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A Pilot Assessment of Relapse Prevention for Heroin Addicts in a Chinese Rehabilitation Center

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Abstract

Objectives—To conduct a pilot assessment of Relapse Prevention group therapy (RP) for heroin-dependent patients in a drug rehabilitation center in China.

Methods—A randomized, case-control study was conducted to assess the efficacy of RP delivered over a 2-month period to male heroin addicts (n=50, RP group) in the Shanghai Labor Drug Rehabilitation Center (LDRC), compared to an equal number of participants (n=50, LR group) in the LDRC program receiving standard of care treatment. Outcomes were assessed by the Beck Depression Inventory (BDI), the Self-rating Anxiety Scale (SAS), the Self-efficacy Scale (SE), and the Self-esteem Scale (SES) after completion of RP, and by the Addiction Severity Index (ASI) and abstinence rates of heroin use at 3-months follow-up post release from the LDRC for both groups.

Results—Significant improvements in scores on SAS, SE, and SES were found in the RP group after completion of the 2-month RP group therapy, compared to the LR group (SAS 7.85±6.20 vs 1.07±5.42, SE 3.88±3.60 vs 0.08±2.89, and SES 3.83±3.31 vs 0.78±2.55). At 3-month follow-up, the RP group participants had more improvements on ASI scores in most domains, and had higher abstinence rates than that in the LR group (37.2% vs 16.7%).

Conclusions—An RP component can be effective in increasing abstinence rates among post-program heroin-dependent individuals and may help reduce anxiety and improve self-esteem and self-efficacy during and following treatment.

Scientific Significance—This study suggests RP as a potentially effective component of treatment for heroin addicts.

Keywords

Heroin dependence; relapse prevention; effectiveness; addiction

INTRODUCTION

Background—Heroin Addiction in China

Drug abuse is a major problem in China with severe medical, legal, social, and economic consequences (1). In late 2005, approximately 1.16 million drug addicts were officially registered in China, but unofficial estimates place this number closer 3.5 million (2). The predominantly abused drug is heroin, and the majority of addicts use this drug by injection. Intravenous drug use is a leading cause of the spread of HIV and other infectious diseases

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(3). Effective interventions are greatly needed for heroin addicts to address the issue of drug problems in China (5).

Drug use in China, as dictated by regulations imposed by the National Peoples' Congress (NPC) in 1990, is illegal (4). The most typical consequence of being registered as a drug user has been commitment to a labor drug rehabilitation center (LDRC) for 12 to 36 months, depending on the severity of drug use. As in the treatment of other substance-dependent patients, relapse is a formidable challenge in the treatment of heroin addicts in China (5). The Chinese government recently sought to better address the issue of drug problems by shifting the responsibility for drug addicts from the justice system to the public health system. While this was a proactive step toward a treatment-oriented approach, effective treatment programs are still lacking in most regions of the country (5).

To be optimally effective, addiction treatment should include comprehensive behavioral therapy to address psychological factors related to relapse (6). Treatment for drug-dependent individuals in China, however, has been compulsory participation in the LDRC programs noted above, as well as short-term medication-assisted detoxification therapy in drug treatment settings available to voluntary participants. Detoxification is not designed to address psychological problems associated with addiction, and therefore does not promote behavioral changes necessary for stable recovery (7-8). Few evidence-based interventions are available there. Therefore, relapse rates are high, and the need for developing and implementing effective behavioral interventions in China to reduce the incidence of relapse is urgent (9-10).

Relapse Prevention for Heroin Addiction

One promising approach in addiction treatment is Relapse Prevention (RP). Based on the cognitive behavioral model of Marlatt and Gordon (11), RP has been widely used and many studies have provided theoretical and practical support for this model (12). Irvin and colleagues (13) conducted a meta-analysis of RP on the basis of 26 studies, representing a sample of 9,504 participants. The overall treatment effects demonstrated that RP was a successful intervention for reducing substance use and improving psychosocial adjustment. Relapse prevention was most effective for individuals with alcohol problems, suggesting that certain characteristics of alcohol use are particularly amenable to the RP model (13). Further development is necessary to refine RP procedures to address other drug problems and to examine the utility of RP in different populations of drug abusers. To the best of our knowledge, the current study is the first of its kind in China to use the RP model in the treatment of heroin dependence and other forms of substance abuse.

To determine whether the RP approach would be effective for heroin-dependent individuals in China, we designed a randomized case-control pilot study to implement RP group therapy in a Shanghai LDRC; the most prevalent treatment context for Chinese drug abusers at the time of the study. The LDRC is a potential setting in which to incorporate a relapse prevention strategy for two main reasons: (1) drug addicts are sent to the LDRC under legal pressure that greatly increases treatment entry and retention, and (2) rigorous regulations ensure a drug-free environment in which individuals function for a sustained period in a manner distinct from a drug-addicted lifestyle. The study sought preliminary evidence of the effectiveness and utility of the RP approach for Chinese heroin addicts in terms of reducing relapse to heroin use following treatment and in reducing the psychological consequences of addiction.

METHODS

Design and Setting

A randomized, case-control study was conducted to assess the efficacy of RP delivered over 2 months to male heroin-dependent individuals compared to an equal number of participants in the LDRC program receiving standard of care treatment. The study included a follow-up interview 3 months after discharge from the LDRC. The study took place in the Shanghai LDRC. The LDRC functions under the justice system and is one of the most common drug rehabilitation settings in China (5). The drug addicts are defined as “special patients” who need “special treatment” (mandatory) in LDRC. The main purpose of the LDRC is to help drug addicts to rehabilitate and reenter society. Drug addicts receive routine medical examinations and receive a multi-level intervention that includes physical work, education, and some level of psychosocial interventions. The study site, the Shanghai LDRC, houses over 1,000 drug addicts at any given time who receive care from a team of 5 certified medical doctors and 3 certified counselors. In order to improve rehabilitation outcomes, collaboration between professionals and researchers and the rehabilitation center are welcomed. This research group has collaborated with the Shanghai LDRC since 1999. Therefore, the Shanghai LDRC provided a good opportunity to test a therapeutic intervention—such as RP—over and above the usual standard of care.

Participants

Inclusion/Exclusion criteria—The criteria for inclusion in the study were: dependence on heroin diagnosed according to DSM-IV criteria before entering the rehabilitation center, time remaining before release of 3 to 6 months, resident of Shanghai, and having more than 5 years of education. Those who had serious physical or mental illness were excluded.

Participant flow: Potential participants were identified from the computerized database of heroin addicts in the Shanghai LDRC. Men over 18 years of age who were heroin dependent (as documented at LDRC intake by DSM-IV criteria) were interviewed by trained researchers, provided information about the study, and invited to participate. Participation was voluntary. No subject was compelled or coerced into participation in the study and interviewees were informed that there would be no negative consequence for not participating. Of 118 prospective subjects who were interviewed, those who agreed to participate (n=100) and who provided informed consent, were administered a self-designed demographics and drug use history questionnaire and other assessments during the intake process. Eligible individuals were then enrolled and randomized to receive two months of RP (n=50) or to continue standard LDRC program activities (n=50). Among the 18 individuals who declined to participate, 12 said that they were not interested and didn’t want to participate, another 6 declined without providing a reason.

Randomization

Those who provided informed consent and met study criteria were randomized into two groups. We numbered the potential participants by the order of their registered number in the Shanghai LDRC. Then, according to the even or odd number of their corresponding random number, the participants were assigned to the RP group or the LR group. Equal numbers were assigned to Labor Rehabilitation as Usual (LR; n=50) or Labor Rehabilitation plus Relapse Prevention group therapy (RP) (n=50).

Intervention Conditions

Relapse Prevention condition—The RP condition included 2 months of RP group therapy which consisted of a total of 20 sessions within the LDRC. The RP group therapy

was based on Marlatt's relapse prevention approach (12-13) derived from cognitive behavioral therapy principles and adapted for group therapy for heroin-dependent patients. For group therapy purposes, the 50 participants in the RP group were divided into 4 groups of 12-13 participants per group. Each group was led by one instructor. Group sessions were conducted 2-3 times per week on weekday afternoons. Each session ran 1.5 hours and was devoted to a specific topic. At the beginning of each group session, the instructor took 10-15min to welcome the participants, review the homework from the previous session, introduce the topic of the present session, and explain treatment goals for that session with tips to achieving these goals. Participants spent the next 45-60 minutes in discussion and work on the current topic under the instructor's guidance. The last 15-30minutes of each session was spent in close-out activities that included a summary of the topic and tips for incorporating lessons learned. The RP group therapy included ten topics focusing on identifying and coping with high-risk situations, enhancing self-efficacy, lapse management, and cognitive restructuring to teach clients to anticipate the possibility of relapse and to recognize and cope with high-risk situations. These topics were adapted to Chinese addicts based on Marlatt's relapse prevention principles, for example, in cognitive restructuring, the counselor worked with the addicts on how to manage their stay in the rehabilitation center as an opportunity to rehabilitate from addiction and how to deal with the stress within the rehabilitation center. These strategies focused on enhancing the individual's awareness of cognitive, emotional, and behavioral reactions in order to prevent an episode of drug use (i.e., a lapse) from escalating into a relapse to chronic use. An example is identification of situations and emotional states that produce craving and that are associated with high risk of relapse; behavioral analysis of the relapse process; and role-play to develop skills to avoid situations that might trigger relapse. Participants are also taught to use alternative behaviors in dealing with triggers in order to avoid a relapse. The 4 groups of 12-13 participants per group were led by two certified psychologists who had been trained in the RP model. Each psychologist was responsible for 2 groups. A variety of activities such as interpretation, demonstration, case discussion, videos, role-play, games, assignment, and other activities were used to provide the participant the opportunity to practice various coping mechanisms and reconstruct their response patterns.

Comparison Condition—LDRC Program as usual—LDRC is an isolated setting. The drug addicts are divided into relatively independent branches (60-80 individuals per branch). Each branch is a relatively closed setting and the addicts cannot go out without permission. Eight to ten drug addicts live together in one dormitory and they are expected to follow military routines and obey a set of rigorous regulations. Drugs, violence and other untoward behaviors are forbidden in LDRC. Writing letters, however, is allowed. Family members are permitted to visit the residents once a month. The daily activities of the addicts are managed by the LDRC and individuals are expected to follow a busy daily schedule. The regular LDRC rehabilitation program consists of presentations that include didactic drug education classes, moral and legal education, physical exercise, and physical labor. The addicts have little free time during the day. They are, however, allowed to watch several hours of television in the evening. Lights out is by 10pm every evening and their day begins by 6:30am each morning.

Measures, Instruments, and Procedures

Outcome Measures—The primary outcome measure was abstinence rates according to self-reported abstinence and urine test at the 3-month follow-up post release from the LDRC. Abstinence was defined as self reported of no heroin use in the previous 3 months since discharge and a negative urine test for opiates. Those who self-reported abstinence but urine test were positive or those who refused to provide urine test were not regarded as abstinent. Secondary measures to assess various psychological states including depression,

anxiety, level of self-esteem and self-efficacy were included as part of the evaluation of post-program outcomes of RP. ASI was included as a secondary measure of 3-month post-program outcome.

Instruments

Baseline Status: A Demographics and drug use history questionnaire was developed by the researchers to assess baseline status by collecting data on demographics, drug use history, treatment history, and particular psychosocial factors pertinent to addiction. This instrument was administered at the initial assessment.

Primary Outcome Measures: To assess the primary outcome of abstinence, a urine test was administered and self-reported abstinence data collected at 3-months post-discharge from the LDRC.

Secondary Outcome Measures: To assess psychological status and drug use problems, the following assessments were administered.

- *Beck Depression Inventory (BDI):* The BDI II (second version) consists of 13 items to evaluate depression, and each item is rated from 0 to 3 according to the degree by which it reflects a patient's state during the previous week. The BDI has a high internal consistency, test-retest reliability, and concurrent validity (14). The Chinese version of the BDI was introduced into China in 1991 (15), and Yang et al. evaluated the BDI as administered to 110 heroin addicts (16).
- *Self-Rating Anxiety Scale (SAS):* The SAS is a 20-item self-report questionnaire with statements on a four-point scale of severity to evaluate anxiety (17). Researchers from the Shandong Mental Health Institute explored the SAS with factor analysis (18), and researchers from the Zhejiang Mental Health Institute reported on SAS use in heroin abusers (19).
- *Self-esteem Scale (SES):* A modified version of the Rosenberg Self-Esteem Scale was used to measure subjects' self-esteem. The SES includes ten items rated on a 4-point scale. The SES has demonstrated good internal consistency (20). In 2006, the SES was evaluated by Chinese researchers, resulting in a change in item 8 which is scored positively in Chinese SES (21).
- *Self-efficacy Scale (SE):* The Self-efficacy Scale developed by Qian was used to measure the extent to which individuals have confidence in their ability to solve problems (22). It was shown to have good reliability and validity in depressed populations. Researches from the Peking University, assessed the SE in drug abusing populations (23).
- *Addiction Severity Index (ASI):* The Addiction Severity Index is a structured clinical research interview designed by McLellan to provide information about areas of a patient's life in which there is often dysfunction associated with drugs (24). The ASI has high reliability and validity (25). The potential problem areas are medical, legal, drug, alcohol, employment, family/social, and psychiatric. Sets of objective and subjective items from each of the problem areas are standardized and summed to produce a composite score that reflects the problem severity in each area. The reliability and validity of the Chinese version of ASI which was adapted from ASI 5.0 also were satisfactory (26). The Chinese version of ASI was modified for heroin users. Items related to heroin use from the standard ASI was used to assess heroin use problems. Similar to alcohol composite scores, heroin composite scores were computed from 4 items concerning heroin use in past 30 days (days of heroin use, days have experienced heroin use problems, the extent of being troubled

or bothered by heroin use problems, the importance of treating their heroin use problems). Considering the participants had been in the rehabilitation center for a period of between 6-12 months when the intake interview was taken, generally drug use was not possible inside the rehabilitation center. In order to assess their natural history of drug use and related problems, the timeframe for ASI assessment was 30 days prior to entry into the rehabilitation center.

Procedures—The study procedures and protocol was approved by the Shanghai Mental Health Center IRB which was registered in the Office for Human Research Protections (OHRP) in US (the assurance number: FWA00003065) and followed standard ethical practices as outlined in the Helsinki Agreement and the Belmont Report.

Informed Consent: Because this study involved prison-like participants, in order to ensure that participants were not coerced into the study, the potential participants were interviewed individually by the trained researchers in private rooms without any monitoring by security personnel. The potential participants were advised of the confidentiality of the interview, that their response had no bearing on their treatment at the Center, and that they were free to withdraw at any time without reason or adverse consequences.

Assessment: After first being administered the battery of assessments described above at intake, all participants were re-assessed by BDI, SAS, SES, and SE after completion of RP and re-assessed by ASI at 3-months follow-up post release from the LDRC. At follow-up, the participants were encouraged, but not required, to provide a urine sample to confirm their self-reported drug status. Urine test for heroin is a simple, one step immunochromatographic assay for the rapid, qualitative detection of opiates and their metabolites of heroin in urine. The cutoff of the test is 300 ng/ml of OPI. Only those whose self-reported abstinent status was confirmed by a urine test were considered abstinent. Those who declined to provide a urine sample or, in fact, were non-abstinent as confirmed by the urine test were excluded from the abstinent rate analyses. As specified in the informed consent, we also obtained information from participants' family members or the local authorities in charge of them if necessary to track them and other necessary information for the assessments at follow-up.

Statistical Analyses

Paired t-tests were used to determine the significance of the difference on quantitative variables between different time points for each group. Independent sample t-tests were used to measure the differences on quantitative variables between the two groups. Chi-square testing was used to determine the difference between each group's abstinence rates at 3-month follow-up. The level of statistical significance was set at 0.05.

RESULTS

Demographic Characteristics and status at Intake

The participants were 100 males with heroin dependence, and all were ethnic Han Chinese. The LR group closely resembled the RP group in terms of demographic characteristics, drug use history, and ASI composite scores ($p>0.05$, table 1), which indicated the two groups were comparable. They had an average age of 36.3 years, their average education was 9.8 years, and 45% of the participants were unemployed. All subjects were heroin users who met DSM-IV criteria for opiate dependence, with an average drug use history of 5.1 years. Their first drug use age was 30.3 years old. 51% of the participants used heroin by injection. The majority of the participants (78%) had experienced several voluntary detoxification treatments or labor drug rehabilitation treatment previously, with an average of 3 previous

drug treatment episodes. Their previous longest period of self-reported abstinence days was 30.7 (SD 53.7) days.

Table 1 compares the scores of SAS, BDI, SES, SE and ASI composite scores between LR and RP groups at baseline. No difference was found between LR and RP group on the scores of SAS, BDI, SES, SE, and ASI composite scores ($P>0.05$) at baseline.

Outcomes after Completion of the Study Protocol within the Center

Table 2 compares the Score Changes of SAS, BDI, SES, and SE between LR and RP groups after the 2-month RP group therapy. The results revealed that the scores of SAS in RP group decreased significantly and the scores of SES and SE improved significantly compared to the LR group, but no difference was found in score changes of BDI ($P>0.05$).

Outcomes at 3-month Follow-up

At the 3-month follow-up, 7 individuals of the RP group (14%) and 8 of LR group (18%) were dropped and excluded from analysis because we could not locate the subjects. The subjects flow of followed and urine test results are presented in table 3.

No difference of the dropout rates was found between RP and LR groups ($p=0.78$). There were 12 subjects who declined to provide urine sample; of which 7 reported being heroin abstinent (3 in LR group and 4 in RP group). The proportions of subjects who declined urine test were not significantly different between the two groups ($p=0.08$). Among the 73 subjects who had the urine test, there were 5 individuals (3 in LR group and 2 in RP group) who reported being heroin abstinent but urine tests were positive. All of the 23 participants who presented negative urine test results reported being heroin abstinent. The remaining 45 subjects who reported heroin use also had positive urine test results. Among the participants who had urine tests, there were more subjects in the RP group that had negative urine test results than the LR group (44.4% vs 18.9%, $p=0.01$).

Abstinence rates—Because of the stigma around drug use and the fact that its use is illegal in China, we have found that drug addicts tend to report abstinence even though they use drugs. Therefore, in this study we define abstinence as self-reported non use of heroin and confirmed by negative urine test results. As mentioned above, there were 12 cases who reported non-drug use but declined to provide urine tests (7 cases) or had positive urine test results (5 cases). These 12 cases were not regarded as abstinent and they were excluded in the calculation of the abstinence rates. At the 3-month follow-up, there were 16 individuals in the RP group and 7 individuals in the LR group who reported no heroin use and confirmed by negative urine test. As showed in table 3, the abstinence rates in RP group (16 out of 43 cases, 37.2%) was higher than that in the LR group (7 out of 42 cases, 16.7%) ($\chi^2=4.54, p=0.02$). Among the relapsed subjects in the LR group, two had been sent to the LDRC again and another two had died from overdose by heroin injection.

ASI Status—Table 4 compares the improvements of ASI scores from baseline to 3-months follow-up between two groups. Improvement scores were calculated as the scores at follow-up less the scores at baseline. Values are reported as mean $\pm$ standard deviation.

Independent t-test results indicated that the RP group showed greater improvement from baseline to follow-up on the scores in medical, employment, heroin use, and psychiatric status than observed in the LR group. ASI legal problems composite scores in the RP group show marginally more improvement than in the LR group ($P=0.06$). The improvements on family/social composite scores were not different between two groups.

DISCUSSION

Results from this study offer preliminary evidence for the effectiveness of RP group therapy in the context of an existing labor drug rehabilitation program. Notably, participants in the RP condition had better ASI scores in general, and reported less heroin use and higher abstinent rates at 3-month follow-up. These results, in heroin-dependent Chinese men, are consistent with a meta-analysis on RP (13) and a review of RP (27) that concluded that RP is generally effective in reducing substance use and improving psychosocial adjustment across various forms of substance use disorders.

Many environmental, interpersonal and emotional situations are linked to increased risk of relapse (7-9, 12). The authors previous work in this area suggest that addicts in the LDRC have considerable problems with depression and anxiety, which are likely contributing to relapse to heroin use (9). This may relate to various psychosocial pressures faced by treated addicts as they re-enter society, including stressors such as unemployment, family conflicts, and economic problems. Similarly, the heroin addicts in this study had higher SAS scores (48.31 and 47.31, respectively in RP and LC group) and BDI scores (11.78 and 12.38, respectively in RP and LC group) in the LDRC, which suggests that interventions are needed to address these high-risk factors of relapse. Although the RP group therapy significantly improved anxiety while in the program, RP participants still had high scores on BDI, indicating that other interventions should address depression among drug addicts in order to improve overall outcome.

Because self-efficacy is a predictor of outcomes of treatment across all types of addictive behaviors (28-29), the RP approach can incorporate a series of efficacy-enhancement procedures such as coping skills training, providing feedback, and promoting overall behavior change (12, 29). Based on results showing improvements in self-esteem and self-efficacy among the RP group compared with the LR group, RP therapy appears to have a positive impact on self-efficacy, results in a better outcome in terms of relapse. The study findings provide empirical support for the effectiveness and utility of the integration of the RP treatment intervention for patients in the LDRC setting in China.

Although this study provides some important practical and theoretic information on the development of an effective RP strategy for heroin addicts in the LDRC in China, the following limitations should be considered: the subjects were all males; the sample size was relatively small; the follow-up period was relatively short; and aftercare support was not integrated into the RP program, which may be the reason why the abstinence rates among the RP group was still relatively lower than expected (37%). An additional limitation of the study is that the provision of the RP strategy within the LDRC precludes relapse during treatment. The period of enforced abstinence of the participants in the LDRC might, therefore, artificially inflate likelihood of success. Further studies are needed in both male and female participants with an improved RP approach that addresses nuances of Chinese populations, such as the inhibitory effects of stigma on treatment entry and engagement, as well as the potential role of family in aiding the recovery process. Future studies are also needed in other drug treatment settings such as voluntary and outpatient treatment clinics to expand the application of RP strategies for heroin addicts in China.

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Table 1

SAS, BDI, SES, SE and ASI composite scores at baseline by group

	RPgroup (n=50)	LC group (n=50)	<i>T</i>	<i>p</i>
SAS	48.31±8.31	47.31±12.50	.42	.68
BDI	11.78±6.87	12.31±7.15	−.35	.73
SE	26.85±4.21	27.50±4.27	−.70	.49
SES	25.81±3.03	26.08±3.53	−.38	.70
Medical	.16±.23	.18±.24	−.39	.69
Employment	.75±.26	.77±.27	−.43	.66
Heroin use	.68±.23	.64±.22	1.01	.32
Legal	.25±.17	.21±.18	1.08	.28
Family/social	.17±.22	.20±.19	−.60	.55
Psychiatric	.29±.19	.25±.22	1.00	.325

Table 2

Group Differences in Score Changes of SAS, BDI, SES, and SE

Scores changes	RPgroup (n=50)	LC group (n=50)	<i>T</i>	<i>p</i>
BDI	-0.20±3.67	1.37±4.69	-1.73	0.09
SAS	-7.85±6.20	-1.07±5.42	-4.98	0.00
SE	3.88±3.60	0.08±2.89	5.29	0.00
SES	3.83±3.31	0.78±2.55	4.58	0.00

Table 3

The subjects flow of followed and had urine test

	LR group (n=50)	RP group (n=50)	P
Not followed(n=15)	8(18%)	7(14%)	0.78
Decline urine test(n=12)	5(12%)	7(16%)	0.08
Self report of no drug use	3(25%)	4(33%)	0.44
Self report of drug use	2(17%)	3(25%)	
Have urine test(n=73)			
Positive	30 (81.1%)	20(55.5%)	0.01
Negative	7 (18.9%)	16(44.4%)	
Abstinence at 3 month follow-up			
Yes (no drug use report and negative urine test)	7 (16.7%)	16(37.2%)	0.02
No (positive urine test or decline urine test)	35(83.3%)	27(62.8%)	

Table 4

Improvements in ASI Scores from Admission to Follow-Up by Group

Improvements scores	RP group (n=43)	LR group (n=42)	<i>t</i>	<i>p</i>
Medical	-.06±.16	0.01±.13	2.11	0.04
Employment	-.08±.14	0.03±.12	3.58	0.00
Heroin use	-.30±.31	-0.14±.28	2.44	0.02
Legal	-.05±.14	0.01±.13	1.91	0.06
Family/social	-.01±.14	-0.01±.06	0.02	0.98
Psychiatric	-.10±.17	-0.01±.09	2.97	0.00