

Group Psychotherapy for Opiate Addicts in Methadone Maintenance Treatment – A Controlled Trial

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Key Words

Group psychotherapy · Methadone maintenance treatment · Cognitive behavioural therapy · Concomitant drug use

Abstract

A controlled trial was conducted evaluating cognitive-behavioural group psychotherapy as a measure to reduce concomitant drug use in methadone maintenance treatment (MMT). 73 opiate addicts were randomly assigned to local routine MMT or to routine MMT plus group psychotherapy (20 sessions over 20 weeks). Psychotherapy was delivered by therapists according to a manual. Drug use (urine screen) was compared at onset of psychotherapy, end of intervention period (6 months after study onset), and 6 months later. Data analysis was done according to intention-to-treat principles. Results indicated that patients in the psychotherapy group ($n = 41$) showed less drug use than control subjects ($n = 32$). This group difference was statistically significant at 6-month follow-up ($p = 0.02$). These findings underscore the usefulness of group psychotherapy in MMT. The delayed effect is comparable to other studies evaluating cognitive-behavioural psychotherapy.

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Introduction

Opioid addicts in methadone maintenance treatment (MMT) show dysfunctional behaviour as part of their addictive disorder, especially the concomitant use of drugs like heroin, cocaine and benzodiazepines. The question is whether MMT should be supplemented by psychotherapeutic treatment in order to reduce patients' drug use more effectively. Despite the large number of opiate addicts receiving MMT, there are few studies of controlled evaluations of additional psychotherapy.

Woody et al. [1] evaluated the effect of individual psychotherapy as an adjunct of MMT. In their study, addicts in MMT received either drug counselling alone, or additional psychodynamic focal psychotherapy called supportive-expressive psychotherapy (SET), or cognitive-behavioural psychotherapy (CBT). All groups showed statistically significant improvement regarding drug use, employment, legal problems and psychopathological symptoms over a 6-month study treatment period. Compared to drug counselling alone, patients receiving additional psychotherapy showed greater improvement in several areas. With regard to self-reported drug-use patients treated with additional SET did not improve significantly more than those with drug counselling alone, and patients

treated with CBT improved significantly less than the two other groups. With regard to drug use confirmed by urine tests, no significant difference was found between the three groups, except for opiates, where SET and CBT groups showed less use than the counselling-only group. At the 12-month follow-up, there was a clear indication for more improvement in the SET and CBT groups than in the drug counselling group with regard to psychiatric symptoms, but not for drug use [2]. Rounsaville et al. [3], comparing methadone treatment with and without additional interpersonal therapy (IPT) in methadone patients with psychiatric comorbidity, did not find an additional effect of IPT on psychiatric symptoms or drug use. It must be noted, though, that standard methadone treatment in this study was very intensive, for example containing group psychotherapy sessions. Another study by Woody et al. [4], comparing 6 months of individual SET with drug counselling (both in addition to usual counselling) for patients with persisting psychiatric symptoms, found significantly more improvement of the SET group in several areas, but not with regard to self-reported drug use or to results of urine analyses. Thus, adjunctive individual psychotherapy not directly aimed at drug use reduction seems to have only a limited additional effect on drug use, at least in the short run.

Rosenblum et al. [5] studied the effects of a cognitive-behavioural, high-intensity relapse prevention program (including group sessions), or of weekly group sessions on cocaine use in MMT clients. They could show that at least treatment completers reduced their cocaine use in both groups. Since their design did not contain a routine treatment condition, results are not easy to interpret with respect to the additional benefit of both interventions. Rawson et al. [6] showed that in MMT patients with comorbid cocaine dependence, cognitive-behavioural group psychotherapy aimed at the reduction of cocaine use was more effective than MMT alone.

Thus, there are indications that group CBT approach is helpful in reducing cocaine use in MMT patients. It remains open to investigation whether it might be beneficial not only for cocaine-addicted MMT patients, but for MMT patients in general, and also with respect to other drugs than cocaine. The results presented here are from a randomised clinical trial comparing local routine MMT with and without additional group CBT aimed at the reduction of concomitant drug use.

Methods

Research Participants

The study was carried out at a maintenance clinic of a psychiatric department of a university hospital. Subjects were recruited from individuals seeking MMT at the urban centre for the assignment of heroin addicts to various MMT clinics and general practitioners. The diagnosis of opiate addiction according to ICD-10 was then established. Patients were informed that in one of the three local MMT clinics, a study evaluating group psychotherapy was being carried out. Patients already in MMT at the study clinic were also asked to participate.

Subjects who met ICD-10 criteria for opiate addiction were included. The study treatment had to be their first episode of MMT. If they were currently in MMT, it should be for more than 6 weeks and less than 6 months [1]. Individuals were excluded who suffered from: (1) severe psychiatric conditions, especially psychosis and clinically significant organic brain syndrome, (2) serious medical, legal or social problems, that would be likely to prevent participation in MMT for at least 6 months after randomisation, e.g. imminent imprisonment.

Over the study period of approximately 2 years, 133 patients entering MMT were personally asked to participate. Nineteen subjects fulfilled exclusion criteria due to severe psychiatric or somatic disorder, or a previous episode of maintenance treatment. Of those 114 patients eligible for the study, 35 (31%) refused to participate and were referred to other maintenance facilities. A further 6 patients dropped out of maintenance treatment during the first 6 weeks before study inclusion. Thus, 73 subjects could be included, securing group sizes comparable to those in most of the former controlled studies about psychotherapy in MMT. After inclusion, each subject was randomly allocated to one of two groups by flipping a coin. None of the randomised subjects dropped out of the study before baseline.

In addition to the routine examinations in MMT (urine screen, blood laboratory work-ups and ECG), every patient received 4 individual diagnostic sessions of about an hour each. Psychiatric diagnoses according to DSM-IV [7, 8] were established using the German versions of the standardised clinical interviews SCID-I and SCID-II [9–11]. Sociodemographic data and drug use history were documented using the European version of the Addiction Severity Index (EuropASI) [12, 13].

Local Routine MMT

The study was carried out in one of the methadone maintenance clinics of a psychiatric university hospital. On average, 70 patients are treated there. MMT is carried out by a multiprofessional team which includes psychiatrists, psychologists and social workers on-site, with at least one individual therapist-patient contact weekly. Methadone dosage is individualised and oriented to a sufficient suppression of withdrawal symptoms and heroin craving. An upper limit of methadone dosage is not defined. After 12 weeks of drug-free urine, take-home dosages are possible. According to a written contract, patients are obliged to adhere to treatment rules with defined rewards, e.g. take-home dosages, or loss of privileges, or exclusion from treatment due to constant drug use.

Cognitive-Behavioural Group Psychotherapy

A manual guided, cognitive-behavioural treatment program was developed based on existing guidelines [14–16]. This consisted of 20

group sessions, each approximately 90 min, including a break. The psychotherapy was aimed at the patient's understanding of the individual situations predisposing them to use drugs. Dysfunctional cognition in difficult situations was identified, and alternative cognition as well as behaviours were established. The analysis of relapse was emphasised as well as the establishment of strategies to prevent it. If a relapse had already occurred, a constructive behaviour ought to be learned.

Besides being given the opportunity to discuss current problems and important life events, each session had a defined goal. During the first 2 sessions, patients were introduced to the therapy plan; the rules of group psychotherapy and experiences with heroin and methadone were discussed. In sessions 3–4, a cognitive-behavioural model of addiction was introduced. In sessions 5–8, accounts of relapse situations for heroin were collected and analysed according to this cognitive-behavioural model of addiction. This was followed by 4 sessions which dealt with concomitant drug use other than heroin. Sessions 13–16 dealt with stressful situations in everyday life, such as family quarrels or negotiating with social agencies, and how to respond appropriately to them. In sessions 17–19, patients were trained to develop day structures and plan for their recreational time, as well as for their future. The last session was devoted to reflections about the course of the therapy and patient's experiences with it.

Treatment Implementation

The psychotherapy was carried out in closed groups of 7–12 patients. Therapists were two psychologists, specialised in CBT. In each group, a principle therapist was assigned, and the other was the observing therapist. Treatment sessions of the first therapy group were audiotaped, sessions of the three subsequent therapy groups were videotaped for supervision and assessment. Quality of psychotherapy was assessed in weekly sessions with an internal supervisor and monthly sessions with an external supervisor.

Outcome Assessment

The main outcome criterion was the use of drugs as measured by 5 randomised urine screens per month (by EmitT-test of Dade Behring Co.). To minimise the risks of manipulation of the urine sample, the fresh urine was checked on temperature using the Franklin collector [17].

The intensity of drug use was determined at the end of intervention phase (6 months after randomisation) and at the end of a 6-month follow-up (12 months after randomisation). This was defined as the relative frequency of urine samples positive for heroin, cocaine, and/or benzodiazepines. Cannabis was excluded from analysis because a reduction of cannabis abuse was regarded an unrealistic goal for the evaluated treatment. Amphetamines and barbiturates were not used in this population.

Analyses

The intensity of drug use was compared between intervention group and control group, using the t-test for independent samples ($p < 0.05$, two-tailed). The analysis was made according to the intent-to-treat principle (ITT), meaning that the data of all included subjects were analysed, whether they had completed the study or not. Following the last observation carried forward principle (LOCF), missing data at months 6 and 12 were substituted by the last available urine samples. Data analysis according to ITT and LOCF was done in order to prevent an artificial improvement of

results by suppressing data from patients dropping out, who were assumed to have greater problems and a higher intensity of drug use. Additional analyses regarded outcome at 3 and 9 months after randomisation in order to obtain a more detailed analysis of the course of changes.

The critical t-value (two-sided test, d.f. 71, $\alpha = 0.05$) to yield a significant result was 1.99. This value would be exceeded if sample group means differed more than 0.45 pooled standard deviations. If the population effect was $d = 0.5$, the statistical power to detect a significant group difference was 0.55. A population effect of $d = 0.8$ could be detected with probability 0.92. With the available sample size, it was very likely to detect large effects and fairly likely to detect medium effects.

Ethical Approval

This study was submitted to the Ethics Committee of the University Hospital of Essen and approved of without objections. Participation was voluntary, and patients gave their written consent.

Results

Sample Description

73 patients were included (53 male, 20 female). Age was between 19 and 41 years (mean 30). The duration of heroin dependence was between 1 and 25 years (mean 7). In 83% of the subjects, an additional current addiction or polydrug dependence was diagnosed. In 71% of the patients, an additional psychiatric disorder other than substance-related disorders was diagnosed.

41 (56%) patients were randomly assigned to the intervention group, 32 (44%) to the control group. As shown in table 1, there were no significant differences between the intervention group and control group regarding sociodemographic and psychiatric characteristics (analysed with $\alpha = 0.1$). The stable methadone dosage at the beginning of the intervention period was 99.9 mg/day (SD ± 42.5 mg) in the psychotherapy group, and 98.9 mg/day (SD ± 46.2 mg) in the control group.

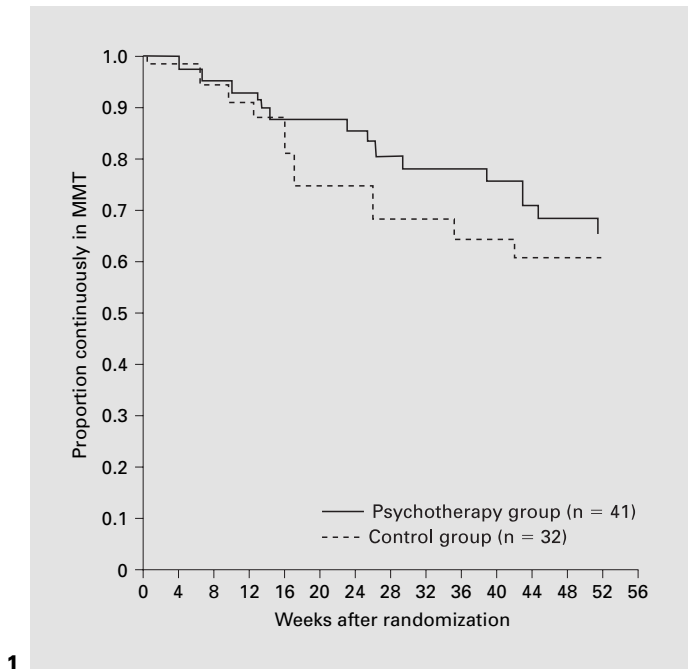
Attrition

At the end of the 6-month follow-up period, 27 patients from the psychotherapy group (63%) and 19 patients from the control group (59%) were continuously in MMT in the same setting. The mean time to drop out was less in the control group (39 weeks) than in the psychotherapy group (43 weeks). The survival distributions (fig. 1) were not significantly different ($p = 0.47$, log-rank test). Nine out of 14 MMT dropouts from the intervention group and 9 out of 13 dropouts from the control group were treatment failures: they were excluded from MMT due to intolerable concomitant drug use (e.g. repeated intoxication states at attendance at the MMT clinic, refusal to

Table 1. Sociodemographic statistics of study participants

	Control group n (%)	Psychotherapy n (%)	Total n (%)
Sex			
Male	20 (63)	33 (81)	53 (73)
Female	12 (37)	8 (19)	20 (27)
Age, years			
Mean (\pm SD)	31 \pm 6	30 \pm 6	30 \pm 6
Ethnic origin of parents			
At least one parent of German origin	30 (94)	40 (98)	70 (96)
No German origin	2 (6)	1 (2)	3 (4)
Educational level			
First examination in secondary school	15 (25)	25 (15)	40 (19)
Secondary modern school	8 (47)	6 (61)	14 (55)
Special school	3 (9)	–	3 (4)
No formal educational level	6 (19)	10 (24)	16 (22)
Occupational training			
No	23 (72)	25 (61)	48 (66)
Yes	9 (28)	16 (39)	25 (34)
Main income			
Employment	2 (7)	1 (2)	3 (4)
Unemployment benefit	13 (42)	20 (49)	33 (46)
Welfare	10 (32)	17 (42)	27 (38)
Others	7 (19)	3 (7)	10 (12)
Accommodation			
Alone	7 (22)	9 (22)	16 (22)
Not alone	21 (69)	23 (56)	44 (62)
Institution etc.	3 (9)	9 (22)	12 (16)
Housing partner with a drug problem			
Yes	10 (31)	8 (20)	18 (25)
No/inapplicable	22 (69)	33 (80)	55 (75)
Age at first heroin use			
Mean (\pm SD)	22 \pm 5	22 \pm 5	22 \pm 5
Years of heroin use			
Mean (\pm SD)	8 \pm 6	6 \pm 4	7 \pm 5
Additional substance induced disorder			
Yes	29 (91)	35 (85)	64 (88)
No	3 (9)	5 (12)	8 (11)
No information	–	1 (2)	1 (1)
Additional axis I disorder			
Yes	12 (38)	15 (37)	27 (37)
No	20 (63)	25 (61)	45 (62)
No information	–	1 (2)	1 (1)
Additional axis II disorder			
Yes	19 (59)	20 (49)	39 (53)
No	13 (41)	20 (49)	23 (45)
No information	–	1 (2)	1 (1)

Remark: All comparisons of means (t tests) and comparisons of frequencies (χ^2 tests) resulted in $p > 0.1$.

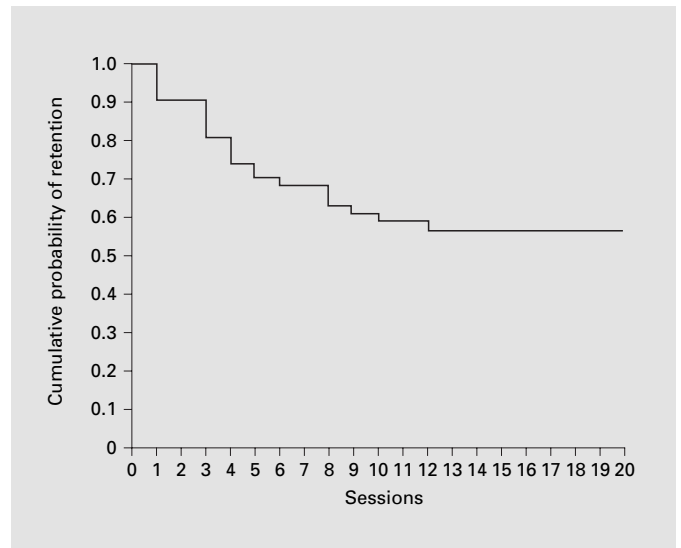


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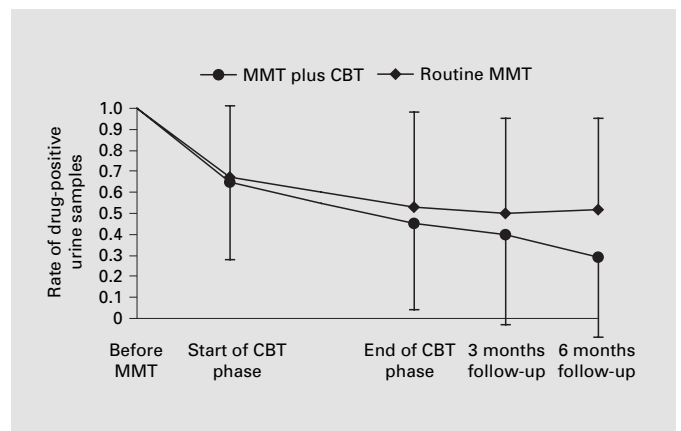
Fig. 1. Retention rates in MMT.

Fig. 2. Retention rate in psychotherapy (termination of treatment is defined as the date of the last participation in a group session).

Fig. 3. Mean (SD) rates of drug-positive urine samples. Missing data replaced by last observation.



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undergo in-patient detoxification treatment in spite of continuously positive drug urines over weeks, violations of treatment rules), or they had discontinued treatment against medical advice. Three patients from each group were incarcerated. The other patients left the study due to referral to an abstinence-oriented in-patient treatment, or moving to another town with continuation of MMT there.

18 (44%) out of 41 patients in the intervention group prematurely terminated group psychotherapy. Four out of these 18 patients terminated MMT at the same time. Most of the premature terminations occurred before the sixth group treatment session (fig. 2).

Outcome Analyses

There was a considerable reduction of drug use, especially of heroin in both groups from the onset of MMT until the start of the study period. A reduction of drug use was observed in both groups from start to the end of the intervention phase (fig. 3, table 2). Further reductions could be observed in the psychotherapy group during follow-up, but not in the control group. The difference between groups was not statistically significant at the end of the intervention period ($p = 0.42$), but at the end of the 6-month follow-up period ($p = 0.02$). This difference could mainly be related to a marked reduction in cocaine use in the intervention group, whereas there were only small group differences regarding the use of heroin and benzodiazepines (fig. 3, table 2).

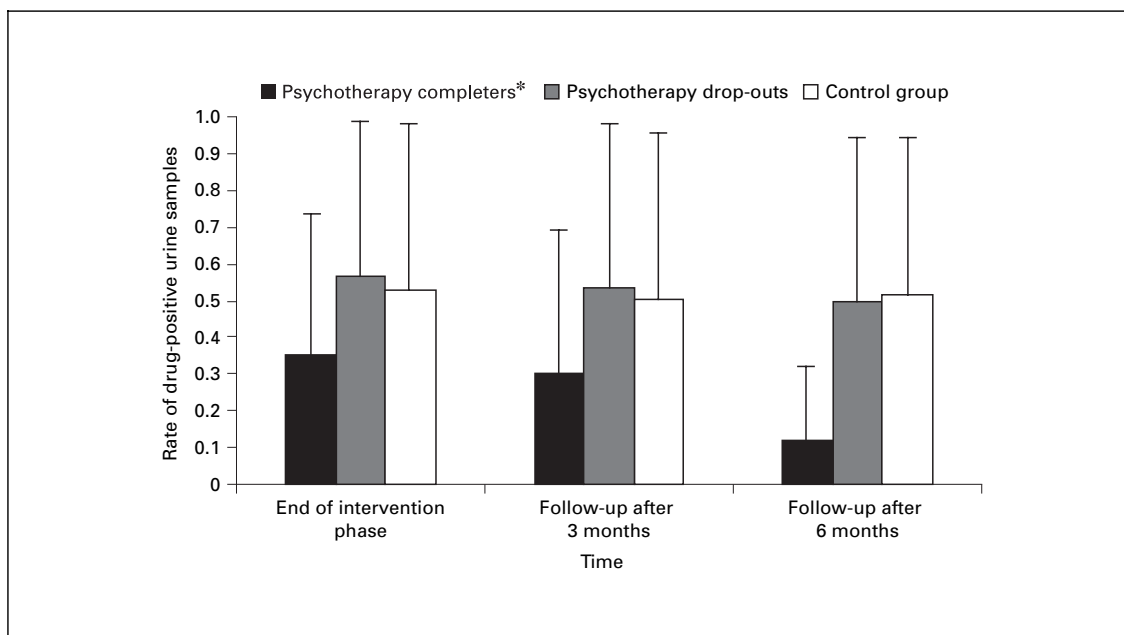


Fig. 4. Relative frequency of drug positive urine samples at the end of intervention period and during follow-up. Participants of the psychotherapy group divided according to treatment compliance. LOCF analysis. * At least 9 sessions attended.

Table 2. Mean (SD) rate of drug-positive urine samples

	BZD	Cocaine	Opiates	Any drug ¹	Group comparisons for 'any drug use' ²
Start of CBT					
Control group	0.28 (0.40)	0.36 (0.47)	0.35 (0.41)	0.67 (0.42)	–
Psychotherapy group	0.36 (0.44)	0.38 (0.40)	0.37 (0.41)	0.65 (0.40)	
End of CBT					
Control group	0.24 (0.40)	0.39 (0.42)	0.21 (0.31)	0.53 (0.45)	p = 0.42
Psychotherapy group	0.23 (0.35)	0.23 (0.32)	0.25 (0.36)	0.45 (0.41)	
3-Month follow-up					
Control group	0.25 (0.39)	0.40 (0.43)	0.24 (0.32)	0.50 (0.45)	p = 0.33
Psychotherapy group	0.17 (0.33)	0.24 (0.36)	0.21 (0.39)	0.40 (0.40)	
6-Month follow-up					
Control group	0.24 (0.38)	0.40 (0.40)	0.23 (0.33)	0.52 (0.43)	p = 0.02 ³
Psychotherapy group	0.15 (0.29)	0.16 (0.30)	0.15 (0.32)	0.29 (0.38)	

¹ Rate of urine samples positive for heroin, cocaine, and/or benzodiazepines, measured in 5 specimens during the month of assessment. Missing observations in the month of assessment were replaced by last available urine data (LOCF).

² Independent samples t tests, d.f. = 71.

³ t = 2.46.

To explore the relationship between psychotherapy compliance and drug use, a comparison was made between patients who had participated in 9 or more therapy sessions ($n = 23$; 'completers') and those who participated in less than 9 sessions ($n = 18$; 'dropouts'; fig. 4). The mean relative frequency of drug positive urine samples in the noncompliant 'dropout' group from the end of intervention period to the end of follow-up period was constant at about 50%, which was approximately the same level as in the control group. The mean frequency of drug positive urine samples in the 'completers' group however, was lower than in the dropout group, as well as in the control group at the end of the intervention period, and decreased further during follow-up. The initial mean frequency of drug use had been the same for both psychotherapy subgroups (fig. 4).

Discussion

A controlled trial of cognitive-behavioural group psychotherapy in MMT was carried out. The retention rates in MMT were quite similar between groups. There was a small yet insignificant difference in drug use at the end of the intervention period. During the follow-up period, however, this difference increased and was significant after the 6-month follow-up. The reduction in drug use was almost totally caused by a reduction of cocaine use in the intervention group. The effectiveness of cognitive-behavioural group therapy specifically aimed at the reduction of cocaine use in cocaine-dependent MMT patients was previously demonstrated in the studies of Rosenblum et al. [18] and Rawson et al. [6].

Patients who had participated in at least 9 of the 20 group sessions had a considerable reduction of drug use, especially in contrast to early dropouts from psychotherapy treatment and control subjects.

Study design and data analysis did not make it easy to establish the effect of an adjunct group psychotherapy when compared with local routine treatment. Patients in the control group received more than methadone administration: These patients participated in MMT including psychiatric and psychological support, as well as social counselling on-site with a treatment contract including contingent rewards and sanctions.

As a result of the relatively high treatment level in the control condition, there was no relevant difference between intervention and control group regarding the retention rate in MMT at the end of the intervention period or at 6 month follow-up. Differences between the two groups

regarding their intensity of drug use cannot be explained by different participation in MMT. In addition, MMT clearly worked for patients under both conditions, as patients in both groups achieved the important goal of reducing their heroin use. Due to the long elimination half-lives of benzodiazepines, quantitative reductions in use of these substances cannot easily be verified by several urine screens per months. Therefore, the observed difference between the groups in the frequency of drug use was almost totally the result of a reduction in cocaine use in the intervention group.

A further aspect of the study design enhancing similarity between conditions was that the psychotherapy occurred during the first 6 months of the first individual treatment episode of MMT. Many addicts are ambivalent towards MMT during this period. Some prematurely terminate treatment because they do not want to attend the methadone clinic every day, or they do not have a long-term goal regarding MMT, and only want short-term relief from the stressful life in the drug scene [19]. Approximately one third of both groups left MMT during the first 12 months of treatment. The data from these dropouts, who were mostly patients with a high and constant level of concomitant drug use during MMT, were included in data analysis according to the principles of ITT and LOCF.

The fundamental question remains as to whether the statistically significant reduction of drug use in the intervention group 6 months after psychotherapeutic intervention period was a result of the psychotherapeutic treatment. There may be other factors, such as getting a job or establishing an intimate relationship, which favourably influenced the course during follow-up period, but accidental changes could have happened in both groups. The reduction in drug use was mainly shown by those patients of the intervention group who participated in at least 9 treatment sessions. This supports the assumption of a correlation between psychotherapy and reduction in drug use.

There was also a trend toward the reduction of drug use in the intervention group during the entire course of study. Excepting baseline, the intervention group showed less intensive drug use than the control group at four measurements, 3, 6, 9 and 12 months after randomisation.

Data on the delayed effects of CBT with drug users has not been systematically analysed. Carroll et al. [20] found a delayed effect at 12-month follow-up after a cognitive-behavioural group psychotherapy for cocaine addiction. Rosenblum et al. [18] also found some evidence of a delayed treatment effect, in that cocaine-dependent

methadone patients who completed treatment increased their positive outcomes during the post-treatment period relative to non-completers. A similar course can be found in the study of Rosenblum et al. [5] on the effects of cognitive-behavioural interventions for cocaine using patients in MMT, where treatment completers further reduced their frequency of cocaine use during 48 weeks of follow-up. As in other treatment evaluations, the reliability of these results has to be assessed in replication studies.

The reasons for a delayed effect of CBT are not clear. According to clinical impression, a substantial number of patients were not yet highly motivated to change their drug use behaviour during intervention. According to the model of Prochaska et al. [21], it might be assumed that they were in a precontemplation or contemplation stage at that time. Behavioural changes should be expected when these patients progressed to an 'action' stage during follow-up, and then made use of the strategies and techniques they had learned during psychotherapy. Whether such an explanation is valid remains open to further investigation on therapeutic processes occurring during and after CBT for drug users.

Additionally, the majority of participants continued MMT after the intervention period in the same methadone clinic and with the same therapists. Therefore, it may be assumed that the patients sometimes received unplanned individual booster sessions during follow-up.

A final question is as to whether the study population is representative of opiate addicts in general. The study set-

ting and MMT guidelines were similar to other methadone clinics in Germany. As in the study of Woody et al. [1], about 60–65% of heroin addicts and patients in MMT suitable for the study treatment were motivated to participate in an additional psychotherapy. The high frequency of premature terminations during the first weeks of intervention might reflect that some patients were simply not motivated for psychotherapy. Inferences from these results regarding the entire population of MMT patients can only be made with caution. There is generally a self-selection of patients commencing psychotherapy; they will begin a psychotherapy if they think it is reasonable to expect help in the conceptual framework of psychotherapy [22].

In conclusion, there was a significant difference in drug use between intervention and control group at follow-up. This is despite the presence of a number of factors which made establishing such a difference difficult, especially a middle grade intense routine MMT as control condition. The delayed occurrence of a significant difference is not uncommon in psychotherapy research, and is in accordance with other studies investigating CBT in drug addicts.

Acknowledgement

Supported by the Deutsche Forschungsgemeinschaft (DFG): Ga-564/2-1.

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