RESEARCH REPORT

Randomized controlled trial of brief cognitive-behavioural interventions among regular users of amphetamine

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Abstract

Aims. To identify whether brief cognitive-behavioural interventions are feasible among regular users of amphetamine, to assess the effectiveness of intervention overall and to pilot two- and four-session interventions. **Design.** Subjects were assigned randomly to individually receive a cognitive-behavioural intervention (n = 32) of either two or four sessions' duration or a self-help booklet (control condition; n = 32). **Setting.** Subjects were volunteers recruited from needle exchange schemes and treatment centres in Newcastle, Australia. Participants. Regular (at least monthly) users of amphetamine were recruited. Intervention. Either four sessions of cognitive-behaviour therapy, consisting of a motivational interview and skills training in avoidance of high-risk situations, coping with craving and relapse prevention, or two sessions consisting of a motivational interview and discussion of skills. Measurements. The Opiate Treatment Index was the main measure at pre-treatment and 6-month follow-up. Findings. There was a significant reduction in amphetamine use among the sample as a whole, with inconclusive differences between intervention subgroups. There was a moderate overall intervention effect, with the intervention group reporting over twice the reduction in daily amphetamine use as the control group. Significantly more people in the cognitivebehavioural intervention condition abstained from amphetamine at 6-month follow-up compared to the control condition. Conclusion. Brief cognitive-behavioural interventions appear feasible among regular users of amphetamine. A larger randomised controlled trial of the effectiveness of such interventions appears warranted.

Introduction

Amphetamine is the second most commonly used illicit drug in Australia (Makkai & McAllister, 1998) and the United Kingdom (Klee, Wright & Morris, 1999) and its use is increasing in the United States (Proudfoot & Teesson, 2000). The most recent Australian National Drug Strategy household survey indicated that amphetamine has been widely available during the last decade and significant numbers of people have used the drug regularly (Makkai & McAllister, 1998). In 1999, amphetamine was the most commonly injected drug in the state of Queensland, Australia (Illicit Drug Reporting

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System, 1999). Heavy and continued use of amphetamine can induce psychosis, rages and violent behaviour and is associated with serious health problems such as stroke (Proudfoot & Teesson, 2000).

Despite the popularity of amphetamine and increasing regular use of the drug and its associated problems, there is a paucity of research evaluating the effectiveness of interventions for regular users of amphetamine. Apart from a recent randomised controlled trial of the feasibility of monitoring controlled prescribing of dexamphetamine (Shearer et al., 1999), the authors are unaware of any other randomized controlled trials evaluating non-pharmacological interventions targeted specifically for regular users of amphetamine. In their review of available interventions for psychostimulant users, Kamieniecki et al. (1998) concluded that the non-pharmacological interventions which have demonstrated the most efficacy in treating psychostimulant (primarily cocaine) users are cognitive-behavioural, particularly relapse prevention for heavy users. They suggested that given the much higher use of amphetamine than cocaine in Australia, and the lack of studies on the use of relapse prevention techniques in treating amphetamine users, further studies of relapse prevention interventions should target amphetamine users. Hando, Topp & Hall (1997) have addressed the question as to whether an amphetamine-specific treatment is needed, given that polydrug use is almost universal among users of amphetamine. They answered affirmatively, pointing out that an amphetamine dependence syndrome is a common harm associated with regular use of the drug, prompting users to seek treatment.

The present study was designed with the primary aim of testing the feasibility of conducting and evaluating cognitive-behavioural interventions for regular users of amphetamine. As this was the first trial of this nature, it was necessary to ascertain whether regular users of amphetamine would present themselves to the researchers and be recruited into the study, retained in treatment and available for follow-up. It was hypothesized that a cognitive-behavioural intervention would be more effective than a selfhelp booklet control condition in reducing amphetamine use and other drug-related harms. The net benefit of treatment was assessed. Two interventions were piloted: a four-session cognitive-behavioural intervention involving motivational interviewing and skills training and a two-session intervention involving motivational interviewing and discussion of skills. The present study sought to examine whether regular amphetamine users would attend an intervention as lengthy as four sessions. It was hypothesized that if four sessions were acceptable to subjects then a four-session intervention would be more effective than a two-session intervention in reducing amphetamine use and related harms.

Methods

Design

Subjects were allocated randomly to either an intervention group (two or four sessions of cognitive-behaviour therapy in addition to a self-help booklet) or to a control group (self-help booklet alone). The self-help booklet was developed by the National Drug and Alcohol Research Centre (NDARC, 1997). Assessments were scheduled at pre-treatment and 6 months following the pre-treatment assessment. Follow-up assessments were conducted by an interviewer blind to the subject's group allocation.

Subjects

The subjects were 64 regular users of amphetamine (at least monthly) and were recruited in the Newcastle region of New South Wales (150 km north of Sydney). Polydrug users and people enrolled in methadone maintenance treatment (MMT) were not excluded from the study provided they reported regular use of amphetamine. This is consistent with the approach taken in other recent studies of amphetamine users (e.g. Shearer et al., 1999; Gossop, Marsden & Stewart, 2000). All subjects were volunteers and were paid a nominal amount (\$20) for attendance at each assessment session. The amount was assumed to be small enough not to influence response to the intervention but adequate to reduce non-compliance caused by any inconvenience in attending sessions.

Procedure

Subjects were recruited between July and December 1998 by means of notices placed within various agencies, cafes and treatment centres and an inner-city needle-exchange scheme in Newcastle, as well as through word of mouth. Notices

stated that university researchers needed the help of regular users of amphetamine by participating in interviews for which they would be reimbursed \$20. Interviews took 45-60 minutes to complete. When a subject volunteered, the purpose and design of the study were described. They were also informed that on giving written consent to participate in the study, they would be assigned randomly to either a control group (assessment plus self-help booklet), two sessions of counselling or to four sessions of counselling. Subjects were assured that all information was strictly confidential, that researchers were independent of the agencies in which the interviews were being conducted, and that refusal to participate would not affect their relationship with the clinic in any way. Half of the subjects (n = 32) were allocated randomly to the control group and half were allocated randomly to an intervention condition (16 subjects to two sessions and 16 subjects to four sessions).

Measures

Pre-treatment measures were documented in an earlier paper (Baker, Boggs & Lewin, 2001) and are described here only briefly. Data collected at the pre-treatment assessment included: demographic characteristics; history of any treatment for drug dependence; current drug use; exposure to blood-borne virus infections; and history of imprisonment. In addition, the following instruments were administered to all subjects: the Opiate Treatment Index (OTI; Darke et al., 1992), the amphetamine version of the Severity of Dependence Scale (SDS; Gossop et al., 1995) and the Contemplation Ladder (Biener & Abrams, 1991). The OTI measured amphetamine and other drug use, HIV risk-taking behaviour (Darke et al., 1991), drug-related health outcomes, social functioning, psychological health via the 28-item General Health Questionnaire (GHQ-28) (Goldberg & Hillier, 1979) and crime. All measurements on the OTI related to the 1 month period prior to interview except for the Social Scale which assessed the 6 months prior to interview. Higher scores indicate higher levels of dysfunction on all scales. Scores on the Contemplation Ladder referred to stage of change for reducing amphetamine use. Because subjects' responses were clustered around the five rungs with verbal anchors, the categories were subsequently collapsed as follows: 0, "No thought of quitting or cutting down" or 1, "Think I need to consider quitting someday" (precontemplation); 2, "Think I should quit but not quite ready" (contemplation); 3, "Starting to think about how to change my use patterns" (preparation); and 4, "Taking action to quit or cut down" (action). At the 6-month follow-up assessment the OTI was readministered, which included measures of amphetamine and other drug use, HIV risk-taking behaviour, drugrelated health outcomes, social functioning, psychological health (GHQ-28) and crime.

Four-session cognitive-behavioural intervention

These sessions were conducted individually and lasted 30-60 minutes. Each session focused on the acquisition of different skills aimed at helping the subject to reduce amphetamine use. Sessions were guided by a therapist manual and involved role-plays. In addition to a self-help booklet on reducing amphetamine use and related harms (NDARC, 1997), subjects were given walletsized pamphlets to refer to when practising new skills for homework between sessions. The first session occurred immediately following the pretreatment assessment and involved a motivational interview (Miller & Rollnick, 1991) which aimed to raise motivation to reduce amphetamine use. The following three sessions focussed on cognitive-behavioural coping strategies and relapse prevention, using techniques developed by Marlatt & Gordon (1985). In the sesession the focus was on assisting identification of high-risk situations for amphetamine use. The third session addressed the issue of craving. Subjects were taught how to reduce craving with progressive muscular relaxation and coping self-talk. A relaxation tape was provided for practice between sessions. The fourth session focused on coping with lapses and preparation of a coping drill for use in future high-risk situations and following lapses.

Two-session cognitive-behavioural intervention

The procedure and content of the first session was the same as described above for the longer intervention. Cognitive-behavioural coping strategies reflecting some of the content of sessions two, three and four of the longer intervention were discussed during the second session.

The same self-help booklet (NDARC, 1997) and pamphlets were given to subjects.

Control group

Subjects were given the same self-help booklet on reducing amphetamine use and related harms (NDARC, 1997) as the intervention conditions.

Therapists

The therapists were two research assistants with 4 years' training in psychology. A therapist manual developed for the project by the first author was used in both initial training and weekly supervision.

Data analysis

In view of attendance patterns among the intervention group, and as detailed below, these subjects were reassigned to three intervention subgroups according to the number of sessions attended (one, two or three-four sessions). Data were analysed using SPSS for Windows (version 9) and PSY2000 (Bird, Hadzi-Pavlovic & Isaac, 2000). Categorical outcome variables (e.g. abstinence vs. continued use) were analysed using chi-square tests. For the continuous outcome variables (e.g. amphetamine use), analyses of variance (ANOVA) were performed using planned contrasts, in which we examined all comparisons between the subgroups as well as overall differences between the control and the combined intervention subgroups. Repeated measures ANOVAs were conducted to ascertain the relationship between treatment and the following variables: level of amphetamine and other drug use; level of injecting risk-taking behaviour; level of psychopathology; health; social functioning and criminal involvement. As a partial control for the number of statistical tests, the threshold for significance was set at p < 0.01.

Results

Patterns of participation

There were 32 control subjects. Of the 16 subjects assigned to the two-session intervention, 11 attended both sessions (11/16, 68.8%). Of the 16 subjects assigned to the four-session condition, eight attended all four sessions and one attended three sessions (9/16, 56.3%), with the

remainder attending only the first session. Analyses of data on key prognostic variables, age, gender, years of education, duration of amphetamine use, stage of change for amphetamine use and level of amphetamine use during the month prior to the initial interview indicated that there were no significant differences between intervention subjects who completed the sessions to which they were assigned (n = 20) and those who did not (n = 12). Accordingly, brief intervention subjects were reassigned to the following subgroups on the basis of the number of sessions actually attended: B1, one session, B2, two sessions or B3, three/four sessions.

Fifty-two subjects (81.3%) were successfully followed-up and there was no significant difference in retention rates across groups (controls, n=28, 87.5%; intervention subgroups: B1, n=8, 66.7%; B2, n=9, 81.8%; B3, n=7; 77.8%; $\chi^2(3)=2.57$, NS). Analysis of data on the same key prognostic variables above indicated that there were no significant differences between subjects who were followed up (n=52) and subjects who were not followed-up (n=12).

Sample characteristics

Overall pre-treatment sample characteristics and patterns of drug use have been reported previously (Baker et al., 2001). The main pretreatment characteristics of the control and intervention groups are shown in Table 1. Analysis of data on the same key prognostic variables above indicated that there were no significant differences. The majority of the subjects were male, with long histories of amphetamine use, and more than one-third were currently enrolled in MMT. Approximately one-fifth (21.9%) of the sample were at the pre-contemplation stage for quitting or reducing amphetamine use, 37.5% were at the contemplation stage, 23.4% were at the preparation stage and 17.2% were at the action stage.

Changes in drug use

Mean pre-treatment, 6-month follow-up and change scores are reported in Table 2 for amphetamines, the two most commonly used drugs, cannabis and tobacco and polydrug use. Standardized change scores and abstinence rates for these outcome measures are also reported in

Control group Intervention group $(n = 28)^a$ $(n = 24)^a$ Demographic characteristics % Male 57.1% (16) 66.7% (16)Mean age (years) 30.57 (8.57)32.79 (8.76)Mean education (years) 10.50 10.66 (1.86)(1.74)Amphetamine use Mean duration of regular use (years) 10.25 (7.03)10.92 (7.84)Mean daily level of amphetamine use (OTI) 0.83 (1.03)1.20 (1.65)Mean stage of change for amphetamine use (0-4) 2.39 (1.07)2.17 (1.40)% Enrolled in methadone maintenance treatment (MMT) 39.3% (11) 33.3% (8)

Table 1. Pre-treatment sample characteristics by group

Table 2; the former facilitate "effect size" comparisons with other intervention studies.

Overall, the repeated measures (treatment group × time) ANOVAs revealed significant main effects for time, but no significant group main effect contrasts or any significant time × group interaction contrasts. phetamine use fell significantly for the sample as a whole [F(1,48) = 17.80, p < 0.001] and there was a (non-significant) tendency for this fall to be greater among the B2 (two-session) intervention group compared to the control group [F(1,48) = 6.80, p < 0.05]. While not statistically significant [relevant interaction F(1,48) = 2.36, p < 0.15, mean daily occasions of use of amphetamine fell 0.44 units among the control group versus 1.02 units among the intervention group as a whole. Expressed in effect size units (0.40 vs. 0.93), this represents a difference of over half a standard deviation, a moderate effect size. There was a significant association between group membership and abstinence from amphetamines at follow-up $[\gamma^2(3) = 11.66,$ p < 0.01]. The overall difference in abstinence rates between the control condition subjects (6/ 28, 21.4%) and the intervention group (14/24, 58.3%) $[\chi^2(1) = 7.43, p < 0.01]$ was due largely to differences between the control and B3 conditions (three/four sessions: 85.7%) $[\gamma^2(1) = 10.27, p < 0.01].$

There was no significant change in cannabis [F(1,31) = 3.54, NS] or tobacco usage [F(1,44) = 2.67, NS] over time nor any differen-

tial change by group. Similarly, there was no association between group membership and abstinence from cannabis $[\chi^2(3) = 2.28, \text{ NS}]$ or tobacco $[\chi^2(3) = 5.49, \text{ NS}]$ at follow-up. Reflecting the significant reduction in amphetamine use among the sample as a whole, there was a significant overall reduction in polydrug use over time [F(1,48) = 12.71, p < 0.01]. There was also a (non-significant) tendency for the reduction in polydrug use to be greater among the B1 (one-session) intervention group compared to the B2 (two-session) intervention group [F(1,48) = 5.15, p < 0.05].

Despite the evidence suggesting some treatment benefits, it is worth noting that among those who received an intervention, the mean OTI scores at follow-up (Table 2) indicate that the typical subject was using amphetamines at least weekly, cannabis three times a day, 19 cigarettes per day, and three-and-a-half classes of drugs per month.

A $2 \times 2 \times (2)$ repeated-measures ANOVA was conducted to assess the contribution of stage of change to patterns of amphetamine use (i.e. action stage of change vs. early stage of change \times control vs. intervention \times time). There were no significant main or interaction effects involving stage of change. A similar analysis examining the effects of duration of regular amphetamine use (8 years or less vs. more than 8 years) revealed no significant main or interaction effects involving duration of amphetamine use.

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

Table 2. Selected OTI pre-treatment, follow-up, change, and abstinence indices by treatment group

			Mea	Mean OTI score (SD)		7	0/ 14-20-1-20-1
OTI drug use	${\rm Treatment\ group}^a$	n^{b}	Pre-treatment	6 month follow-up	Change	Standardised change (effect size units) ^c	at 6 month follow-up
Amphetamines	C: Control B: Brief intervention B1: 1 session B2: 2 sessions B3: 3-4 sessions Overall	28 24 8 7 7 52	0.83 (1.03) 1.20 (1.65) 0.84 (0.93) 2.10 (2.33) 0.46 (0.29) 1.00 (1.35)	0.39 (0.62) 0.18 (0.52) 0.06 (0.13) 0.43 (0.80) 0.01 (0.01) 0.29 (0.58)	0.44 (1.28) 1.02 (1.23) 0.78 (0.96) 1.67 (1.63) 0.45 (0.29) 0.71 (1.28)	0.40 0.93 0.71 1.53 0.41	21.4% 58.3% 62.5% 33.3% 85.7%
Cannabis	C: Control B: Brief intervention B1: 1 session B2: 2 sessions B3: 3-4 sessions Overall	19 16 6 4 7 35	7.43 (8.96) 5.93 (7.53) 10.76 (10.34) 2.76 (2.74) 3.22 (3.76) 6.75 (8.25)	4.94 (5.68) 3.00 (4.36) 4.89 (5.86) 1.18 (1.88) 2.33 (3.61) 4.06 (5.14)	2.49 (7.59) 2.93 (6.64) 5.87 (9.86) 1.57 (1.68) 0.90 (4.09) 2.69 (7.07)	0.36 0.42 0.84 0.23 0.13 0.39	26.3% 6.3% 16.7% 0.0% 0.0% 17.1%
Товассо	C: Control B: Brief intervention B1: 1 session B2: 2 sessions B3: 3-4 sessions Overall	21 8 8 8 48	18.09 (7.77) 22.90 (20.38) 17.56 (8.28) 31.67 (30.33) 17.40 (9.91) 20.19 (14.69)	16.36 (8.78) 19.43 (11.21) 17.50 (7.07) 24.13 (11.67) 15.00 (15.07) 17.70 (9.93)	1.73 (5.62) 3.47 (14.27) 0.06 (2.15) 7.54 (22.26) 2.40 (9.24) 2.49 (10.24)	0.14 0.28 0.00 0.60 0.19 0.20	0.0% 4.8% 0.0% 0.0% 20.0% 2.1%
Polydrug (out of 11)	C: Control B: Brief intervention B1: 1 session B2: 2 sessions B3: 3-4 sessions Overall	28 8 8 8 7 25	5.00 (1.22) 4.38 (1.28) 4.88 (0.99) 3.56 (0.88) 4.86 (1.57) 4.71 (1.27)	4.32 (1.68) 3.54 (1.44) 3.38 (1.41) 3.67 (1.32) 3.57 (1.81) 3.96 (1.61)	0.68 (1.61) 0.83 (1.40) 1.50 (1.41) -0.11 (1.27) 1.29 (0.95) 0.75 (1.51)	0.46 0.56 1.01 - 0.07 0.86 0.50	%0.0 %0.0 %0.0 %0.0

^a C: Control—assessment only; B: Brief intervention, with three subgroups: B1: 1 session, motivational interview (MI); B2: 2 sessions, MI + change strategies (CS); B3: 3-4 sessions, MI + CS + more detailed relapse prevention.

^c Using as a reference point the grand standard deviation for the relevant OTI drug use category (i.e. across both assessment occasions). ^b Excluding non-users (at pre-treatment) and those who did not complete both assessment occasions.

Changes in amphetamine related harms

Similar repeated-measures (treatment group X time) ANOVAs were conducted for the amphetamine-related harm variables. There were no differential changes in OTI crime scores across the groups; however, there was a significant reduction in crime for the sample as a whole, from a mean score of 1.87 to 0.79 [F(1,48) = 8.19,p < 0.01]. Similarly, OTI health scores also improved for the sample as a whole, from a mean score of 20.15 to 16.04 [F(1,48) = 8.43, p < 0.01]. While there were no differential changes across groups, the B2 (two-session) intervention group had significantly better (i.e. lower) overall health scores than the controls [12.56 vs. 19.23, F(1.48) = 7.47, p < 0.01] and the B1 (one-session) intervention group [12.56 vs. 21.00, F(1,48) = 7.43, p < 0.01]. There was no significant change in levels of injecting risktaking behaviour; however, the control group had significantly higher injecting risk-taking scores overall compared to the intervention groups [9.02 vs. 5.34, F(1,48) = 9.24, p < 0.01, particularly when compared to the B2 (two-session) intervention group [9.02 vs. 3.89, F(1,48) = 11.37, p < 0.01]. There were no significant differences between groups or changes over time in GHQ-28 scores or OTI social functioning.

Discussion

The results of the present study indicate that further studies of brief cognitive-behavioural interventions among regular users of amphetamine are feasible and warranted. As documented previously (Baker et al., 2001), the current sample comprises a group of regular amphetamine users with high levels of: dependence on amphetamine, injecting risk-taking behaviour, psychopathology, social dysfunction and crime. Although only 17.2% of the initial sample were at the action stage for reducing amphetamine use, 81.3% (52/ 64) were retained at 6-month follow-up. More than half (59.4%, 19/32) of all subjects assigned to intervention conditions attended all sessions. Thus, regular users of amphetamine, many of whom are ambivalent about change, can be recruited, treated and retained for follow-up evaluation.

As this was a small feasibility study and groups were formed as a result of both intended assignment to the two- and four-session intervention and actual patterns of attendance, the results regarding intervention effectiveness should be interpreted with caution. Furthermore, use of a flyer to attract study participants and reimbursement for attendance at assessment interviews may have attracted more pre-contemplators compared to a clinical setting. With these caveats, the findings are suggestive of a moderate overall intervention effect. The differential reduction in mean daily amphetamine use among the intervention versus control groups (1.02 vs. 0.44) represents a moderate difference in effect size units (0.93 vs. 0.40), which is of a clinically significant magnitude. The difference in abstinence rates between the control and intervention conditions attained statistical significance, lending support to the comparative effectiveness of the intervention.

Brief cognitive-behavioural interventions may be beneficial for many amphetamine users within existing drug treatment services, including MMT. In a recent study (Gossop et al., 2000), psychostimulant users were found to improve following treatment in existing services, yet it was suggested that the provision and effectiveness of services should be improved. Amphetamine users with co-morbid psychological problems may need more intensive interventions addressing both mental health and drug issues. Future research should address the contribution of psychological functioning (e.g. as assessed by the GHQ) to intervention outcome.

The failure to detect a significant difference between groups on the OTI amphetamine use score, while detecting a significant difference between control and intervention groups in the proportion of subjects reporting abstinence, raises several methodological issues. First, we may simply have too small a sample size to consistently detect intervention effects. Secondly, the discrepancy in findings may call into question the sensitivity of the OTI in assessing amphetamine as opposed to opioid use. Shearer et al. (1999) reported inconsistency between OTI amphetamine scores and reductions in injecting frequency and the proportion of subjects reporting abstinence in their study of amphetamine substitution therapy. They point out that subjects who actually reduce their mean daily level of amphetamine use and who use less regularly in the form of a binge may receive inflated OTI scores as the OTI score estimates mean use during the last binge and extrapolates this to the entire month. Shearer et al. (1999) suggest that a 30-day

diary of use could be completed by subjects. A third methodological issue is that, within the context of this small study, random assignment resulted in an uneven distribution of heavy versus less heavy users of amphetamine. For example, the comparatively lower OTI amphetamine use scores at pre-treatment among the B3 group (see Table 2) could have resulted in a "floor" effect, limiting the amount of change that was able to be demonstrated. Conversely, and associated with their comparatively lower initial amphetamine use scores, abstinence may have been an easier outcome for the B3 group to achieve at follow-up. By comparison, the B2 group had higher initial OTI amphetamine scores, were more able to demonstrate sizeable improvement, and had the lowest abstinence rates at follow-up (see Table 2). The B2 group also had the lowest OTI polydrug use scores, which is consistent with the finding that they had better overall health (compared to C and B1) and injecting risk-taking scores (compared to C). If this study is replicated with a larger sample size, then a more even distribution of pre-treatment amphetamine scores is likely and the capacity to demonstrate intervention effects would be more equivalent. The general decrease in amphetamine use for all groups is likely to partially reflect regression to the mean effects, in that subjects were recruited at a time of high amphetamine use. The non-specific effects of being identified as a regular user of amphetamine and the use of a self-help booklet may also have contributed to improvement.

A significant reduction in crime and a significant improvement in health detected among the sample as a whole is consistent with the overall reduction in amphetamine use among the sample. This attests to the community and public health benefits that accompany an overall reduction in amphetamine use among a cohort of regular amphetamine users.

The main conclusion from the present study is that brief cognitive-behaviour therapy appears to be feasible and moderately effective among regular users of amphetamine. The results of this study suggest that a larger randomized controlled trial of the effectiveness of cognitive-behavioural therapy should be conducted.

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