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Original Article

Impact of oryzanol plus femoston on efficacy, sleep quality, and quality of life in perimenopausal syndrome patients

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Abstract: Objective: To evaluate the therapeutic impact of Oryzanol combined with Femoston on symptom relief, sleep quality, and quality of life in patients with perimenopausal syndrome (PMS). Methods: A total of 201 PMS patients were included and allocated into two groups based on treatment: Femoston monotherapy (control) and Femoston plus Oryzanol (research group). Clinical outcomes were compared, including overall efficacy, adverse events, sex hormone levels, endometrial thickness, bone mineral density (BMD), lipid profiles, neurotransmitter concentrations, sleep quality, and quality of life. Results: The research group demonstrated significantly higher therapeutic efficacy than the control group, with fewer adverse events. Post-treatment improvements were more pronounced in the research group across multiple parameters, including hormonal balance, endometrial thickness, BMD, lipid metabolism, neurotransmitter activity, sleep quality, and overall quality of life (all $P<0.05$). Conclusions: Co-therapy with Oryzanol and Femoston is highly effective for PMS management. It alleviates neurological symptoms, corrects lipid abnormalities, improves sleep, enhances quality of life, and provides measurable benefits for endometrial and BMD.

Keywords: Oryzanol, Femoston, perimenopausal syndrome, efficacy, sleep quality and quality of life

Introduction

Perimenopause typically occurs between the ages of 40 and 60 and represents the transitional period before and after menopause, lasting approximately 2-10 years, and is characterized by a gradual decline in reproductive hormone secretion [1, 2]. Globally, the number of perimenopausal women is projected to reach 1.2 billion by 2030, with nearly 80% residing in developing countries [3]. Perimenopausal syndrome (PMS) encompasses a range of endocrine, biological, and clinical changes during this transition, including hot flashes, fatigue, insomnia, menstrual irregularities, mood swings, and musculoskeletal pain [4, 5]. These symptoms impose substantial physical and psychological burdens, adversely affecting daily functioning, sleep quality, and overall quality of life (QoL) [6].

Hormone therapy remains the mainstay of PMS treatment, capable of reducing osteopenia and bone loss by inhibiting osteoclast activity, while alleviating vasomotor symptoms such as hot flashes and thereby improving QoL [7, 8]. However, hormone therapy alone often yields suboptimal responses and is associated with adverse effects [9], underscoring the need for adjunctive or alternative therapeutic strategies.

Femoston, a hormone replacement therapy consisting of estradiol/dydrogesterone, is structurally related to naturally occurring progesterone [10]. Previous studies reported that its combination with Ziyin Jianghuo Ningxin decoction or dehydroepiandrosterone can help control menopausal symptoms, restore hormone balance, prevent osteopenia or osteoporosis, and improve sleep quality [11]. It has also been

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shown to benefit patients with premature ovarian failure by nourishing Yin, tonifying Yang, improving ovarian blood flow, and regulating sex hormone levels [12].

Oryzanol, a bioactive compound extracted from rice bran oil, exhibits diverse pharmacological properties, including anti-inflammatory, antioxidant, antitumor, and antidiabetic effects, and has demonstrated efficacy in alleviating perimenopausal symptoms [13]. Animal experiments further suggest that Oryzanol mitigates depressive-like behaviors in ovariectomized mice through modulation of the ERβ-nNOS-ERK-CREB-BDNF pathway, supporting its therapeutic potential for PMS [14].

Given the limited clinical evidence on combined Oryzanol-Femoston therapy, this study investigates the effects of this regimen on treatment efficacy, sleep quality, and QoL in patients with PMS.

Materials and methods

Patient information

This retrospective study was approved by the Ethics Committee of Guangzhou Huadu District Maternal and Child Health Hospital.

Inclusion criteria [15]: Patients meeting the diagnostic criteria for PMS; decreased serum and urinary estradiol (E2) with elevated follicle-stimulating hormone (FSH) and luteinizing hormone (LH) levels; varying degrees of reproductive organ and secondary sexual characteristic atrophy; irregular menstruation or amenorrhea, accompanied by hot flashes, sweating, palpitations, irritability, insomnia, or depression.

Exclusion criteria: Patients with bilateral oophorectomy, ovarian tumors, or other endocrine disorders; those with essential hypertension, hypotension, or chronic anemia; allergy to study drugs; prior hormonal therapy within 3 months; unexplained vaginal bleeding or endometrial thickening; pregnancy or lactation; psychiatric or consciousness disorders secondary to gynecological or organic diseases; or incomplete medical records.

A total of 201 PMS patients admitted between April 2023 and April 2024 were screened according to these criteria. Of these, 99 were assigned to the control group (Femoston monotherapy) and 102 to the research group (Femoston plus Oryzanol). Baseline characteristics were comparable between the two groups ($P>0.05$).

Medication regimen

All participants received routine interventions, including dietary, exercise, health, and psychological counseling.

Control group: Oral Femoston tablets (Guangzhou Gongxiang Pharmacy Co., Ltd., HJ2015-0345), 10 mg once daily. White tablets were taken during the first two weeks, and gray tablets were taken during the subsequent two weeks, for a total of 4 weeks.

Research group: In addition to the above, oral Oryzanol (Jining Ankang Pharmaceutical Co., Ltd., H37022480) was administered, one tablet three times daily, for 4 consecutive weeks.

Evaluation indices

Efficacy [16]: *Marked response*: complete disappearance of hot flashes, flushing, dizziness, tinnitus, palpitations, and insomnia. *Response*: improvement of the above symptoms. *Non-response*: persistence or worsening of symptoms.

The overall response rate (ORR) was defined as the proportion of patients achieving marked response or response.

Safety [17]: Adverse events (e.g., breast tenderness, vaginal bleeding, stomach pain, nausea) were recorded and incidence rates calculated.

Sex hormone levels [18]: Fasting peripheral venous blood (5 mL) was collected, centrifuged, and analyzed for E2, LH, and FSH by chemiluminescence immunoassay using commercial kits (Shanghai YuDuo Biological Technology Co., Ltd.; 9478, 3342, 7315). Procedures strictly followed manufacturer protocols.

Endometrial thickness (ET) and bone mineral density (BMD) [19]: ET was assessed by transvaginal ultrasonography. Lumbar spine BMD (L2-L4) was measured by dual-energy X-ray absorptiometry (DXA; QiSheng (Shanghai) Medical Equipment Co., Ltd.).

Blood lipid parameters [20]: Serum high/low-density lipoprotein cholesterol (HDL-C/LDL-C), total cholesterol (TC), and triglycerides (TG),

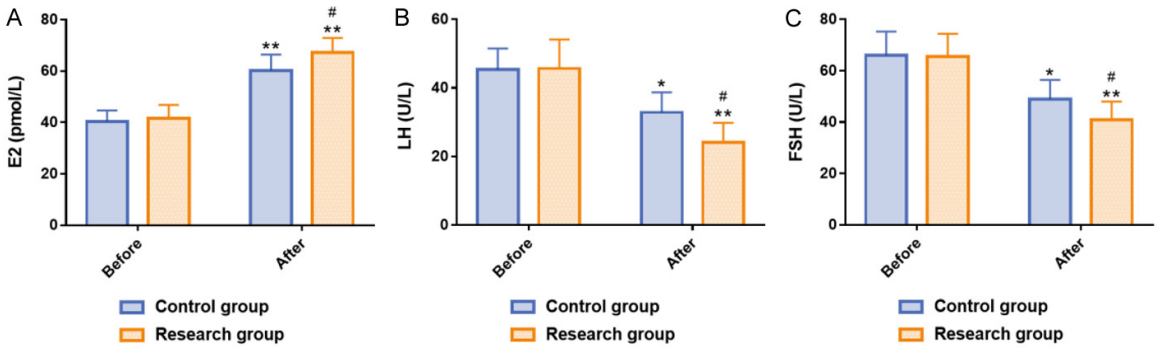

Figure 1. Comparative analysis of E_2, LH, and FSH levels pre- and post-treatment. A. E_2 comparison. B. LH comparison. C. FSH comparison. Note: E_2, estradiol; LH, luteinizing hormone; FSH, follicle-stimulating hormone. *P<0.05 and **P<0.01 *vs.* before treatment; #P<0.05 *vs.* Control.

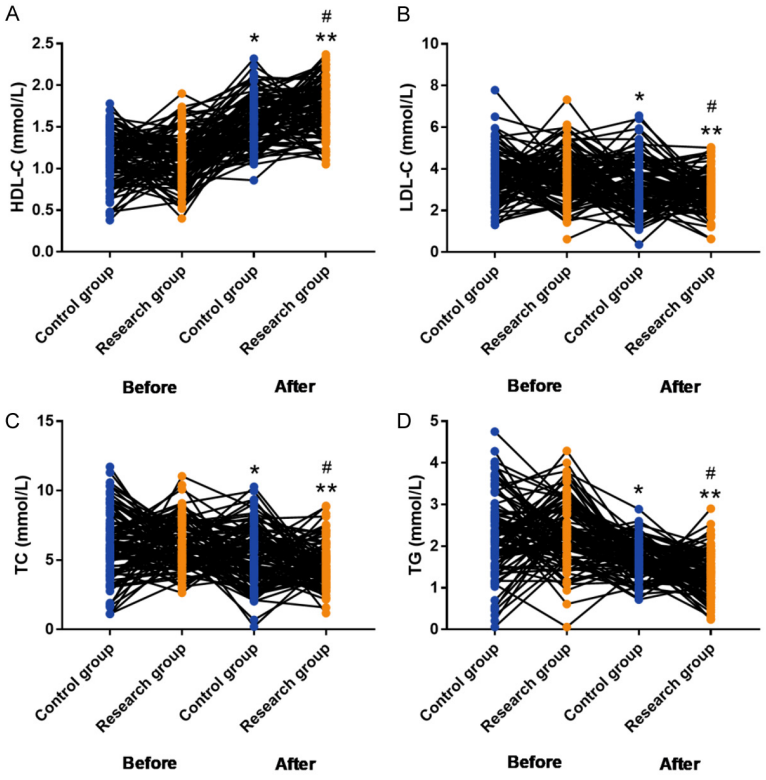

Figure 2. Blood lipid parameters pre- and post-treatment. A. Changes in HDL-C levels. B. Alterations in LDL-C concentrations. C. Variations in TC levels. D. Pre- and post-treatment TG concentrations. Notes: HDL-C/LDL-C, high/low-density lipoprotein cholesterol; TC, total cholesterol; TG, triglycerides. *P<0.05, **P<0.01 versus baseline measurements; #P<0.05 versus control group.

were determined using an automated biochemical analyzer (Xi'an Tianlong Science and Technology Co., Ltd., ZY-680).

Neurotransmitter levels [21]: Serum dopamine (DA), serotonin (5-HT), and norepinephrine (NE) were quantified pre- and post-treatment using ELISA kits (Shanghai Jianglai Biotechnology Co., Ltd., 1531-141865, KB10009; YOBIBIO (Shanghai) Biotechnology Co., Ltd., U96-1002E), strictly following manufacturer's instructions.

Sleep quality and QoL: Sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI; range 0-21), with higher scores indicating poorer sleep [22]. QoL was evaluated by the Menopause-Specific Quality of Life Questionnaire (MENQOL) [23], covering vasomotor symptoms (3 items, max 18), psychological symptoms (7 items, max 42), physical symptoms (16 items, max 96), and sexual function (3 items, max 18). Higher scores indicated poorer QoL.

Statistical analysis

Continuous variables were expressed as mean ± SEM. Between-group comparisons were performed using independent-sample t-tests, while within-group pre-/post-treatment comparisons used paired t-tests. Categorical variables were expressed as proportions (%) and compared with χ^2 tests. Statistical analyses were conducted with SPSS 23.0. Graphs were generated with GraphPad Prism 7.0 (**Figures 1-3**) and Hiplot (**Figures 4, 5**). Statistical significance was set at P<0.05.

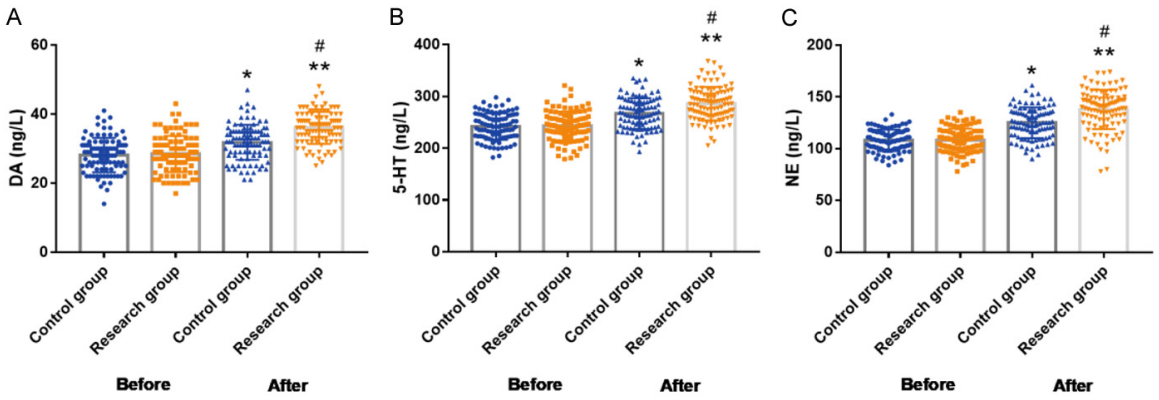

Figure 3. Neurotransmitter level comparisons. A. DA concentration changes. B. 5-HT concentration changes. C. NE concentration changes. Notes: DA, dopamine; 5-HT, serotonin; NE, norepinephrine. *P<0.05, **P<0.01 versus pre-treatment values; #P<0.05 versus control group.

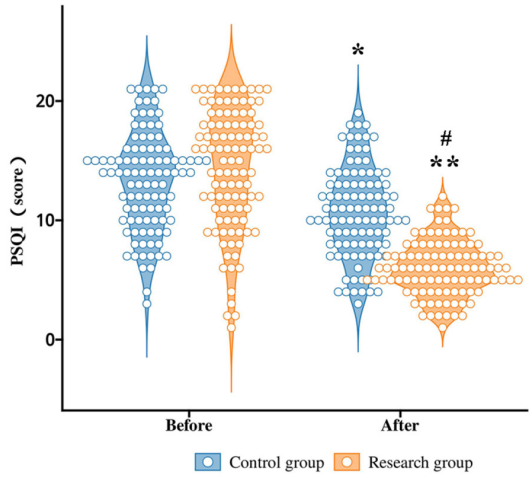

Figure 4. Pre- and post-treatment PSQI scores. Note: PSQI, Pittsburgh Sleep Quality Index. *P<0.05 and **P<0.01 *vs.* before treatment; #P<0.05 *vs.* Control.

Sample size was calculated using the two-sample proportion formula (α=0.05, β=0.3). The minimum required sample size was 94 per group, which was exceeded by the final enrollment.

Results

Baseline data

No significant differences were observed between the control and research groups in age, disease duration, body weight, education level, or menopausal status (all P>0.05) (**Table 1**).

Efficacy analysis

The ORR was significantly higher in the research group (95.10%) compared with the control group (79.80%) (P<0.05) (**Table 2**).

Safety analysis

The main adverse events included breast tenderness, colporrhagia, stomachache, and nausea. The incidence of adverse events was 5.88% in the research group and 15.15% in the control group, indicating a significant intergroup difference (P<0.05) (**Table 3**).

Sex hormone levels

Baseline E_2, LH, and FSH levels were comparable between the two groups (both P>0.05). After treatment, both groups exhibited increased E2 levels and decreased LH and FSH levels (all P<0.05). The research group showed a more pronounced elevation in E2 and greater reductions in LH and FSH compared with the control group (P<0.05) (**Figure 1**).

ET and BMD

Baseline ET and BMD values did not differ significantly between the two groups (both P> 0.05). Both parameters improved significantly after treatment in both groups (P<0.05). The improvements were significantly greater in the research group than those in the control group (P<0.05) (**Table 4**).

Blood lipid profiles

At baseline, HDL-C, LDL-C, TC, and TG levels were comparable between the two groups (all P>0.05). Following treatment, both groups demonstrated significant improvements: HDL-C increased, while LDL-C, TC, and TG decreased (all P<0.05). The research group achieved sig-

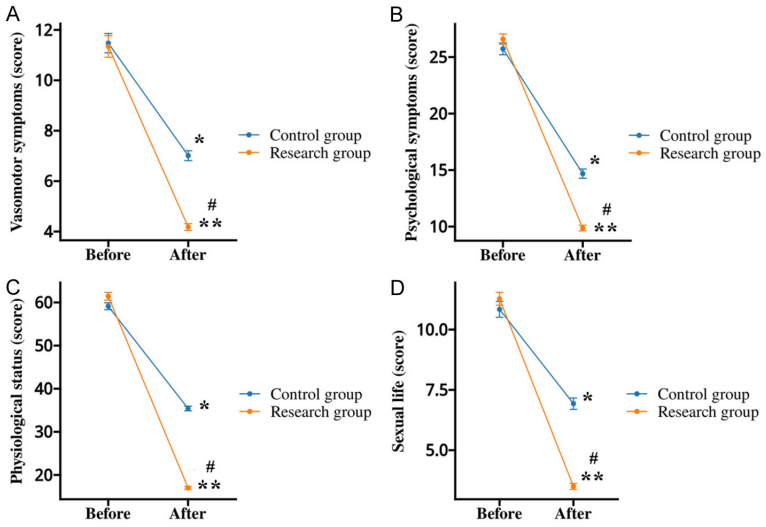

Figure 5. MENQOL scale scores of the two groups in various domains (vasomotor symptoms, psychological symptoms, physiological state, and sexual life). A. Vasomotor symptom scores. B. Psychological symptom scores. C. Physiological state scores. D. Sexual life scores. Note: MENQOL, Menopause-Specific Quality of Life Questionnaire. *P<0.05 and **P<0.01 *vs.* before treatment; #P<0.05 *vs.* Control.

nificantly better lipid profile improvements, with higher HDL-C and lower LDL-C, TC, and TG levels compared with controls (all P<0.05) (**Figure 2**).

Neurotransmitter profiles

Baseline serum DA, 5-HT, and NE concentrations did not differ significantly between the two groups (all P>0.05). After treatment, all three neurotransmitters increased significantly in both groups (all P<0.05), with greater increases observed in the research group (all P<0.05) (**Figure 3**).

Sleep quality

Baseline PSQI scores were similar between the two groups (P>0.05). After treatment, PSQI scores decreased significantly in both groups (P<0.05), with a more pronounced reduction in the research group (P<0.05) (**Figure 4**).

QoL

QoL was assessed using the MENQOL scale across vasomotor, psychological, physiological, and sexual domains. No significant baseline differences were noted (all P>0.05). After treatment, MENQOL scores decreased significantly in both groups (P<0.05), with significantly greater reductions in the research group (all P<0.05) (**Figure 5**).

Discussion

Perimenopause is a natural life stage for women, with age, obesity, ethnicity, psychiatric history, and lifestyle all recognized as risk factors for PMS [24]. Hormone replacement therapy remains the most widely used treatment for alleviating PMS symptoms, but it may increase recurrence risk in some patients [25]. Thus, optimizing PMS management remains a clinical challenge.

In this study, the research group achieved a significantly higher ORR than the control group, indicating that Oryzanol combined with Femoston is more effective than Femoston alone. Mechanistically, Oryzanol regulates hypothalamic secretion and pituitary hormone release, thereby correcting endocrine imbalance and improving clinical symptoms. When used in combination with Femoston, Oryzanol may exert synergistic effects, thereby enhancing overall therapeutic efficacy [26].

Safety analysis further demonstrated a significantly lower incidence of adverse events in the research group compared with the control group. This suggests that the Oryzanol-Femoston regimen not only improves efficacy but also reduces treatment-related risks, including breast tenderness and abnormal uterine bleeding. The improved safety profile may be attributed to Oryzanol's role in maintaining endocrine homeostasis and modulating exogenous hormone absorption [27].

In terms of biochemical outcomes, patients in the research group exhibited higher post-treatment E2 levels and lower LH and FSH levels compared with both the baseline and the control group, confirming the positive regulatory effect of the combined therapy on sex hormone balance. Additionally, the Oryzanol-Femoston regimen significantly improved ET and BMD. The therapy also corrected abnormal lipid

Table 1. Baseline information

Indicators	Control group (n=99)	Research group (n=102)	χ^2/t	P
Age (years)	45.72±6.95	46.44±7.97	0.682	0.496
Course of disease (months)	19.31±6.88	21.23±8.22	1.793	0.075
Body mass (kg)	59.59±4.87	58.18±7.41	1.589	0.114
Education level			0.256	0.613
Senior high school or below	54 (54.55)	52 (50.98)		
Junior college or above	45 (45.45)	50 (49.02)		
Pausimenia			0.501	0.479
Yes	35 (35.35)	41 (40.20)		
No	64 (64.65)	61 (59.80)		

Table 2. Efficacy analysis

Indicators	Control group (n=99)	Research group (n=102)	χ^2	P
Marked response	59 (59.60)	72 (70.59)		
Response	20 (20.20)	25 (24.51)		
Non-response	20 (20.20)	5 (4.90)		
Overall response	79 (79.80)	97 (95.10)	10.799	0.001

Table 3. Safety analysis

Indicators	Control group (n=99)	Research group (n=102)	χ^2	P
Breast tenderness	3 (3.03)	2 (1.96)		
Colporrhagia	6 (6.06)	1 (0.98)		
Stomachache	2 (2.02)	2 (1.96)		
Nausea	4 (4.04)	1 (0.98)		
Total	15 (15.15)	6 (5.88)	4.613	0.032

Table 4. Endometrial thickness and bone mineral density in two patient groups

Indicator	Control group (n=99)	Research group (n=102)	t	P
Endometrial thickness (mm)				
Before	2.98±0.79	3.20±0.88	1.863	0.064
After	3.50±1.27*	3.91±1.51**	2.080	0.039
Bone mineral density (g/cm^3)				
Before	0.92±0.24	0.92±0.22	0.321	0.748
After	1.10±0.28*	1.20±0.27**	2.578	0.011

Note: *P<0.05, **P<0.01 *vs.* pretreatment values.

metabolism, as shown by increased HDL-C and decreased LDL-C, TC, and TG, consistent with findings by Yan et al. [28], who demonstrated that Oryzanol exerts anti-hyperlipidemic effects by modulating gut microbiota and amino acid metabolism.

Neurotransmitter analysis revealed that the combined therapy significantly elevated DA, 5-HT, and NE concentrations. These neurochemical improvements may be explained by Oryzanol's ability to upregulate γ-aminobutyric acid and downregulate glutamate, thus maintaining excitatory - inhibitory balance in the central nervous system [29]. Correspondingly, the research group showed greater reductions in PSQI scores and MENQOL scores, reflecting substantial improvements in sleep quality and QoL across vasomotor, psychological, physiological, and sexual domains. As a 5-HT receptor agonist, Oryzanol enhances serotonin signaling by binding to the 5-HT1A receptor, thereby influ-

encing thermoregulation, mood stabilization, and sleep regulation [30, 31].

Taken together, these results confirm that the Oryzanol-Femoston combination improves treatment efficacy, reduces adverse events, and enhances hormone balance, ET, BMD, lipid metabolism, neurotransmitter activity, sleep quality, and QoL. Our findings are in line with Kuang et al. [19], who also demonstrated significant clinical benefits of this combined therapy, including normalization of sex hormones and improvement in sleep quality.

This study contributes novel insights into two aspects. First, it provides clinical evidence that combining Oryzanol with Femoston is more effective than Femoston monotherapy. Second, it comprehensively evaluates the multidimensional benefits of this therapy, from symptom relief and safety to biochemical, structural, and neuropsychological improvements, thus presenting a holistic perspective on its therapeutic value.

Nevertheless, some limitations should be acknowledged. First, the study did not explore patient-specific factors that may influence treatment response. Second, potential dose-dependent effects of Oryzanol-Femoston co-administration were not assessed. Third, the absence of long-term follow-up data, particularly beyond five years, limited evaluation of sustained efficacy and prognosis. Future prospective, large-scale, and multi-center studies with extended follow-up are warranted to validate these results, explore dose-response relationships, and clarify the long-term mechanisms of Oryzanol-Femoston co-therapy in PMS.

In conclusion, the Oryzanol-Femoston regimen offers significant clinical benefits with a favorable safety profile in PMS management. This dual therapy not only improves hormone regulation, neurotransmitter balance, lipid metabolism, ET, and BMD, but also alleviates sleep disturbances and enhances overall QoL. These findings support its potential as a promising treatment option and provide evidence-based guidance for future clinical practice.

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Disclosure of conflict of interest

None.

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