Effect of Baduanjin Qigong and transcranial direct current stimulation on quality of sleep and disease impact in elderly patients with fibromyalgia: a randomised, sham-controlled study

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Abstract

Objective

The aim of this randomised double-blinded controlled trial was to investigate the effect of Baduanjin Qigong (BQG) and transcranial direct current stimulation (tDCS) on quality of sleep and disease impact in elderly patients with fibromyalgia (FM).

Methods

A randomised, double-blind, clinical trial conducted, involving 68 elderly female and male patients with FM were selected through convenience sampling, and randomly assigned into one of four intervention groups: (1) BQG combined with the tDCS group (BQGT) (n=17); (2) BQG combined with the sham tDCS group (BQGS) (n=17); (3) walking combined with tDCS (WAT) (n=17); and (4) walking combined with sham tDCS (WAS) (n=17). All participants were assessed at baseline and 12 weeks post-test for disease impact and sleep quality using the Revised FM Impact Questionnaire (FIQR) and the Pittsburgh Sleep Quality Index (PSQI), respectively. Data were analysed using Multivariate Analysis of Variance (MANOVA).

Results

Sleep quality was significantly associated with individual interventions ($F(21, 167) = 2.88$, $p<0.05$, Wilk's $\Lambda=0.411$, partial $\eta^2=0.257$). FIQ scores also showed significant associations ($F(3, 64) = 4.47$, $p< 0.05$, Wilk's $\Lambda=0.210$, partial $\eta^2=0.173$). Treatments significantly affected FIQR ($F(3) = 3.901$, $p<0.05$, partial $\eta^2=0.155$), FIQR symptoms ($F(3) = 4.458$, $p<0.05$, partial $\eta^2 = 0.173$), PSQI total ($F(3) = 6.044$, $p<0.05$, partial $\eta^2 = 0.221$), sleep disturbances ($F(3) = 10.314$, $p<0.05$, partial $\eta^2=0.326$), and sleep dysfunction ($F(3) = 11.487$, $p<0.05$, partial $\eta^2=0.350$). Significant differences were found between WAT and WAS for FIQR ($p=0.016$), and between BQGT and WAS ($p=0.049$), and WAT and WAS ($p=0.009$) for FIQR symptoms. PSQI total showed significant differences between BQGT and BQGS ($p=0.030$), BQGT and WAT ($p=0.039$), and BQGT and WAS ($p=0.000$). Significant differences in sleep disturbances were observed between BQGT and BQGS ($p=0.000$), BQGT and WAT ($p=0.001$), and BQGT and WAS ($p=0.000$). Further differences were found between BQGT and WAS ($p=0.000$), BQGS and WAS ($p=0.004$), and WAT and WAS ($p=0.000$).

Conclusion

This study shows that physical activity interventions, and especially BQG, significantly improve sleep quality and disease symptoms, with notable effects on PSQI scores and FIQR, especially when combined with tDCS across different groups. These findings highlight the importance of combining interventions into holistic brain-body treatments for managing FM effectively.

Key words

Baduanjin Qigong, elderly, fibromyalgia, sleep quality, transcranial direct current stimulation

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Received on November 7, 2024; accepted in revised form on March 24, 2025.

Trial registration: this clinical trial was registered with Iran's Clinical Trial Registration Center (IRCT [IRCT20190908044722N3] on 16 February 2024.

Competing interests: none declared.

Introduction

Fibromyalgia (FM) is a condition characterised by chronic pain and is linked to maladaptive changes in neural central circuits (1). It is identified by a combination of symptoms, most notably widespread chronic pain, chronic fatigue, and sleep disturbances (2). A reduction in the quality of sleep is strongly associated with the intensity of pain, fatigue, depression, and stress symptoms as well as a decline in overall quality of life, particularly in terms of mental well-being. This indicates that managing this condition should involve addressing sleep disturbances through interventions (3). Typical therapeutic methods involve the use of antidepressants, along with specific pain and sleep medications (4). Many of these pharmacological approaches carry significant side effects, and the therapeutic benefits are typically modest and short-lived (5). Patient dissatisfaction with traditional medical treatments for FM may contribute to the widespread use of complementary and alternative therapies in this patient population (6).

In recent years, there has been an increase in interest in mind-body interventions for treating illnesses. In this area, research has increasingly focused on investigating the effectiveness of Baduanjin Qigong (BQG) in managing symptoms of FM (7). In BQG, "Qi" refers to the universe's air, and "Gong" refers to practice and exercise, while Baduanjin is primarily designated as a form of medical qigong, meant to improve health. Simply put, BQG is a system of coordinated body-posture and movement, breathing and meditation (8). As a mind-body intervention, BQG is divided into internal and external practices. Previous research has demonstrated that BQG has significant potential as a complementary treatment for a variety of physical and psychological conditions (4, 9-11). This growing interest is supported by recent reviews highlighting the advancements in non-pharmacological strategies for FM, including exercise programmes and non-invasive brain stimulation techniques (12).

In terms of psychological effects, BQG has been demonstrated to activate the prefrontal lobe (13). The prefrontal cortex is recognised for its involvement in regulating sleep processes (14). These effects of BQG are important in that earlier research has connected brain abnormalities in individuals with FM to hastened brain aging. Specifically, previous research has found that individuals with FM have reduced grey matter volumes in both the left medial prefrontal cortex and the right dorsal posterior cingulate cortex (15). These brain regions have been linked to various cognitive, emotional, and non-emotional aspects of pain processing (15). While the activation of the prefrontal cortex is noted, the specific neural mechanisms by which BQG influences pain perception and sleep regulation in FM remain to be fully elucidated.

Research comparing the effectiveness of BQG with other non-pharmacological interventions could provide deeper insights into its relative benefits for various conditions. However, current studies are employing traditional neuromodulation methods to adjust the excitability of the primary motor cortex (M1) and alleviate chronic pain symptoms (16, 17). Prior research has demonstrated enhanced daily functioning in individuals with FM following transcranial direct current stimulation (tDCS) targeted at the M1 (18). Roizenblatt *et al.* (18) have previously found that stimulating M1 improved sleep efficiency and decreased arousal, while stimulating the dorsal lateral prefrontal cortex (DLPFC) had the opposite effect (19).

With the increase in holistic multi- and inter-disciplinary focus on health and disease management, there has been a recent emphasis on the use of multiple intervention techniques in rehabilitation to produce synergistic or additive effects, leading to quicker, improved and longer-lasting rehabilitation results (20). A typical combination of therapies is the use of the combination brain stimulation and physical exercise to improve brain-body pathways (1).

While the research exploring the impact of combined tDCS and physical exercise are as yet inconclusive, Mendonca *et al.* (1) and Riberto *et al.* (21) have found that by combining exercise with tDCS, a greater improvement was

found in treatment outcomes than using individual treatments. In contrast, Matias *et al*. (22) and Arroyo-Fernández *et al*. (23) have failed to find superior outcomes in their studies when combining tDCS and functional exercises.
However, it may be that an optimal combination of tDCS and exercise. It may be that the optimal diversity of combinations related to exercise design may be elusive at this stage (*i.e.* frequency, intensity, modality, and duration), especially when combined with tDCS (22). Hence, the aim of this randomised controlled trial was to investigate the effect of Baduanjin Qigong (BQG) and transcranial direct current stimulation (tDCS) on quality of sleep and disease impact in elderly patients with FM. The hypothesis developed was that the application of M1 stimulation in combination with BQG, would yield superior results in reducing the impact of the disease while enhancing sleep quality when compared to individual benchmark or *gold standard* interventions of walking and walking combined with tDCS.

Materials and methods

Research design

The study employed was a randomised, single-blind, parallel-group, sham-controlled, clinical trial. Prior to participation in the study, all participants provided written informed consent and were assured that they could withdraw from the research at any stage. The Ethics Committee of Urmia University approved the study (ID IR.URMIA.REC.1402.026). This study was registered as a clinical trial on the Iranian Registry of Clinical Trials (https://irct.behdasht.gov.ir/) (IRCT20190908044722N3) on 16 February 2024. This clinical trial was conducted in accordance with the CONSORT 2010 guidelines to ensure adherence to best practices in reporting and transparency within the study.

Participants

A total of 68 elderly female and male patients with FM were selected through convenience sampling, in strict adherence to the study's inclusion and exclusion criteria. The sample size was initially determined to be 62 participants. This estimate was based on a desired test power of 80% and a confidence interval of 95%, calculated using the following statistical formula:

$$n = \left(\frac{Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}}{d}\right)^2, d = \frac{\mu_1 - \mu_2}{\delta\sqrt{2}}$$

$$Z_{1-\frac{\alpha}{2}} = 1.96, d = 0.5, n = 31, Z_{1-\beta} = 0.84$$

To accommodate the possibility of participants dropping out, the total number of participants was increased to 68.

Eligibility criteria

Men and women aged 60 to 65 years who had been diagnosed with FM by a certified rheumatologist and met the criteria of the American College of Rheumatology for FM diagnosis (2), no prior experience in Baduanjin Qigong, no engagement in regular exercise for at least the past six months as confirmed through self-report, presence of widespread bilateral pain across various body regions within the previous week, self-reported fatigue and post-sleep tiredness within the previous week, and obtaining a sleep quality score higher than six in the Pittsburgh Sleep Quality Index (PSQI).
Exclusionary criteria included metal implants in the head; moderate to severe brain trauma or brain surgery; brain tumour, epilepsy, or stroke; a history of substance use within the last six months; diagnosis of a psychiatric disorder; uncontrolled rheumatologic pathology; as well as coexisting autoimmune pathology or chronic inflammatory disease (23). Patients with diagnosed diabetes, thyroid disorders, neuropathies, or Lyme hepatitis disease or those diagnosed with a psychiatric disorder were excluded from participation in the study.

Patient status, progress and outcomes assessment

The Revised FM Impact Questionnaire (FIQ) was utilised to assess patient status, progress and outcomes as it has been designed to measure the components of health status that are believed to be most affected by FM (24). The FIQ was administered at the start and conclusion of the 12-week treatment period. The FIQ includes 21 questions across three categories, namely: function, impact and symptoms. Each question is rated on an 11-point Likert scale, with 0 indicating no difficulty or problem and 10 indicating extreme difficulty, inability to perform tasks, or severe symptoms (24). This study utilised the Persian version of the Revised FM Impact Questionnaire which has previously demonstrated good reliability with a Cronbach's α of 0.87 (25)

Sleep quality assessment

The Pittsburgh Sleep Quality Index (PSQI) was utilised to at assesses sleep quality over a one-month time interval. The PSQI consists of 19 individual items, creating seven components that produce one global score. The validity and reliability of this questionnaire were previously examined in Iran, demonstrating a high level of internal consistency (α=0.83) and a strong correlation coefficient (0.88) (26).

Procedures

Following a visit to a clinic in Urmia, patients diagnosed with FM were evaluated by an experienced rheumatology specialist, following the criteria outlined by the American College of Rheumatology. The study involved 68 elderly patients who were purposefully selected based on their willingness to participate and met the research criteria. Prior to their involvement, participants received comprehensive information about the research objectives, implementation procedures, and potential side effects. After obtaining informed consent, they were invited for their initial assessment. First, the pre-test evaluation was conducted. To determine the sequence of random grouping for participants in this study, Random Allocation software version 1.0.0 (Freeware for Windows XP/Vista/7/8/10/11) was employed. As a result, the participants were randomly assigned into one of four groups, each consisting of 17 individuals. One of the authors enrolled participants and assigned them to interventions. The 68 participants were randomly divided into one of four groups: 1) BQG combined with the tDCS group (BQGT), 2) BQG combined with the

Table I. Baseline characteristics of fibromyalgia patients.

Characteristics	BQG combined with the tDCS group (BQGT) (n=17)	BQG combined with the sham tDCS group (BQGS) (n=17)	Walking combined with tDCS group (WAT) (n=17)	Walking combined with sham tDCS group (WAS) (n=17)
Gender (male/female)	1/16	0/17	2/15	2/15
Marital status (married/single)	17/0	14/13	11/6	17/0
Age (years)	67.12 ± 1.79	65.65 ± 0.70	67.88 ±3.83	65.71 ±3.05
Weight (kg)	64.12 ± 7.809	72.18 ± 11.57	84.82 ±15.26	76.94 ±7.53
Height (m)	160.06 ± 1.74	158.59 ± 1.97	175.47 ±5.24	162.00 ±2.69
Time since diagnosis (months)	15.23 ± 5.65	10.70 ± 4.72	16.23 ±4.43	12.58 ±4.87
FIQR	40.34 ± 25.46	42.46 ± 21.35	32.00 ±17.06	50.13 ±23.75
FIQR function	11.01 ± 6.52	12.90 ± 6.70	10.27 ±5.42	12.72 ±6.58
FIQR overall status	10.47 ± 11.20	7.23 ± 5.81	5.88 ±6.06	13.00 ±12.94
FIQR symptoms	18.85 ± 11.49	22.32 ± 11.56	15.85 ±7.24	24.41 ±11.65
PSQI total	9.94 ± 2.70	11.88 ± 3.87	11.52 ±2.50	13.82 ±5.05

Data are presented as mean ± SD.
BQG: Baduanjin Qigong; tDCS: direct transcranial electrical stimulation; kg: kilograms; m: meters; PSQI: Pittsburgh Sleep Quality Index; FIQR: Revised Fibromyalgia Impact Questionnaire.

sham tDCS group (BQGS), 3) walking combined with tDCS (WAT), and 4) walking combined with sham tDCS (WAS). After the 12-week interventions, a post-test was conducted. All assessments were performed by one of the authors who were unaware of the patients' grouping. The trial took place from November 2023 to March 2024 under the supervision of an experienced exercise professional and medical doctor.

Interventions

All interventions were performed under supervision at the same venue for one hour thrice weekly for 12 weeks.

Baduanjin Qigong (BQG) combined with the direct transcranial electrical stimulation (tDCS) group (BQGT)

- *BQG portion*. Participants in the BQGT performed BQG exercises combined with tDCS for one hour, three times weekly for 12 weeks in line with the protocol previously described in Xiao and Zhuang (27). Patients performed BQG exercises under the supervision of a qualified trainer.
- *tDCS portion*. In this study, a two-channel electrical brain stimulation device (Neurostim 2, Medinateb, Iran) was used for tDCS. The current source of this device is a 4.8-volt battery, with dimensions of 15.5x5.9x 5 centimeters and a weight of 0.35 kilograms (kg). The maximum current intensity utilized was mA DC. To prevent a sudden onset or stop of stimulation in the first and the last 10 seconds, while using tDCS, the stimulation was gradually ramped up or down. The anode electrode (16cm^2) was placed on the (M1) of the motor and premotor areas (area 10-20% of Cz point in left hemispheres based on the 10-20 system) and was tied by a stretch on the head, and the cathode electrode (24cm^2) was placed in the centre of the forehead to prevent the direct lateral current (28). During both the real and sham tDCS treatments, an expert with a license to use the brain stimulation device closely monitored the entire process. In the BQGT intervention, tDCS was performed during the first 20 minutes of BQG exercises.

Baduanjin Qigong (BQG) combined with the sham direct transcranial electrical stimulation (tDCS) group (BQGS)

- *BQG portion*. Participants in the BQGS performed BQG exercises consistent with those of the BQGT.
- *Sham tDCS portion*. In the sham tDCS condition, setup was consistent with that of the BQGT. However, as part of the sham condition, current was initially increased to 2 mA at 30s and immediately decreased to 0 mA to avoid actual stimulation of the target area.

Walking combined with direct transcranial electrical stimulation (tDCS) tDCS group (WAT)

- *Walking portion*. The WAT underwent walking training at an intensity of 50-70% of maximum heart rate (HR_{max}). Exercise intensity was monitored continuously as heart rate (HR) using telemetry (Polar Accurex Plus Monitor, Polar Electro Oy, FIN-90440 Kempele, Finland) to ensure workload and the achievement of target heart rate.
- *tDCS portion*. In the tDCS condition, setup was consistent with that of the BQGT and was applied during the first 20 minutes of the walking.

Walking combined with sham direct transcranial electrical stimulation (tDCS) group (WAS)

- *Walking portion*. The WAS participants underwent walking training consistent with that of the WAT.
- *Sham tDCS portion*. In the sham tDCS condition, setup was consistent with that of the WAT. However, as part of the sham condition, current was initially increased to 2 mA at 30 s and immediately decreased to 0 mA to avoid actual stimulation of the target area.

Statistical analysis

Data were analysed using SPSS v. 20.0 software (SPSS Inc., Chicago, IL, USA). We performed a Shapiro-Wilk test to check the normality of the continuous variables. For data with a normal distribution, one-way analysis of variance (ANOVA) was used to compare baseline characteristics, and the analysis of one-way multivariate (MANOVA) was used to compare post-intervention changes across the four groups. Prior to running MANOVA, it was ascertained whether data fulfil the assumptions of applications. The assumption of normality of data was tested using Shapiro-Wilk test. Since the data was accomplishing the key assumptions, the test was run at alpha level of 0.05. Relationship between dependent and independent variables were inferred from Wilk's Lambda and Roy's Largest Root scores. LSD *post-*

Table II. Effect of Baduanjin Qigong (BQG) and transcranial direct current stimulation (tDCS) on quality of sleep and disease impact in elderly patients with fibromyalgia.

	BQG combined with the tDCS group (BQGT) (n=17)		BQG combined with the sham tDCS group (BQGS) (n=17)		Walking combined with tDCS group (WAT) (n=17)		Walking combined with sham tDCS group (WAS) (n=17)	
	Pre-test	Post-test	Pre-test	Post-test	Pre-test	Post-test	Pre-test	Post-test
FIQR	40.34±25.46	31.08±19.76	42.46±21.35	38.72±19.48	32.00±17.06	28.07±15.71	50.13±23.75	49.42±23.68
FIQR function	11.01±6.52	9.47±5.35	12.90±6.70	12.19±6.18	10.27±5.42	9.84±5.49	12.72±6.58	12.80± 6.76
FIQR overall	10.47±11.20	6.52±6.09	7.23±5.81	6.64±5.03	5.88±6.06	5.17±5.39	13.00±12.94	12.35±13.47
FIQR symptoms	18.85±11.49	15.08±9.30	22.32±11.56	19.88±11.00	15.85±7.24	13.05±7.08	24.41±11.65	24.26±11.26
PSQI total	9.94±2.70	7.35±3.29	11.88±3.87	10.64±3.58	11.52±2.50	9.58±2.52	13.82±5.05	11.64±2.82
Subjective sleep quality	1.94±0.74	1.47±0.79	2.05±0.65	1.88±0.78	1.76±.56	1.58±0.61	1.82±.72	1.88±0.69
Sleep latency	2.11±0.99	1.52±1.06	2.11±0.78	1.82±0.88	2.05±.96	1.64±0.99	1.76±1.03	1.82±1.01
Sleep duration	1.88±0.99	1.64±1.05	2.17±1.33	2.11±1.31	2.17±0.80	2.00±0.70	1.76±0.66	1.88±0.69
Sleep efficacy	1.11±0.78	0.70±0.91	1.29±1.21	1.23±1.14	1.29±1.04	1.01±0.92	1.11±1.05	1.11±0.92
Sleep disturbances	1.41±0.61	0.82±0.52	1.82±0.63	1.76±0.56	1.94±0.55	1.52±0.71	1.76±0.56	1.82±0.52
Sleep medication	1.05±1.47	1.05±1.47	1.05±1.39	1.05±1.39	1.29±1.44	1.29±1.44	1.58±1.46	1.58±1.37
Daytime dysfunction	0.41±0.61	0.11±0.33	1.29±1.04	0.76±0.90	1.00±1.06	0.41±0.71	1.70±0.84	1.52±0.87

Data are presented as mean ± SD.
BQG: Baduanjin Qigong; tDCS: direct transcranial electrical stimulation; kg: kilograms; m: meters; MMSE: mini mental state examination; PSQI: Pittsburgh Sleep Quality Index; FIQR: Revised Fibromyalgia Impact Questionnaire.

hoc test was applied for multiple comparisons between variables.

Results

Study population

The baseline characteristics of the study participants are presented in Table I. Table II presents the pre- and post-test data of the effect of BQG or walking and tDCS on quality of sleep and disease impact in elderly patients with FM.

Using Wilk's Lambda and Roy's Largest Root scores, results of this study indicate that quality of sleep was significantly ($p \leq 0.05$) associated with the individual interventions ($F(21, 167)=2.88$ $p<0.05$, Wilk's $\Lambda=0.411$; partial $\eta 2=0.257$). In addition, FIQ scores were also significantly associated with the individual interventions ($F(3, 64) =4.47$ $p<0.05$, Wilk's $\Lambda=0.210$; partial $\eta 2=0.173$).

Results of the study show that the individual treatments had a significant effect on FIQR ($F(3) =3.901$, $p<0.05$; partial $\eta 2 =0.155$), FIQR symptom ($F(3) =4.458$, $p<0.05$; partial $\eta 2=0.173$), PSQI total ($F(3) =6.044$, $p<0.05$; partial $\eta 2 = 0.221$), sleep disturbances ($F(3) =10.314$, $p<0.05$; partial $\eta 2=0.326$ and sleep dysfunction ($F(3)=11.487$, $p<0.05$; partial $\eta 2=0.350$) (Table III). Conversely, no significant ($p>0.05$) effects were found for FIQR overall, FIQR function, subjective sleep quality, sleep latency, sleep duration, sleep efficacy and sleep medication (Table III). The *post-hoc* testing results for multiple comparisons between groups revealed significant differences in disease impact and sleep quality. Specifically, significant differences were observed between WAT and WAS for FIQR ($p=0.016$) (Table IV). Additionally, differences were found between BQGT and WAS ($p=0.049$), and WAT and WAS ($p=0.009$) for FIQR symptoms. For the PSQI total, significant differences were found between BQGT and BQGS ($p=0.030$), BQGT and WAT ($p=0.039$), and BQGT and WAS ($p=0.000$). Regarding sleep disturbances, significant differences were also observed between BQGT and BQGS ($p=0.000$), BQGT and WAT ($p=0.001$),

Table III. Individual treatments effects on quality of sleep and disease impact in elderly patients with fibromyalgia.

Dependent variable	Type III sum of squares	Degrees of freedom	Mean square	F	Significance	Partial eta squared
FIQR	4618.871	3	1539.624	3.901	0.013*	0.155
FIQR function	141.739	3	47.246	1.323	0.275	0.058
FIQR overall	518.412	3	172.804	2.529	0.065	0.106
FIQR symptom	1286.250	3	428.750	4.458	0.007*	0.173
PSQI total	172.750	3	57.583	6.044	0.001*	0.221
Subjective sleep quality	2.235	3	0.745	1.407	0.249	0.062
Sleep latency	1.059	3	0.353	0.358	0.783	0.017
Sleep duration	2.059	3	0.686	0.715	0.547	0.032
Sleep efficacy	2.750	3	0.917	0.944	0.425	0.042
Sleep disturbances	10.750	3	3.583	10.314	0.001*	0.326
Sleep medication	3.221	3	1.074	0.530	0.663	0.024
Sleep medication	3.221	3	1.074	0.530	0.663	0.024
Daytime dysfunction	18.941	3	6.314	11.487	0.001*	0.350

FIQR: Revised Fibromyalgia Impact Questionnaire; PSQI: Pittsburgh Sleep Quality Index.
*Statistically significant at $p \leq 0.05$.

Table IV. Multiple comparisons between groups and the variables of impact of disease and sleep quality.

Variable	Group I	Group J	Mean Difference (I-J)	Std. Error	*p*	95% confidence interval	
						Lower bound	Upper bound
FIQR	BQGT	BQGS	-7.637	6.814	1.000	-26.190	10.916
		WAT	3.010	6.814	1.000	-15.543	21.563
		WAS	-18.333	6.814	0.055	-36.886	0.219
	BQGS	WAT	10.647	6.814	0.739	-7.906	29.200
		WAS	-10.696	6.814	0.728	-29.24	7.857
	WAT	WAS	-21.343	6.814	0.016*	-39.896	-2.790
FIQR symptoms	BQGT	BQGS	-4.794	3.364	0.954	-13.953	4.365
		WAT	2.029	3.364	1.000	-7.129	11.188
		WAS	-9.176	3.364	0.049*	-18.335	-0.018
	BQGS	WAT	6.824	3.364	0.280	-2.335	15.982
		WAS	-4.382	3.364	1.000	-13.541	4.776
	WAT	WAS	-11.206	3.364	0.009*	-20.365	-2.047
PSQI total	BQGT	BQGS	-3.294	1.059	0.003*	-5.409	-1.179
		WAT	-2.235	1.059	0.039*	-4.350	-0.120
		WAS	-4.294	1.059	0.000*	-6.409	-2.179
	BQGS	WAT	1.059	1.059	0.321	-1.056	3.174
		WAS	-1.000	1.059	0.348	-3.115	1.115
	WAT	WAS	-2.059	1.059	0.056	-4.174	0.056
Sleep disturbances	BQGT	BQGS	-0.941	0.202	0.000*	-1.345	-0.537
		WAT	-0.706	0.202	0.001*	-1.110	-0.302
		WAS	-1.000	0.202	0.000*	-1.404	-0.596
	BQGS	WAT	0.235	0.202	0.249	-0.169	0.639
		WAS	-0.059	0.202	0.772	-0.463	0.345
	WAT	WAS	-0.294	0.202	0.151	-0.698	0.110
Daytime dysfunction	BQGT	BQGS	-0.647	0.254	0.013	-1.155	-0.139
		WAT	-0.294	0.254	0.252	-0.802	0.214
		WAS	-1.412	0.254	0.000*	-1.920	-0.904
	BQGS	WAT	0.353	0.254	0.170	-0.155	0.861
		WAS	-0.765	0.254	0.004*	-1.273	-0.257
	WAT	WAS	-1.118	0.254	0.000*	-1.626	-0.610

FIQR: Revised Fibromyalgia Impact Questionnaire; PSQI: Pittsburgh Sleep Quality Index; BQGT: BQG combined with the tDCS group; BQGS: BQG combined with the sham tDCS group; WAT: walking combined with tDCS group; WAS: walking combined with sham tDCS group.
*Statistically significant at $p \leq 0.05$.

and BQGT and WAS (p=0.000). Further significant differences were found between BQGT and WAS (p=0.000), BQGS and WAS (p=0.004), and WAT and WAS (p=0.000).

Discussion

The main hypothesis of this study was that the joint application of M1 stimulation when combined with physical activity interventions, and especially the mind-body intervention of BQG, may yield superior results in enhancing sleep quality and reducing the impact of the disease compared to individual BQG and walking interventions. In this regard, the findings of this study indicate that individual interventions have a significant impact on both sleep quality and disease symptoms. Notably, sleep quality (PSQI total, sleep disturbances, and sleep dysfunction) and FIQ scores were significantly associated with the treatments administered. The combined interventions demonstrated marked effects on FIQR, with the concurrent BQG and tDCS treatment proving superior to the individual treatments and to the concurrent walking and tDCS treatment.

The results of this study suggest that the mind-body exercise of BQG in combination with tDCS as a holistic brain-body treatment improves sleep quality in patients with FM. While prior research integrating physical activity with tDCS in patients with FM have yielded conflicting results (1, 21, 22), our results are in line with those of Mendonca *et al*. (1) and Riberto *et al*. (21). Further, our findings add to the body of knowledge that BQG has a positive impact on sleep (29, 30). This is because BQG focuses on harmonising the body, mind, and spirit, promoting better respiratory function through relaxation and fostering consistent and deep breathing. Additionally, BQG aids in regulating the functioning of all internal organs through controlled movements of the hands and legs, thereby promoting a balance between qi energy and alleviating tension in the body (31, 32). On the other hand, tDCS applied to the primary motor cortex or M1 can modulate neural activity. This is because the thalamus plays a crucial role in regulating sensory information, including pain perception and sleep-wake cycles. Thalamic reticular neurons release gamma-aminobutyric acid (GABA), an inhibitory neurotransmitter that affects thalamocortical communication (33). Dysfunctional thalamic activity may impact both sleep quality (33) and pain perception (34). While tDCS primarily targets cortical areas, its effects can indirectly influence subcortical structures like the thalamus (35). This aligns with broader evidence supporting the role of non-pharmacological interventions, particularly exercise, in managing FM. For example, Lucini *et al*. in their clinical practice guide, emphasised the importance of tailored exercise programmes in mitigating the core pathophysiological mechanisms of FM and improving associated conditions like stress and obesity (36), highlighting the potential of physical activity as a pivotal component in a patient-centred approach to FM management.

In this clinical trial, the WAT and BQGT group both demonstrated lower FIQR scores compared to both the BQG sham and walking sham interventions. The observed improvement in health status and reduction in FM symptoms following the concurrent interventions is not unexpected in that recent research demonstrates tDCS's impact on primary symptoms in individuals with FM. Specifically, applying tDCS to the motor cortex has been associated with decreased pain levels in the short and medium term for FM patients (37). The pain-relieving effects of tDCS are multifaceted and is achieved by increasing cortical excitability, modulating neurotransmitter levels, and influencing neural connections across various brain regions, tDCS may alleviate pain perception. Notably, these changes primarily occur in the M1 and its associated areas (18). Ultimately, reducing pain can significantly mitigate the overall impact of the disease. However, what is particularly noteworthy is that the concurrent training which combined either walking or BQG with tDCS demonstrated an additive effect of the two combined interventions. Most notably, the study found that the use of the mind-body BQG was superior to the use of the benchmark walking intervention. The enhanced symptom improvements observed following the concurrent BQG with tDCS treatment when compared to the concurrent walking and tDCS treatment may be mediated by several underlying mechanisms related to BQG exercise. While the mechanisms by which BQG may improve FM symptomology are unclear, one possible mechanism is the enhanced immune state regulation through BQG, involving factors like C-reactive protein (CRP) and interleukin-6 (IL-6) (38). Additionally, BQG may influence hormonal stress levels, optimise the hypothalamic-pituitary-adrenal axis (HPA) axis and modulate autonomic nervous system activity (39, 40). An optimised autonomic nervous system can reduce proinflammatory cytokine production, potentially leading to decreased pain levels. Stimulating the M1 can also lead to pain relief by modulating sensory aspects of pain perception (41). In FM, pain is often associated with abnormal information processing, characterised by a deficiency in inhibitory control over somatosensory processing (42). The synergistic effects of BQG and tDCS may enhance symptom relief through complementary neural mechanisms. These findings are further supported by Giorgi *et al*. who highlighted that mind-body and strengthening exercises are particularly effective in reducing fatigue, one of the most common and debilitating symptoms in FM (43).

The findings from the present clinical trial indicating a significant difference in the reduction of FM symptoms between the two groups BQGT and BQGS is unique in that it contradicts previous research that failed to find any additional effects of tDCS when combined with exercise on disease impact in patients with FM (22, 23). In this study both the benchmark walking and novel mind-body BQG interventions improved FM symptoms when combined with tDCS. What is particularly noteworthy is that BQG demonstrated improved efficacy when combined with tDCS. As such, it appears that the synergistic effect of tDCS and exercise appears to be influenced by the specific modality of exercise employed.

Limitations

This study, despite its significant findings, presents several limitations. In this regard, the sample size of 68 participants is relatively small, which may limit the generalisability of the results to the broader population of patients with FM. The convenience sampling method used for participant selection could introduce selection bias, potentially affecting the representativeness of the sample. Additionally, the study was conducted with a specific demographic group, elderly individuals, which may not make the findings applicable to younger populations or those with different demographic characteristics. The reliance on self-reported measures such as the FIQR and PSQI could also introduce response bias, as participants' perceptions of their symptoms and sleep quality may be influenced by various external factors.

Conclusions and clinical implications

In this randomised double-blinded clinical sham-controlled trial, we investigated the combined impact of Baduanjin Qigong (BQG) and transcranial direct current stimulation (tDCS) on disease impact and sleep quality in elderly patients with FM. Our results showed that by combining BQG with tDCS, healthcare professionals and clinics can enhance treatment outcomes for FM. Further, the findings of this clinical trial support the inclusion of non-pharmaceutical interventions like BQG with tDCS to holistically improve patient outcomes and reduce healthcare costs.

Acknowledgements

We thank the patients who participated in this study.

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