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## 研究成果の刊行物

RESEARCH

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# Isometric yoga improves the fatigue and pain of patients with chronic fatigue syndrome who are resistant to conventional therapy: a randomized, controlled trial

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## Abstract

**Background:** Patients with chronic fatigue syndrome (CFS) often complain of persistent fatigue even after conventional therapies such as pharmacotherapy, cognitive behavioral therapy, or graded exercise therapy. The aim of this study was to investigate in a randomized, controlled trial the feasibility and efficacy of isometric yoga in patients with CFS who are resistant to conventional treatments.

**Methods:** This trial enrolled 30 patients with CFS who did not have satisfactory improvement after receiving conventional therapy for at least six months. They were randomly divided into two groups and were treated with either conventional pharmacotherapy (control group,  $n = 15$ ) or conventional therapy together with isometric yoga practice that consisted of biweekly, 20-minute sessions with a yoga instructor and daily in-home sessions (yoga group,  $n = 15$ ) for approximately two months. The short-term effect of isometric yoga on fatigue was assessed by administration of the Profile of Mood Status (POMS) questionnaire immediately before and after the final 20-minute session with the instructor. The long-term effect of isometric yoga on fatigue was assessed by administration of the Chalder's Fatigue Scale (FS) questionnaire to both groups before and after the intervention. Adverse events and changes in subjective symptoms were recorded for subjects in the yoga group.

**Results:** All subjects completed the intervention. The mean POMS fatigue score decreased significantly (from  $21.9 \pm 7.7$  to  $13.8 \pm 6.7$ ,  $P < 0.001$ ) after a yoga session. The Chalder's FS score decreased significantly (from  $25.9 \pm 6.1$  to  $19.2 \pm 7.5$ ,  $P = 0.002$ ) in the yoga group, but not in the control group. In addition to the improvement of fatigue, two patients with CFS and fibromyalgia syndrome in the yoga group also reported pain relief. Furthermore, many subjects reported that their bodies became warmer and lighter after practicing isometric yoga. Although there were no serious adverse events in the yoga group, two patients complained of tiredness and one of dizziness after the first yoga session with the instructor.

**Conclusions:** Isometric yoga as an add-on therapy is both feasible and successful at relieving the fatigue and pain of a subset of therapy-resistant patients with CFS.

**Trial registration:** University Hospital Medical Information Network (UMIN CTR) UMIN000009646.

**Keywords:** Chronic fatigue syndrome, Isometric yoga, Fatigue, Treatment, Fibromyalgia

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## Background

Chronic fatigue syndrome (CFS) is a debilitating disease characterized by persistent fatigue that is not relieved by rest and by other nonspecific symptoms, all of which last for a minimum of six months [1]. The pathophysiological mechanisms underlying CFS are not yet fully understood. Currently, patients with CFS are treated with antidepressants, cognitive behavioral therapy (CBT), and/or graded exercise therapy (GET) [2-5]. However, there are patients who do not fully recover even with these treatments.

Yoga is one of the most commonly accepted mind/body therapies of complementary and alternative medicine and is recommended as an alternative therapy for improving unexplained chronic fatigue [6]. In fact, several studies have demonstrated that yoga is effective in improving the fatigue of patients with cancer [7,8] as well as of healthy subjects [9]. We hypothesized that yoga is also effective in improving the fatigue of patients with CFS. However, as the yoga programs practiced in previously published studies were not uniform, it was difficult to identify which program or which component of yoga is useful for alleviating fatigue. Furthermore, patients with CFS complain of severe fatigue, especially after exertion. Therefore, before starting this study, we discussed the yoga program with yoga instructors to determine which type of practice had the least probability of exacerbating a patient's fatigue. We selected isometric yoga, as described in the methods section.

The aims of this study were to assess the feasibility of isometric yoga among patients with CFS and to assess the effect of isometric yoga on fatigue and related psychological and physical symptoms of patients with CFS who did not respond to conventional therapies. To our knowledge, this is the first study to investigate the effect of isometric yoga on the fatigue of patients with CFS.

## Methods

This study was approved by the Institutional Review Board of Kyushu University. Written informed consent was obtained from all participants before they were enrolled.

## Subjects

This study enrolled outpatients with CFS who visited the Department of Psychosomatic Medicine of Kyushu University Hospital. Inclusion criteria were the following: (1) the subject's fatigue did not improve sufficiently with ordinary treatment given in our Department (as an example see [10]), including pharmacotherapy (for example, antidepressants, Japanese traditional herbal medicine [11,12], and/or coenzyme Q10), psychotherapy, and/or GET; in some cases, a four-week inpatient treatment program was also included [10]) for at least six months; (2) the subject was between 20 and 70 years old; (3) the subject's level of

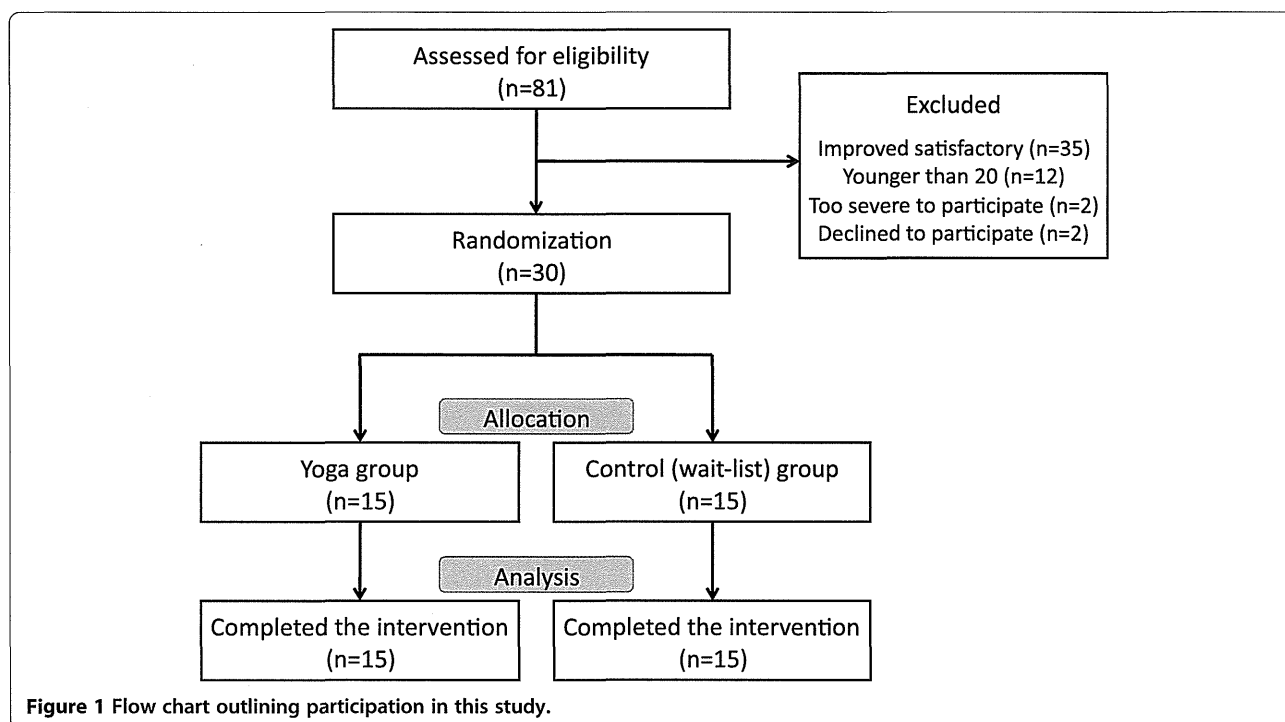
fatigue was serious enough to cause an absence from school or the workplace at least several days a month but not serious enough to require assistance with the activities of daily living; (4) the subject was able to fill out the questionnaire without assistance; (5) the subject could sit for at least 30 minutes; and (6) the subject could visit Kyushu University Hospital regularly every two or three weeks. Subjects were excluded if (1) their fatigue was due to a physical disease such as liver, kidney, heart, respiratory, endocrine, autoimmune, or malignant disease, severe anemia, electrolyte abnormalities, obesity, or pregnancy; and (2) they had previously practiced yoga. The diagnosis of CFS was made for patients meeting the diagnostic criteria of the 1994 international research case definition of CFS [1]. Patients with idiopathic chronic fatigue were not included in this study.

## Methods

Following enrollment, eligible participants were randomized using a computer-generated randomization list to receive either an isometric yoga practice together with conventional pharmacotherapy group (yoga group,  $n = 15$ ) or to a conventional pharmacotherapy alone group (waitlist control group,  $n = 15$ ) for approximately two months. As the patients visited the hospital every two or three weeks, the intervention period lasted  $9.2 \pm 2.5$  (mean  $\pm$  standard deviation (SD)) weeks after the start of the intervention (Figure 1).

## Development of the yoga program

Before starting this trial, we consulted yoga instructors to identify a program that would satisfy the following requirements. Firstly, because patients with CFS have severe fatigue, it should not exacerbate their symptoms or cause post-exertion malaise. Secondly, because the patients are deconditioned, it should also act as an exercise therapy. Thirdly, because the patients' concentration and short-term memory are impaired, it should be simple and easy to do. Fourthly, because the patients would be treated at the hospital, not at a yoga studio, it must be able to be practiced in an outpatient setting, where space is limited. To satisfy these requirements, we determined that the trial would include isometric yoga, or an isometric yogic breathing exercise, as a treatment for patients with CFS. Isometric yoga, which was developed by Dr. Keishin Kimura, differs from traditional yoga postures in several ways. The predominant difference is that the poses consist mainly of isometric muscle contractions. Since the patients can change resistance depending on their fatigue level, we thought that isometric yoga would help prevent worsened fatigue. These poses do not include isotonic muscular contractions or strong stretching and require less physical flexibility. Therefore, we hypothesized that practicing this form of yoga would



be easy on the patients, preventing over-stretching, which is detrimental and may increase pain. However, as are traditional yoga poses, these poses are conducted slowly in accordance with breathing and with awareness of inner sensations. We intentionally avoided standing postures, because a considerable number of CFS patients suffer from orthostatic intolerance, including postural orthostatic tachycardia syndrome [13]. This 20-minute yoga program can be practiced in a sitting position and consists of three parts. First, patients are asked to be aware of their spontaneous breathing for one minute. Next, they practice six poses. These poses are very slow movements that are coordinated with the timing of breathing, with or without sounds, and isometric exercise at 50% of the patient's maximal physical strength. Lastly, the patients practice abdominal breathing for one minute (Figure 2).

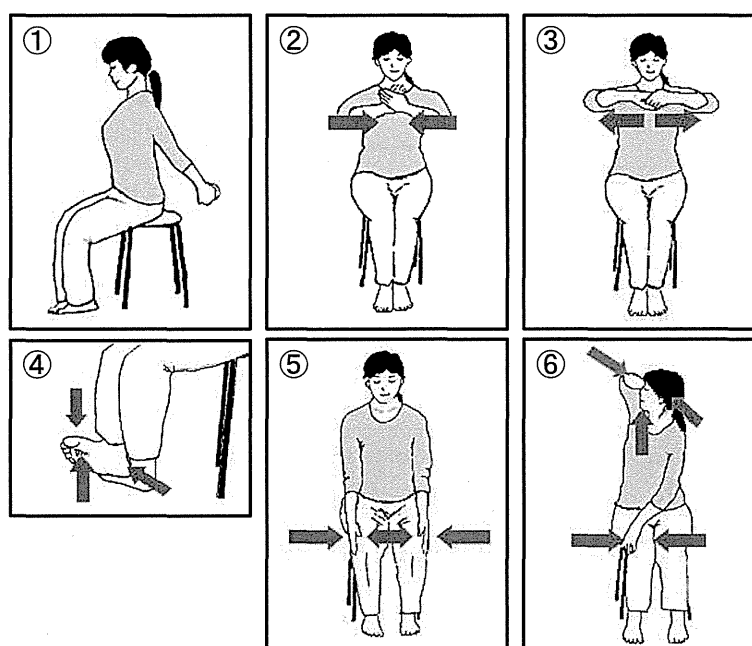
### Yoga intervention

Patients in the yoga group practiced isometric yoga in a quiet room for 20 minutes on a one-to-one basis with an instructor who has over 30 years of experience. The sessions occurred between 2 pm and 4 pm on the day they visited the hospital. In this program, the yoga instructor was not allowed to use background music, which is often used in the yoga studio to facilitate the participants' relaxation, because many patients with CFS are sensitive to sounds. Before and after practicing isometric yoga, the doctors in charge checked the patient's

condition and recorded any adverse events or any changes caused by practicing isometric yoga. In addition to receiving a private lesson, the participants were asked to practice this program on non-class days if they could, with the aid of a digital videodisc and a booklet. Most patients visited their doctor every two to three weeks during the intervention period. Therefore, all patients practiced isometric yoga at least four times (mean  $\pm$  SD,  $5.6 \pm 1.7$  times) with the instructor during the intervention period. Basically, all patients practiced the same 20-min program, both with an instructor and at home. However, the program was modified on a patient-to-patient basis, in most cases skipping a certain pose or decreasing the number of repetitions of poses, depending on the severity of their fatigue and the pain associated with the pose.

### Outcome assessment

To assess the acute effects of isometric yoga, the fatigue (F) and vigor (V) scores of the Profile of Mood States (POMS) questionnaire [14] were assessed immediately before and after the final 20-minute session of isometric yoga with the instructor. To assess the chronic effects of isometric yoga, fatigue was assessed with Chalder's fatigue scale (FS) [15] before and after the intervention period in the yoga and control groups. Chalder's FS is a well-validated, self-reported scale that measures the physical and mental symptoms of fatigue. In the yoga group, the assessments were conducted just before



**Figure 2 Illustration of the six poses of the isometric yoga program used in this study.** The 20-minute isometric yoga program consisted of three parts. **1)** The patients practiced being aware of their spontaneous breathing for one minute. **2)** The patients practiced six isometric poses **4–6** times: (i) stretching both arms behind the back; (ii) pushing the palms against each other; (iii) pulling the palms away from each other; (iv) pushing the feet against each other; (v) pushing both knees inward with hands on the outside; and (vi) twisting. **3)** The patients practiced abdominal breathing for one minute. The postures were practiced slowly in association with exhalation or inhalation with 50% of the maximal physical strength. After the postures were repeated **4–6** times, the patients decreased their physical exertion and returned slowly to the basic position while exhaling.

practicing yoga. Patients in this group also completed the Medical Outcomes Study Short Form 8, standard version (SF-8™) before and after the intervention period to assess their health-related quality of life (QOL) [16]. Questionnaires were collected by a nurse.

#### Adverse events and adherence

Adverse events were monitored in two ways. First, at each visit to the hospital, the doctors in charge determined if a subject experienced any uncomfortable symptoms after practicing yoga with the instructor. Second, patients in the yoga group were asked to keep a “yoga diary,” in which they could record the amount of time they practiced and how they felt after practicing yoga. On the day of the visit, before the patient practiced yoga with the instructor, the doctors checked the diary and determined if the patient had had any symptoms of discomfort. After the intervention period, the diary was collected and checked to determine how often the subjects had practiced yoga at home.

#### Statistical analyses

The data are presented as the mean  $\pm$  SD. The differences in the outcome measures were tested by two-way,

repeated measures, analysis of variance (ANOVA) of the mean scores. Two comparisons were made: one compared the scores of the yoga group to those of the control group; the other compared the scores measured before the intervention to those measured after. The differences in the patients’ POMS, Chalder’s FS, and SF-8 scores measured before and after the intervention were tested by use of a paired-sample *t* test. Between-group differences in age and in the POMS, Chalder’s FS, and SF-8 scores measured before and after the intervention were tested by use of an independent-sample *t* test. Two-tailed tests were used. Fisher’s exact probability test was also used when appropriate. Data were analyzed by using SPSS for Windows, V.17.

## Results

### Participants

The study comprised 30 subjects, with 15 in the yoga group (age range: 24–60 years; mean age (mean  $\pm$  SD): 38.0  $\pm$  11.1 years; 3 men) and 15 in the control group (age range: 20–59 years; mean age: 39.1  $\pm$  14.2 years; 3 men). All patients completed the study. There were no significant differences in age, sex, or Chalder’s FS total and sub-scale scores measured before the intervention between the

yoga group and the control group (Table 1). The mean Chalder's FS score at the first hospital visit of both groups was  $30.8 \pm 4.5$ .

#### Short-term effects of isometric yoga on fatigue and vigor

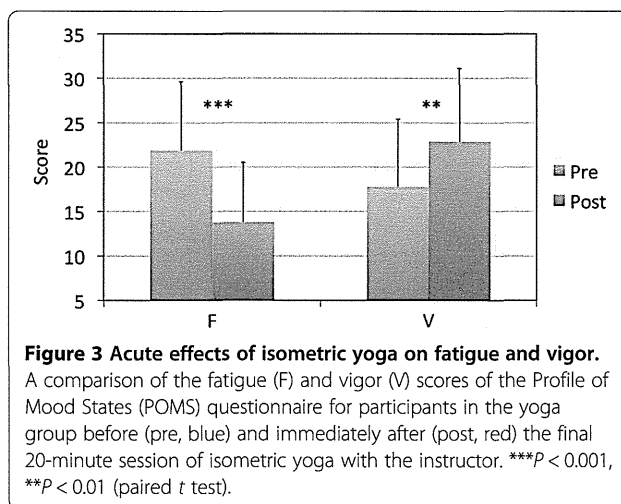
We assessed the short-term effects of isometric yoga on fatigue by comparing the POMS F and V scores before and after the patients completed the final 20-minute session of isometric yoga with the instructor. We used the POMS because the Chalder's FS is not appropriate for evaluating short-term changes in fatigue. Practicing isometric yoga significantly decreased the mean F score (from  $21.9 \pm 7.7$  to  $13.8 \pm 6.7$ ,  $P < 0.001$ ) and increased the mean V score (from  $17.8 \pm 7.6$  to  $22.9 \pm 8.2$ ,  $P = 0.002$ ) (Figure 3).

#### Long-term effects of isometric yoga on fatigue

To assess the long-term effects of regular practice of isometric yoga on fatigue, we compared the Chalder's FS total score and the subscale scores for physical and mental symptoms of the control group to those of the yoga group before and approximately two months after the intervention. At baseline, the three scores did not differ significantly between the two groups.

We observed a significant main effect of time in the repeated measure ANOVA for the total score and for the two subscores (total score;  $f(1) = 12.4$ ,  $P = 0.001$ ; physical symptoms subscore;  $f(1) = 11.0$ ,  $P = 0.002$ ; and mental symptoms subscore;  $f(1) = 8.6$ ,  $P = 0.007$ ). We also found a significant interaction between the intervention and time (total score;  $f(1) = 10.2$ ,  $P = 0.003$ ; physical symptoms subscore;  $f(1) = 7.9$ ,  $P = 0.009$ ; and mental symptoms subscore;  $f(1) = 8.6$ ,  $P = 0.007$ ) (Figure 4 and Table 2). This finding indicates that patients who practiced yoga experienced a greater improvement in fatigue than did those who did not. The main effect for group was not significant for any score (total score;  $f(1) = 2.5$ ,  $P = 0.124$ ; physical symptoms subscore;  $f(1) = 2.9$ ,  $P = 0.099$ ; and mental symptoms subscore:  $f(1) = 1.4$ ,  $P = 0.252$ ).

At the time of the post-intervention evaluation, both the physical symptoms subscale score and the total score of the yoga group were significantly lower than those of



**Figure 3 Acute effects of isometric yoga on fatigue and vigor.**  
 A comparison of the fatigue (F) and vigor (V) scores of the Profile of Mood States (POMS) questionnaire for participants in the yoga group before (pre, blue) and immediately after (post, red) the final 20-minute session of isometric yoga with the instructor. \*\*\* $P < 0.001$ , \*\* $P < 0.01$  (paired  $t$  test).

the control group ( $P = 0.005$ ,  $P = 0.022$ , respectively by the independent-sample  $t$  test). In the control group, neither the total score nor the two subscores differed significantly between the pre- and post-intervention evaluations. In contrast, in the yoga group the mean physical and mental symptoms subscores and the mean FS total score decreased significantly after the intervention period ( $P = 0.004$ ,  $P = 0.004$ ,  $P = 0.002$ , respectively, by the paired-sample  $t$  test; Figure 4).

#### Effect of regular practice of isometric yoga on health-related QOL

To assess if the regular practice of yoga affects health-related QOL, we compared the SF-8™ scores of participants in the yoga group before and after the intervention. At baseline, all subscale scores were less than 50, suggesting that the QOL of patients with CFS is lower than that of the average Japanese population. Among the 10 subscale scores, the mean scores for three increased significantly after regular practice of isometric yoga: bodily pain (BP, from  $41.3 \pm 6.7$  to  $48.1 \pm 7.9$ ,  $P = 0.0001$ ), general health (GH, from  $39.3 \pm 5.3$  to  $43.6 \pm 6.0$ ,  $P = 0.002$ ), and physical component summary (PCS, from  $35.8 \pm 7.2$  to  $40.6 \pm 4.7$ ,  $P = 0.024$ ) (Table 3). These data suggest that yoga relieved the patients' pain and improved their general health.

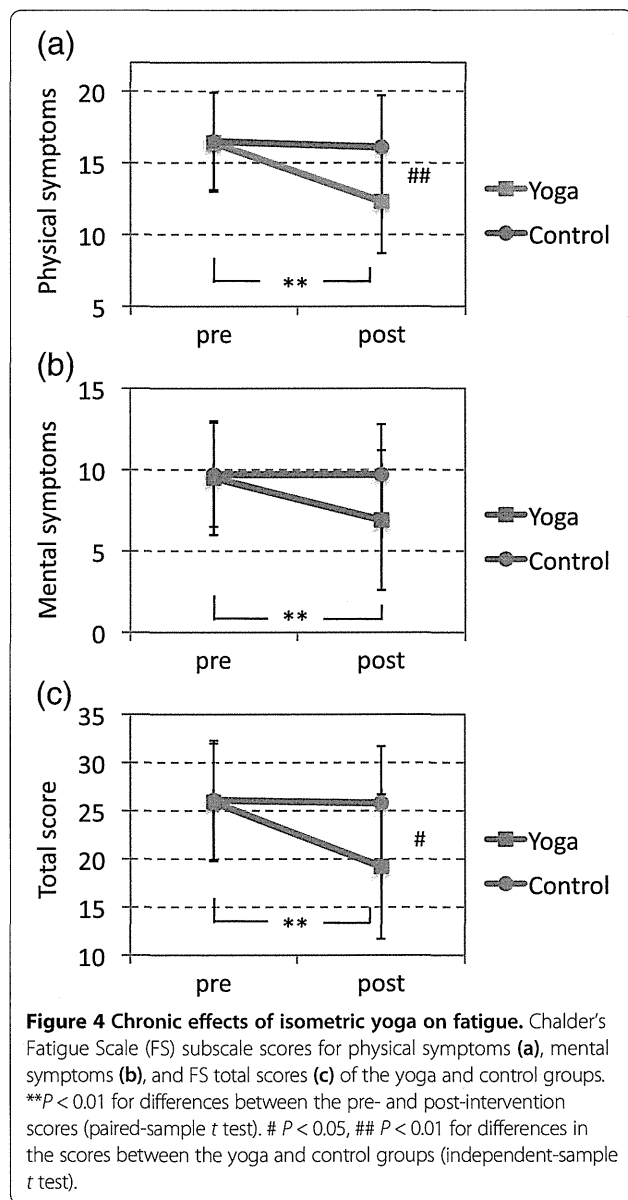
#### Safety and adverse events

At the hospital, one female subject complained of dizziness after her first yoga session. However, she did not require any specific treatment and she did not experience any negative symptoms in the subsequent sessions. After the first yoga session, two patients reported that they felt tired because they had to concentrate and follow the instructions. In subsequent sessions, neither reported that they experienced this symptom. None of the other patients reported any adverse symptoms. During the home

**Table 1 Demographic characteristics of the participants**

	Yoga group	Control group
Number(m:f) <sup>#</sup>	15(3:12)	15(3:12)
Age (years)*	38.0 ± 11.1	39.1 ± 14.2
Chalder's fatigue scale, Physical fatigue*	16.4 ± 3.5	16.5 ± 3.4
Chalder's fatigue scale, Mental fatigue*	9.5 ± 3.5	9.7 ± 3.2
Chalder's fatigue scale, Total score*	25.9 ± 6.1	26.1 ± 6.2

The data shown are the mean ± standard deviation (SD). <sup>#</sup>Not significant by the Fisher exact probability test. \*Not significant by an independent-sample  $t$  test.



practice, two patients reported that they felt light-headed when they practiced yoga with their eyes closed or on bad days, but not with their eyes open or on good days. Finally, none of the patients reported disabling post-exertion malaise after they practiced yoga.

#### Other patient reported outcomes

The short-term effects commonly reported by the patients after practicing isometric yoga included a feeling of warmth ( $n = 11$ ) and lightness ( $n = 8$ ). One subject mentioned that these benefits lasted for one hour. Seven patients reported that they felt more calm, relaxed, and worry-free. Five patients reported pain relief during their yoga practice. Two patients who have fibromyalgia syndrome as well as CFS skipped the arm-stretching pose

because it was difficult and painful for them. They reported that, in the beginning, practicing yoga caused a transient increase in pain because they had to focus on the inner sensations of their bodies. However, as their practice proceeded, they were able to become detached from the pain, and they noticed that the severity of the pain decreased during a yoga session. Regarding the long-term effects, seven patients reported that they now noticed how tense they were in their daily lives and how helpful it was to release muscular tension during yoga. Two patients reported "After regular practice of yoga, I started to wake up more easily in the morning, which had been hard, because tiredness in the morning decreased."

#### Adherence

Adherence was very good overall. All patients practiced yoga with an instructor when they visited the hospital. Fourteen of the 15 patients kept yoga diaries. Based on the records in their diaries, these 14 patients practiced isometric yoga at home for a mean of  $5.8 \pm 1.8$  days/week and  $5.7 \pm 1.8$  days/week during the first and last weeks of the intervention period, respectively.

#### Satisfaction

Fourteen of the 15 patients cited high satisfaction and described isometric yoga as being useful and helpful. One subject reported that she did not want to continue her yoga practice after the intervention period because she was afraid to close her eyes and to see inside.

#### Discussion

The present study demonstrated that isometric yoga together with conventional therapy was more effective in relieving fatigue than was conventional therapy alone in patients with CFS who did not respond adequately to conventional therapy. To our knowledge, this is the first clinical trial that assessed the effects of yoga on the fatigue of CFS patients.

The first aim of this study was to assess the feasibility of isometric yoga as a treatment for CFS. Some patients with CFS experience adverse events such as worsening of fatigue and physical function even when treated with conventional therapies such as CBT and GET [17]. Although two patients in this study complained of tiredness at the first yoga session, they did not have this complaint after they became accustomed to the procedures. Participants had neither serious adverse events nor post-exertion malaise lasting for more than 24 hours. Furthermore, this study exhibited an excellent level of adherence and participant satisfaction. Taken together, our results suggest that an isometric yoga program is both feasible and acceptable for patients with CFS.

Our results also indicate that isometric yoga can significantly improve fatigue, enhance vigor, reduce pain,



**Table 2 Changes in Chalder's Fatigue Scale (FS) subscale and total scores from baseline to post-intervention of patients in the yoga group compared with the score changes of those in the control group**

Chalder's fatigue scale	Yoga group mean (SD)	Control group mean (SD)	Significance of change (P values)		Time x group interaction
			Within- group		
			Yoga group	Control group	
Physical symptoms					
Pre-intervention	16.4 (3.5)	16.5 (3.4)	0.004	0.779	0.009
Post-intervention	12.3 (3.8)	16.1 (3.6)			
Mental symptoms					
Pre-intervention	9.5 (3.5)	9.7 (3.2)	0.004	0.395	0.007
Post-intervention	6.9 (4.4)	9.7 (3.1)			
Total score					
Pre-intervention	25.9 (6.1)	26.1 (6.2)	0.002	0.550	0.003
Post-intervention	19.2 (7.5)	25.8 (5.9)			

Tested with repeated measures analysis of variance (ANOVA), followed by post-hoc, within-group, paired-sample t tests.

and improve QOL, and thus may offer a promising new treatment modality for patients with therapy-resistant CFS. The isometric yoga intervention reduced Chalder's FS scores, especially the physical symptoms subscore. It also improved the BP, GH, and PCS subscores of the SF-8, although it did not improve the mental component summary subscore. Therefore, isometric yoga may improve the physical components of CFS, including physical fatigue or pain, more effectively than the psychological ones. Interestingly, isometric yoga improved pain as well as fatigue. In the yoga group, two patients who were diagnosed with both CFS and fibromyalgia syndrome also reported pain relief. Therefore, isometric yoga might be an effective treatment for both conditions.

Some patients reported these benefits even just after their first session with an instructor. In contrast, others reported adverse events such as dizziness in the beginning. For some patients, it was an effort to memorize

the procedures. However, as they practiced, they eventually felt the beneficial effects described above. In most cases, the patients began to feel beneficial effects within one month of practicing isometric yoga, as determined from their yoga diary and interviews.

Previous studies have demonstrated that yoga improves the fatigue of patients with cancer [7]. Although the precise mechanisms of cancer-related fatigue are not yet fully understood, several common mechanisms are suggested to exist between cancer-related fatigue and the fatigue associated with CFS. These include dysfunction of the autonomic nervous system and the hypothalamic-pituitary-adrenal axis, disruption of circadian rhythms, and misregulation of cytokine expression [18-23]. Yoga has been reported to reduce serum levels of cortisol [24] and proinflammatory cytokines such as interleukin-6 [25,26]. It also increases heart rate variability and shifts the autonomic nervous system from a state predominated by sympathetic activity to one predominated by parasympathetic activity [27,28]. All of these changes may contribute to the beneficial effects of isometric yoga, one of which is reduced fatigue. As many patients reported that their bodies became warmer during a yoga session, isometric yoga may improve systemic circulation, and this physiological change might also reduce the pain and fatigue of CFS. However, the mechanisms behind the beneficial effects of this isometric yoga program are not fully understood yet. Therefore, these will be the focus of a future study. We have already investigated the changes in autonomic functions and in the blood levels of several biomarkers, the results of which will be published soon.

#### Limitations

This study had several limitations. Firstly, the effects of yoga were evaluated for patients (1) whose fatigue level was not serious enough to require assistance with the activities of daily living, and (2) whose fatigue did not

**Table 3 Changes in Short-Form 8 (SF-8) scores obtained before (pre-) and after (post-) the intervention for participants in the yoga group**

	Pre	Post	P value
Physical functioning (PF)	39.6 ± 9.1	42.5 ± 7.1	n.s.
Role physical (RP)	34.4 ± 8.4	38.4 ± 6.4	n.s.
Bodily pain (BP)	41.3 ± 6.7	48.1 ± 7.9	P = 0.0001
General health perception (GH)	39.3 ± 5.3	43.6 ± 6.0	P = 0.0021
Vitality (VT)	43.7 ± 4.9	43.5 ± 6.1	n.s.
Social functioning (SF)	37.6 ± 7.8	37.6 ± 7.8	n.s.
Role emotional (RE)	39.2 ± 12.6	44.4 ± 9.3	n.s.
Mental health (MH)	45.8 ± 9.5	46.8 ± 9.5	n.s.
Physical component summary (PCS)	35.8 ± 7.2	40.6 ± 4.7	P = 0.024
Mental component summary (MCS)	44.1 ± 8.5	44.5 ± 7.9	n.s.

The data shown are the mean ± standard deviation (SD). The P values assess the differences in scores between the pre- and post-intervention periods (paired-sample t test).

recover fully with ordinary treatment for more than six months. Secondly, we customized the yoga program for the patients in this study. Therefore, further studies are necessary to determine if we can generalize these findings to all patients with CFS or to any kind of yoga program. Thirdly, as this study evaluated the feasibility of a yoga program, we assessed the effects of isometric yoga for a relatively small number of patients and for a short intervention period. Two months might not be sufficient to fully evaluate the feasibility and the effects of yoga. Future studies should evaluate the long-term effects of isometric yoga. Finally, one subject did not want to continue practicing isometric yoga after the intervention period. This patient experienced psychological trauma at a young age and had a difficult life after that. Therefore, future studies should evaluate and treat comorbid psychiatric diseases, especially posttraumatic stress disorder, before considering treatment with yoga.

## Conclusions

This study demonstrated that a combination therapy consisting of isometric yoga and pharmacotherapy is feasible and that it can relieve the fatigue and pain of patients with CFS who are resistant to conventional therapy. Further studies are needed to determine the mechanisms by which isometric yoga improves fatigue.

## Abbreviations

ANOVA: Analysis of variance; BP: Bodily pain; CFS: Chronic fatigue syndrome; CBT: Cognitive behavioral therapy; F: Fatigue; GET: Graded exercise therapy; GH: General health perception; MCS: Mental component summary; MH: Mental health; SD: Standard deviation; SF: Social functioning; SF-8: Short form-8; PF: Physical functioning; PCS: Physical component summary; POMS: Profile of mood states; QOL: Quality of life; RE: Role emotional; RP: Role physical; V: Vigor; VT: Vitality.

## Competing interests

The authors declare that they have no competing interests.

## Authors' contributions

TO designed the study protocol, treated patients, analyzed the data, and drafted the manuscript. TO consulted with Dr. Keishin Kimura and Ms. Hisako Wakita to develop the isometric yoga program for CFS patients. TT also treated patients. TT and TC assisted with data collection. NS looked over the study. TC, BL, and KO assisted with data analysis. All authors read and approved the final manuscript.

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## 慢性疼痛に対するヨガの有効性と安全性

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**要 旨：**近年、腰痛症や線維筋痛症などの疼痛性疾患に対するヨガの有用性を検討した研究が増えてきている。ヨガは腰痛症患者の痛みを軽減するだけでなく機能障害に対しても有効である。また精神症状や破局化傾向も改善することが報告されている。ヨガを練習すると、脳内 GABA が増加し、末梢ストレスマーカーや炎症マーカーが低下すること、さらに交感神経系の緊張が低下し、心拍変動が増加することが明らかにされており、これらの変化は心因の関与する疼痛性疾患患者に対して有効に作用すると考えられる。しかしながら一部の患者では腰痛が増悪すること、線維筋痛症の痛みに対する有効性に関しては一定の結論が得られていない点には注意が必要である。我々は慢性疲労症候群患者に対してアイソメトリックヨガを取り入れ、アイソメトリックヨガによって疲労と疼痛が改善することを見いだした。慢性疲労症候群と線維筋痛症を合併した症例の疼痛にも有効であるため、あわせて紹介する。

索引用語： ヨガ；慢性疼痛；線維筋痛症；慢性疲労症候群；ストレス

## Safety and effectiveness of yoga for chronic pain

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Keywords: Yoga; Chronic pain; Fibromyalgia syndrome; Chronic fatigue syndrome; Stress

## はじめに

近年、ヨガはストレスを軽減したり、健康を維持、増進するために広く用いられている。実際、ヨガには抗ストレス作用が存在することが明らかにされており、医学的効果に関する臨床研究も進んでいる。例えば2000年から2012年の間には212のランダム化比較試験（randomized, controlled trial, RCT）が報告されている。そのなかでも多いのが、乳がん生存者と疼痛性疾患に対するヨガの有効性を検討した研究である。そこで本稿では、疼痛性疾患

に対するヨガの有用性とその機序、および治療法としてヨガを選択する際の注意点について考察する。

## 医学領域で用いられるヨガ

ヨガの教典である「ヨガ・スートラ」によると、ヨガとは心の作用の抑制である。心の作用を抑制し解脱に至るためには8つの段階（8支則）がある。8支則のうち、どの要素を重視するか、誰がはじめた方法かなどによって、ハタヨガ、アシュタンガヨガ、アイアンガーヨガなど、様々な呼称があるが、医療

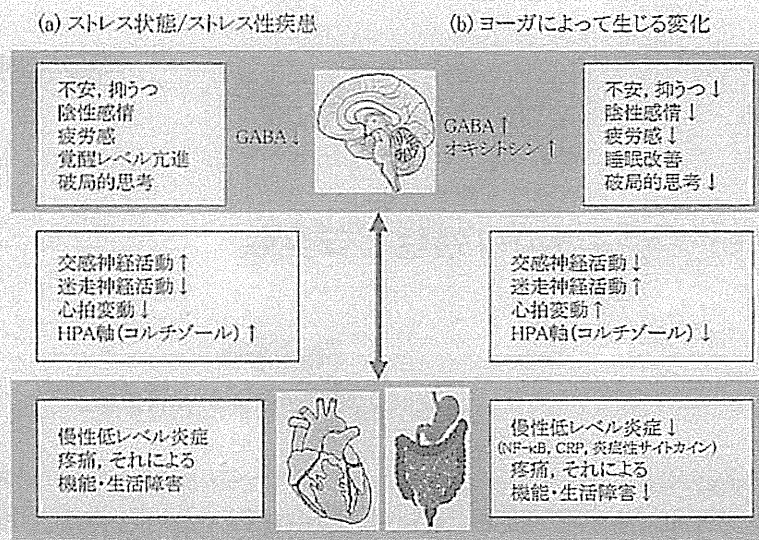


図1 ヨガによって生じる心理生理的变化

- (a) ストレス状態, もしくはストレス性疾患患者でみられる病態  
 (b) ヨガによって生じる変化; ヨガはストレス状態に対しておおむね抑制的に作用することがわかる(文献1より一部改変して引用)  
 HPA, 視床下部-下垂体-副腎皮質系; GABA,  $\gamma$ -アミノ酪酸

の中で用いられているヨガプログラムは, 主にアーサナ(体位法), プラーナヤーマ(呼吸法), ディアーナ(瞑想法)の3つを組み合わせたものが多い。

### ヨガの抗ストレス, 抗炎症作用

慢性疼痛患者は痛みだけでなく, しばしば不安感や抑うつ気分, 落胆などの精神症状を訴え, 破局的な思考に陥るなどの認知の変化も生じている。不眠や疲労感も訴える者も多い。痛みの存在や, 精神的ストレスは交感神経・副腎髄質系と視床下部-下垂体-副腎皮質系の活動を亢進させる一方で, 心臓迷走神経活動を抑制し, 心拍変動(HRV)を低下させる。慢性ストレス状態は炎症マーカーを上昇させ, 慢性低レベル炎症を持続, 増悪させる。

ヨガを練習すると, 慢性疼痛患者でみられるこれらの変化に対して, おおむね拮抗的な反応が生じる(図1)<sup>1)</sup>。つまり不安, 抑うつ, 陰性感情, 疲労感は減少し, 痛みに対する破局的思考や睡眠障害が改善する。また交感神経活動と血中, 唾液中コルチゾール値が低下し, HRVは増加する。慢性疼痛患者では抑制性神経伝達物質である $\gamma$ -アミノ酪酸( $\gamma$ -

aminobutyric acid, GABA)の脳内レベルが低下しているが, ヨガを練習すると脳内GABAが増加すること<sup>2)</sup>や, 鎮痛作用を持つ血漿中オキシトシン濃度が増加する<sup>3)</sup>ことも明らかにされている。

さらにヨガの練習は炎症に対して抑制的に作用する。例えばヨガを練習すると血中CRPやIL-1 $\beta$ , IL-6, TNF- $\alpha$ などの炎症マーカー値は低下<sup>4,5,6,7)</sup>, もしくはストレス性に生じる増加は抑制される<sup>8)</sup>。炎症性転写因子であるNF- $\kappa$ Bやtype I IFNに関連する転写物がダウンレギュレートされるが, このような変化は, 主に単球, NK細胞で生じることが示唆されている<sup>9)</sup>。Type I IFNや炎症性サイトカインの低下は, ヨガが炎症や疼痛に対してのみならず, 疲労に対しても有効であることを説明するかもしれない。

### 筋骨格系疼痛性疾患に対するヨガの有効性

腰痛に対する効果を検討した8つのRCT論文のメタ解析(meta-analysis, MA)によると, ヨガは腰痛症患者の痛みと機能障害を改善する<sup>10)</sup>。それぞれの論文の中では異なったヨガ(ハタヨガ, アイア



ンガーヨガ、ヴィニヨガなど) が用いられているにもかかわらず、同様な効果が得られていることから、臨床効果には一連のポーズの違いよりも、ヨガで強調される、筋力、柔軟性、呼吸、意識の集中といった共通の要素が重要な影響を与えていると考えられる。また、腰痛に限定せず、リウマチ、変形性膝関節症等の筋骨格性疾患全般に対する RCT を検討した MA<sup>11,12)</sup> によると、ヨガの練習は疼痛、機能障害を改善すると同時に、疼痛患者の心理的なアウトカムも改善する。またヨガは慢性もしくは再発性腰痛症患者の医療費を軽減するとの報告もある<sup>13)</sup>。

注意点としては、① ヨガによって逆に腰痛が悪化する者もいること (8~15%)<sup>14,15)</sup>、② 待機群と比較した RCT が多く、積極的コントロール群 (運動等) と比較した研究は少ないため、運動療法と比較したヨガの特長が不明であること、③ ヨガによる効果の持続時間、適正練習量 (臨床効果をあげるためには週に何回、何時間、練習する必要があるのか) が不明な点、などが挙げられる。

### 線維筋痛症に対するヨガの効果

現在、線維筋痛症 (fibromyalgia syndrome, FMS) に対するヨガプログラムの有効性を検討した報告は多くはない。ヨガは FMS 患者の不安、抑うつなどの精神症状や破局的思考を改善する効果はあるが、痛みそのものに対する効果に関しては一致した結論は得られていない<sup>16,17,18,19)</sup>。

### 慢性疲労症候群と線維筋痛症合併例に対するアイソメトリックヨガの有用性

筆者は通常の治療を 6 ヶ月以上行っても十分な改善の得られなかった慢性疲労症候群 (chronic fatigue syndrome, CFS) 患者に対して、アイソメトリックヨガ (図 2) を併用すると、疲労感と疼痛の程度が改善することを報告してきた (図 3)<sup>20)</sup>。

筆者が CFS の治療にヨガを導入することを考えたのは以下の理由による。がん患者の疲労に対して

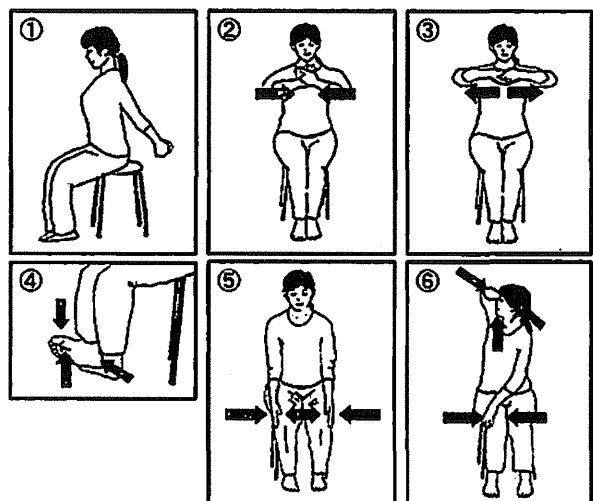


図 2 20分間のアイソメトリックヨガ (座位編) で行うポーズ (文献 20 より引用)

SF-8BP

「過去1ヶ月間に、身体の痛みはどれだけありましたか。」

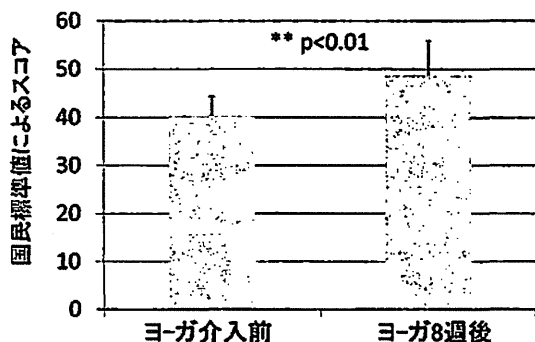


図 3 CFS 患者の痛みに対するアイソメトリックヨガの長期効果 (介入前~8 週後の比較, n=15)

SF-8BP 「過去1ヶ月間に、身体の痛みはどれだけありましたか」国民標準値によるスコアの変化。50 点が日本国民の平均値で、得点が高いほど、痛みによって生活が支障をきたさなかったことを示す。

ヨガが有効であると言う報告があり、また、がん患者の疲労と CFS 患者の疲労には、NF-κB を含む炎症マーカー異常などの共通点が示唆されている<sup>21)</sup> ため、CFS 患者の疲労に対しても有効ではないかと考えた。しかしながら、具体的なプログラムを定める際には以下のことを考慮した。CFS 患者は強い疲労を訴える疾患であり、特に労作後疲労感 (post-exertional malaise, 労作後、休息をとっても回復が著しく遅れ、数日間、寝込んでしまうことも

ある)を特長とする疾患であるため、疲労を増強させないものであること、集中力、短期記憶が著しく障害される病気であるため、簡単なプログラムであること、デコンディショニングが問題となる疾患であるため運動療法としても意味のあるプログラムであること、起立不耐症のものが多く、立って行うポーズは含まないこと、治療の一環として病院で行うため、スペースを要さないものであること。このような条件を満たすプログラムとして、20分間の座位で行うアイソメトリックヨガを採用した。アイソメトリックヨガは、意識を身体に向け、呼吸と動作を一致させ、ゆっくりとアイソメトリック負荷をかけた後に、ゆっくり弛緩するプログラムであり、ストレッチを主眼として難しいポーズをとるハタヨガとは異なっている。

CFS患者は、しばしばFMSを合併する。FMSを合併したCFS患者のアイソメトリックヨガに対する感想を紹介する。

IMさん、37歳女性。薬物療法を拒否したので、認知行動療法と段階的運動療法によって治療。その後、アイソメトリックヨガを導入。「ヨガをすることでからだポカポカして軽くなる。ポカポカすると痛みが楽になる。」

YEさん、26歳女性。入院治療中にアイソメトリックヨガを導入。「ヨガをさせていただいてありがとうございます。最初は『しんどいのには毎週するのはつらい』と思っていたのですが、途中から楽しみになって、それと同時にやっと岡先生が私に体験してほしかったこと(リラックスした状態など)がわかりました。」ヨガでゆっくりと動作ができるようになると、「それまで痛くても速く歩いていたのが、ヨガのときだけでなく、ゆっくり動いてみようかなと思えるようになりました。」

MSさん、28歳女性。ヨガ練習中、身体感覚に意識を向けることは、最初は身体の痛む部位に注意が向き、つらいと訴えていたが、練習が進むにつれ、ヨガ練習中は無心になれるようになり、痛みの訴えが減った。「ヨガはとて素晴らしいです。身体が楽になり、長く動けるようになりました。以前は、夕

方になるとハッとため息をついていたのが、きつなく一日を終えることができるようになりました。今日のヨガも身体がスーっというか、ふわっというか、疲労感がとれました。痛みも随分らくになりました。」ヨガの練習により失感情、失体感傾向も改善した(2ヵ月の介入前後で、TAS-20は66点から51点に、失体感症スケールは73点から61点に減少)。

### ヨガを安全に、有効に利用するために

筆者らは、全国のヨガ教室受講者2508名を対象として、ヨガ教室で生じる好ましくない症状に関する実態調査を行った。その結果、最も多かったのが筋骨格系の症状、つまり筋肉痛(5.3%)、関節痛(4.9%)、足がつる(1.7%)であった。それらのほとんどは、実習に支障をきたさない程度の軽微なものであったが、有害事象の発生頻度は、①持病があると、その病気に関連した症状の発生率が高くなる(腰痛症をもっている人がヨガを練習すると、そうでない人に比べて、筋骨格系の有害事象を訴える頻度が高くなる)こと、②その日の体調や無理をする程度によって左右される(その日の体調が悪い、身体的、精神的に無理をすると有害事象の発生率が高くなる)ことがわかった。そこで筆者らは、病気を持った人がヨガを習うときの注意点について解説したガイドブック(「ストレス関連疾患に対するヨガ利用ガイド」医療従事者用と患者用)を作成した。<http://okat.web.fc2.com/>より無料でダウンロードできるので、活用していただけると幸いである。

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# A large-scale survey of adverse events experienced in yoga classes

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## Abstract

### Background

Yoga is a representative mind-body therapy of complementary and alternative medicine. In Japan, yoga is practiced widely to promote health, but yoga-associated adverse events have also been reported. To date, the frequencies and characteristics of yoga-related adverse events have not been elucidated. This study was conducted to elucidate the frequencies and characteristics of adverse events of yoga performed in classes and the risk factors of such events.

### Methods

The subjects were 2508 people taking yoga classes and 271 yoga therapists conducting the classes. A survey for yoga class attendees was performed on adverse events that occurred during a yoga class on the survey day. A survey for yoga therapists was performed on adverse events that the therapists had observed in their students to date. Adverse events were defined as “undesirable symptoms or responses that occurred during a yoga class.”

### Results

Among 2508 yoga class attendees, 1343 (53.5%) had chronic diseases and 1063 (42.3%) were receiving medication at hospitals. There were 687 class attendees (27.8%) who reported some type of undesirable symptoms after taking a yoga class. Musculoskeletal symptoms such as myalgia were the most common symptoms, involving 297 cases, followed by neurological symptoms and respiratory symptoms. Most adverse events (63.8%) were mild and did not interfere with class participation. In contrast, 1.9% of the attendees with adverse events had to immediately discontinue their class participation. The risk factors for adverse events were examined, and the odds ratios for adverse events were significantly higher in attendees with chronic disease, poor physical condition on the survey day, or a feeling that the class was physically and mentally stressful. In particular, the occurrence of severe adverse

events that interfered with subsequent yoga practice was high among elderly participants (70 years or older) and those with chronic musculoskeletal diseases.

## **Conclusions**

The results of this large-scale survey demonstrated that approximately 30% of yoga class attendees had experienced some type of adverse event. Although the majority had mild symptoms, the survey results indicated that attendees with chronic diseases were more likely to experience adverse events associated with their disease. Therefore, special attention is necessary when yoga is introduced to patients with stress-related, chronic diseases.

## **Keywords**

Yoga, Adverse event, Risk factor, Stress, Large-scale survey

## **Introduction**

Yoga is a representative mind-body therapy of complementary and alternative medicine. In Japan, yoga has been widely practiced to promote health, particularly among young women. Yoga has been reported to improve various stress-induced complaints of the mind and body, including anxiety, insomnia, and fatigue. The mechanism is gradually being elucidated regarding how yoga improves these symptoms. However, reports on yoga-associated adverse events have also been increasing. Glenn Black, a yoga teacher for almost 40 years, stated in a 2012 New York Times article that an increasing number of people have yoga-induced injuries and are in poor physical condition. These injuries include whiplash, muscle damage, and back strain. In addition, serious conditions such as stroke can also occur. Black has been warning people practicing yoga regarding these adverse effects of yoga [1].

Most reports on yoga-associated adverse events have been from randomized controlled clinical trials on the usefulness of yoga and case reports of individuals practicing yoga (for review, see [2]). Lower back pain and muscular pain are the most common symptoms in these reports [3,4]. While yoga has been suggested to relieve chronic neck pain and lower back pain [5], it has also been reported to adversely affect individuals by aggravation of pain [6-9]. Yoga has been indicated to cause musculoskeletal pain in healthy individuals [10], but such pain is mild in many cases. However, some musculoskeletal disorders are serious, such as bone fractures [11,12], tendon and ligament injuries [13,14], muscle strain [15], and myositis ossificans of the forearm [16]. Non-musculoskeletal disorders include ocular disorders such as keratectasia, central retinal vein occlusion, and progressive optic neuropathy in glaucoma patients [17-22], dyspnea and pneumothorax [23-25], and rectus sheath hematoma [26,27]. Rare adverse events are headache [28], sciatic nerve injury [29], hallucination [30], and dental erosion [31]. These adverse events were reported in articles only when they were unique or were seen in specific treatment settings. Only one web-based national survey in Australia investigated the yoga-related injury rate [32]. The results demonstrated that the incidence of yoga-related injuries was relatively low (21.3% of respondents reported some kind of yoga-related injury, and 4.6% sustained an injury in the previous 12 months). However, to date, no study has elucidated the frequency and causes of adverse events in regular yoga classes.

It is important to understand the characteristics, frequencies, and risk factors of yoga-associated adverse events before yoga becomes even more prevalent for stress reduction in healthy individuals and treatment of stress-related disorders. Our study involved a national survey that aimed (1) to elucidate the frequencies and characteristics of adverse events associated with yoga class, (2) to examine the risk factors of adverse events, and (3) to examine the condition of adverse events that yoga therapists observed in their students. In this study, adverse events are defined as “undesirable symptoms or responses that occurred during a yoga class.” Some of these results were reported previously in abstract form [33].

## **Subjects and methods**

### **Subjects**

The subjects were attendees of yoga classes taught by yoga therapists certified by the Japan Yoga Therapy Society and yoga therapists. The yoga classes were in 224 locations in 40 nationwide prefectures in Japan. There were 2508 class attendees (129 men and 2379 women) who responded to the survey. The mean age was  $58.5 \pm 12.6$  years (mean  $\pm$  standard deviation). There were 271 yoga therapists (13 men and 258 women) with a mean age of  $54.1 \pm 10.1$  years. The attendees had taken yoga classes for a mean of  $6.0 \pm 5.56$  years, and the yoga therapists had taught yoga for a mean of  $10.7 \pm 8.4$  years.

### **Methods**

A self-administered questionnaire was conducted among attendees of a yoga class and yoga therapists. The attendees were asked about adverse events that had occurred during the class on the survey day. The yoga therapists were asked about adverse events that they had observed in their students to date.

The author of this study (Matsushita) explained the purpose and methods of this study to the yoga therapists in a seminar. A questionnaire for yoga therapists was given to the therapists, who provided written consent to participate in this survey. The yoga therapists explained the purpose and methods of the survey to yoga class attendees. A questionnaire for attendees was given to the attendees who provided written consent to participate in this survey. The survey period was between April and June 2013.

### **Questionnaire**

#### ***Questionnaire items for yoga class attendees***

A list of physical and psychological symptoms was created based on the Cornell Medical Index (CMI). The class attendees were asked to check the symptoms that they had after taking the class and to report the symptoms using a free-response format. They were asked about their condition on the day of class: physical condition before participation on the day of the yoga class, effort in yoga class (level of overexertion), and physical and mental burden of yoga class (physical and mental strain). Other questionnaire items were on the presence or absence of chronic diseases and their details.

## ***Questionnaire items for yoga therapists***

The questionnaire items for yoga therapists were on adverse events that they had observed in their students to date. They were asked to rate the adverse events by severity (mild, moderate, and severe) and to indicate their frequencies. In addition, they were asked to write about the causes of the adverse events in a free-response format.

## **Statistical analyses**

Results are presented as mean  $\pm$  standard deviation. To assess the risk factors for adverse events, we used the chi-square test and the multiple logistic regression test. Data were analyzed with SPSS ver.21 for Windows.

## **Ethical considerations**

This study was conducted with the approval of the ethics committee of the Institute of Health Science at Kyushu University. Informed consent was obtained from all subjects before the survey was conducted. Their written consent was obtained regarding the use of the questionnaire items. For subjects who were minors, informed consent was obtained from their parents.

## **Results**

### **Frequency and characteristics of adverse events reported after a yoga class**

Table 1 shows the demographic characteristics of yoga attendees who responded to the survey. Their ages ranged from 12 to 93 years and their mean age was  $58.5 \pm 12.6$  years. They consisted of 129 men and 2379 women. There were 1343 attendees (53.5%) with chronic disease and 1063 attendees (42.3%) who were being treated at hospitals as outpatients. The most common chronic diseases were orthopedic disorders such as lower back pain and shoulder muscle stiffness in 537 attendees (21.4%), followed by cardiovascular disease such as hypertension in 479 attendees (19.0%), endocrine and metabolic diseases such as hyperlipidemia and diabetes mellitus in 182 attendees (7.2%), neurological diseases such as dysautonomia and headache in 84 attendees (3.3%), and psychiatric disorders such as depression and insomnia in 79 attendees (3.1%). Other chronic diseases included respiratory diseases, gastrointestinal disorders, and previous cancer (Figure 1).

**Table 1 Demographic characteristics of yoga class attendees**

<b>Age</b>	<b>Men</b>	<b>Women</b>	<b>Total</b>	<b>%</b>
10s	1	0	1	0.0%
20s	4	32	36	1.4%
30s	5	190	195	7.8%
40s	10	371	381	15.2%
50s	21	486	507	20.2%
60s	35	880	915	36.5%
70s	41	369	410	16.3%
80s	12	48	60	2.4%
90s	0	3	3	0.1%