



## CASE REPORT

# Chinese herbal medicine formula *Jieduhuayu* granules improves cognitive and neurophysiological functions in patients with cirrhosis who have minimal hepatic encephalopathy: A randomized controlled trial



Chun Yao<sup>a,\*\*</sup>, Guochu Huang<sup>b,\*</sup>, Meng Wang<sup>b</sup>, Meng Xia<sup>b</sup>,  
Fan Yao<sup>b</sup>, Dengfeng Niu<sup>b</sup>, Yuer Zhang<sup>b</sup>, Shan Li<sup>b</sup>, Yu Zhong<sup>b</sup>

<sup>a</sup> Department of Hepatology, First Affiliated Hospital, Guangxi University of Chinese Medicine, PR China

<sup>b</sup> Guangxi University of Chinese Medicine, Nanning, Guangxi, PR China

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### KEYWORDS

Minimal hepatic encephalopathy;  
Chinese herbal medicine;  
Lactulose;  
NCT;  
MMSE;  
P300;  
Randomized controlled trial

### Summary

**Background:** Minimal hepatic encephalopathy (MHE) impairs patients' cognitive and neurophysiological functions. In this study, we investigated the effect of treatment-related improvement in cognitive and neurophysiological functions.

**Methods:** We measured psychometric performance by number connection tests part A (NCT-A), digit symbol test (DST), mini-mental state examination (MMSE) and event related potential P300 wave of 80 patients with cirrhosis who have minimal hepatic encephalopathy on inclusion into the study and 15 days later. They were randomly assigned in a 1:1:1:1 ratio to four groups, to receive treatment of Chinese herbal medicine formula (HMG) or lactulose (LG) or Chinese herbal medicine formula combined with lactulose (HMCLG) for 15 days ( $n=20$ ) or no treatment (CG) ( $n=20$ ). This study was not blind.

**Results:** The mean number of NCT-A and MMSE scores improved significantly in patients in the HMG (0 day,  $102.00 \pm 24.49$  for NCT-A,  $18.55 \pm 2.89$  for MMSE; 15 days,  $78.30 \pm 22.55$  for NCT-A,  $24.20 \pm 2.78$  for MMSE) compared with patients in the CG after 15 days of follow-up

\* Corresponding author at: Guangxi University of Chinese Medicine, 179 Mingxiu East Road, Nanning, Guangxi 530001, PR China. Tel.: +86 13084993691.

\*\* Corresponding author at: First Affiliated Hospital, Guangxi University of Chinese Medicine, 89-9 Dongge Road, Nanning, Guangxi 530023, PR China.

E-mail addresses: [1197840425@qq.com](mailto:1197840425@qq.com) (C. Yao), [huangguochu@msn.cn](mailto:huangguochu@msn.cn) (G. Huang), [46636308@qq.com](mailto:46636308@qq.com) (M. Wang), [77053615@qq.com](mailto:77053615@qq.com) (M. Xia), [106454516@qq.com](mailto:106454516@qq.com) (F. Yao), [729691050@qq.com](mailto:729691050@qq.com) (D. Niu), [694239998@qq.com](mailto:694239998@qq.com) (Y. Zhang), [429391675@qq.com](mailto:429391675@qq.com) (S. Li), [172355125@qq.com](mailto:172355125@qq.com) (Y. Zhong).

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(0 day,  $103.00 \pm 24.98$  for NCT-A,  $17.90 \pm 2.99$  for MMSE; 15 days,  $95.65 \pm 24.34$  for NCT-A,  $18.85 \pm 3.12$  for MMSE),  $P < 0.05$ ; the mean number of P300 latency (ms) and wave amplitude ( $\mu V$ ) improved significantly among patients in the HMG after 15 days of treatment (0 day,  $341.90 \pm 14.04$  for latency,  $8.40 \pm 1.73$  for wave amplitude; 15 days,  $305.45 \pm 23.95$  for latency,  $13.00 \pm 3.80$  for wave amplitude) compared with patients in the CG after 15 days of follow-up (0 day,  $343.85 \pm 14.88$  for latency,  $8.29 \pm 1.77$  for wave amplitude; 15 days,  $340.40 \pm 13.06$  for latency,  $8.50 \pm 1.82$  for wave amplitude),  $P < 0.05$ . Similar improvement were also found among patients in the LG and HMCLG; improvements among patients in the HMG were significantly greater than they were in the LG ( $P < 0.05$ ). Synergistic action were shown among patients in the HMCLG ( $P < 0.05$ ).

**Conclusion:** Treatment with Chinese herbal medicine formula Jieduhuayu granules and lactulose may improve cognitive and neurophysiological functions in patients with cirrhosis who have MHE. Compared with lactulose alone, Chinese herbal medicine formula Jieduhuayu granules has higher efficacy of improving cognitive and neurophysiological functions in patients with cirrhosis who have MHE, and the two of them together show synergistic action. *Trial registration number:* ACTRN12614000193673.

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## Introduction

Minimal hepatic encephalopathy (MHE) is a special type of hepatic encephalopathy (HE). It has no clinical symptoms. The diagnosis of MHE requires neuropsychological testing such as the "numbers connecting test" A and B (NCT-A and B, measuring the speed at which one could connect randomly dispersed numbers 1–25), the "block design test", the "digit-symbol test" and so forth. MHE patients' operating and response capabilities are reduced to a certain level, increasing the risks of accidents. Also, if MHE patients are not treated correctly, their MHE will stand a great chance of progressing into hepatic coma, which increases the mortality of those patients. In this study, we aim to observe the affections of a particular Chinese herbal formula (Jieduhuayu granules) on the neurophysiological functions of cirrhotic patients with MHE, to seek out an effective formula of Chinese herbal medicine for MHE. These Jieduhuayu granules have been clinically used in treating cirrhosis patients with MHE for a few years. During the time, it was found that this formula may be able to drop the ammonia level of MHE patients and may improve their cognitive and neurophysiological functions. The study proceeded as follows.

## Methods

This study is founded and approved by the National Natural Science Foundation of China, the Ethics Committee of Guangxi Health Department, a government organization in Guangxi, PR China approved the study. Every subject was given written informed consent before being included in the study.

## Assessments

A battery of neuropsychological, clinical and laboratory assessments were performed in this study to enroll the patients and to measure the improvements. These included:

1. The diagnosis of cirrhosis was based on clinical, biochemical, and ultrasonographic or liver histological data, standard by Chinese Medical Association of Hepatology and Chinese Medical Association of Infectious Diseases (2010).<sup>1</sup>
2. The diagnosis of MHE was made with the administration of a combination of quantitative NP tests including the number connection tests (NCT), the digit symbol test (DST) and the Mini Mental State Examination (MMSE). These tests were easy to administer and fast to perform (20–30 min). The clinical significance of these tests has been evaluated in a large number of healthy volunteers and patients with MHE. Different variations of NCTs and DSTs were used for serial evaluation in order to avoid any effect of learning occurring. The NCT consists of two parts in which the subject is instructed to connect a set of 25 dots as fast as possible while still maintaining accuracy.<sup>2</sup> It can provide information about visual search speed, scanning, speed of processing, mental flexibility, as well as executive functioning. The task requires a subject to 'connect-the-dots' of 25 consecutive targets on a sheet of paper. The test has two parts: A, in which the targets are all numbers (1, 2, 3, etc) and the test taker needs to connect them in sequential order; and B, in which the subject alternates between numbers and letters (1, A, 2, B, etc).<sup>3</sup> In this study, we only use NCT-A (Figs. 1 and 2) because a lot of our patients cannot read the English letters.

The NCT test results were expressed as time in seconds, indicating the differences (in standard deviations) between the observed and expected times given education and age based on the test results of a large sample of healthy volunteers. Results that were higher than a mean + 2 standard deviations ( $\bar{X} + 2SD$ ) were referred to as abnormal NCT tests (Table 1).

The DST (Figs. 3 and 4) is a universally applicable test for assessing mental state that transcends the barriers of illiteracy and linguistic differences. The DST test results were expressed as scores the patients get within 90 s, results that were less than two SD from the mean for the

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