

Clinical Efficacy Observation of Integrated Traditional Chinese and Western Medicine in the Treatment of Type 2 Diabetic Peripheral Neuropathy

Yan Wang, Huanhuan Miao*

The Affiliated Hospital of Hebei University, Baoding 071000, Hebei, China

**Author to whom correspondence should be addressed.*

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Abstract: *Objective:* To investigate the clinical efficacy of combined treatment of Chinese & Western medicine on type 2 diabetic peripheral neuropathy (T2DPN) by means of randomized controlled trials. *Methods:* In total, 80 qualified patients of T2DPN were selected for this study and divided randomly into a control group and a treatment group, each with 40 patients. Patients in the control group took mecobalamin plus alpha-lipoic acid, patients in the treatment group took mecobalamin plus alpha-lipoic acid and the traditional Chinese medicine (TCM) prepared with the effects of tonifying qi, nourishing yin, activating blood circulation, and unblocking collaterals, receiving acupuncture at the same time. *Results:* The nerve conduction velocity, TCM symptom score, fasting plasma glucose, glycosylated hemoglobin, and lipid profile before treatment were compared to those 12 weeks later. At the end of the intervention lasting for 12 weeks, compared to the control group, there were significantly better changes in the treatment group over every observed indicator: faster motor and sensory conduction velocity of the median nerve and common peroneal nerve, more pronounced reduction in TCM syndrome scores, better correction of glucose metabolism, and blood fat indexes. The intergroup difference was highly significant ($P < 0.001$). Throughout the whole observation process, neither of these groups had any notable adverse reaction reported. *Conclusion:* Therefore, comprehensive treatment combining traditional Chinese and Western medicines can simultaneously act on many aspects of pathogenesis in order to achieve the dual goals of improving neurofunction and metabolism of people with T2DPN so they will have a positive prognosis. Such a strategy has definite clinical efficacy and good tolerance, which makes it worthy of being popularized further throughout the medical community.

Keywords: Type 2 diabetes mellitus; Diabetic peripheral neuropathy; Integrated Chinese-Western medicine; Nerve conduction velocity; TCM syndrome score; Clinical efficacy

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1. Introduction

Diabetic peripheral neuropathy (DPN) shows that it represents one of the most significant chronic complications of type 2 diabetes mellitus. Moreover, the findings indicate that its prevalence increases progressively with disease duration and substantially impairs patients' quality of life and long-term prognosis. Furthermore, the evidence demonstrates that epidemiological data indicate that more than 50% of diabetic patients develop varying degrees of peripheral nerve damage

over the course of their illness. Additionally, the evidence shows that these approaches appear to partially relieve symptoms in the short term. Given that significant findings demonstrate that long-term efficacy remains limited, the data indicate that adverse drug reactions are not uncommon and that patient adherence could require improvement^[1-3]. Therefore, the evidence demonstrates that multiple clinical studies have shown that combining TCM syndrome differentiation-based treatment with conventional Western therapy significantly improves nerve conduction velocity and clinical symptomatology in DPN patients^[4,5]. However, the significant findings show that existing studies vary markedly in sample size, efficacy evaluation criteria, and follow-up duration. In light of these results, the data indicate that a unified, evidence-based standard appears still lacking^[6,7]. Studies show a unified standard is absent. Given that the evidence demonstrates that this background warrants systematic investigation, the present study shows that adopting a randomized controlled design appears appropriate to systematically observe the clinical efficacy of integrated Chinese-Western medicine therapy in the treatment of type 2 DPN. Additionally, the findings indicate that the aim could provide objective and reliable reference evidence for the standardized clinical management of this condition.

2. Methods

2.1. Study design

In this study, we adopted the RCT model. The study subjects were patients diagnosed with DPN who went to our hospital's endocrine outpatient clinic or inpatient ward for diagnosis and treatment from June 2022 to June 2024. Using the method of random numbers to draw lots to divide the qualified cases evenly into a control group and a treatment group. There were 40 people in each group, 80 people altogether. The control group took the usual Western medicine treatment, such as blood sugar regulation, nutrition of nerves, and improve microcirculation. In the treatment group, on the basis of Western medicine treatment, adding TCM treatment according to symptom differentiation such as oral decoction of Chinese medicine and taking acupuncture. The intervention lasted twelve weeks. After treatment, the clinical efficacy, nerve conduction velocity, changes of TCM symptom scores, etc., were recorded and compared statistically between the two groups in detail^[8].

2.2. Study participants

The subjects of this study were all patients with type 2 DPN who came to the endocrinology department of our hospital from June 2022 to June 2024. Their inclusion criteria included: (1) they conform to the diagnostic criteria made by the Chinese Diabetes Society in 2020, meanwhile there was damage to peripheral nerves which has been verified by neurophysiological examination; (2) their symptom belonged to qi-yin deficiency combined with blood stasis according to TCM syndrome differentiation; (3) they were 40–75 years old, had suffered for at least two years; (4) no other TCM-related treatment had been administered within the preceding three months; (5) willing to take part in this research project and have obtained the signed informed consent. The exclusion criteria were: (1) Severe heart failure, liver failure, or kidney failure; (2) Other causes of peripheral neuropathy, including alcoholic neuropathy or drug-induced nerve injury^[9]; (3) Pregnancy or lactation; (4) Mental illness or brain function disorders affecting participation in clinical studies; (5) Known allergy to any herb used in the present investigation. In the end, 80 qualified patients were screened out and divided into a control group and a treatment group randomly. Each group had 40 participants.

2.3. Treatment protocol

In the course of this period, all subjects of the two groups took part in diabetes health education, dietary guidance, and exercise counseling, and their hypoglycemic drugs were also adjusted according to their own blood glucose levels. They needed to make sure FBG was below 7.0 mmol/L while GlycoHb was within 7.5%. Subjects of the control group were treated with mecobalamin tablets at dosage of 500 µg oral administration three times daily, combined with intravenous infusion of alpha-lipoic acid injection 600 mg once daily, which lasted totally twelve weeks. All the above interventions

were given to the treatment group, plus they received a Chinese herbal decoction which was designed to tonify qi, nourish yin, activate the blood circulation, and unblock collaterals. Its basic ingredients included 30 g *Astragalus* (Huangqi), 15 g Prince ginseng (Taizishen), 15 g *Rehmannia* root (Shengdihuang), 12 g *Ophiopogon* (Maidong), 20 g *Salvia* (Danshen), 10 g *Ligusticum* (Chuanxiong), 15 g *Spatholobus* stem (Jixueteng), 10 g Earthworm (Dilong), 9 g Cinnamon twig (Guizhi). The decoctions were made by the hospital's pharmacy; one dose each day, twice a day—morning and evening; meanwhile acupuncture was carried out at primary acupoints Zusanli (ST36), Sanyinjiao (SP6), Yanglingquan (GB34), Taixi (KI3), and Xuehai (SP10). Every session lasted half an hour and it was done every other day, three times a week throughout the entire duration of the study period (total twelve weeks)^[10]. Close monitoring of changes in blood glucose and the occurrence of adverse events was done during the whole course of treatment.

2.4. Outcome measures

The outcome measures were divided into three parts: primary efficacy indicators, secondary efficacy indicators, and safety indicators. Primary efficacy indicators were: (1) nerve conduction velocity measured by electromyography, recording MNCV (motor nerve conduction velocity) and SNCV (sensory nerve conduction velocity) of median nerve, ulnar nerve, and common peroneal nerve respectively. Baseline data and post-test data were collected at baseline and at week 12; (2) score of TCM syndrome scale. According to the severity of the main symptoms such as limb numbness, pain, cold sensation, fatigue, and dry mouth, patients' symptom scores of the above symptoms were calculated according to the evaluation criteria of *Guidelines for Clinical Research of New Chinese Medicines*^[11], then the sum of these scores was counted as total score of TCM syndrome. Baseline data, mid-examination data, and post-test data were collected at baseline, week 6, and week 12. The secondary efficacy indicators were FBG, 2hPBG, HbA1c, TC, TG, SOD, and MDA. Secondary indicators were assessed at baseline and week 12. Safety indicators included tests of liver and kidney function, routine blood counts, and the incidence of adverse events. It can reflect the safety characteristics of the integrated treatment protocol to some extent.

2.5. Statistical analysis

All data were analyzed using SPSS version 26.0, with normality assessed for continuous variables prior to analysis.

3. Results

3.1. Comparison of baseline characteristics between the two groups

The study enrolled a total of 80 eligible patients, with 40 assigned to each group. However, the baseline characteristics show that the two groups were well matched, as summarized in **Table 1**. In light of these findings, the distribution of baseline characteristics is illustrated in **Figure 1**.

Table 1. Comparison of baseline characteristics between the two groups (mean ± SD)

Indicator	Control group (n = 40)	Treatment group (n = 40)	t/χ ²	P value
Age (years)	58.3 ± 6.7	57.9 ± 7.1	0.162	0.872
Disease duration (years)	7.2 ± 2.3	7.5 ± 2.5	0.234	0.815
FBG (mmol/L)	8.6 ± 1.2	8.4 ± 1.1	0.302	0.763
HbA1c (%)	8.9 ± 0.8	8.7 ± 0.9	0.201	0.841
BMI (kg/m ²)	25.4 ± 2.1	25.1 ± 2.3	0.263	0.793
Male / Female (cases)	22 / 18	21 / 19	0.051	0.821

Note: FBG = fasting blood glucose; HbA1c = glycated hemoglobin; BMI = body mass index. $P > 0.05$ indicates no statistically significant difference between groups.

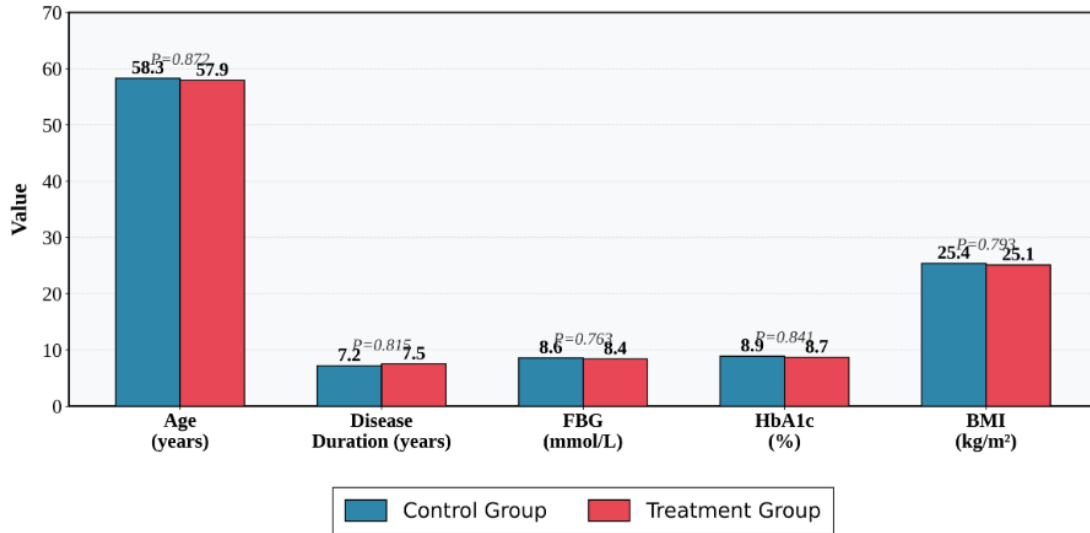


Figure 1. Distribution of baseline characteristics in the two groups

3.2. Comparison of TCM syndrome score changes between the two groups

The results indicate that mean TCM syndrome scores at baseline were 24.6 ± 3.2 points in the control group and 24.9 ± 3.1 points in the treatment group. In light of the significant data, the detailed results are presented in **Table 2** and **Figure 2**.

Table 2. Comparison of TCM syndrome score changes between the two groups ($\bar{x} \pm s$, points)

Group	n	Baseline	Week 6	Week 12	F value	P value
Control group	40	24.6 ± 3.2	19.8 ± 3.0	15.3 ± 2.8	48.32	< 0.001
Treatment group	40	24.9 ± 3.1	16.2 ± 2.7	9.4 ± 2.2	112.56	< 0.001
t value	—	0.431	5.612	11.847	—	—
P value	—	0.668	< 0.05	< 0.001	—	—

Note: Within-group comparisons were performed using repeated measures ANOVA. Between-group comparisons used independent samples t-tests. $P < 0.05$ indicates a statistically significant difference.

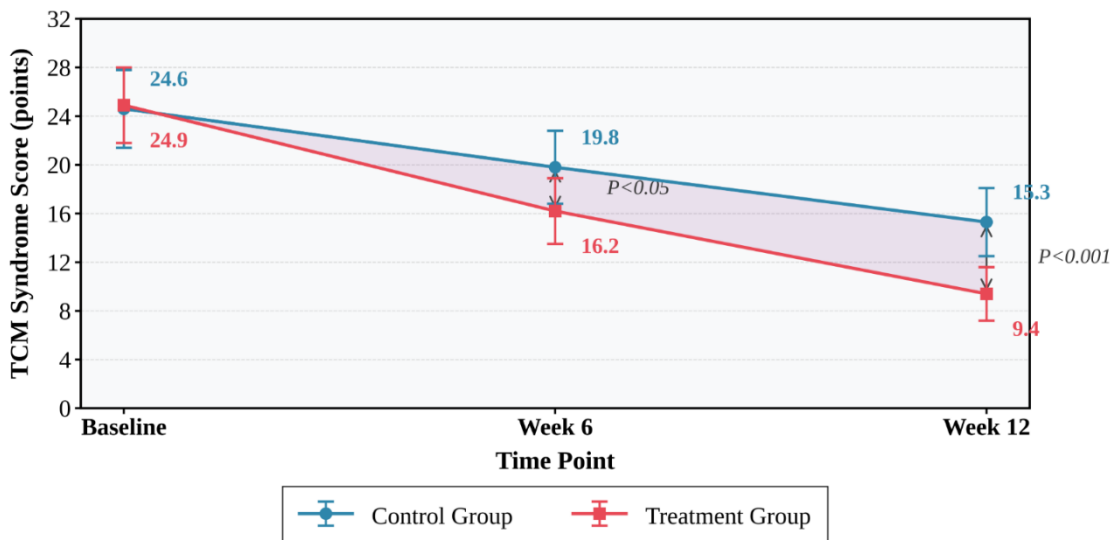


Figure 2. Comparison of TCM syndrome score changes between the two groups

3.3. Comparison of nerve conduction velocity changes between the two groups

The study indicates that no statistically significant differences existed between the two groups in median nerve motor nerve conduction velocity (MNCV), median nerve sensory nerve conduction velocity (SNCV), common peroneal nerve MNCV, or common peroneal nerve SNCV at baseline (all $P > 0.05$). Therefore, the detailed data are shown in **Table 3** and **Figure 3**.

Table 3. Comparison of nerve conduction velocity before and after treatment between the two groups (mean \pm SD, m/s)

Indicator	Time point	Control group ($n = 40$)	Treatment group ($n = 40$)	t value	P value
Median nerve MNCV	Baseline	41.2 \pm 4.2	41.5 \pm 4.3	0.318	0.751
	Post-treatment	44.8 \pm 4.2	49.6 \pm 4.1	5.214	< 0.001
Median nerve SNCV	Baseline	36.8 \pm 3.7	37.1 \pm 3.8	0.357	0.722
	Post-treatment	40.3 \pm 3.7	46.7 \pm 3.5	7.893	< 0.001
Common peroneal nerve MNCV	Baseline	38.5 \pm 4.1	38.8 \pm 4.1	0.325	0.746
	Post-treatment	42.1 \pm 4.0	48.3 \pm 3.9	7.021	< 0.001
Common peroneal nerve SNCV	Baseline	33.6 \pm 3.5	33.9 \pm 3.5	0.383	0.703
	Post-treatment	37.2 \pm 3.4	44.1 \pm 3.3	9.147	< 0.001

Note: MNCV = motor nerve conduction velocity; SNCV = sensory nerve conduction velocity. $P < 0.05$ indicates a statistically significant difference.

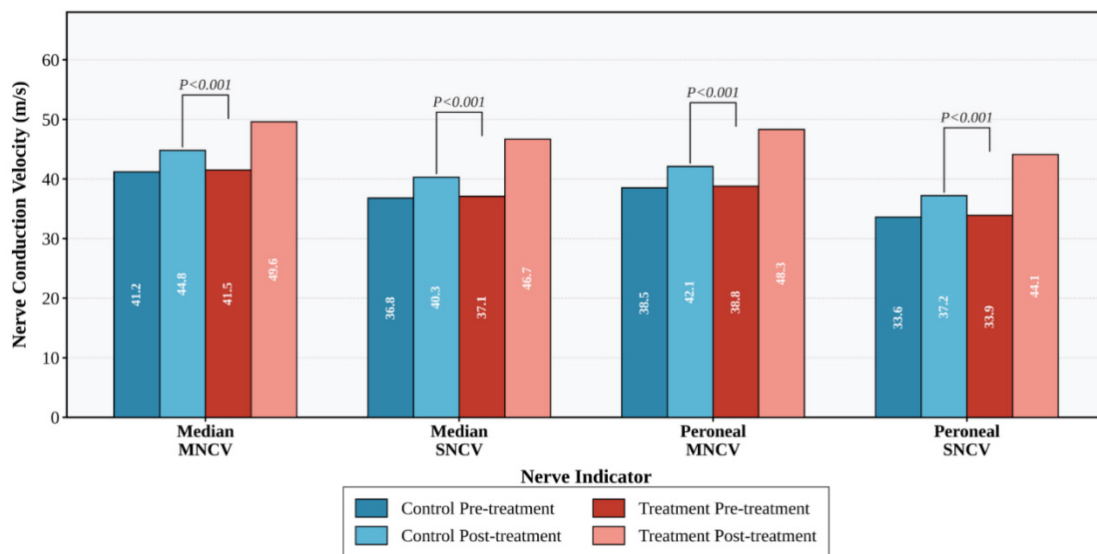


Figure 3. Comparison of nerve conduction velocity before and after treatment between the two groups

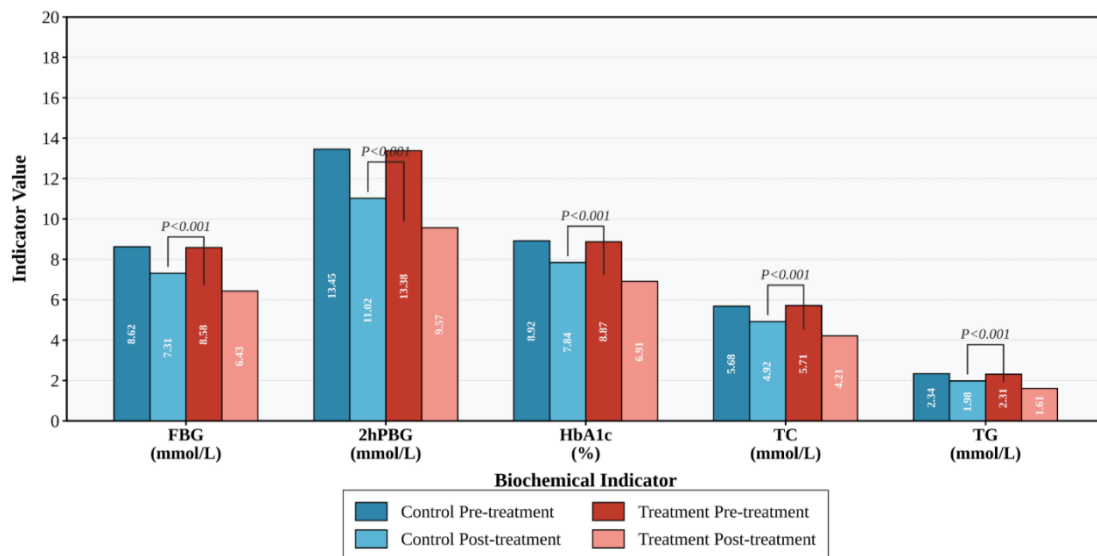
3.4. Comparison of blood glucose and biochemical indicator changes between the two groups

The study indicates that no statistically significant differences were observed between the two groups in fasting blood glucose (FBG), 2-hour postprandial blood glucose (2hPBG), glycated hemoglobin (HbA1c), total cholesterol (TC), or triglycerides (TG) at baseline (all $P > 0.05$). Notwithstanding these results, the important evidence indicates that the results could support conclusions regarding combined therapeutic approaches. Results show therapy affects glycemic and lipid regulation. Detailed data are presented in **Table 4** and **Figure 4**.

Table 4. Comparison of blood glucose and biochemical indicators before and after treatment between the two groups (mean \pm SD)

Indicator	Time point	Control group (n = 40)	Treatment group (n = 40)	t value	P value
FBG (mmol/L)	Baseline	8.62 \pm 1.08	8.58 \pm 1.04	0.172	0.864
	Post-treatment	7.31 \pm 0.92	6.43 \pm 0.87	4.416	< 0.001
2hPBG (mmol/L)	Baseline	13.45 \pm 1.91	13.38 \pm 1.86	0.165	0.869
	Post-treatment	11.02 \pm 1.74	9.57 \pm 1.53	3.938	< 0.001
HbA1c (%)	Baseline	8.92 \pm 0.79	8.87 \pm 0.76	0.287	0.775
	Post-treatment	7.84 \pm 0.71	6.91 \pm 0.64	6.104	< 0.001
TC (mmol/L)	Baseline	5.68 \pm 0.82	5.71 \pm 0.83	0.162	0.872
	Post-treatment	4.92 \pm 0.76	4.21 \pm 0.72	4.266	< 0.001
TG (mmol/L)	Baseline	2.34 \pm 0.54	2.31 \pm 0.54	0.248	0.805
	Post-treatment	1.98 \pm 0.47	1.61 \pm 0.41	3.718	< 0.001

Note: FBG = fasting blood glucose; 2hPBG = 2-hour postprandial blood glucose; HbA1c = glycated hemoglobin; TC = total cholesterol; TG = triglycerides. $P < 0.05$ indicates a statistically significant difference.

**Figure 4.** Comparison of blood glucose and biochemical indicators before and after treatment between the two groups

4. Discussion

Diabetic peripheral neuropathy shows that its clinical burden represents one of the most significant chronic complications of type 2 diabetes mellitus. Moreover, the findings indicate that its pathogenesis could demonstrate a multifactorial character. Furthermore, the evidence shows that key mechanisms include oxidative stress injury induced by sustained hyperglycemia, microvascular damage, neurotrophic factor deficiency, and abnormalities in the polyol metabolic pathway. Furthermore, the results show that treatment must therefore address both root and branch simultaneously—tonifying qi, nourishing yin, activating blood circulation, and unblocking the collaterals^[12]. Given that the significant evidence demonstrates that herbal formula composition appears carefully coordinated, the findings indicate that *Astragalus* (Huangqi) and Prince ginseng (Taizishen) replenish qi and consolidate the foundation. Herbs target roots and branches. However, the results show that *Rehmannia* root (Shengdihuang) and *Ophiopogon* (Maidong) nourish yin and moisten

dryness. Additionally, the evidence demonstrates that *Salvia* (Danshen), *Ligusticum* (Chuanxiong), and *Spatholobus* stem (Jixueteng) invigorate blood, resolve stasis, and promote vascular circulation ^[13]. Moreover, the findings indicate that Earthworm (Dilong) searches out wind and unblocks the collaterals, while Cinnamon twig (Guizhi) warms the channels and disperses cold. Furthermore, the results indicate that they additionally reduce blood viscosity and modulate nerve growth factor expression. Therefore, the significant evidence demonstrates that acting through multiple targets and pathways, they synergistically support neurological recovery. Notwithstanding the complexity of the acupuncture protocol, the findings show that targeted points include Zusanli (ST36), Sanyinjiao (SP6), Yanglingquan (GB34), Taixi (KI3), and Xuehai (SP10) ^[14]. Acupuncture enhances peripheral perfusion. Moreover, the important evidence indicates that needling these points stimulates meridian qi, harmonizes qi and blood, and dredges the collaterals. Additionally, the findings show that this further enhances peripheral blood perfusion and neurotrophic supply to the distal limbs.

5. Conclusion

This study employed a randomized controlled trial design to systematically observe and compare the clinical efficacy of integrated Chinese-Western medicine therapy against conventional Western medicine alone in the treatment of type 2 DPN. These findings suggest that integrated Chinese-Western medicine therapy improves both neurological function and metabolic status in type 2 DPN patients through synergistic multi-target and multi-pathway mechanisms. The approach demonstrates considerable potential for broader clinical application. Several limitations should be acknowledged. The sample size was relatively small and the follow-up period was short. Future research should therefore conduct multicenter, large-sample, long-term randomized controlled trials to further validate and consolidate the evidence base for integrated Chinese-Western medicine treatment of type 2 DPN.

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Disclosure statement

The authors declare no conflict of interest.

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