

Effects of *Qi* Therapy (External *Qigong*) on Premenstrual Syndrome: A Randomized Placebo-Controlled Study

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ABSTRACT

Objectives: To assess the effects of *qi* therapy on premenstrual symptoms in women with premenstrual syndrome (PMS).

Design: A randomized placebo-controlled trial.

Subjects: Thirty-six (36) college women with symptoms of PMS.

Intervention: After 2 months of screening, subjects with PMS were randomized to receive real *qi* therapy (18 subjects) or placebo (18 subjects). The subjects were informed that they would receive one of two types of treatment. They did not know which treatment they received. Each intervention was performed eight times during the second and third cycles with subjects completing a PMS diary.

Results: There were significant improvements in the symptoms of negative feeling, pain, water retention, and total PMS symptoms in subjects receiving *qi* therapy compared to placebo controls.

Conclusion: *Qi* therapy may be an effective complementary therapy for managing the symptoms of PMS.

INTRODUCTION

Retrospective community surveys estimate that some 30%–90% of women have suffered from premenstrual symptoms (Chung et al., 1996; Jeong et al., 2001; Lee et al., 1994) and 82.6% of college-educated women in Korea have experienced painful premenstrual symptoms (Han and Huh, 1999). Premenstrual syndrome (PMS) is characterized by a spectrum of physical and mood symptoms, which appear during the week before menstruation and usually resolve within a week after the onset of menses. Most women in their reproductive years experience some premenstrual symptoms. Thus, the management of PMS is important for women's health. However, there is considerable debate regarding the nature and extent of PMS symptoms. This has resulted in an ongoing search for explanatory theories, each of which has stimulated the evaluation of new treatments.

Common pharmacologic treatments include the use of natural progesterone and synthetic progestins, diuretics for edema, antiprostaglandins, bromocriptine, a dopamine receptor agonist, and pyridoxine, a water-soluble B vitamin for PMS (Magos, 1990; Michener et al., 1999; O'Brien and Abukhalil, 1999; Robinson et al., 1977; Wyatt et al., 1999).

Nonpharmacologic interventions such as cognitive therapy, relaxation responses, reflexology, and massage therapy result in effective PMS control (Blake, et al., 1998; Goodale et al., 1990; Hernandez-Reif et al., 2000; Oleson and Flocco, 1993). While pharmacologic treatments are, appropriately, the central component of PMS therapy, the underutilization of effective nonpharmacologic strategies (NPS) may contribute to the problem of PMS among reproductive women.

According to ancient Chinese thought, *qi* denotes essential substances of the human body that maintain its vital activities, and the functional activities of organs and tissues

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(Xinnong, 1987; Shin, 2002). *Qi* is commonly viewed as vital energy or the life force, and is the source of vitality and strength. *Qi* acts extensively in the human body by permeating all parts. The meridians in the body are the main pathways through which *qi*, or life force energy, moves and flows. In fact, all of nature, including humanity, is dependent on this vital force. When *qi* flows smoothly, all of life's processes operate rhythmically and harmoniously. If *qi* is weak, unbalanced, and blocked, the human body succumbs to illness and enters a diseased state. Ultimately, the cause of all disease derives from energetic imbalances. A practical extension of these basic ideas is to diagnose the disease before it manifests in the physical body by measuring the energetic imbalances, and to treat the disease (with energy) by normalizing the energetic imbalances. Therefore, sustaining *qi* energy is more important than anything else in order to keep the body strong and healthy.

Medical *qigong* has been used as a traditional complementary intervention to prevent and cure disease, to improve health, and to strengthen the vital energy through practice or by receiving it from practitioners (Chen and Yeung, 2002; Lin and Chen, 2002). It is divided into two kinds: internal and external *qigong*. Internal *qi* training refers to *qigong* practice or to cultivation by oneself to achieve optimal health for both mind and body. External *qi* therapy refers to the process by which *qigong* practitioners direct or emit their *qi* energy with the specific intention of helping patients clear *qi* blockages and move the bad *qi* out of the body so as to relieve pain, or to balance the *qi* flow in the body and get rid of diseases. Accordingly, external *qi* therapy may be helpful in rectifying *qi* deficiency and eliminating blockages and stagnation.

Although neither the *qi* therapy itself nor the mechanism of its effects is understandable or explicable within any paradigm of modern medical science, its effects on the human body are apparent, as is its effectiveness in many clinical and psychological illnesses (Lee et al., 2003a). While much of the research on *qi* therapy effects is limited by methodological flaws, recent randomized controlled trials have found several beneficial effects of *qi* therapy compared to placebo. Two weeks of *qi* therapy significantly reduced the pain level and improved mood in elderly subjects compared to a general care control group, but this was not a placebo-controlled study (Lee et al., 2001a). Another recent randomized placebo-controlled study showed that *qi* therapy modulated hormone levels, and increased immune functions and mood compared to placebo controls (Lee et al., 2001b). *Qi* therapy has proved to be useful in reducing heart rate and stabilizing the sympathetic nervous system (Lee et al., 2003b). Elderly subjects receiving *qi* therapy showed a significant decrease in systolic and diastolic pressure, and reduced anxiety, depression, pain, and fatigue levels compared to placebo controls (Lee et al., 2003c).

Thus, *qi* therapy may have beneficial psychological, physiological, and immunologic effects on health. In our previ-

ous study, *qi* therapy stabilized cardiac autonomic tone and the sympathetic nervous system (Lee et al., 2003b), and patients exhibited increased alpha intensity compared to placebo-treated controls (Lee et al., 2004). These results showed that *qi* therapy helps relax the mind and body. A relaxed brain produces a reduction in anxiety and depression, and mood elevation. This is consistent with reduced levels of cortisol, heart rate, and blood pressure (Lee et al., 2001b, 2003b, 2003c). One of the interesting features of *qi* therapy is that the *qi*-receiver feels a rapid renewal of energy or reduced fatigue levels (Lee et al., 2003c). Another feature is that *qi* experts can direct *qi* flow to any part of the patient's body to relieve stress and pain. Higuchi et al. (2001) reported that the adrenaline and noradrenaline levels of *qi* receivers significantly decreased, and their β -endorphin levels slightly increased at 40 minutes after *qi* therapy. *Qi* therapy may also enhance the delivery of pain-killing substances such as endorphins or drugs to control pain (Sancier and Hole, 2001).

Recent *in vitro* studies (Lee et al., 2001c, 2003d; Yu et al., 2003) show that emitted *qi* or the master's intention affects the activity of natural killer cells, neutrophil function, and human prostate cancer in a positive manner. In addition, it may be possible to store information about emitted *qi* in media used for cell culture (Fukushima et al., 2001). In the field of biophysics, many attempts have been made to verify the process of distant or spiritual healing and the existence of emitted *qi*. Some authors have proposed non-localized quantum energy, and holoenergetic quantum consciousness theories (Gough 1999; Rein, 1992, 1998, 2004). Such theories may provide guidance for maintaining the intercellular communication processes that are essential for human growth and health. In addition, a functional role of biofields (endogenous energy fields of the body) in the body's innate self-healing mechanisms has been hypothesized, based on the concept of bioinformation. This, mediated by consciousness, is supposed to function globally at a molecular quantum level to supply coherence, phase, spin, and pattern information to regulate and heal physiological processes (Rein, 1992, 2004). The intercellular communication between healer and receiver, or in the healing of oneself, is thought to be involved in increasing "coherence" between cells (Gough 1999; Rein, 1992, 1998; Sancier and Hole, 2001). However, the true mechanism requires further study.

From the perspective of Oriental medicine, the symptoms of PMS are principally ascribed to impeded flow of *qi* and blood in the uterus (Xinnong, 1987). Deficiency or stagnation of *qi* and blood may cause irregular menstrual flow, disharmony between *qi* and blood, and injury of the meridians. If it is possible to remove the blockage, stagnation, deficiency, and imbalance of *qi*, this may alleviate symptoms of PMS. Thus, the purpose of this study was to investigate the effects of *qi* therapy in college students with PMS compared to a placebo control group.

MATERIALS AND METHODS

Subjects

Volunteers were recruited for the study from Wonkwang Health Science College in Iksan, Korea. One hundred and fourteen (114) received Menstrual Distress Questionnaires (MDQ; Moos, 1968) and 83 (72.8%) completed them. The selection criteria for each subject were as follows: (1) marked disruption of work, school, or social activities and relationships; (2) regular menstrual cycles; (3) no oral contraceptive use; (4) no past or present diagnosis of psychiatric, internal, or obstetric illness; (5) no history of practicing a relaxation-responding technique within the past 6 months; (6) no current prescription medication use or any other therapy for PMS; (7) no habitual smoking or drinking; and (8) at least two severe symptoms of PMS from a list of eight premenstrual symptoms (pain, concentration lapses, behavioral changes, changes in autonomic nervous system reactions, water retention, negative feeling, and changes in arousal and self-control). Subjects who failed to meet each of these criteria were excluded from the study.

Of the 114 subjects who were originally screened, 51 entered the initial phase of the study. Before admission into the study, the potential subjects underwent a pretreatment assessment of symptoms over two successive cycles to confirm a diagnosis of PMS. Of the 51 potential subjects, 15 were excluded before they received any intervention, leaving 36 subjects who completed the study. Reasons for exclusion included: no PMS symptoms in the next cycle (2), did not complete the PMS diary (4), were too busy or working (5), and wanted to quit (4). The remaining subjects completed a full round of treatments. They were asked to attend their scheduled intervention and were telephoned routinely before intervention by four assistants who checked that they adhered to the schedule.

The remaining subjects were randomized into a *qi* therapy group ($n = 18$) and a placebo control group ($n = 18$) by block randomization. The subjects were informed that they would receive one of two types of *qi* therapy, each of which had the potential to relieve premenstrual symptoms because we introduce the nature of *qi* therapy and procedures of experiment. They did not know which treatment they received. Subjects were blinded as to whether they were receiving real or sham *qi* therapy, as were the clinical observers assessing the endpoints. Four assistants contacted the subjects and checked their diaries.

The groups received 10 minutes daily of *qi* therapy, or sham *qi* therapy, 14, 7, 4, and 1 day before the menses of the first and second cycles (total eight times over two cycles) in addition to completing the PMS diaries. To time the exact date of the cycle, we used the Billings Ovulation Method (BOM; Billings, 1982). The BOM is a method of natural family planning based on a single-index cervical mucus parameter that enables a woman to recognize her time

of potential fertility. It also enables her to recognize the infertile parts of her cycle after ovulation and in the preovulatory phase of the cycle. All of the subjects learned about this method by viewing videotapes about BOM several times. Thus, there were three missed cases of menstruation date in the second cycle (two in the experimental and one in the control group) and two missed in the third cycle (one in each group). For both of those cases, the subjects received treatment immediately. The study received institutional approval from the Human Investigation Ethics Committee and administrative approval from the Human Subjects Review Board in Wonkwang University Hospital and School of Medicine before we approached the subjects and obtained written consent from all of them. After the experimental periods, both groups were offered complimentary *qi* therapy on a volunteer schedule. All subjects completed the study and received a free membership card to receive complimentary *qi* therapy for 2 months (valued at approximately US \$300).

Premenstrual symptoms diary

The PMS diary allowed the subjects to list 27 common symptoms of premenstrual distress: 19 symptoms proposed by Abraham (1982) and 8 from the CU-PS calendar used at the PMS clinic in the Catholic University Medical Center, Seoul, Korea. Each symptom was scored from 1 to 4 (1, none, symptom not present; 2, mild, noticeable but not troublesome; 3, moderate, interferes with normal activities; 4, intolerable, unable to perform normal activities), according to the intensity experienced by the patient. The symptom items were grouped into five factors: negative feelings, pain, autonomic nervous system reactions, water retention, and behavioral changes. We used subscales according to the results of the previous study using a Q-methodological approach (Jang, 1999). Analysis of this experiment indicated a high level of internal consistency for the total PMS scale (Cronbach $\alpha = 0.94$, which is based on all 27 symptoms).

Interventions

In this experiment, Korean *qi* therapy (called ChunSoo Energy Healing) was performed by a *qi* therapist in Ki Health International. The Qi master was a female nurse, 36 years old, who had practiced *qi* training for 8 years. *Qi* therapy was administered by the standard procedures outlined in the textbook for *qi* therapy and there were no differences between interventions.

The subjects received attention for 10 minutes according to described procedures in the following standard sequence.

1. The *qi* master centers the self, forming a conscious intent to help the subject while becoming mentally aware of the self as one with the cosmos.
2. The *qi* master's hand is moved approximately 3–10 cm from the body in a pattern from head to toe, with the master becoming aware of changes in sensory cues.

3. The *qi* master concentrates on areas of perceived accumulated tension in the subject's body and subjectively "projects" *qi* from his or her hand.
4. The master then concentrates attention on specific perceived directions of energy flow (sensory cues), finishing by holding the subject's feet.
5. The subject is turned over and receives the same procedure for 5 minutes on the other side of the body.

Sham QT was administered by the same *qi* master, who aimed to mimic the gestures used in the actual *qi* therapy without any effort or intention to emit real *qi*. She followed the experiment schedules and attempted to emit *qi* with positive thinking to restore harmony and balance to the energy systems of the subjects or mimicked it using the same protocol so that the subjects were unaware of her intentions. She was not involved in any other aspect of the study. The master who delivered the two treatments appeared and behaved equally credibly to an independent observer. The real *qi* treatment and placebo treatment were administered in no set order during the treatment routine.

Only one *qi* therapy practitioner was used in this study to maintain consistency of the intervention protocols and minimize practitioner bias.

Statistical analysis

All analyses were performed using the SAS statistical package for personal computers, version 6.12 (SAS Institute, Cary, NC). The results present as means \pm standard

deviations (SD). Total premenstrual means for each of the symptom categories were calculated from the scores for the week before menstruation, at the first (baseline), second, and third cycles. χ^2 and *t* tests were used to compare the homogeneity of general characteristics and categorical variables between placebo and experimental groups. Two-by-three repeated-measures analysis of variance (ANOVA) was used to examine the differences in scores of menstruation symptoms and subscales between two groups (placebo-controlled and *qi* therapy) as three repeated factors (months [first {baseline}, second, and third cycle] of each premenstrual symptom [1–7 days before menstruation]).

RESULTS

The demographic characteristics for the subjects are shown in Table 1. The groups did not differ significantly in age, age at menarche, the duration, pattern, and amount of blood loss in the menstruation cycle, perceived health state, method of relieving PMS, or total PMS score.

Figure 1 shows the means and SDs for total PMS scores for the *qi* therapy and placebo control groups for the three periods. For each of these three measures, total premenstrual scores were similar for the two groups during baseline charting, and showed greater reduction for the *qi* therapy group than the control group after 1 and 2 months of treatment. Repeated-measures ANOVA on total PMS score revealed a significant effect of time [$F(2,68) = 26.41, p < 0.001$] and

TABLE 1. CHARACTERISTICS OF SUBJECTS ON *QI* THERAPY AND PLACEBO CONTROL

Characteristics	Qi therapy (n = 18)	Control (n = 18)	t or χ^2	p
Age (yr)	20.78 \pm 1.83	22.16 \pm 2.81	-1.76	0.09
Age at menarche (yr)	13.55 \pm 0.78	13.78 \pm 0.88	-0.80	0.43
Menstruation				
Cycle	30.83 \pm 4.52	29.89 \pm 4.84	0.60	0.56
Duration	5.44 \pm 1.10	5.50 \pm 1.38	-0.13	0.90
Pattern			1.03	0.32
Regular	8 (44.5%)	11 (61.1%)		
Irregular	10 (55.5%)	7 (38.9%)		
Amount			0.18	0.91
Profuse	3 (16.7%)	4 (22.2%)		
Moderate	13 (72.2%)	12 (66.7%)		
Scanty	2 (11.1%)	2 (11.1%)		
Perceived health condition			2.49	0.29
Good	14 (77.8%)	10 (55.5%)		
Normal (average)	4 (22.2%)	7 (38.9%)		
Poor	0 (0.0%)	1 (5.6%)		
Relief way of PMS				
Rest	5 (27.8%)	9 (50.0%)	0.38	0.28
Oral analgesics	5 (27.8%)	5 (27.8%)		
Heat pack	5 (27.8%)	1 (5.6%)		
Psychologic diversion	3 (16.6%)	3 (16.6%)		
Total premenstrual score	68.87 \pm 13.40	66.88 \pm 10.29	0.50	0.62

Values are expressed as mean and standard deviations.
PMS, premenstrual syndrome.

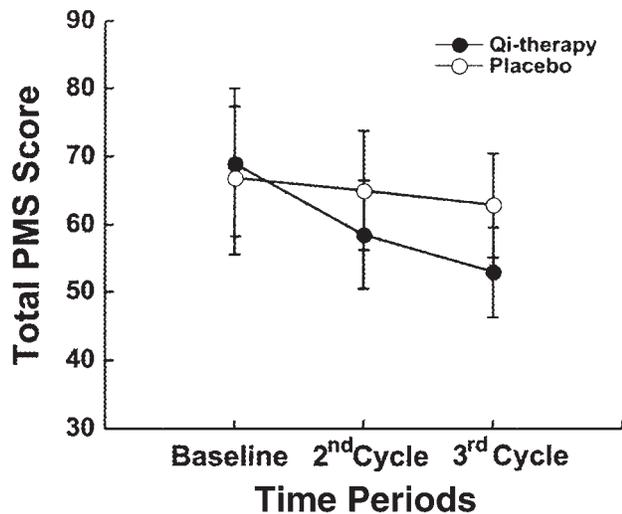


FIG. 1. *Qi* therapy reduced total premenstrual syndrome (PMS) scores compared to placebo-treated controls. PMS symptoms were reported at baseline and during the second and third menstrual cycles. Values are means and standard deviations. There was significant group-by-time interaction ($p < 0.001$).

a significant group-by-time interaction [$F(2,68) = 9.89, p < 0.001$].

The self-reported symptoms of PMS (negative feelings, pain, autonomic nervous reaction, water retention, and behavioral changes) are shown in Table 2. For the negative feeling scale there was a significant decrease in the *qi* therapy group but not in the placebo group. There was signifi-

cant group-by-time interaction effect [$F(2,68) = 7.12, p < 0.01$] and a significant time effect [$F(2,68) = 9.30, p < 0.001$]. For pain and water retention, the pattern was similar between groups. The repeat-measures analysis for the pain scale was statistically significant for group-by-time interaction [$F(2, 68) = 10.65, p < 0.001, HF - \epsilon = 0.87$] and time effect [$F(2, 68) = 23.6, p < 0.001, HF - \epsilon = 0.87$]. Likewise, the repeat-measures analysis for the water retention scale showed a significant group-by-time interaction [$F(2, 68) = 8.24, p < 0.001$], time effect [$F(2, 68) = 23.50, p < 0.001$], and group effect [$F(1, 34) = 6.64, p < 0.05$]. There were significant time effects in autonomic nervous system reactions [$F(2, 68) = 4.47, p < 0.05, HF - \epsilon = 0.92$] and behavioral changes [$F(2, 68) = 14.55, p < 0.001$].

DISCUSSION

Women in this study who received *qi* therapy reported fewer premenstrual symptoms. There were significant differences in the improvement of symptoms of negative feeling, pain, water retention, and total PMS symptoms between subjects in the *qi* therapy and the placebo control groups. Statistically, the improvements in the *qi* therapy group were significantly greater than those in the placebo control group. This difference might be interpreted as being caused by the effects of *qi* on the body of women experiencing a low level of *qi*. Thus, *qi* therapy could have an important role for managing the various symptoms of PMS.

TABLE 2. EFFECTS OF *Qi* THERAPY ON SYMPTOMS OF PREMENSTRUAL SYNDROME

Subscale	Time			Group \times time $F(2,68)$
	Baseline	2nd Cycle	3rd Cycle	
Negative feeling				7.12*
<i>Qi</i> therapy	15.29 \pm 2.61	12.41 \pm 1.24	12.05 \pm 1.23	
Placebo	14.22 \pm 2.68	14.22 \pm 2.45	13.87 \pm 1.81	
Pain				10.65*
<i>Qi</i> therapy	14.52 \pm 4.22	11.71 \pm 2.72	10.03 \pm 2.40	
Placebo	14.05 \pm 3.49	13.65 \pm 2.64	13.14 \pm 1.82	
Autonomic nervous reaction				0.52
<i>Qi</i> therapy	12.52 \pm 2.11	12.11 \pm 2.16	11.44 \pm 1.88	
Placebo	12.22 \pm 1.54	12.33 \pm 1.88	11.67 \pm 1.47	
Water retention				6.64*
<i>Qi</i> therapy	13.67 \pm 3.50	10.28 \pm 1.36	9.40 \pm 1.73	
Placebo	13.44 \pm 2.39	12.50 \pm 2.00	12.38 \pm 2.84	
Behavioral change				2.88
<i>Qi</i> therapy	12.88 \pm 3.37	11.86 \pm 2.34	10.15 \pm 1.74	
Placebo	12.94 \pm 2.44	12.28 \pm 1.75	11.84 \pm 1.82	

Values are expressed as mean and standard deviations.

* $p < 0.001$.

The present study showed a significant reduction of pain levels in the *qi* therapy group compared with placebo-treated controls. This finding is consistent with prior work. According to our recent report, *qigong* therapy increases oxygen and decreases carbon dioxide concentrations in the blood (Lee et al., 2002). This may enable the removal of pain-inducing substances such as metabolic waste products from the tissues. *Qi* therapy may also enhance the circulation of pain-killing substances such as endorphins and other agents to control pain (Sancier and Hole, 2001).

There were significant improvements in the PMS symptoms of water retention and in negative feelings. The improved supply of *qi* may thus have harmonized *qi* and blood, and restored the health of those meridians related to the uterus. There is evidence that women have increased norepinephrine receptor sensitivity during the few days before menses (Ghose and Turner, 1977). This hypersensitivity might explain the commonly experienced increases in negative premenstrual feelings such as anxiety, depression, and anger because these moods are heavily influenced by the noradrenergic system. In our recent reports in a randomized placebo control study, *qi* therapy reduced the blood pressure, stabilized the sympathetic nervous system, and decreased cortisol levels compared to placebo controls (Lee et al., 2001b, 2003b). Regular *qi* therapy is believed to result in a decreased norepinephrine response that may help alleviate these premenstrual symptoms, but further study is needed to clarify this.

Some nonpharmacologic methods especially related with relaxation therapy, cognitive therapy, and manual therapy have suggested that there is high treatment response for PMS patients (Blake et al., 1998; Goodale et al., 1990; Hernandez-Reif et al., 2000; Oleson and Flocco, 1993). The results showed that a 22% reduction in PMS symptoms by massage therapy is similar to that produced by *qi* therapy (Hernandez-Reif et al., 2000). The 22% reduction in premenstrual symptoms found by using true *qi* therapy directed at subjects is lower than the 44% improvement found by Blake et al. (1999) in women who received cognitive therapy. Moreover, relaxation response management and reflexology for PMS has achieved successes of 58% and 46%, respectively (Goodale et al., 1990; Oleson and Flocco, 1993). However, these are difficult to compare. First, the present study did not use the full potential of the patient's active participation in the healing process or self-practice of *qigong*. Second, the previous studies used different assessment measures for evaluating PMS, and both invasive and noninvasive therapies for relieving the symptoms. A clinically controlled comparison of several different noninvasive therapies for women using the same PMS assessment form would be valuable.

Although we found that *qi* therapy gradually improved the symptoms of PMS compared to the placebo control group, additional evaluation of residual effects of *qi* therapy is needed for clinical applications. More objective clinical measures are needed in addition to the self-reported im-

provement found using a PMS diary. Further studies should also examine the possible effects of *qi* therapy on the hormonal changes associated with the menstrual cycle to clarify the possible mechanisms involved.

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