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Short Communication

The effectiveness comparison of Jitai tablets versus methadone in community-based drug treatment: A 1-year follow-up study ☆

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HIGHLIGHTS

- This is the first post-marketing effectiveness study of Jitai tablets.
- We carried out a cohort study with one year follow-up.
- Both methadone and JTT gained effective relapse prevention.
- JTT can be recommended to clinical doctors and drug addicts.

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ABSTRACT

Objective: The aim of the study was to compare the effectiveness of Jitai tablets (JTT) versus methadone in a community drug treatment program.
Methods: A cohort study was conducted with 386 eligible subjects from 7 districts to 65 communities in Shanghai. The subjects were placed into the JTT group (n = 206) or the methadone group (n = 180). The data were collected at 8-, 26- and 52-week follow-ups.
Results: The retention rates of the methadone group at the 8-, 26-, and 52-week follow-ups were 97.78%, 91.67%, and 85.00%, respectively. The retention rates of the JTT group at these follow-ups were 90.78%, 83.50%, and 74.27%, respectively. A Chi-square test indicated a significant difference, and the *P* values were 0.0037, 0.0161, and 0.0095 for each follow-up. The relapse rates for the JTT group were 3.88%, 6.31% and 11.17% for each follow-up, and those for the methadone group were 1.11%, 2.78%, and 7.78% for each follow-up. The Chi-square test indicated no significance, and the *P* values were 0.1128, 0.1005 and 0.2594. A survival analysis indicated that the relapse survival curve had no significant difference between the two groups (log-rank test, $P = 0.188$).
Conclusion: Methadone and JTT combined with psychological intervention and social support provided effective maintenance treatment and relapse prevention in a community drug treatment program. The retention rate in the methadone group was higher, but the JTT group had the same relapse prevention as the methadone group. JTT can be recommended to clinical doctors and drug addicts.

1. Introduction

Modern science has confirmed that heroin addiction is a chronic recurrent brain disease (Friedman & David, 2009; O'Brien & McLellan, 1996). Detoxification alone has little benefit and high rates of relapse. Drug therapy combined with psychological rehabilitation and social intervention measures is more effective in the treatment of heroin addiction (Leshner, 1997; McLellan, Arndt, Metzger, et al., 1993; McLellan, Lewis, O'Brien, et al., 2000; Woody, McLellan, Luborsky, et al., 1995). With the implementation of a new anti-drug law on June 1, 2008, China's existing drug treatment strategy is centered on community drug treatment and mobilizes social services to help drug abusers return to society. The previous drug abuse policies based on required labor and compulsory treatment have been incorporated into the required isolation from society treatment model. As the number of

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drug abusers increases, using community resources to develop a community-based drug-abuse recovery model has been a growing trend in relapse prevention and successful detoxification.

Jitai (JTT), which has been approved for the treatment of opiate addiction by the Chinese State Food and Drug Administration (SFDA), consists of 15 drugs, including Rhizoma corydalis, Radix salviae miltiorrhizae, Radix angelicae sinensis, Ligusticum Chuanxiong, and Flos Daturae. Animal experiments have shown that JTT provides a positive effect equivalent to clonidine in detoxification treatment in morphine-addicted animals, with less harmful side effects (Lu, Pan, Fang, et al., 1998). Clinical research findings have shown that JTT can not only effectively control withdrawal symptoms in heroin addicts but can also relieve protracted withdrawal symptoms after a specific period of detoxification and consolidate the detoxification curative effects. JTT has no dependence potential and no obvious adverse effects (Dong, Wang, & Zhou, 2002; Xiong, Xiao, Li, et al., 2001; Xu, Duan, Wang, et al., 2000). There have been no reports of a post-marketing evaluation of JTT, such as effect evaluation and the surveillance of drug-adverse reactions in large populations. This study aims to explore the effectiveness of JTT combined with psychosocial intervention in community drug treatment and uses methadone, which is recognized worldwide for its effectiveness, as a control drug.

2. Materials and methods

2.1. Design and interventions

A cohort study with controls was designed with the research groups and intervention measures as follows.

Methadone group: We implemented methadone combined with psychological intervention and social supports according to the current community methadone maintenance treatment plan, with a treatment period of 1 year, including baseline screening and 8-, 26-, and 52-week follow-ups.

JTT group: We implemented JTT medication treatment combined with psychological intervention and social supports, with a treatment period of 1 year, including baseline screening and 8-, 26-, and 52-week follow-ups. The psychological intervention consisted of group psychological intervention and individual counseling.

The group psychology interventions consisted of 12 sessions over a 6-month period, with 1 session every two weeks, and were conducted by social workers who had been trained by qualified specialist physicians of the Shanghai mental health center. Each session had a theme, referred to as a group discussion, on topics including the following; role cognition; scene training; changing false understandings of family, social and personal behavior; providing help; and emergency measures. These sessions were scheduled for 1.5 h. Individual counseling was conducted by setting up a psychological consultation telephone hotline for actively seeking psychological support. The social support systems included providing subsidies, recommending employment, vocational training, medical fee reduction, conflict mediation, and family counseling, among others. Social workers are advocates for the participants and help the relevant agencies address the needs of the program participants.

Medication in treatment: JTT is dispensed in tablets of 0.4 g each. It can be taken at home under the supervision of family members. The participants receive a follow-up supply of the tablets according to a community doctor's prescription, and the residual tablets are returned at the next stage. The specific medication directions for taking JTT are as follows: 3 tablets 2× per day for 8 weeks, 2 tablets 2× per day for 8–26 weeks, and then 1 tablet 2× per day for 16–52 weeks. Methadone is an oral liquid, given flexibly according to the individual situation by doctors in doses of 15 ml to 120 ml everyday.

2.2. Setting and participants

The research sites covered 65 streets in the following seven districts of Shanghai: Yangpu, Pudong, Baoshan, Zhabei, Changning, Putuo, and Hongkou. The participants were recruited from June 2010 to September 2010. All of the participants who were opiate dependent (based on a clinical assessment), had not been prescribed either study drug for the preceding month, and were requesting maintenance treatment (for whom it was appropriate) were invited to participate. To be included, the patients were required to meet all of the following inclusion criteria: (1) between 18 and 65 years old; (2) completed the acute detoxification treatment; (3) meet the Diagnostic and Statistical Manual for Mental Disorders (4th ed., DSM-IV, American Psychiatric Association, 1994) criteria for opiate dependence; (4) patients (with a legal guardian) signed informed consent, agreed to comply with medication regime and completed the relevant information records for the duration of the study-based treatment; and (5) accept the authority of police and anti-drug social workers.

The patients were excluded if they had any of following exclusion criteria: (1) the presence of comorbid severe mental illness (schizophrenia, manic episodes, mental retardation); (2) a recent (in the last 3 months) serious organic disease; (3) pregnancy or lactation; or (4) ongoing medication treatment.

2.3. Measures

2.3.1. Treatment retention

$$\text{Retention rate} = (\text{the number of participants retained in treatment} / \text{all of the participants}) \times 100\%$$

Retained time was defined as the length of maintenance therapy from the initial prescription until lost to follow-up or the end of research. The subjects were considered to be “not retained” in the trial if they met one of the following standards: (1) canceled the informed consent; (2) lost to follow-up; (3) poor compliance; (4) adverse or serious adverse events occurred that could not be overcome; (5) appearance of suicide ideation, self-injury or impulsive action during the trial; (6) pregnancy; (7) violation of the experiment design; or (8) other reasons that the researchers considered unfavorable to continue medication.

2.3.2. Illicit drug use

Illicit drug use is reflected as a relapse rate. Relapse was defined as participants who failed a urine toxicology test for illicit drugs or were arrested by police and subject to compulsory isolation treatment during the follow-up period. The frequency of urine sample testing was a flexible schedule based on the level of engagement and on suspected or reported illicit drug use.

2.3.3. Safety indicators

The incidence rate and clinical manifestations of adverse events and side effect were monitored.

2.4. Data processing and statistical analysis

We used the EpiData version 3.02 to set up the data. All analyses were performed using SAS version 9.1. All of the statistical tests that we reported were two sided, and statistical significance was implied at $P \leq 0.05$. The continuous data, expressed as the means and standard deviations, were analyzed using a *t*-test, and the frequencies or proportions of the categorical data were analyzed using Chi-square test or Fisher's exact test to compare the baseline characteristics and medical outcomes between the treatment projects. Kaplan–