Psychology Research and Behavior Management

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CLINICAL TRIAL REPORT

Effects of Baduanjin Exercise on Depression Severity and Heart Rate Variability in Adults with Major Depressive Disorder: A Pilot Randomized Controlled Trial

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Objective: Major depressive disorder is a common psychiatric condition characterized by persistent sadness and a lack of interest in life. It is often associated with alterations in autonomic nervous system functioning. This study examined the impact of a 10-week Baduanjin exercise program on heart rate variability and depression severity in individuals with major depressive disorder.

Methods: The present study was a two-arm, single-blind, pilot randomized controlled trial. Thirty-four participants were randomly assigned to either a Baduanjin group (n = 17) or a control group (standard care) (n = 17). The Baduanjin group participated in 60-minute sessions twice weekly while the control group were given the standard care appropriate for people with major depression disorder. Heart rate variability (HRV) and depression severity were assessed at baseline, Week 5, and Week 10.

Results: Results showed no significant interaction effect between group and time. However, there was a group effect for ratio of low-frequency-to-high-frequency (LF/HF ratio) HRV (p=0.049) only. Between-group differences were observed with Baduanjin exercise (Mean±SD: 0.27±0.33) group having higher scores than the control group (0.01±0.40). Also, there were significant time effects for depression, high-frequency (HF) HRV, low-frequency (LF) HRV, LF norm HRV, and total power (ps<0.05). Depression severity significantly decreased in both groups by Week 5 and Week 10 (ps<0.05) while low-frequency HRV and total power HRV increased in both groups by Week 5 and Week 10 (ps<0.05).

Conclusion: These findings suggested that Baduanjin exercise may positively influence aspects of autonomic function. Future research with larger sample sizes and longer follow-up periods is needed to investigate its long-term effects and potential benefits for depressive symptoms in individuals with major depressive disorder. This study was registered with the Chinese Clinical Trial Registry (ChiCTR1900027222).

Keywords: Baduanjin, major depressive disorder, heart rate variability, mind-body exercise, autonomic function

Introduction

Depression, a prevalent mental disorder, significantly contributes to global public health challenges and is notably associated with an increased risk of suicide.[1] It is common and frequently recurrent, affecting about 4.4% of the global population.[2] Major depressive disorder (MDD) is a leading cause of disability worldwide and its prevalence continues to rise annually.[3] Approximately 300 million people in the world suffer from MDD which is characterized by both emotional and physical symptoms, including significant weight and appetite changes and persistent fatigue.[4,5]

Received: 9 October 2024
Accepted: 17 February 2025
Published: 3 March 2025

Recently, the primary treatments for MDD include pharmacological and psychological therapies. Pharmacological interventions can effectively mitigate depressed symptoms. However, discontinuation of the medication often leads to rapid recurrence of symptoms.[6] Psychological treatments, such as cognitive behavior therapy (CBT) and counseling, are effective in relieving the syndromes caused by MDD. However, these techniques are often resource-consuming and expensive. Furthermore, cultural barriers and a general lack of mental health awareness in some countries including the Chinese population can deter individuals with MDD from seeking these professional treatments due to fears of stigma.[7,8]

Baduanjin is a traditional Chinese mind-body exercise that has been practiced for thousands of years in China. It is well accepted within Chinese culture and has shown potential benefits for various health conditions. Previous studies indicated significant positive effects of Baduanjin exercise on depression,[9] anxiety,[10] pain intensity,[11,12] cognitive function,[13] and quality of life.[14] A study by Ye et al[15] showed that a 12-week Baduanjin exercise program (60 minutes each session, twice a week) can effectively improve depressive syndromes, quality of life enjoyment and satisfaction in patients with MDD. Furthermore, systematic reviews and meta-analyses suggested that Chinese mind–body interventions, such as Tai chi and acupuncture, may improve heart rate variability (HRV) and alleviate depressive syndromes in adults with MDD via modulating the autonomous nervous system.[16,17]

Heart rate variability (HRV) is a key indicator of autonomic nervous system function, reflecting the dynamic balance between sympathetic and parasympathetic activity.[18] Reduced HRV, particularly in the high-frequency (HF) domain, has been consistently observed in individuals with depression.[19] Improving HRV may have clinical relevance for individuals with MDD. Higher HRV has been linked to better emotional regulation and overall autonomic stability.[20] A systematic review by Schiweck et al[21] highlighted this relationship, emphasizing that lower HRV is not only a marker of depression severity but may also serve as a potential target for therapeutic interventions.[21] While the association between HRV and depression is well-established, there is limited research on the practical interventions that can simultaneously improve HRV and alleviate depressive symptoms in individuals with MDD. Mind-body exercises have been shown to have beneficial effects on depression. Liu et al[16] demonstrated that a 24-week Tai Chi program statistically improved depressive symptoms and modulated HRV in elderly individuals with depression, suggesting that relaxation-focused exercises may have a dual benefit for mental and autonomic health. Similarly, a randomized control trial by Wang et al[22] found that a 16-week Baduanjin training program significantly enhanced HRV parameters among college students, indicating its potential for improving HRV and mental well-being.[22]

Despite existing findings, research specifically examining the impact of Baduanjin exercise on HRV in adults with MDD remains limited. To date, little is known about how this traditional mind-body exercise influences HRV in this population. Therefore, the present study aimed to address this gap by investigating the effects of Baduanjin exercise on HRV parameters in individuals with MDD, thereby providing insight into the potential mechanisms by which Baduanjin exercise could affect MDD. Specifically, the objective of the present pilot randomized controlled trial was to examine the impact of a 10-week Baduanjin exercise program on heart rate variability and depression severity in individuals with major depressive disorder.

Materials and Methods

Study Design

The present pilot randomized controlled trial (RCT) was conducted as a single-blind, two-arm parallel assignment to evaluate the effects of Baduanjin exercise on HRV and depression severity among individuals with MDD. The study procedures and results were reported using the CONSORT checklist.[23] This study was registered with the Chinese Clinical Trial Registry (ChiCTR1900027222) and complied with the Declaration of Helsinki and its later amendments.

Participants, Enrolment, and Randomization

Eligibility criteria for participants included (1) ages 18 to 65 years; (2) diagnosis of a current episode of MDD by two psychiatrists according to the DSM-5 criteria; (3) a baseline score of 12 or higher on the Hamilton Rating Scale for Depression 17 ($HRSD_{17}$);[24] and (4) a MoCA score of 20 or higher. Exclusions were made for participants with (1) primary diagnoses other than MDD; (2) pregnancy or lactation; (3) substance use or drug dependence; (4) acute suicidal

or violent tendencies; (5) chronic medical conditions such as diabetes, autoimmune diseases, cardiovascular disease, hypertension, chronic fatigue syndrome, or asthma; (6) a history of regular mind-body exercises, such as Baduanjin and Taichi, within the past six months; and (7) mobility problems preventing participants in exercising. Ongoing treatments such as antidepressants or psychotherapy were permitted during the study. A total sample size of 58 is needed for the present RCT which is attained using GPower software (version 3.1) with 0.8 power, medium effect (0.25), 0.05 level of significance, and a 20% attrition rate. However, as this pilot study aimed to explore the potential effectiveness of the intervention, the final sample size was adjusted to approximately one-third of the total calculated sample size based on expert recommendations.[25,26] Therefore, a minimum of 20 participants was deemed sufficient for the two groups.

Potential participants with MDD were referred by psychiatrists or rehabilitation therapists from a rehabilitation hospital in Fujian, China, between October 2020 and October 2021. The study received ethical approval from the local research ethics committee (approval number: 2020YJS-003-01).

A research assistant explained the research and conducted an initial screening to determine eligibility. All eligible individuals were randomly assigned to either the experimental Baduanjin exercise group or the control group in a 1:1 ratio using computer-generated numbers. Participants were informed of their group allocation via phone after baseline assessments. Outcome assessments were performed by a research assistant who was blinded to the group assignments. All participants were asked to sign their informed consent forms before participation.

Intervention Protocol and Control Condition

Participants in the Baduanjin group underwent a 10-week Baduanjin exercise with two sessions per week (ie, 20 sessions in total). In the first two weeks, there was a group-based Baduanjin training program led by a certified Qigong instructor with over three years of experience. The regimen consisted of two 60-minute sessions per week with each session beginning with a 5-minute warm-up, followed by 50 minutes of Baduanjin exercise, and concluding with a 5-minute cool-down period. The Baduanjin training regime was in line with the Health Qigong-Baduanjin published by the Health Qigong Management Centre of General Administration of Sport of China.[27] Participants in the Baduanjin group received their training in the hospital (ie, in-hospital Baduanjin exercise) for the first two weeks. From the third week onwards, they were encouraged to practice Baduanjin exercise at home. Regular phone calls were given to remind the participants to practice the in-home Baduanjin exercise. All participants were instructed to log their daily exercise activities to support adherence and practice consistency of Baduanjin exercise. These logs were reviewed weekly and feedbacks were given if needed.

Participants in the control group received standard care for individuals with MDD and were asked to keep their lifestyle as usual during the study period but received Baduanjin training classes after the conclusion of the 10-week study period.

Outcome Measures

Outcome assessments were done at baseline, 5th, and 10th week by a research assistant who was blinded to participants' group assignments. Participants in both groups were required to complete the $HRSD_{17}$ and HRV parameters.

$HRSD_{17}$: The HRSD is the predominant tool used by clinicians to quantify depression severity.[24] This 17-item scale is rated on a three- or five-point scale and assesses symptoms experienced over the previous week. Higher scores indicate more severe depressive symptoms.

HRV: Participants were instructed to sit calmly in a chair at a room temperature of 26°C for 15 minutes prior to measurements, with instructions to relax and breathe normally. HRV data was captured using a portable HRV device (Check MyHeart™, Daily Care Biomedical, Taiwan). A 5-minute ECG recording was conducted at a sampling rate of 250 samples per second. Two electrodes were placed on both sides of the inner forearms. The raw ECG data were transferred to a PC via USB for analysis. Frequency-domain analysis of HRV was conducted using the non-detrend method of fast Fourier transformation (FFT). Selected frequency-domain parameters included low-frequency power (LF), high-frequency power (HF), normalized LF (LF norm), normalized HF (HF norm), the LF/HF, and total power. Time-domain parameters such as standard deviation of NN intervals (SDNN) and root mean square of the successive differences (RMSSD) are recommended for long-term HRV recordings of at least 18 hours.[20]

Safety Record

A questionnaire was administered to assess possible adverse events and changes in health status. Adherence and occurrence of adverse events were documented using an adverse event case report form. All recorded adverse events were analyzed by the research team to determine their relevance to the intervention.

Data Analysis

The participants' demographics and baseline characteristics were summarized using descriptive statistics. The Shapiro–Wilk test was applied to assess the normality of the data. The Log 10 transformations were performed on outcome variables that did not display normal distribution. A mixed factor analysis of variance (group x time) was utilized to explore the interaction effects between the group and time. A separate subgroup analysis with post hoc pairwise comparison between any two endpoints with the Bonferroni adjustment was conducted if a significant interaction effect existed. An intention-to-treat (ITT) analysis with the last observation carried forward (LOCF) method was employed for missing data. Only participants who attended at least 75% (15 out of 20 sessions) of the total training sessions would be included in the ITT analysis.[28] All statistical tests were performed using the statistical software SPSS (version 22; SPSS Inc, Chicago, IL, USA). A *p*-value of less than 0.05 was considered as statistically significant.

Results

Participants' characteristics and baseline data are detailed in Tables 1 and 2. The average age was 42.40 years for the Baduanjin group, and 39.9 years for the control group. Approximately 80% of the participants were female. The baseline measurements for both groups did not differ significantly (*p*s>0.05).

Table 1 The Characteristics of Patients With MDD

Characteristics	BD (n=17)	Con (n=17)	*P* value
Age, years	42.40 ±14.42	39.90±11.80	0.583
Gender, female (%)	13, 77%	14, 82%	0.671
Height, cm	164.06±10.81	167.47±8.07	0.305
Weight, Kg	58.41±9.45	60.12±9.67	0.607
Education status, n (%)			
Low (< 9 years)	12 (66)	8(47)	0.371
Medium (9–12 years)	4(24)	6(35)	0.527
High (>12 years)	1(6)	3(18)	0.317
MoCA	24.00±3.95	24.35±2.50	0.758

Abbreviations: BD, Baduanjin group; Con, Control group.

Table 2 The Baseline Value of Outcome Variables

Variables	BD	Con	*P* value
	Mean±SD	Mean±SD	
$HRSD_{17}$	1.28 ±0.10	1.29 ±0.10	0.783
HF (ms^2)	2.01 ±0.68	2.09 ±0.97	0.779
HF norm (nu)	1.63 ±0.17	1.66 ±0.21	0.723
LF (ms^2)	2.09 ±0.57	2.08 ±0.63	0.955
LF norm (nu)	1.75 ±0.12	1.68 ±0.20	0.200
LF/HF (%)	0.08 ±0.32	−0.01 ±0.45	0.487
Total power (ms^2)	2.43 ±0.55	2.80 ±0.61	0.070

Abbreviations: BD, Baduanjin group; Con, Control group; $HRSD_{17}$, the Hamilton Rating Scale for Depression with 17 items; HF, high-frequency; LF, low-frequency; LF/HF, the ratio of low-frequency-to-high-frequency.

Out of 85 participants initially approached, 34 were recruited for the study. Reasons for non-participation included failing initial assessments (32 participants) and not signing the informed consent due to family issues (19 participants). Pandemic-related absences were reported for 3 participants in the Baduanjin group and 4 in the control group who missed post-assessment sessions. Study procedure details are presented in Figure 1. No adverse events were reported during the 10-week intervention period.

Moreover, there was no group effect and interaction effect for depression except for the time effect ($p < 0.001$) (Table 3).

Statistical analysis of HRV showed a significant effect of the intervention on the LF/HF ratio ($p = 0.049$) (Table 3), with the Baduanjin group exhibiting a higher LF/HF ratio compared to the control group. There was no interaction effect ($p > 0.05$) although there was a time effect on HRV total power ($p < 0.001$) and its subscales including HF, LF, and LF norm (Tables 4, 5 and Figure 2).

Safety Report

No adverse events were reported in either group during the 10-week intervention period.

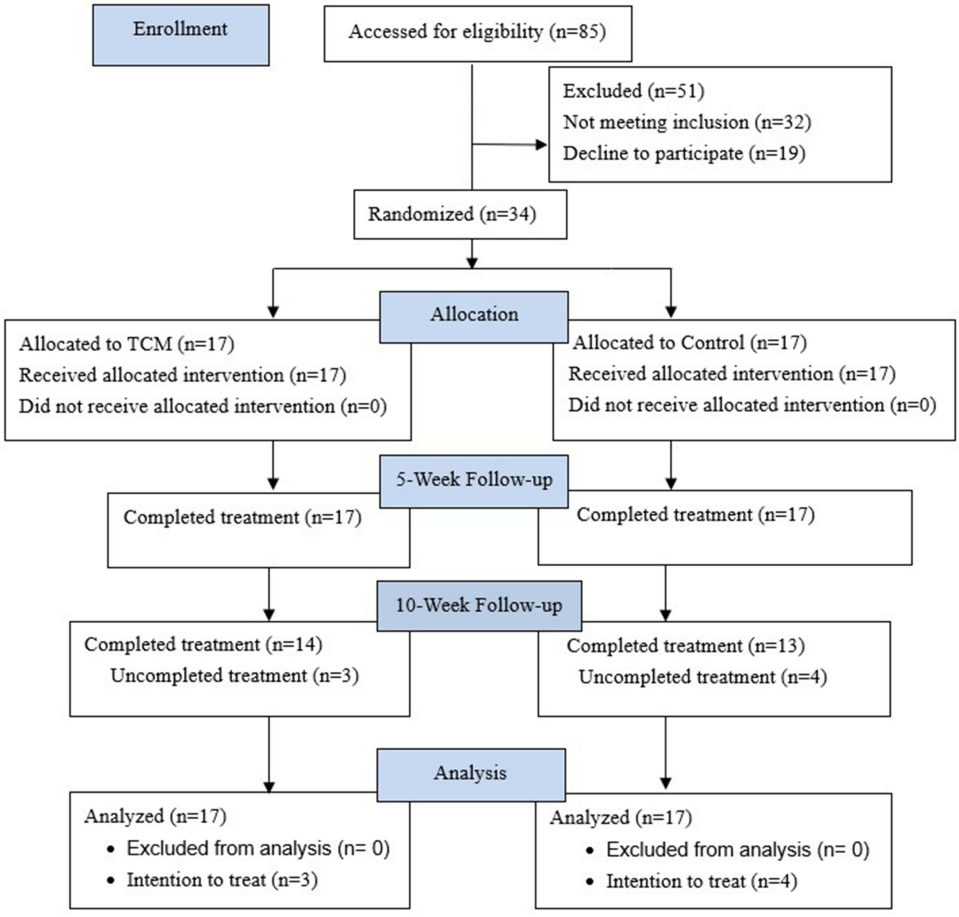

Figure 1 CONSORT flow diagram of the trial.

https://doi.org/10.2147/PRBM.S499936

Table 3 Mean and SD for All Outcome Variables

Variable Group	Mean ± SD		Group Effect	Time Effect	Group X Time Effect		
	Week 5	Week 10	*P*	*P*	F	*P*	η2
$HRSD_{17}$			0.330	<0.001	1.007	0.366	
BD	1.18±0.10	1.16±0.18					0.005
Con	1.22±0.13	1.22±0.14					
HF			0.509	<0.001	0.121	0.886	
BD	2.62±0.54	2.40±0.71					0.044
Con	2.83±0.80	2.51±0.73					
HF norm			0.070	0.125	0.991	0.377	
BD	1.63±0.19	1.52±0.23					0.036
Con	1.72±0.12	1.66±0.22					
LF			0.466	<0.001	0.257	0.759	0.069
BD	2.77±0.37	2.67±0.64					
Con	2.60±0.81	2.52±0.49					
LF norm			0.522	0.028	0.132	0.265	0.342
BD	1.90±0.75	1.79±0.11					
Con	2.02±0.41	1.61±0.26					
LF/HF			0.049	0.148	0.712	0.495	0.062
BD	0.09±0.31	0.27±0.33					
Con	−0.09±0.27	0.01±0.40					
Total power			0.389	<0.001	1.311	0.275	0.404
BD	3.32±0.46	3.13±0.67					
Con	3.33±0.86	3.19±0.56					

Abbreviations: BD, Baduanjin group; Con, Control group; $HRSD_{17}$, the Hamilton Rating Scale for Depression with 17 items; HF, high-frequency; LF, low-frequency; LF/HF, the ratio of low-frequency-to-high-frequency.

Table 4 Comparison of Between-Group Differences in Outcome Measures

Variable		Week 5	Week 10
$HRSD_{17}$	*P*	0.226	0.306
	95% CI	−0.13 to 0.03	−0.17 to 0.05
HF	*P*	0.375	0.651
	95% CI	−0.69 to 0.27	−0.61 to 0.39
HF norm	*P*	0.084	0.080
	95% CI	−0.21 to 0.01	−0.30 to 0.02
LF	*P*	0.436	0.441
	95% CI	−0.27 to 0.61	−0.25 to 0.55
LF norm	*P*	0.570	0.012
	95% CI	−0.54 to 0.30	0.04 to 0.32
LF/HF	*P*	0.076	0.043
	95% CI	−0.21 to 0.39	0.01 to 0.52
Total power	*P*	0.986	0.803
	95% CI	−0.48 to 0.48	−0.49 to 0.38

Abbreviations: BD, Baduanjin group; Con, Control group; $HRSD_{17}$, the Hamilton Rating Scale for Depression with 17 items; HF, high-frequency; LF, low-frequency; LF/HF, the ratio of low-frequency-to-high-frequency.

Table 5 Analyses of Within-Group Differences Over Time

Variable		Pre vs Week 5		Week 5 vs Week 10		Pre vs Week 10	
		BD	Con	BD	Con	BD	Con
$HRSD_{17}$	P	0.001	0.004	0.689	0.784	0.003	0.001
	95% CI	0.06 to 1.56	0.02 to 0.03	−0.05 to 0.08	−0.03 to 0.04	0.025 to 0.19	0.03 to 0.11
HF	P	0.024	0.003	0.277	0.069	0.085	0.006
	95% CI	−1.11 to −0.09	−1.18 to −0.29	−0.19 to 0.63	−0.03 to 0.66	0.83 to 0.06	−0.69 to −0.14
HF norm	P	0.926	0.231	0.019	0.142	0.133	0.991
	95% CI	−0.14 to 0.16	−0.18 to 0.05	0.02 to 0.20	−0.02 to 0.15	−0.04 to 0.27	−0.14 to 0.13
LF	P	0.002	0.021	0.604	0.519	0.008	0.005
	95% CI	−1.06 to −0.29	−0.94 to −0.09	−0.29 to 0.49	−0.18 to 0.33	−0.98 to −0.17	−0.72 to −0.16
LF norm	P	0.433	0.019	0.561	0.005	0.380	0.360
	95% CI	−0.53 to −0.24	−0.61 to −0.06	−0.28 to 0.49	0.14 to 0.68	−0.12 to 0.05	−0.09 to 0.23
LF/HF	P	0.912	0.491	0.021	0.178	0.139	0.846
	95% CI	−0.28 to 0.26	−0.15 to 0.30	−0.32 to 0.03	−0.24 to 0.05	−0.45 to 0.07	−0.24 to 0.20
Total power	P	0.001	0.029	0.333	0.246	0.001	0.019
	95% CI	−0.13 to −0.48	−0.99 to 0.06	−0.21 to 0.60	−0.11 to 0.39	−1.01 to −0.40	−0.70 to −0.07

Abbreviations: BD, Baduanjin group; Con, Control group; $HRSD_{17}$, the Hamilton Rating Scale for Depression with 17 items; HF, high-frequency; LF, low-frequency; LF/HF, the ratio of low-frequency-to-high-frequency.

Discussion

The present study explored the effects of a 10-week Baduanjin exercise program on depressive symptoms and heart rate variability (HRV) in individuals with MDD. Results suggest that this traditional Chinese exercise not only influences both sympathetic and parasympathetic regulations but also may offer benefits in modulating autonomic functions and enhancing mental health in patients with MDD.

Impact on Depression

The depression severity significantly reduced over time in both the Baduanjin exercise and control groups, indicating an improvement in depressive symptoms among the participants. This suggests that both Baduanjin exercise and standard

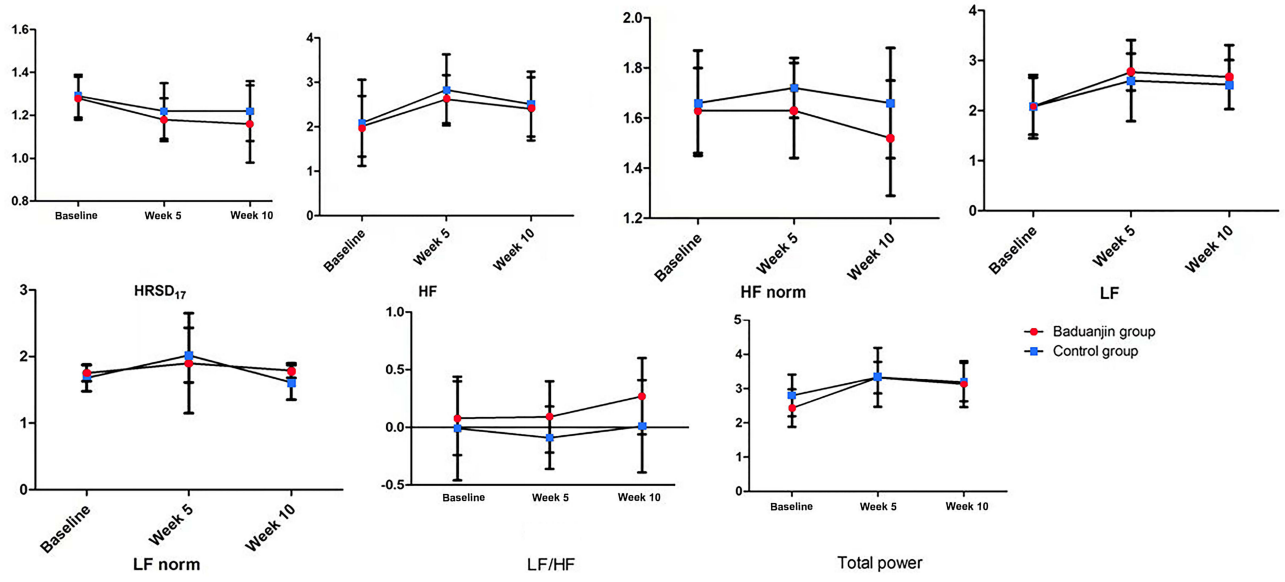

Figure 2 Trends in outcomes of Heart Rate Variability and Depression over time.
Abbreviations: $HRSD_{17}$, Depression severity; HF, High-Frequency; HF norm, High-Frequency norm; LF, Low-frequency; LF norm, Low-frequency norm; LF/HF, Ratio of low-frequency-to-high-frequency.

https://doi.org/10.2147/PRBM.S499936

care are capable of improving depression especially as there is no significant difference between the Baduanjin group and control group. This is consistent with previous research suggesting that regular physical activity, including traditional Chinese exercises like Baduanjin, can have antidepressant effects.[15,29] A meta-analysis conducted by Zeng et al[30] highlighted Tai chi, a traditional Chinese exercise, as an alternative therapy for reducing depression in middle-aged and older adults. Similarly, an RCT supported these findings, indicating that Tai Chi and yoga can significantly improve depressive symptoms in pregnant women with depression.[31] However, as no significant between-group difference was found in the present study, the improvement cannot be conclusively attributed to the Baduanjin intervention alone. The observed trend of changes may be associated with general benefits of physical activity, such as endorphin release and enhanced neuroplasticity,[32] which are known to be stimulated through exercise. Further studies are needed to investigate the specific mechanisms and therapeutic effects of Baduanjin on depression.

Autonomic Regulation

Significant changes in HRV parameters, including increases in HF and total power, indicated improved autonomic function over the initial 5 weeks. Increases in HF typically reflect enhanced parasympathetic activity, while total power represents overall heart rate variability.[33] These enhancements suggest that Baduanjin may help in rebalancing the autonomic dysregulation often observed in MDD. However, changes in the LF/HF ratio and HF norm from Week 5 to Week 10, and LF from baseline to Week 5, do not align with typical findings from other studies. Previous research has generally shown that mind-body exercises like yoga and Tai Chi can decrease LF and LF/HF values, and increase HF norm in individuals with mood disorders, attributed to their roles in alleviating stress, anxiety, and depression levels.[16,34,35] Our results, however, do not consistently align with these findings, possibly due to the distinctive physical components of Baduanjin exercise. These elements might influence autonomic pathways differently compared to Tai Chi and yoga. For instance, Movement 2, "Drawing the Bow to Shoot the Eagle", involves simulating the action of drawing a bow, which requires significant muscular strength and coordination. This can increase heart rate, activating the sympathetic nervous system and potentially leading to an increase in LF and LF/HF ratio and a decrease in HF.

Additionally, discrepancies may arise from variations in the study population, such as differences in baseline characteristics, severity of depression, or adherence to the exercise regime. The pandemic lockdown may also contribute significantly to these discrepancies. Participants were instructed to stay home and could not go outside without permission, possibly increasing tension and leading to heightened sympathetic nervous activity. Further research is required to elucidate these findings. Future studies should involve controlled designs, larger sample sizes, and consistent monitoring of exercise adherence to provide more definitive conclusions.

Admittedly, between-group differences were observed in LF/HF ratio after a 10-week Baduanjin intervention. Participants in the control group were instructed to maintain their usual daily treatments. Both groups took medications during the 10-week study period. Consequently, significant improvements occurred in some outcomes within the control group as well. Future studies may consider using a medication-free treatment protocol to investigate the efficacy of Baduanjin exercise among individuals with MDD.

Limitations and Future Directions

The study presents several limitations that may impact its generalizability and interpretation. Firstly, the small sample size limited the ability to generalize findings and reduced statistical power, potentially obscuring smaller yet significant effects. Secondly, a relatively high dropout rate, primarily due to pandemic-related issues (eg, lockdown and quarantine limited 10th-week follow-up assessment), could introduce bias by possibly overestimating the benefits if those remaining were more likely to experience positive effects. Thirdly, the absence of a control group performing different exercises or receiving alternative interventions meant improvements cannot be solely attributed to Baduanjin exercise. Additionally, the control group received conventional treatments during the study period. Future studies should consider employing medication-free participants to draw more definitive conclusions. Lastly, the short duration of 10 weeks, without follow-up assessments, restricts our understanding of the long-term efficacy of the intervention. Studies with long-term intervention and follow-up assessments are required to better understand the efficacy of Baduanjin exercise.

Conclusion

The present pilot RCT demonstrated that a 10-week Baduanjin exercise regime, consisting of 60-minute two sessions per week, is safe and can lead to significant improvements in HRV among adults with MDD. The findings indicate that Baduanjin, a traditional Chinese exercise known for its gentle movements and meditative components, may assist in rebalancing autonomic dysregulation. The observed changes in HRV parameters, particularly increases in LF/HF ratio, suggested enhanced parasympathetic activity and improved autonomic function.

Given that the study was impacted by the pandemic, future research should utilize larger and more diverse samples and extend the duration of the study with follow-up assessments to better evaluate the long-term benefits of Baduanjin. Additionally, employing medication-free individuals with MDD would provide clearer insights into the specific effects of this exercise regime, thereby enabling more definitive conclusions about its efficacy.

Data Sharing Statement

The data supporting this study's findings are available from the corresponding author upon reasonable request. All personal information was securely stored separately from the other files at the laboratory. No digital information was obtained. Other information that could expose a participant's identity will not be released. The data will be unavailable after 5 years.

Ethics Approval and Informed Consent

This study was registered with the Chinese Clinical Trial Registry (ChiCTR1900027222) and complied with the Declaration of Helsinki. The study received ethical approval from the local research ethics committee (approval number: 2020YJS-003-01) of the Rehabilitation Hospital Affiliated to Fujian University of Traditional Chinese Medicine.

Acknowledgments

The authors would like to express their sincere gratitude to Ms. Duo Ye for her assistance in revising the images and to all participants who contributed to this study.

Funding

High-Level Key Discipline Construction Project in TCM Rehabilitation under the National Administration of Traditional Chinese Medicine (Ref. zyyzdxk-2023102). Application and demonstration of the computing assistant system and cognitive function assessments(Ref. 2024ZD01007). Major project of Fujian Medical and Health Commission.

Disclosure

The authors report no conflicts of interest in this work.

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