Introduction

Indulgence in the consumption of neurotrophic drugs to the extent of addiction has become a common social problem affecting a broad-range of populations [1]. The drugs popular to addicts carry a wide range, from the classical opioid groups to stimulants and antipsychotics [2]. In Hong Kong the affected people involve a lot of young working individuals and since 3 decades ago, teenagers in school are also victims. The addicting drug used was ketamine that disappointed a lot of users because of bladder problems [3]. This could have been the cause that in the recent years methamphetamine, nicknamed “Ice”, has become the stimulant that young people adore [4].

The majority of young people trapped within the ice addiction circle eventually find it necessary to rid themselves of the “ice” dependence. With self-determination and family/friends supports, they would need to go through a painful process. Charity Community Services have been trying hard to help this group of people [5].

The success of withdrawal for every single case depends on the hard work of the social worker (sometimes psychologists): counselling and facilitating the positive changes. During the process, medications could be helpful. Psychiatrists do provide their excellent services and interventions including drugs, which unfortunately are not always successful. Given the general effects and reactions of herbal medicine in the local Chinese
Community, Chinese Medicine could conveniently be included as an additional way of management.

The Chinese community of Hong Kong has a strong inclination and trust on the use of Traditional Chinese Medicine, particularly when they are not happy (for various reasons) about the conventional modern treatment in hospital and special clinics [6]. Charity organizations have started involving Traditional Chinese Practitioner in a joint effort to help the victims of “ice” addition to relieve themselves from the disastrous indulgence.

The aim of the study is to evaluate the efficacy of a Chinese herbal formula on improving sleep disorder, reducing symptoms of withdrawal from methamphetamine addiction or discomfort and enhancing the motivation for withdrawal.

**Methods**

**Design**

This study was designed as a self-controlled trial. Subjects who met the inclusion/exclusion criteria were given the prescription made by TCM Practitioners for 3 weeks. Afterwards a fixed herbal formula was given for another 5 weeks. Before and after taking the Chinese herbal medicine, the Insomnia Severity Index (ISI), Fatigue Severity Scale (FSS), Epworth Sleepiness Scale (ESS), ice demand (Craving), Hospital Anxiety and depression scale (HADS) and Contemplation Ladder (BDF) were evaluated respectively.

**Study population**

Subjects, aged over 16 years old, were Methamphetamine (ice) addict volunteers received free service provided by Evangelical Lutheran Church Social Service-Hong Kong.

For the subjects of “ice” addiction, during the withdrawal phase, intense fatigue and failure to fall asleep, developing to anxiety and depression are the major symptoms.

The anti-addiction service was managed by social workers and psychiatrists, who collaborated with each other through sessions of counselling and administration of standard medications.

**Uniform herbal formula**

The uniform herbal formula composes of 6 herbs including Semen Ziziphispinosae (酸棗仁), Caulis PolygoniMultiflori (夜交籐), Poria cum Radix Pini (茯神), FructusTritici Levis (浮小麥), RhizomaAnemarrhenae (知母) and Radix Polygalae (遠志).

![Figure 1](image)

**Table 1** Schedule of assessments and evaluations

<table>
<thead>
<tr>
<th></th>
<th>Prescribed herbal TCM</th>
<th>Study herbal formula</th>
<th>Follow-up</th>
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<tbody>
<tr>
<td></td>
<td>Week 1</td>
<td>Week 2</td>
<td>Week 3</td>
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<tr>
<td>Informed consent</td>
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<tr>
<td>Inclusion/Exclusion criteria</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Prescribed TCM</td>
<td>x</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Study herbal formula</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>ISI</td>
<td>x</td>
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<td></td>
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<tr>
<td>FSS</td>
<td>x</td>
<td></td>
<td></td>
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<tr>
<td>ESS</td>
<td>x</td>
<td></td>
<td></td>
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<tr>
<td>Craving</td>
<td>x</td>
<td></td>
<td></td>
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<td>HADS</td>
<td>x</td>
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<td>BDF</td>
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<tr>
<td>Adverse events</td>
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</table>

![Table 1](image)
Procedures
The study period using Traditional Chinese Medicine was divided into three consecutive sessions (Figure 1, Table 1):

Session One: Three weeks of management and medications purely under the TCM expert who succeeds gaining confidence from his client and happily prescribe syndrome soothing herbal formulations.

Session Two: Five weeks of standard treatment using one uniform innovative herbal formula. The TCM expert continues to supervise in case of need and on to detect adverse effects.

Session Three: All treatments stopped in this subsequent 2 weeks and all assessments repeated to check the aftermath and residual effects of the TCM treatment.

Efficacy Parameters
Before and after taking the herbal medicine, the subjects were assessed the following instruments/questionnaires:

» Insomnia Severity Index(ISI),
» Fatigue Severity Scale (FSS),
» Epworth Sleepiness Scale (ESS),
» Craving for ‘Ice’ (Craving),
» Hospital Anxiety and Depression Scale (HADS),
» Contemplation Ladder (BDF)

Safety assessment
Adverse events observed by the researchers or voluntarily provided by the subjects, whether or not caused by the study herbal formula, should be recorded by the researchers. Adverse events should be followed up until they were properly resolved or returned to normal or the researchers believed that follow-up could be terminated.

Statistical analysis
Data was analyzed using the SPSS software (version 22, SPSS Inc.). Characteristics are presented as descriptive statistics (frequency (%) or mean, standard deviation (SD), minimum, median and maximum). Mean values and SD for each domain were calculated, analysis of variance (One-Way ANOVA) and Paired t-tests were performed for comparing the four visits. Chi-square test was used for frequency data analysis. Comparison between visits, number of treatments was based on Paired t-test. Significance level was defined as a = 0.05.

Results
Subjects were “ice” addict volunteers who received free anti-addiction service. Medical assessment and evaluations were provided by the psychiatrists according to the protocol. The TCM expert received the patients and was fully responsible for their three weeks treatment without any interference from the psychiatrists. The medication was designed according to the belief that Yin-Yang’ harmony theories. After three weeks of TCM expert care, medication shifted over to an innovative fixed formula created by bio-scientists and TCM researchers for the promotion of better sleep. [7]

Baseline Information
The pilot study recruited 56 “ice” addicts coming for withdrawal. They were over 18 years of age (average 37) with a male/ female ratio of 31/25 and the addiction duration ranged from 4 to 240 months (Table 2).

Efficacy assessment
In the first three weeks of treatment, subjects received herbal medication from the TCM expert according to his own judgement. This was followed by 5 weeks of standard (one uniform herbal formula) treatment aiming at sleep support. Finally, two weeks of no medication were allowed for completion of standard evaluation.

The evaluation methods chosen were those approved as standard indices for the assessments of changes in mood., craving for drugs and state of sleep, namely, Index of Severity of Insomnia (ISI); Fatigue assessment (FSS); Day time self-evaluation on sleep yearning (ESS); (Craving) for drug; Anxiety (HADS) and Evaluation of Self Determination (BDF).

Result of three weeks of TCM expert prescription on general support, followed by five weeks of standard sleep promotion herbal formula was encouraging.

With regard to sleep promotion there was quality improvement and less daytime yearning (Figure. 3 & 4).

With regard to Fatigue relief and mental support, alleviation was obvious after herbal medications (Figure.5). They became less anxious (Figure. 6).

Impressive outcome with regard to the withdrawal itself was also present. Craving for “ice” decreased. (Figure.7) and apparently “ice” addicts became more determined to carry on with the withdrawal exercise (Figure.8).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N =56</th>
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<tbody>
<tr>
<td>Age (year)</td>
<td>36.9 ± 10.6 (18-68)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
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<tr>
<td>Male</td>
<td>31 (55.4%)</td>
</tr>
<tr>
<td>Female</td>
<td>25 (44.6%)</td>
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<tr>
<td>High (cm)</td>
<td>165.5 ± 9.1</td>
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<tr>
<td>Body weight (kg)</td>
<td>66.2 ± 11.5 (35.0-93.3)</td>
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<tr>
<td>BMI</td>
<td>24.1 ± 3.7(17-36)</td>
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<tr>
<td>Blood pressure (mmHg)</td>
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<tr>
<td>Systolic</td>
<td>124 ± 16</td>
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<tr>
<td>Diastolic</td>
<td>80 ± 13</td>
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<tr>
<td>Heart rate</td>
<td>82 ± 14</td>
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<tr>
<td>Average drug use time(month)</td>
<td>84.4 (4-240)</td>
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<td>Time to stop using drugs(month )</td>
<td>16.2 (1-96)</td>
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</table>
Apart from the general outcome as had been discussed, the sequence of changes following the three weeks of TCM expert treatment, the five weeks of standard uniform formula for sleep disorder was interesting and remarkable. The obvious sequential improvement followed one pattern: initial rapid improvement followed by sustenance of effects.
Discussion

In a modern hospital setting, specialists find it difficult to discuss with TCM experts because the professional language of the two streams never coincide with each other. Specialists might not object sending patients over to TCM experts. They care about the final results of TCM treatment only and never bother to help or give suggestions. Integrative care to them means very much a staged or additional treatment session from the TCM experts. On the other hand, the easiest way of the TCM expert to fulfill his role of "integrative care" was to work on his own, prescribed his own treatment undisturbed.

In this study the compromised new form of arrangement gave the TCM expert full authority to help his clients in the usual conventional way: to reach trust and confidence, then shifting to an uniform innovative simple herbal formula created according to the modern understanding of pathology which might not be agreeable with the TCM expert. With the compromised arrangement the results could favorably be subjected to standard clinical evaluation instruments like any clinical trial using pharmaceutical drugs.

"Ice addiction" is a chronic problem. Eliminating dependence involves physical and emotional barriers. New symptoms such as anxiety, depression and sleep problems always develop [8,9]. These new issues are not acute, it takes time to control [10,11]. With this regard, TCM’s slow harmonizing effects have a lot to offer. In this study, with the support of all parties, herbal treatment can effectively alleviate symptoms. More studies would be able to further confirm the positive results. It is believed that the cultural acceptance might not be the only reason of the positive outcome. The non-aggressive way of treatment offered by Chinese Medicine adds more to the acceptance and preference from the addict victims [12 - 14].

Conclusion

The application of traditional Chinese medicine in the treatment of methamphetamine addicts' fatigue, anxiety, depression and insomnia during withdrawal exercise has achieved positive results. Special cooperation and integrated arrangements between psychiatrists and traditional Chinese medicine doctors have proved to be a practical way to ensure mutual respect and best results from two different healthcare systems.

Acknowledgement:

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References

8. yellow light forensic toxicology!,2005;95-99