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ORIGINAL ARTICLES AND REVIEWS

Can reinforcement-based interventions to reduce drug use successfully be adapted to routine opioid maintenance treatment?

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Abstract

Introduction. Comorbid substance related disorders are a major health problem for patients in opioid maintenance treatment (OMT). It was investigated whether a reinforcement scheme adapted to the regulatory and financial restrictions of routine treatment reduces concomitant drug use.

Methods. OMT patients from 7 clinics who were using cocaine, benzodiazepines, heroin or amphetamines were randomly allocated to either treatment as usual (n = 64) or treatment with an additional escalating reinforcement scheme (n = 72) in which a patient's number of weekly take-home dosages was increased after 1, 4, 8 and 12 consecutive weeks with drug-free urine specimens. Trial duration was 26 weeks.

Results. Completion rates were 64% for controls and 62.5% in the experimental group. Mean number of drug-free weeks was 11.3 (SD 8.5) for the control group and 9.8 (8.9) for the experimental group (p = 0.30).

Conclusion. The intervention was not effective compared to routine treatment. Additional features might be necessary to achieve an effect, *e.g.* a higher frequency of urine sampling or use of other reinforcers. It has to be further investigated how interventions which have been proven effective in experimental studies can successfully be adapted to routine care conditions.

Key words
- opiate dependence
- opioid maintenance treatment
- concomitant drug use
- reinforcement

INTRODUCTION

Many opiate dependent patients admitted to opioid maintenance treatment (OMT) with methadone or buprenorphine show additional substance related disorders, mostly concerning cocaine, benzodiazepines (BZD), alcohol, or cannabis [1]. While OMT is an effective treatment for opiate dependence [2], many patients persist in concomitant substance use during treatment [3-6]. This may compromise the achievement of satisfactory clinical outcomes during OMT [4, 7]. Therefore, there is a need for improved treatment schemes which reduce concomitant substance use.

Such modifications of clinical routine practice could consider principles taken from learning theory. Reinforcement schemes derived from that theoretical framework seek to increase abstinence from psychotropic substances by rewarding the patient if he refrains from co-drug use. In such schemes, patients who

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show the target behaviour "delivery of a drug free urine drug screen" (as a proxy for staying abstinent), as consequence receive a desired reinforcer. Experimental studies on this approach were typically carried out using highly structured research protocols; they demonstrated at least moderate effects on the use of a range of psychotropic substances within the context of OMT [8-10].

While such approaches have demonstrated their efficacy in experimental research, effectiveness in routine treatment is a matter of further investigation. Routine practices to be considered here as components of an improved treatment scheme will include urine drug screenings and the regulation of take home medication privilege, which has shown to be an effective reinforcer [10].

Take home medication relieves patients from daily attendance at the clinic, therefore it might improve their quality of life and social rehabilitation (*e.g.* facilitate attendance at work). On the other hand, patients with take-home medication can be supervised less, especially with regard to drug and alcohol use, which could be a particular problem in patients with poor response to treatment. Studies have shown that take-home medication is associated with improved retention, less concomitant drug use, and fewer hospital admissions, but this effect requires that patients receive take-home only after they have shown sufficient response to treatment. Moreover, to dispense take-home dosages independent from treatment outcome can even have detrimental effects [11, 12]. In the German treatment system, for example, the take home medication privilege (up to a maximum of 6 days per week) is granted if patients satisfy a set of specific criteria, including: to be judged by treatment staff as clinically stable; not to consume substances which combined with the maintenance drug could lead to health risks; to keep scheduled appointments with physicians and the social workers; to show advanced psychosocial reintegration; and to show no signs that they would divert their take-home medication [13].

One main prerequisite for take-home medication is that stable abstinence from concomitant drug use has been controlled through objective measures, such as urine tests. In the present study the routine regulation of take-home dosages is compared to a scheme which has been identified as most effective in reinforcement-based intervention trials within drug treatment settings [14]. In that escalating scheme with "reset" condition, the first takehome medication is granted after one week of drug-free urines; the number of take-home dosages increases from week to week; and verified drug use leads to the patient being reset to the starting point. Such a scheme appears well adaptable to the German system routine care conditions.

METHODS

Setting

The study was carried out in 7 outpatient OMT facilities in Germany. In each facility, some 70 to 170 patients received methadone or buprenorphine maintenance treatment. All facilities adhered to comparable standards with regards to staffing, services and procedures, which included treatment by a physician specialized in addiction medicine, provision of pharmacological and psychotherapeutic treatment for psychiatric disorders, and regular contact to a social worker in order to solve problems regarding *e.g.* housing, financial issues, health security payments. Patients received their opiate agonist dose in the clinic under supervision. Dose of the opiate agonist is determined in such a way that opiate withdrawal symptoms are effectively blocked while sedating effects should be avoided. Concomitant drug use was regularly monitored via urine screenings, and harmful alcohol use was assessed with the help of breath analysis and clinical evaluation. If concomitant substance use compromised the achievement of the aims of OMT, patients were offered inpatient detoxification treatment for the respective substances. The use of cannabis was mostly tolerated, as long as it did not make worse a comorbid psychiatric illness (such as psychosis) and did not markedly disable a patient (*e.g.* repeatedly prevent him/her from attending the clinic because of cannabis-induced tiredness). Alcohol use was also usually tolerated within routine treatment, as long there were no clinical or laboratory signs of severe alcohol abuse.

Inclusion and exclusion criteria

Patients could be included into the study if they were opiate dependent according to ICD-10 (F 11.25, F 19.25 including opiate use); were at least 18 years old; were currently in methadone or buprenorphine maintenance treatment for at least 1 month duration; and according to urine screens or self-reports had presented with use of the target drugs (see below) in at least 3 of the 8 treatment weeks prior to randomization. Exclusion criteria included: clinical or laboratory signs of alcohol abuse as assessed through weekly breath alcohol measurements, mean corpuscular volume (MCV) and gamma-glutamyltransferase levels; and concurrent formal diagnosis of either a severe psychiatric (*e.g.* psychosis) or medical (*e.g.* endocarditis) disorder.

Participation was voluntary. The study was approved by the Ethics Committee of the University Hospital Essen. All patients signed an informed consent and were informed that they could withdraw from the study at any time without any explanation and without suffering any negative consequences for doing this.

Randomization

Central randomization of patients was carried out using those strata given by the expected median age (< 31 or ≥ 31 years, with the median age having been estimated from previous studies carried out on this population); gender; and intensity of concomitant drug use (percentage of drug positive weeks at baseline: $< 80\%$ or $\geq 80\%$).

Procedure

Duration of intervention was of 26 weeks. If, during the trial, subjects were referred to inpatient detoxification due to concomitant use of drugs, the intervention period was increased accordingly (inpatient detoxification is a means for a patient to achieve abstinence and was considered as being in accordance with the inter-

vention goal; it was expected that the intervention increased maintenance of abstinence, regardless of how initially achieved; we nevertheless performed a sensitivity analysis where these patients were counted as drop-outs). All study patients received daily dosages of methadone or buprenorphine; dosage changes were allowed by the protocol. Patients submitted one urine sample per week, with the sampling day (Monday to Friday) being randomly chosen; the randomization procedure for urine collection was carried out locally, by the respective centre. Urine specimens were tested using the routine procedures in the participating centres. Whilst in some centres this involved the use of the immediate testing/quick test stripes procedure, in other centres the urine toxicology samples were sent out to an outside laboratory, with the results being typically received during the following working day. On the same occasion as the submission of a urine sample, patients were also breath analyzed for alcohol (routine treatment in the facilities did not contain daily breath alcohol tests, except for patients with clinical or laboratory signs of harmful alcohol use, which however were excluded from the present study). Urines were screened for amphetamines, BZD, cocaine, morphine, methadone and buprenorphine. Patients were informed about their toxicology testing results either immediately or at the next possible occasion.

In the experimental group, patients received a 1-day take-home dosage for 1 week of drug-free urine screen; a 2-day take-home dosage for 4 consecutive weeks of drug-free screens; a 3-day take-home dosage for 8 consecutive weeks of drug-free screens; and a 4-day take-home dosage for 12 weeks of drug-free screens. In case of either a positive urine toxicology test or alcohol breath test, patients were reset to a 'no take-home' regime. They could then regain their take-home privilege through submission of drug-free urine screens, with a weekly increase of take-home dosages. In case of two consecutive positive drug screens, the patient had to start from the very beginning. In accordance to the German regulations, take-home dosages were delivered by the local pharmacy on presentation of the doctor's prescription. Patients could determine beforehand on which days of the week they wished not to attend the clinic.

Control group patients could obtain their take-home dosage privilege under the routine conditions of the participating centres. Under these conditions, patients were required to provide a series of 12 consecutive drug-free weekly urine screens to receive a take-home dosage for 4 days. In case of either a positive urine test or alcohol-positive breath test, the take-home dosage privilege was suspended but could be achieved once again through the submission of drug-free urine specimens during 4 consecutive weeks. In case of 2 consecutive drug positive screens, patients had to start again the whole procedure. As in the intervention group, patients with take-home privileges could choose on which days they were attending the local dispensing pharmacy.

All staff members were trained by the investigators in terms of the both the rationale and the procedures of the trial itself. Adherence to the study conditions and to the pre-defined rules for take-home dosages were monitored through regular (*e.g.* twice a month on average) visits of the study investigators to the clinics.

Data analysis

The primary outcome criterion was number of weeks with urine specimens negative for amphetamines, BZD, cocaine, and opiates. The maximum number of drug negative weeks was 26. Missing urine screens, *e.g.* due to premature study termination, were here considered as a positive toxicity test. Secondary outcome criteria included: proportion of drug negative weeks during participation; and number of patients achieving 4, 8 and 12 consecutive drug-free urine tests. In addition, the primary outcome for the subgroup of study completers and time until a patient's first submission of a drug-negative urine sample (response) were analysed. Possible moderators here analyzed included: study centre; intensity levels of drug use at baseline (number of substances detected in baseline urine screens; and rate of positive drug urine screens at baseline); and type of drug use at baseline (heroin, cocaine, or BZD).

Continuous outcome measures were analyzed using the t-test for independent samples ($p < 0.05$, two tailed) and included all patients who started the intervention period. Categorical outcomes were analyzed using the Chi-square test. For time-dependent data, the Kaplan-Meier survival analysis with log-rank test was used. The possible moderator effects were tested using the analysis of covariance, with group x moderator interactions.

With the sample size achieved (n = 136) during the study period, there was an 80% power to detect a medium main effect for "group" (Cohen's d = 0.5). Management and analysis of data according to Standard Operating Procedure s was monitored by the Institute of Medical Informatics, Epidemiology and Biometry, Essen.

RESULTS

Participation rate

Patients were screened on a regular basis, as their eligibility status could change over time due to varying intensity levels of concomitant drug use. Monitoring of the recruitment process revealed that 52% of patients did not fulfil the inclusion criteria (*e.g.* because they already were in possession of a take-home privilege, or did not reach the required rate of drug positive screens), 20% were excluded due to alcohol abuse, 6% due to psychosis, and 6% because the clinics' staff judged them as being clinically too unstable. There were 4% of patients who were eligible but refused to participate. Overall, some 12% of the total number of patients attending the study clinics could be included in the study.

Sample characteristics

Using the stratified randomization procedure described above, 64 patients were allocated to the control condition, and 72 to the experimental condition (total n = 136). Participants were between 20 and 52 years old, mean 35.6 years *(Table 1)*. Typical subjects were males, unemployed, and not living alone. On average, subjects had started misusing with substances (except nicotine) at the age of 14.6 years, with their mean age of first her-

Table 1
Characteristics of the study sample (n = 136)

Age	**Mean (SD)**	**35.6 (6.3)**
Gender	Male	66.9%
Employment status	Part-time	11.8%
	Full-time	16.2%
	Unemployed	72.0%
Living arrangements	Alone	44.4%
	With partner or family	50.7%
	Institution	5.2%
Age at first use of alcohol or drugs	Mean (*SD*)	14.6 (3.5)
Age at first heroin use	Mean (*SD*)	20.5 (5.1)
Years of heroin use	Mean (*SD*)	11.0 (6.1)
Intensity of drug use during baseline	No drug-free urine	55%
	Proportion of drug-positive urine specimens	0.84 (0.21)
Target drugs used at baseline	Heroin only	25.9%
	Cocaine only	5.2%
	BZD only	5.2%
	Heroin & cocaine	17.0%
	Heroin & BZD	22.2%
	Cocaine & BZD	3.7%
	Heroin, Cocaine, BZD	20.7%

oin use being 20.5 years. The current methadone dose (or equivalent buprenorphine dose, estimated as 8 mg buprenorphine being equivalent to 60 mg methadone) was between 35 and 150 mg/d, with median 80 mg.

Regarding the levels of substance use, more than half (55%) of participants had not submitted any urine test negative for all target substances during baseline. Most subjects (85.8%) had shown use of heroin, 46.6% of cocaine, and 51.8% BZD. No amphetamine consumption was identified at baseline. For 63.7% of the sample there was evidence of polydrug use (heroin and cocaine 17%; heroin and BZD 22.2%; cocaine and BZD 3.7%; and heroin, cocaine and BZD 20.7%). Urine screens showing positivity for only one substance throughout baseline were identified in 36.3% of patients (25.9% heroin; 5.2% cocaine; and 5.2% BZD).

Retention rate

The study was completed by 63.2% of subjects. Completion rates (64.1% of controls, 62.5% in the experimental condition) were not significantly different between groups (p = 0.85). The most frequent reasons for drop-out (total n = 50 cases) included: discontinuation of OMT (n = 21); study termination but ongoing provision of OMT (n = 15), and incarceration (n = 5). For the whole sample, mean duration of participation was 21 weeks (SD 8) with no significant difference between groups (controls, 22.0 weeks, SD 6.9; experimental group, 19.8 weeks, SD 9.2; p = 0.13, Welch test). Six (9.4%) patients from the control group and 9 from the experimental group (11.1%) were admitted to an inpatient detoxification treatment during trial participation.

Group effects on outcome

As can be seen from *Table 2*, there were no statistically significant differences between groups regarding primary and secondary outcomes. Drug-negative urine rates for both groups remained widely stable during the course of the study (*Figure 1*, intent-to-treat sample). Considering only the subgroup of study completers, there was an increase of drug-negative urine rates over time for the experimental group (from 0.36 in week 1 to 0.57 in week 13 and 0.55 in week 26) as well as for the control group (from 0.39 in week 1 to 0.61 in week 12 and 0.59 in week 26). Also, if patients who entered intermittent inpatient detoxification treatment during study participation were counted as drop-outs (n = 9 from the experimental group and n = 6 from the control group), the result for the main outcome criterion remained unaffected (experimental group: 8.9, SD 9.0, negative weeks, control group: 10.5, SD 8.7, negative weeks, p = 0.30).

Time to response

Overall, at least one negative urine sample was submitted over time by 83.1% of subjects (85.9% of the control group and 80.6% of the experimental group). For those who submitted a negative urine specimen, time to first appearance of a negative test result was 3.4 weeks (SD 4.0) in the control group and 4.0 weeks (SD 4.5) in the experimental group. With Kaplan-Meier analysis, median time to submission of the first negative sample was 2 weeks for the control group and 3.5 weeks in the experimental group (p = 0.28, log-rank test). As can be seen from *Table 2*, 60.9% of the control group and 54.2% of the experimental group showed at least 4 consecutive weeks characterized by negative drug screenings. Me-

Table 2
Group comparisons for the primary and secondary outcome criteria

	Treatment as usual (n = 64)	Experimental cond. (n = 72)	p
Primary outcome			
Number of drug-negative weeks (mean, *SD*)	11.3 (8.5)	9.8 (8.9)	0.30
Secondary outcomes			
Rate of drug-negative weeks during study participation (Mean, *SD*)	0.49 (0.33) (n = 64)	0.48 (0.35) (n = 69)	0.99
Four consecutive weeks of negative urine screenings	60.9%	54.2%	0.43
Eight consecutive weeks of negative urine screenings	34.4%	29.2%	0.51
Twelve consecutive weeks of negative urine screenings	20.3%	23.9%	0.61
Number of drug-negative weeks (only study completers; mean, *SD*)	14.2 (7.7) (n = 41)	14.2 (8.0) (n = 45)	0.98

dian time to start observing this favourable clinical sequence was 11 weeks for the control group and 18 weeks for the experimental group (p = 0.39, log-rank test).

Center effects

When those 3 centers with only small numbers of participants were excluded from the analysis, then this did not alter the result of an insignificant group effect. The mean number of negative urines then was 11.5 (SD 8.3) in the control group (n = 58), and 9.9 (8.7) in the experimental group (n = 60) (p = 0.30). In addition, in an ANOVA with group and center as factors, there were no significant effects of center (p = 0.21) or of the group*center interaction (p = 0.63) on outcome.

Effects on the use of single substances

Analysing the screening results of the three substances (heroin, cocaine, BZD) separately, no statistically significant group differences were identified with regard to number of weeks with drug-free urine specimens (heroin 12.4 (SD 9.9) in the experimental group *vs* 14.6 (8.9) in the control group, p = 0.16; cocaine 14.9 (9.6) *vs* 17.6 (8.6), p = 0.09; BZD 15.2 (9.4) *vs* 17.4 (8.2), p = 0.16). Of those who showed at least 1 heroin-positive test at baseline (n = 64 study subjects and n = 52 controls), respectively 60.9% and 71.2% achieved at least 4 consecutive weeks with heroin-negative urine specimens during the trial. In those who were using cocaine at baseline (n = 33 study subjects and n = 30 controls), respectively 72.2% and 70% achieved 4 consecutive cocaine-free weeks, whilst for BZD users (n = 40 study and n = 30 control subjects), rates of 4 BZD-free weeks resulted to be 72.5% and 90%, respectively.

Moderator analyses

Drug-related moderators included: type of drug used

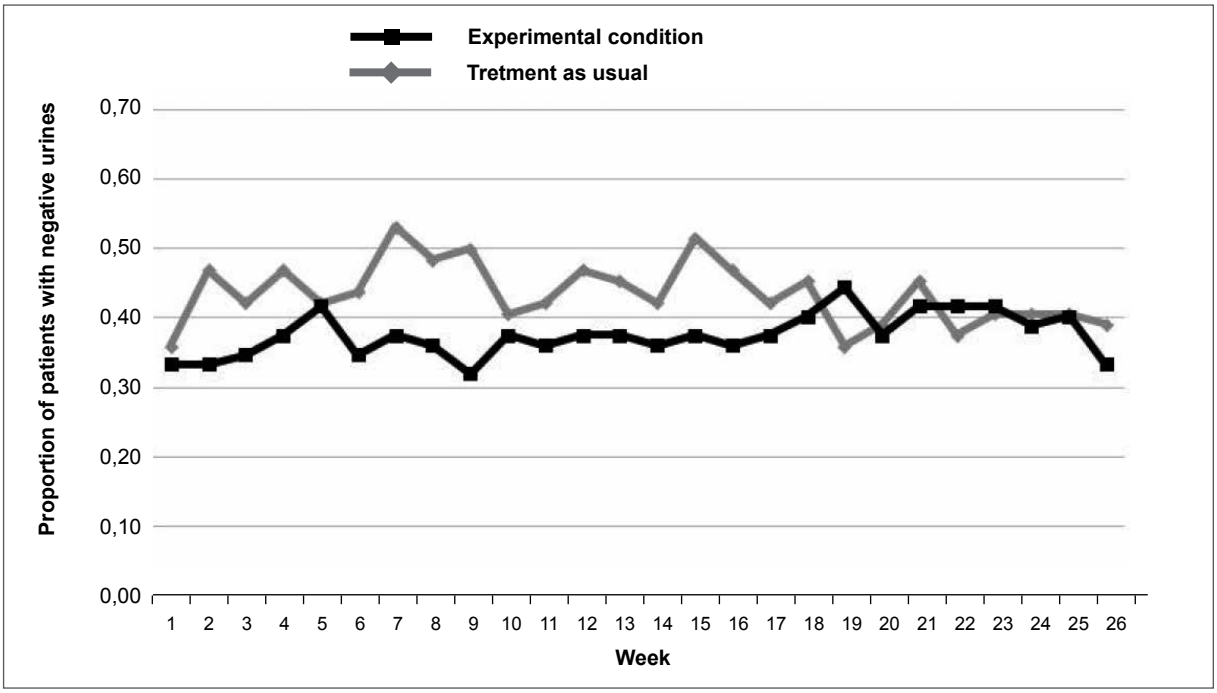

Figure 1
Rates of drug-negative urine samples per study week; intention-to-treat sample.

at baseline (heroin yes/no; cocaine yes/no; and BZD yes/no); positive urine tests' rates at baseline; and number of substances used at baseline. Significant main effects of baseline rates on the number of positive drug screens in general ($F(1;132) = 17.5$, $p < 0.001$) and of heroin-positive drug screens ($F(1;132) = 5.3$, $p = 0.023$) were here identified. Both characteristics were negatively associated with outcome. There were no main effects of baseline cocaine use ($p = 0.65$), BZD use ($p = 0.74$) or number of substances used ($p = 0.052$) on outcome levels. There were no interaction effects for any of the moderators here considered, the smallest p-value being 0.33. Time to providing feedback of urine test results was recorded in four clinics. In those two clinics which used quick testing stripes, feedback was usually given shortly after patient submission of a urine sample. In those two other clinics which sent specimens to an outside laboratory, feedback was given 1-2 days later. There was a main effect of time to feedback ($F(1;114) = 3.96$, $p = 0.049$, in clinics with longer time to feedback outcome was better), but no interaction effect ($p = 0.47$).

DISCUSSION

In this randomized controlled trial it was investigated whether an escalating scheme of medication take-home regulation, when compared with treatment as usual, was associated with lower levels of concomitant drug use. There were no statistically significant differences between conditions regarding both the primary outcome (number of weekly urine screens negative for amphetamines, BZD, cocaine, and heroin), or secondary outcome variables.

The current escalating scheme characterized by reinforcement after the first drug-free urine and with reset option was previously considered to be more effective if compared with unsystematic reinforcement [15]. It could be possible that the control condition here considered, in which after 12 consecutive weeks of abstinence 4 take-home dosages were granted, was too similar to the modified scheme. On the other hand, in direct comparisons with other schemes, the scheme used here had proven most effective in a study with amphetamine users [16]; therefore, improved outcomes were to be expected.

Overall, previous experimental investigations of reinforcement-based interventions in OMT and other drug treatment settings described moderate effects [10, 16, 17]. Present control group results (*e.g.* 43.3% rate of drug free urines) were better than those described in some (10% [18], or 23% [9]), but comparable to other studies (39% [19], or 45% [20]). The lack of effect of the modified take-home scheme here identified is therefore not explained by an outstandingly high abstinence rate in the control condition.

The mean rate of drug-negative weeks in the experimental condition (37.7%) was lower than those reported in previous studies with comparable primary outcome measures (45-60% [15, 20, 21]). However, previous studies often designed their interventions using features which can increase the effect of reinforcement schemes, but were not used here in the modified routine treatment. *Time to reinforcement* should favourably not be longer than 24 hours after submission of the urine sample [10, 16]. Only two clinics in our study used quick tests and could immediately give feedback about the test results and hand out take-home receipts. Those clinics using outside laboratories could give feedback only the following day or later. We found no moderating impact of these different practices on the effect of the intervention. While the time gap between a patient's delivery of a urine sample and reinforcement provision could be shortened here through the use of quick testing stripes and immediate delivery of the take-home receipt, several other features appear difficult to be implemented in routine OMT. Most studies in OMT restricted the *number of target substances* to 1 (most prominently, cocaine). In the context of the present study, to restrict the number of target substances to just one would mean that polydrug users (63.6% of the patients here included) could receive a take-home medication for being abstinent from one substance while still regularly using other substances. This would conflict with inflexible treatment regulations regarding take home privileges (see introduction) and could also be considered unrealistic from a clinical point of view. In addition, results did not indicate moderating effects of number or type of drugs used. *Drug testing frequency* was low in the present study, compared with studies which used 2 or 3 screenings per week. But although moderator analyses have shown that 3 screenings per week produce better results, on average, than lower screening frequencies, reinforcement schemes have demonstrated efficacy with weekly or even monthly screenings [10, 21]. We chose a once weekly testing scheme here because under the present conditions, or health insurances do not finance a higher frequency as part of routine treatment. And regarding the *choice of the reinforcer*, there would be no reimbursement for issuing *e.g.* vouchers to OMT patients in routine treatment.

Limitations

A limitation for the interpretability of the results is posed by the fact that researchers, staff and subjects were not blinded with respect to treatment received. This is an unevitable shortcoming of studies on reinforcement schemes in OMT and in the past did not prevent the demonstration of experimental treatment effects. It nevertheless cannot be ruled out that in the present study it interfered with the experimental intervention, for example by negative attitudes of staff or patients against the new procedure.

A great part of the sample in our study had not or not successfully tried to attain a take-home receipt before. Therefore, it is possible that the similarity of drug using behaviour in both treatment groups was, at least in part, due to a low attractiveness of the reinforcer, or to other patient characteristics which prevented them from response to the prospect of receiving take-home medication. It could be useful in this kind of study to assess the value of reinforcers as perceived by the subjects. Generalizability may also be limited by differences to the standard practices in other OMT settings *e.g.* the frequency of urine testing, or the prerequisites for take-home medication. If take-home medication is much more restricted and difficult to attain, then patients may more easily be ready to conform to the requirements of the reinforcement scheme used here.

Finally, the study did not address issues of possible medication diversion. Since we found no superiority of the experimental scheme, a discussion about costs and benefits of its introduction as standard practice, in-

cluding possible costs caused by medication diversion, seemed expendable here.

CONCLUSIONS

The present study took into account the typical healthcare resources available in (German) routine treatment and showed no apparent superiority of a modified scheme over standard care. One could however argue that the OMT package (which not only included opioid maintenance, but also psychiatric treatment and support by social workers) was able to produce satisfactory retention rates and moderate drug consumption rates in both groups.

When reinforcement-based interventions which have demonstrated their efficacy in experimental trials are to be adopted into clinical routine, there will often be elements of such interventions which are difficult to implement adequately, *e.g.* for financial or organisational reasons. More research is needed regarding the effectiveness of different versions of intervention adapted to routine care conditions.

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Conflict of interest statement

The authors declare that they have no competing interests.

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