3.71, SD 4.35) ($F_{1,136} = 29.14$, $P < 0.001$), with no significant change between post-treatment (mean 4.58, SD 4.58) and 6-month follow-up scores (mean 3.55, SD 4.12) ($F_{1,105} = 4.61$, NS). There were no significant differences between intervention conditions. There were also no significant reductions in sexual risk-taking behaviour over time or between intervention conditions.

Involvement in criminal activity significantly fell for the overall sample between pre-treatment (mean 1.67, SD 2.20) and post-treatment (mean 1.06, SD 1.74) ($F_{1,148} = 7.34$, $P < 0.01$) and between pre-treatment (mean 1.82, SD 0.76) and 6-month follow-up (mean 0.76, SD 1.29) ($F_{1,146} = 24.71$, $P < 0.001$), with no significant difference between post-treatment (mean 0.94, SD 1.70) and 6-month follow-up (mean 0.65, SD 1.19) ($F_{1,114} = 4.55$, NS). There were no significant differences between intervention groups.

Changes in mental health

There was a significant reduction over time in overall psychiatric distress (BSI Global Severity Index) between pre-treatment (mean 1.43, SD 0.76) and post-treatment (mean 1.18, SD 0.77) ($F_{1,148} = 22.26$, $P < 0.001$). There was a significant overall reduction in BSI scores between pre-treatment (mean 1.49, SD 0.78) and 6-month follow-up (mean 1.08, SD 0.79) ($F_{1,142} = 45.90$, $P < 0.001$), with no significant difference between post-treatment (mean 1.19, SD 0.80) and 6-month follow-up (mean 1.06, SD 0.79) ($F_{1,111} = 2.09$, NS).

There was a significant overall improvement in level of depression (BDI-II) between pre-treatment (mean 27.19, SD 13.20) and post-treatment (mean 19.35, SD 13.09) ($F_{1,148} = 48.61$, $P < 0.001$) and between pre-treatment (mean 27.87, SD 13.09) and 6-month follow-up (mean 17.95, SD 13.05) ($F_{1,146} = 51.77$, $P < 0.001$), with no difference between post-treatment (mean 19.22, SD 13.69) and 6-month follow-up scores (mean 17.74, SD 13.42) ($F_{1,114} = 0.28$, NS). There was a significant overall interaction between treatment status and time (pre-treatment versus post-treatment) ($F_{3,148} = 8.10$, $P < 0.001$). Scheffé follow-up tests revealed that the extent of the reduction in depression was related linearly to the number of sessions attended (linear trend by time interaction: $F_{1,148} = 12.49$, $P < 0.001$). There were no other significant effects for depression, with the control group continuing to reduce in depression scores to a level comparable with the intervention group at 6-month follow-up. With respect to the clinical significance of the BDI-II changes, over two-thirds of the sample (152 of 214, 71.0%) scored in the moderately to severely depressed range at pre-treatment (i.e. BDI-II scores of 20 or above), compared with less than half at 5 weeks post-treatment (66 of 155, 42.6%) and a similar proportion at the 6-month follow-up (60 of 153, 39.2%).

Predictors of level of improvement in amphetamine use from baseline to the 6-month follow-up

Finally, levels of improvement in amphetamine use at 6 months follow-up were categorized as: 'abstinent at 6 months follow-up' (63 of 153, 41.2%); 'reduced by more than half' (38 of 153, 24.8%); 'less marked improvement' (21 of 153, 13.7%); and 'deteriorated from baseline' (31 of 153, 20.3%). Differences between these outcome groups on key demographic, drug use and mental health variables were examined using χ^2 and ANCOVAs. No variables emerged as significant predictors of outcome status. We also examined correlations between change in amphetamine use and change in levels of depression, alcohol consumption and cannabis use and no significant associations were found.

DISCUSSION

Before reviewing the findings, it is useful to consider briefly the nature of the current study. RCTs, particularly double-blinded drug evaluation studies, often adopt as their main analysis strategy a relatively conservative ITT analysis. This is typically the case because interest is focused primarily on programme effectiveness (and not

treatment efficacy) and protocol deviations (e.g. non-compliance, treatment switching, missing outcome data) are likely to be minimal or an anticipated component of subsequent real-world applications. Imputation of missing data is also considered to be acceptable (e.g. binary outcomes, where missing data is assigned to the non-preferred outcome). By comparison, the current study was concerned primarily with treatment efficacy. That is, how did the actual treatments received within the current context relate to the desired outcomes, while adjusting for any observed or likely recruitment, allocation or participation biases. This is not to suggest that programme effectiveness is not important; rather, that we first need to demonstrate that the treatment is efficacious and then to determine how to optimize its implementation and effectiveness in real-world treatment settings. However, while the majority of the analyses reported in this paper relate to treatment actually received (i.e. as-treated), we also undertook a series of traditional ITT-based analysis (see Tables 3 and 4). Imputation of missing data for the continuous outcome measures was considered to be less than satisfactory (i.e. attempting to estimate current levels of substance use, symptomatology or risk-taking behaviours), but was conducted nevertheless for the key outcome variable, OTI amphetamine use. There were no differential treatment effects on the level of amphetamine use in either the efficacy (non-ITT) analyses or the programme effectiveness (ITT) analyses. For the abstinence analyses, it was considered more appropriate to at least entertain the possibility that all missing follow-up data were from individuals who were still using amphetamines—in which case, the overall 6-month abstinence rate would drop from 41.2% (63 of 153) to 29.4% (63 of 214). However, for both the ITT and non-ITT analyses it was reasonable to conclude that abstinence rates were improved modestly by treatment.

The main finding of this study was that there was a significant increase in the likelihood of abstinence from amphetamines among those who received two or more treatment sessions. In addition, the number of intervention sessions attended had a significant short-term beneficial effect on level of depression. There were no intervention effects on any other variables (HIV risk-taking, crime, psychiatric distress). Although only a small proportion of the sample had urine tests at the 6-month follow-up, these were consistent with self-reported amphetamine use.

At pre-treatment, the present sample comprised a group of regular amphetamine users with long histories of amphetamine use who had high levels of: dependence on amphetamines, injecting risk-taking behaviour, polydrug use, depression and psychiatric illness. Although only 35% of the initial sample were at the 'action' stage for reducing amphetamine use, 71.5% (153 of 214) were retained at 6-month follow-up. Approximately 70% (97 of 140) of participants assigned to intervention conditions attended all sessions. Thus, as in the pilot study, regular users of amphetamines, many of whom are ambivalent about change, can be recruited, treated and retained for follow-up evaluation.

The results of the present study indicated that, overall, there was a marked reduction in amphetamine use among this sample over time and that, apart from abstinence rates and short-term effects on depression level, this was not differential by treatment group. Reduction in amphetamine use was accompanied by significant improvements in stage of change, benzodiazepine use, tobacco smoking, polydrug use, injecting risk-taking behaviour, criminal activity level, psychiatric distress and depression level. This overall reduction in amphetamine use, and associated improvements, was likely to be related to participation in the project, the assessment process, provision of a self-help booklet and multiple follow-up occasions.

These results are consistent with findings from an RCT comparing the effectiveness of a brief motivational intervention and a non-intervention control condition in reducing HIV risk-taking behaviour among 200 IDUs not enrolled in treatment for drug dependence (Baker *et al*. 1994). In that study, there were significant reductions for the sample as a whole in injecting risk-taking behaviour between pre-treatment and 6-month follow-up, with no significant differences between groups. Baker and colleagues concluded that assessments conducted among IDUs not in treatment can have a significant impact on behaviour. Similarly, Miller *et al*. (2003) reported that a single-session motivational interview did not improve outcomes among in-patients and out-patients entering public agencies for treatment of drug problems, with the entire sample showing substantial increases in abstinence. They suggest that the 5-hour baseline assessment may have diluted possible treatment effects of the motivational interview.

Apart from the possible effects of assessment and scheduled follow-up on amphetamine use and other problems, the two other main findings of the present study, (i) that the likelihood of abstinence was significantly higher among participants who had received two or more treatment sessions and that (ii) the extent of reduction in depression between pre- and post-treatment was greatest among participants who had completed more sessions of treatment, suggest the effectiveness of at least three possible tiers of intervention among regular amphetamine users.

The first possible tier of intervention could consist of an initial assessment accompanied by a self-help booklet and scheduled monitoring. The second tier of intervention could consist of two sessions of CBT for amphetamine

use among people who desire a substantial reduction in use of or abstinence from amphetamines but who do not attain either of these via the first tier of intervention. The third tier of intervention could consist of four sessions of CBT for amphetamine use among users with clinically significant depression. Further intervention among participants who do not reduce their amphetamine use to desired levels and/or continue to experience distressing levels of psychiatric symptomatology may also be needed, representing a possible fourth tier of intervention. In support of the need for more extensive interventions for some amphetamine users is the fact that 53.6% (82 of 153) of the sample were still above the recruitment threshold (weekly use) at the 6-month follow-up.

Thus, the results of the present study may be taken to suggest that a stepped-care approach, in which 'a more intensive or different form of care or treatment is offered only when a less intensive form has been insufficient' (Schippers, Schramade & Walburg 2002), may be beneficial among regular amphetamine users and worthy of further research (see Baker & Dawe in press). In settings such as needle and syringe programmes, where extended counselling of the sort described in this study may not generally be feasible, the first tiered intervention (above), comprising assessment, a self-help booklet and regular monitoring, may be practicable and sufficient for some people. Given the superior results in terms of abstinence from amphetamines in the present study for those receiving two or more sessions of CBT, at least two sessions of counselling could be offered initially to regular amphetamine users presenting to treatment settings, with four sessions of CBT for amphetamine use negotiated depending upon desired goals and response. A proportion of regular users may benefit from longer-term out-patient CBT interventions, day programme attendance as described in the Matrix Outpatient Treatment model currently being evaluated in a controlled trial (Rawson *et al.* 2002), different psychotherapy or pharmacotherapy. Front-line workers may need training in many of these intervention strategies.

With respect to study limitations, the main concerns relate to overall participant recruitment, engagement and retention. Individually, the participation rates in this RCT were reasonably satisfactory: three-quarters of those screened were recruited into the study; attendance at treatment sessions was approximately 80%; and 70% of those recruited were retained at the 6-month follow-up, although there were some location differences in retention rates. However, there were only approximately 50 participants per group at the conclusion of the study, which would have provided sufficient statistical power (80%) to detect differential population treatment effects (on key continuous measures such as changes in OTI amphetamine use) of the order of 0.69 of a standard deviation, using 0.01-level, two-tailed significance tests (or 0.57 of a standard deviation for analyses utilising the full recruited sample of approximately 74 participants per group). In order to detect population differences of approximately half a standard deviation satisfactorily (conventionally, a moderate effect size), retained samples of approximately 95 participants per group would have been required, which would have necessitated planning for almost double the number of initial referrals to the study, well beyond our available resources. Clearly, as is generally the case, the current study's findings need to be replicated and extended.

In conclusion, the findings of the present study were that CBT among regular amphetamine users, whether two or four sessions in length, was associated with a significantly higher rate of abstinence from amphetamines at 6-month follow-up, compared with a control condition consisting of a structured assessment, self-help booklet and regular scheduled follow-up. The number of CBT sessions attended for amphetamine use was also associated with a significantly faster improvement in depression level. The process of being enrolled in a study and participating in the activities required of the control condition (assessment, self-help booklet, regular scheduled follow-up) appear beneficial in terms of amphetamine use and related harms for many people. A stepped-care approach, in which the first step, particularly suited to non-treatment settings, is a structured assessment, followed by the provision of self-help material and regular monitoring of amphetamine use and related harms, is recommended. Those who present to treatment settings could be offered two sessions of CBT, while people with moderate to severe levels of depression may best be offered four sessions of CBT for amphetamine use from the outset, with further treatment for amphetamine use and/or depression depending on response. Pharmacotherapy and/or longer-term psychotherapy may be suitable for non-responders. An RCT of a stepped-care approach among regular amphetamine users is suggested.

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