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Impact of Medical Qigong on quality of life, fatigue, mood and inflammation in cancer patients: a randomized controlled trial

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Background: Substantial numbers of cancer patients use complementary medicine therapies, even without a supportive evidence base. This study aimed to evaluate in a randomized controlled trial, the use of Medical Qigong (MQ) compared with usual care to improve the quality of life (QOL) of cancer patients.

Patients and methods: One hundred and sixty-two patients with a range of cancers were recruited. QOL and fatigue were measured by Functional Assessment of Cancer Therapy—General and Functional Assessment of Cancer Therapy—Fatigue, respectively, and mood status by Profile of Mood State. The inflammatory marker serum C-reactive protein (CRP) was monitored serially.

Results: Regression analysis indicated that the MQ group significantly improved overall QOL ($t_{144} = -5.761$, $P < 0.001$), fatigue ($t_{153} = -5.621$, $P < 0.001$), mood disturbance ($t_{122} = 2.346$, $P = 0.021$) and inflammation (CRP) ($t_{99} = 2.042$, $P < 0.044$) compared with usual care after controlling for baseline variables.

Conclusions: This study indicates that MQ can improve cancer patients' overall QOL and mood status and reduce specific side-effects of treatment. It may also produce physical benefits in the long term through reduced inflammation.

Key words: cancer, fatigue, inflammation, mood, quality of life

introduction

Over the past 50 years, the prognosis associated with a diagnosis of cancer has markedly improved due to developments in multidisciplinary care [1]. Nonetheless, cancer is a profoundly stressful disease, posing both physical and psychological threats to the patient. The emotional distress of a diagnosis of cancer and the persistent side-effects of treatment significantly compromise patients' quality of life (QOL) [2, 3].

A desire for more 'holistic' care [4] has led individuals diagnosed with cancer to seek out supportive and complementary medicine (CM) therapies to serve as adjuncts to standard medical care. For example, in Australia, 52% of cancer patients report having used CM [5], while in the United States, figures of up to 83% have been reported [6]. Despite the high rate of CM use in cancer patient populations, there is little available evidence from randomized trials to inform health professionals and patients in regard to the safety and efficacy of many CM therapies.

One CM therapy that is frequently used by cancer patients, but is yet to be thoroughly evaluated, is Medical Qigong (MQ). Qigong, a mind–body practice first developed over 5000 years ago, is an important part of traditional Chinese medicine [7]. MQ is a mind–body practice that uses physical activity and meditation to harmonize the body, mind and spirit. It is on the basis of the theory that discomfort, pain and sickness are a result of blockage or stagnation of energy flow in the energy channel in the human body. According to this theory, if there is a free flow and balance of energy, health can be improved and/or maintained and disease can be prevented [8]. Within western medicine, MQ can be understood within the mind–body medicine model, developed after the scientific discovery of the 'relaxation response' [9] and the development of the theory of psychoneuroimmunology [10]. Within this model, the efficacy of MQ is seen as having its source in an integrated hypothalamic response, resulting in homeostasis of the sympathetic and parasympathetic nervous systems. This in turn causes reduced emotional and physical tension and improved immune function.

Several studies have indicated that MQ has many health benefits, such as decreased heart rate [11], decreased blood pressure [12], lowered lipid levels [13], decreased levels of

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circulating stress hormones [14] and enhanced immune function [15, 16]. Within the cancer literature, several uncontrolled studies have indicated that MQ may also have an impact on survival [8]. A review of the literature conducted by Chen et al. [8] indicated that MQ interventions can improve physical well-being (PWB) and psychological well-being in cancer populations and are cost effective because they can be run as group therapy. Unfortunately, most research evaluating Qigong has suffered from a lack of appropriate randomization and utilization of control groups. Studies have also tended to focus on limited numbers of biological and physical outcomes. To address this paucity of data in the literature, a small pilot study was conducted in 2007 to determine the effect of MQ on PWB and psychological well-being of cancer patients [17]. Using a randomized controlled design, we showed that MQ could improve the QOL of cancer patients; however, due to a small sample size more robust conclusions could not be drawn [17].

These encouraging preliminary data led us to conduct a larger randomized controlled trial of Qigong. The primary hypothesis of this study was that the MQ group would experience significant improvements in QOL compared with the control group. On the basis of the mind–body model, it was expected that the MQ group would also show greater reduction in fatigue and mood and decreased levels of inflammation by 10 weeks of follow-up. Inflammation was included as a marker of impact on the cancer itself. Several studies have indicated that chronic inflammation is associated with cancer incidence, progression and even survival [4–6].

patients and methods

The study population consisted of 162 adult patients diagnosed with cancer recruited from three large, university teaching hospitals. Patients who had a confirmed diagnosis of malignancy of any stage, were aged ≥18 years and had an expected survival length of >12 months were eligible for the trial. Patients were excluded from the study if they had a diagnosis of a major medical or psychiatric disorder (other than cancer), had a history of epilepsy, brain metastasis, delirium or dementia, had medical contraindications for exercise (e.g. significant orthopedic problem or cardiovascular disease) or were already practicing Qigong.

Figure 1 shows the flow of participants through the trial. In the first phase of recruitment, from July 2006 to August 2007, trained recruiters approached cancer patients, whose oncologists identified them to be eligible, in the patient waiting room at the Medical Oncology Department of the participating hospitals. Eighty-one participants were recruited. In the second phase of recruitment from August 2007 to May 2008, those patients considered by their medical oncologist to be eligible received an invitation letter from their medical oncologist through the post. Another 81 participants were recruited. In both phases of recruitment, interested patients were invited to attend an information session about the study at which patients were further screened for exclusion criteria. After giving written consent, patients completed the baseline QOL measure and gave blood and were randomly assigned into the intervention and control groups. During the study, a total of nine MQ programs were offered at three hospitals. The number of participants in each group varied from 7 to 20 depending on the number recruited at each phase. Randomization, by computer, was stratified by treatment at baseline (currently undergoing or completed cancer treatment). Blinding the participants to the allocation was not possible due to the nature of intervention. The study received ethics approval from the University of Sydney and the participating hospitals.

outcome measurement

QOL, fatigue, mood, and an inflammatory biomarker [C-reactive protein (CRP)] were measured at baseline preintervention and at 10 weeks postintervention. The primary outcome of QOL was measured with the Functional Assessment of Cancer Therapy—General (FACT-G) [18]. This well-validated and widely used measure is a 27-item patient self-reported instrument designed to measure multidimensional QOL in 'heterogeneous' cancer patients. The FACT-G consists of four subscales assessing PWB, emotional well-being (EWB), social well-being (SWB), and functional well-being (FWB) with higher scores reflecting better QOL. Cancer-related fatigue (CRF) was assessed by the Functional Assessment of Cancer Therapy—Fatigue (FACT-F) subscale. High scores on this 13-item scale reflect greater fatigue [19]. Mood was measured by the total score of the Profile of Mood State [20], which has six subscales with high scores reflecting more negative mood states. Inflammation was assessed by the serum CRP. This is recognized as a primary marker of inflammation and has been found in several studies to be an independent predictor of cancer prognosis [7, 8]. CRP measurement was determined in the Biochemistry Department of participating hospitals by particle-enhanced immunological agglutination using a Roche (Roche Diagnostics GmbH, Mannheim, Germany)/Hitachi analyzer (Hitachi High-Technologies Corporation, Tokyo, Japan).

intervention

Patients assigned to the intervention group received usual medical care and were invited to attend an MQ (group therapy) program, held in the hospital where they were treated. The MQ program was run for 10 weeks with two supervised 90-min sessions per week. Participants were also encouraged to undertake home practice every day for at least half an hour.

The MQ intervention program was a modified traditional Qigong program, developed and delivered by the first author (BO), an experienced MQ instructor. The instructor is a Chinese medicine practitioner with >20 years experience of Qigong who trained in traditional Qigong in Korea, Daoist Qigong in China and Buddhist Qigong in Australia and has received clinical training in mind–body medicine at the Harvard Medical School. The program was modified from traditional Qigong practice by the instructor to specifically target the needs of cancer patients to control emotions and stress as well as to improve physical function. Each session consisted of 15-min discussion of health issues, 30-min gentle stretching and body movement in standing postures to stimulate the body along the energy channels, 15-min movement in seated posture (Dao Yin exercise for face, head, neck, shoulders, waist, lower back, legs, and feet), 30-min meditation including breathing exercises on the basis of energy channel theory in Chinese medicine, including natural breathing, chest breathing, abdominal breathing, breathing for energy regulation, and relaxation and feeling the Qi (nature's/cosmic energy) and visualization.

To assess home practice, a diary was given to the participants to complete and return at the end of the 10-week program. Participants were advised to report or discuss any adverse effects with the MQ instructor, however none were reported.

Participants assigned to the control group received usual care and completed all outcome measures in the same time frame as the intervention group. Usual care comprised appropriate medical intervention, without the offer of additional CM. Participants were advised to undertake normal activities but were asked to refrain from joining an outside Qigong class. As the intervention was offered to these participants after the last outcome measurement, no patient joined an outside class.

statistical power and analyses

A total of 64 patients per arm were required to detect a clinically important difference [0.5 standard deviation (SD) effect size] between the intervention and control groups on the primary outcome measure of FACT-G, with 80%

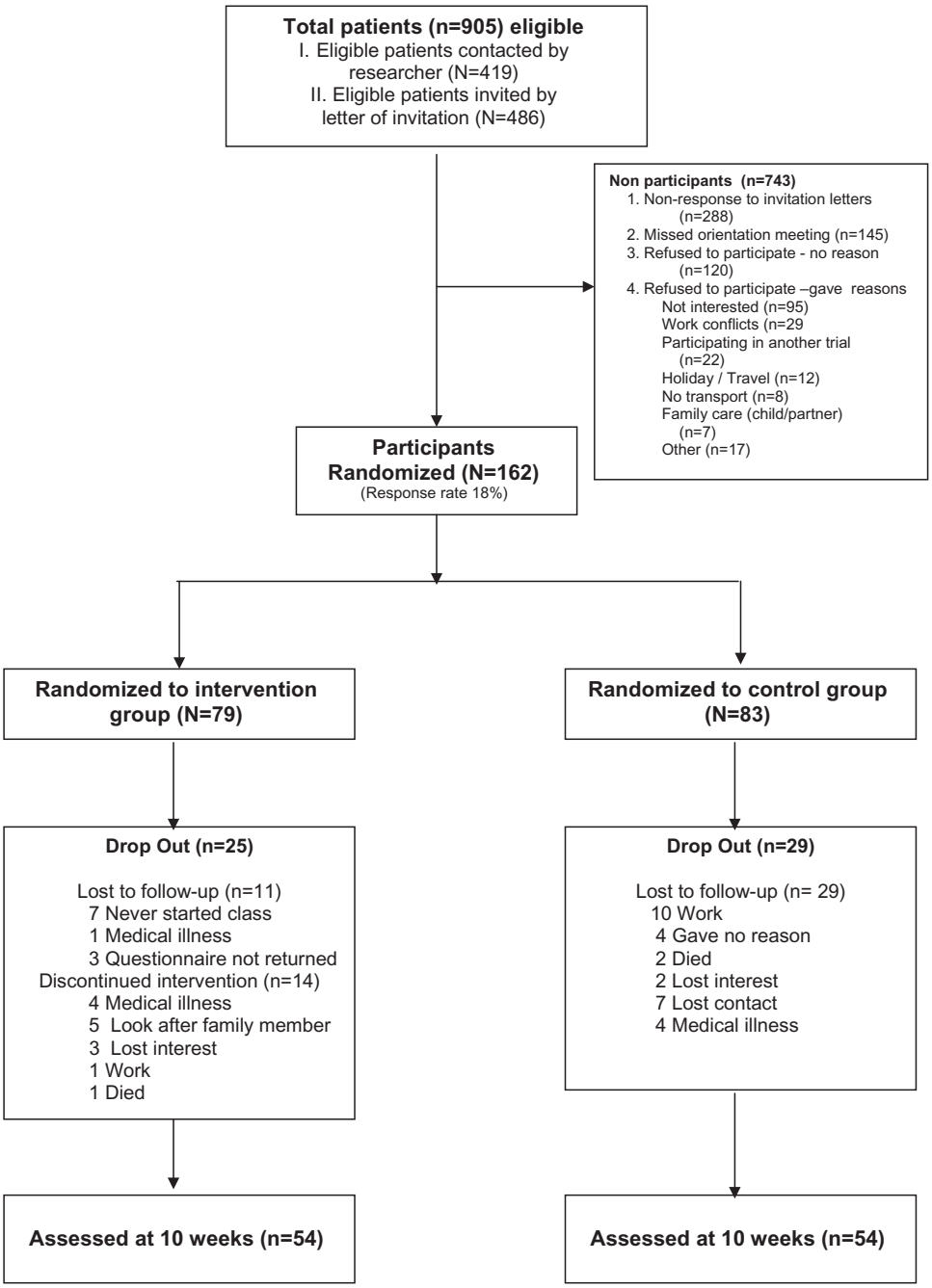

Figure 1. Consort diagram of patients flow in this trial.

power, a type I error rate of 5% (two sided) and an (SD) of 15. To allow for dropouts (30%) and within-site clustering (intra-cluster correlation coefficient 0.03, design effect 1.10), 84 patients were required in each treatment group.

Data analyses were conducted using SPSS 15 and STATA 10.0. Descriptive statistics (frequency, mean, and SD) were used to describe and summarize baseline data. Chi-square tests and Mann–Whitney tests were carried out to investigate differences between the control and intervention groups, and completers and dropouts. To conduct an intention-to-treat analysis, missing data were dealt with by multiple imputations adjusted for gender, age, status of cancer treatment (completed anticancer treatment or undergoing anticancer treatment), week 0 baseline scores and intervention status. After multiple imputations, linear regression analyses were conducted to examine between-group differences in the outcome variables of QOL, fatigue, side-effects of treatment and symptoms, mood status and inflammation biomarker (CRP) at week 10 after controlling for the corresponding baseline variables.

results

A total of 162 adult patients participated in the study. Baseline characteristics (Table 1) were well balanced between intervention and control groups. The mean age of participants in this study was 60 years at baseline (SD = 12 years) ranging from 31 to 86 years. The most common primary cancer diagnosis among participants

Table 1. Demographic characteristics of participants at baseline

	Intervention ($n = 79$)	Control ($n = 83$)	Test statistic	*df*	*P* value
Mean age (SD)	60.1 (11.7)	59.9 (11.3)	$t = 0.210$	159	0.834
Gender, *n* (%)			$\chi^2 = 0.314$	1	0.575
Female	48 (60.8)	45 (54.2)			
Male	31 (39.2)	38 (45.8)			
Martial status, *n* (%)			$\chi^2 = 0.016$	1	1.000
Currently married or *de facto* relationship	54 (70.1)	54 (71.1)			
Never married	8 (10.4)	7 (9.2)			
Separated/divorced	8 (10.4)	11 (14.5)			
Widowed	7 (9.1)	4 (5.3)			
Ethnicity, *n* (%)			$\chi^2 = 2.850$	1	0.108
Caucasian	57 (77.0)	49 (64.5)			
Asian	10 (13.5)	17 (22.4)			
Indigenous Australian	1 (1.4)	1 (1.3)			
Other	6 (8.1)	9 (11.8)			
Educational level, *n* (%)			$\chi^2 = 0.792$	2	0.420
Primary	1 (1.3)	7 (9.2)			
Secondary	35 (45.5)	34 (44.7)			
Undergraduate	19 (24.7)	19 (25.0)			
Postgraduate	22 (28.6)	16 (21.1)			
Primary cancer diagnosis, *n* (%)			$\chi^2 = 0.702$	1	0.473
Breast cancer	26 (37.7)	21 (30.9)			
Lung cancer	6 (8.7)	3 (4.4)			
Prostate cancer	6 (8.7)	4 (5.9)			
Colorectal cancer/bowel cancer	8 (11.6)	8 (11.8)			
Other	23 (33.3)	32 (47.1)			
Completion of cancer treatment, *n* (%)			$\chi^2 = 0.030$	1	0.861
Completed	40 (52.6)	40 (54.1)			
In progress	36 (47.4)	34 (45.9)			

n values vary due to missing data. $n < 10$ collapsed for χ^2 test.
SD, standard deviation.

was breast cancer (34%) followed by colorectal cancer (12%). There were no significant differences in measurements of QOL, fatigue, mood status and inflammation biomarkers between intervention and control groups at baseline (Table 2).

Dropout was relatively high but equivalent between the groups (32% in the intervention arm and 35% in the control). There were no significant differences between completers and dropouts on demographic or disease characteristics. Completers attended on average 8 of the 10 scheduled sessions. Only 50% of participants kept the home diary and returned it at the end of the program, making the calculation of home compliance difficult. Missing data were uncommon in outcome measures.

Within- and between-group changes in QOL, fatigue, mood and inflammation are summarized in Table 3.

Participants in the MQ group reported larger improvements in QOL than those in the usual care group at 10-week follow-up when controlling for baseline scores ($t_{144} = -5.761$, $P < 0.001$). QOL subdomain analyses also showed that changes in scores were significantly larger for all subdomains of QOL [PWB ($t_{152} = -3.720$, $P < 0.001$), SWB ($t_{148} = -4.663$, $P < 0.001$), EWB ($t_{150} = -3.677$, $P < 0.001$) and FWB ($t_{151} = -4.467$, $P < 0.001$)] in the intervention compared with the control group.

Participants in the MQ group had significantly larger improvements in scores on fatigue ($t_{153} = -5.621$, $P < 0.001$) measured by the FACT-F than those in the control group at 10 weeks. Participants in the MQ intervention had a greater reduction in mood disturbance than those in the control group overall ($t_{122} = 2.346$, $P = 0.021$) and on four subscales: tension and anxiety, depression, lack of vigor and fatigue. However, there were no differences between intervention and control groups on the remaining two subscales: anger and hostility, and confusion. Finally, participants in the MQ group had significant differences in the level of the inflammation biomarker (CRP) ($t_{99} = 2.042$, $P = 0.044$) than the control group at week 10.

discussion

To our knowledge, our study is the first randomized controlled trial with adequate statistical power which has been used to measure the impact of MQ in patients with cancer. The findings provide evidence for the impact of MQ on QOL, fatigue, mood status and inflammation in patients with cancer, major issues for cancer patients.

Our major findings were that scores on total QOL and all domains (PWB, SWB/family well-being, EWB and FWB)

Table 2. Baseline outcome measurement of participants

Variables	Mean (SD)		Test statistic	*df*	*P* value
	Intervention	Control			
QOL measured by FACT-G[a]					
Physical well-being	20.24 (5.48)	20.63 (5.49)	−0.439	157	0.661
Social well-being	23.41 (6.47)	23.63 (7.15)	−0.208	153	0.836
Emotional well-being	17.72 (4.13)	17.21 (4.99)	0.689	156	0.492
Functional well-being	17.42 (5.73)	17.81 (6.06)	−0.420	157	0.675
Total QOL	78.93 (16.16)	79.21 (18.21)	−0.103	150	0.918
Fatigue measured by FACT-F[a]					
Fatigue	33.35 (11.45)	33.09 (11.57)	0.141	158	0.888
Mood status measured by POMS[b]					
Tension and anxiety	10.23 (7.02)	11.20 (7.39)	−0.826	150	0.410
Depression	9.33 (9.99)	12.32 (12.87)	−1.555	142	0.122
Anger and hostility	7.55 (6.92)	10.07 (9.38)	−1.826	141	0.070
Lack of vigour	18.34 (6.87)	16.55 (6.92)	1.585	147	0.115
Fatigue	10.10 (6.66)	10.15 (7.01)	−0.052	149	0.959
Confusion	7.75 (5.51)	8.21 (5.93)	−0.494	151	0.622
Total mood status	62.85 (35.43)	68.34 (41.75)	−0.813	129	0.418
Inflammation					
C-reactive protein (mg/l)	9.90 (23.78)	12.25 (25.71)	−0.503	110	0.616

[a]A higher score reflects a positive effect.

[b]A lower score reflects a positive effect.

SD, standard deviation; QOL, quality of life; FACT-G, Functional Assessment of Cancer Therapy—General; FACT-F, Functional Assessment of Cancer Therapy—Fatigue; POMS, Profile of Mood State.

measured by the FACT-G were significantly improved in participants who completed the Qigong intervention at 10-week follow-up compared with the usual care control group. These results are consistent with the study of Tsang et al. [21] of MQ in elderly patients with chronic illness. It is sometimes the case that interventions may lead to improvements in outcomes that, while statistically significant, may not be clinically relevant and important. This does not appear to be the case in this study, where individuals in the MQ intervention scored an average of 8.23 points higher on the FACT-G measure of QOL than individuals in the usual care control group at 10-week follow-up. A 5- to 10-point difference on the FACT-G is considered to represent both a clinically and a socially important difference in QOL and functioning in cancer patients [22].

Another significant finding from this study was the positive effects of MQ on inflammation as measured by the CRP. While the precise mechanism through which MQ is able to decrease inflammation is unclear, one possible pathway is through MQ's effect on the immune system. A number of studies have indicated that MQ leads to improved immune function [23, 24]. These findings indicate a need for further research on the impact of MQ on biological changes, such as immune function, cytokines and inflammation, in order to more fully understand these effects.

In this study, patients in the MQ intervention group experienced significantly less CRF than those in the usual care control group. A change of >3 points on the FACT-F measure of CRF is considered to represent a clinically important change in fatigue in a cancer population [25]; patients in the MQ intervention group reported a 6.34-point change in CRF as measured by that scale. Thus, the reduction in CRF reported was clinically as well as statistically significant. Results are consistent with other research which has found that MQ can lead to improvements in CRF [26] and to research that has linked mindfulness-based stress reduction [27], relaxation breathing exercises [26] and yoga [28] to reduction of CRF in a range of cancer populations. Physical exercise is also often recommended by cancer care professionals as a method of minimizing CRF and improving QOL. However, recent randomized controlled trials have reported that fatigue and QOL were not improved with physical exercise [29, 30]. The current study finding indicates that management of CRF and QOL may be more effective if improvements in psychological and emotional functioning are targeted as well as physical functioning, as in the case of the MQ intervention. More research may be necessary to clarify the relationship between CRF, QOL, MQ and physical exercise.

Moreover, participation in the MQ intervention led to better total mood status among cancer patients, specifically reduced tension, anxiety and depression and increased vigor. This is supported by previous research which found an effect of MQ on mood in elderly patients with chronic illness [21], although another study found no impact of Qigong on mood in patients with cancer [31]. There may be differences in the delivery of Qigong which account for these divergent results, emphasizing the need for very clear descriptions of intervention content in evaluation studies.

Finally, no adverse effects of MQ were reported by the cancer patients in this trial, which is reassuring. Safety of MQ practice for cancer patients is also supported by previous literature [32].

Although these results are positive and promising, there are some limitations to the study and methodological approach that should be taken into account when interpreting the results. First, inclusion of a control group receiving usual care means

Table 3. Effects of Medical Qigong (intention-to-treat analysis using multiply imputed data) within- and between-group differences

Variables	Within group (week 10–week 0)		Between groups (intervention and control)			
	Mean difference from baseline (95% CI), independent samples *t*-test		Mean difference between groups (95% CI), independent samples *t*-test	Regression statistics		
	Medical Qigong group ($n = 79$)	Control group ($n = 83$)		*t* value	*df*	*P* values
QOL measured by FACT-G[a]						
Physical well-being	3.06 (1.97 to 4.14)	0.98 (0.04 to 1.91)	2.08 (0.66 to 3.50)	−3.720	152	<0.001
Social well-being	2.29 (1.25 to 3.32)	−0.97 (−2.00 to 0.06)	3.26 (1.81 to 4.71)	−4.663	148	<0.001
Emotional well-being	1.60 (0.86 to 2.35)	0.05 (−0.75 to 0.85)	1.55 (0.47 to 2.63)	−3.677	150	<0.001
Functional well-being	2.46 (1.51 to 3.42)	−0.13 (−0.94 to 0.68)	2.60 (1.35 to 3.84)	−4.467	151	<0.001
Total QOL	8.86 (6.41 to 11.32)	−0.13 (−2.48 to 2.22)	9.00 (5.62 to 12.36)	−5.761	144	<0.001
Fatigue measured by FACT-F[a]						
Fatigue	6.34 (4.38 to 8.30)	0.64 (−0.74 to 2.02)	5.70 (3.32 to 8.09)	−5.621	153	<0.001
Mood status measured by POMS[b]						
Tension and anxiety[c]	−1.71 (−2.94 to −0.48)	−0.47 (−1.84 to 0.90)	−1.24 (−3.06 to 0.58)	2.239	136	0.027
Depression[c]	−1.01 (−2.62 to 0.59)	1.54 (−0.52 to 3.61)	−2.56 (−5.14 to 0.01)	2.215	108	0.029
Anger and hostility[c]	−0.05 (−1.30 to 1.21)	−0.30 (−1.83 to 1.24)	0.25 (−1.71 to 2.20)	1.359	104	0.177
Lack of vigor[c]	−3.81 (−4.91 to −2.72)	0.53 (−0.65 to 1.71)	−4.34 (−5.93 to −2.75)	4.839	139	<0.001
Fatigue[c]	−2.42 (−3.79 to −1.05)	−1.30 (−2.63 to 0.03)	−1.12 (−3.01 to 0.77)	2.632	126	0.010
Confusion[c]	−0.76 (−1.68 to 1.17)	0.11 (−0.90 to 1.12)	−0.87 (−2.23 to 0.49)	1.929	137	0.056
Total mood status	−8.73 (−14.62 to −2.84)	1.91 (−5.25 to 9.07)	−10.64 (−19.81 to −1.47)	2.346	122	0.021
Inflammation biomarker[b]						
C-reactive protein (mg/l)[c]	−3.60 (−9.03 to 1.82)	19.57 (5.37 to 33.76)	−23.17 (−37.08 to −9.26)	2.042	99	0.044

[a]Higher scores reflect positive effect of intervention.
[b]Lower scores reflect positive effect of intervention.
[c]Logarithmic transformations were used in the model.
CI, confidence interval; FACT-G, Functional Assessment of Cancer Therapy—General; QOL, quality of life; FACT-F, Functional Assessment of Cancer Therapy—Fatigue; POMS, Profile of Mood State.

that the significant results may have been due to the additional attention received rather than the intervention. A usual care control group was chosen rather than a placebo sham group due to the early stage of this research. If a difference was detected between the groups, a subsequent larger study was planned to control for the effect of attention, and indeed this is now in the planning stage.

Secondly, contrary to recommendations for drug trials, neither the participants nor the instructors were blind to condition. Due to the nature of the intervention, it was not possible to make use of a blinding protocol. As such, it is possible that the benefits reported from the MQ intervention were due to experimental bias and confounding factors (e.g. extra care versus non-extra care), participants' expectancy (placebo effects) and social interactions. To reduce the likelihood that patients who knew they were in the intervention arm of the study would provide socially desirable responses, a third independent person distributed and collected the pre and post intervention questionnaires and carried out all data entry.

In this study, the completion rate was relatively low (76%) compared with other similar studies (85%) [30, 33]. Some studies that reported a low dropout rate (15%) recruited early-stage breast cancer patients [33], while studies that have reported a high dropout rate (35%) have recruited cancer patients with all stages of disease [34], similar to the current study. Dropout rate may be more dependent on the health status of participants than on other factors.

Participation in this study was voluntary and that may have created a potential selection bias, with those patients interested in Qigong participating and those with no interest in Qigong declining. This may limit the generalizability of the findings but does not invalidate the results for this sample.

Moreover, this study investigated the short-term benefits of the MQ intervention but not the longer term. It may be worthwhile to investigate whether the benefit is sustained in the long term with participants who continue to practice MQ at home.

Despite these limitations, the findings of this study are positive and provide evidence that MQ is safe and effective in improving QOL, fatigue, mood status and reducing symptoms, side-effects and inflammation in cancer patients. Further studies examining long-term benefits of MQ, including a potential association between improvement in QOL and survival rate, may provide additional information that may assist patients with cancer and clinicians in providing optimal comprehensive cancer care.

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disclosure

All authors declare that there is no conflict of interest.

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