

## ORIGINAL ARTICLE

# Yoga as a Therapy for Adolescents and Young Adults With Cystic Fibrosis: A Pilot Study

瑜伽作为少年和青年囊性纤维化患者的疗法：初步研究

El yoga como terapia para adolescentes y adultos jóvenes con fibrosis quística: Estudio piloto

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## ABSTRACT

**Rationale:** Yoga has been shown to improve outcomes in patients with asthma but has not been investigated in cystic fibrosis (CF) patients.

**Methods:** This was a prospective pilot study to evaluate the safety of a standardized yoga program among CF patients aged 12 to 25 years. Participants engaged in a 50-minute yoga session twice weekly for 8 weeks conducted by a certified yoga instructor using a standardized program designed to be safe for health-compromised individuals. Yoga sessions were individual to avoid transmission of infections. Primary outcome was safety and tolerability. Secondary outcome measures included respiratory symptoms, the Cystic Fibrosis Quality of Life instrument (CFQ-R), lung function, Ease of Breathing Score (measure of exercise tolerance), and weight.

**Results:** Eleven participants were enrolled, and 10 completed the study. Adherence was very good; the mean (SD) number of sessions completed was 14.2 (1.3) out of 16 sessions. Eight patients reported 25 adverse events. The most common was cough, reported in 7. Two events were possibly related to study procedures: calf pain and headache. There were no significant changes in dyspnea or pain scales. The mean (SD) CFQ-R respiratory domain score increased from screening to end of study: 67.9 (11.4) to 82.1 (9.9),  $P=.04$ . There were no significant changes in the other outcome measures.

**Conclusions:** In this pilot study, a standardized 8-week yoga program was safe and well tolerated among adolescent and young adult CF patients with mild to moderate lung disease. This study may be helpful to yoga instructors who are interested in working with CF patients. Larger controlled trials are warranted to determine further benefits.

## 摘要

基本原理：已经显示瑜伽改善哮喘患者的结局，尚未在囊性纤维化 (Cystic Fibrosis, CF) 患者中研究。

方法：这是一项前瞻性初步研究，旨在对年龄在 12 至 25 岁的 CF 患者评价一项标准化瑜伽程序的安全性。参与者每周两次参加 50 分钟瑜伽课程持续 8 周，该课程由认证的瑜伽教师使用设计成对健康受损个体安全的标准化程序实施。瑜伽课程单独进行以避免感染传播。主要结果是安全性和耐受性。次要结果指标包括呼吸道症状、囊性纤维化生活质量仪器记录 (Cystic Fibrosis Quality of Life, CFQ-R)、肺功能、轻松呼吸评分 (锻炼耐受性指标) 和体重。

结果：招募了 11 名参与者，并且 10 名完成本研究。依从性非常好；完成课程的平均 (Standard Deviation, SD) 次数是 16 节课中完成了 14.2 节 (1.3)。8 名患者报告 25 例不良事件。最常见不良事件是咳嗽，有 7 名患者报告。以下 2 例事件可能与研究程序相关：小腿疼痛和头痛。呼吸困难或疼痛评分不存在显著变化。平均

(SD) CFQ-R 呼吸领域评分从筛选至研究结束增加：67.9 (11.4) 增至 82.1 (9.9),  $P=0.04$ 。其他结果指标不存在显著变化。

结论：在这项初步研究中，一项为期 8 周的标准化瑜伽程序在患有轻度至中度肺疾病的少年和青年 CF 患者当中安全及耐受良好。这项研究对有兴趣与 CF 患者合作的瑜伽教师有帮助。有必要进行更大的对照试验以确定其他益处。

## SINOPSIS

**Justificación:** Se ha demostrado que el yoga produce una mejoría en los pacientes con asma, pero no se han investigado sus efectos en los pacientes con fibrosis quística (FQ).

**Métodos:** Este fue un estudio piloto prospectivo para evaluar la seguridad de un programa de yoga estandarizado en pacientes con FQ con edades comprendidas entre los 12 y 25 años. Los participantes asistieron a dos sesiones de yoga de 50 minutos a la semana durante 8 semanas, impartidas por un instructor de yoga cualificado, en las que se empleaba un programa estandarizado con un diseño seguro para las personas con problemas de salud. Dichas sesiones eran individuales para evitar la transmisión de infecciones. El criterio principal era evaluar la seguridad y tolerabilidad. Los criterios secundarios incluían los síntomas respiratorios, el cuestionario revisado sobre calidad de vida para la fibrosis quística (Cystic Fibrosis Quality of Life, CFQ-R), la función pulmonar, el índice de capa-

cidad respiratoria (prueba de tolerancia al ejercicio) y el peso.

**Resultados:** Se inscribieron once participantes, de los cuales diez finalizaron el estudio. El cumplimiento terapéutico fue muy elevado; la media de sesiones completadas (DE) fue de 14,2 (1,3) sobre 16. Ocho pacientes notificaron 25 acontecimientos adversos. El más frecuente fue la tos, notificada en 7 ocasiones. Es posible que dos acontecimientos

estuvieran relacionados con los procedimientos del estudio: el dolor de pantorrillas y la cefalea. No se produjeron cambios significativos en la disnea ni en las escalas de dolor. La puntuación media (DE) de la sección respiratoria del cuestionario CFQ-R aumentó desde la selección hasta el final del estudio: de 67,9 (11,4) a 82,1 (9,9),  $P = 0,04$ . No se produjeron cambios significativos en los demás criterios de valoración.

**Conclusiones:** En este estudio piloto, el programa estandarizado de yoga de 8 semanas demostró ser seguro y tolerarse bien entre los pacientes adolescentes y adultos jóvenes de FQ con enfermedad pulmonar de leve a moderada. Este estudio podría resultar útil para los instructores de yoga interesados en trabajar con pacientes de FQ. Merece la pena efectuar ensayos controlados más amplios para determinar otras posibles ventajas.

## INTRODUCTION

Cystic fibrosis (CF) is a multisystem, life-shortening, inherited disease that affects approximately 30,000 children and adults in the United States and 70,000 worldwide. Chronic lung disease is the main cause of morbidity and mortality in CF.<sup>1</sup> Despite advances in medical therapy, patients with CF continue to suffer from declining lung function and health-related quality of life (HRQoL).<sup>2,3</sup> Interventions that address not only specific organ problems but also overall HRQoL of CF patients are needed.

The practice of yoga involves breathing, stretching, strengthening, and meditation activities. Yoga programs focus not only on physical fitness but also on control of breathing and stress reduction. These activities are typically done in a structured setting with an instructor and can then be easily incorporated into a patient's daily living. Research suggests benefits of yoga for various diseases including respiratory, musculoskeletal, and mental health conditions as well as diabetes.<sup>4-8</sup> In the realm of pulmonary diseases, evidence supports the efficacy of yoga in adults and children with asthma<sup>9-12</sup> and adults with chronic obstructive pulmonary disease (COPD).<sup>4</sup> Yoga has the potential to be beneficial for patients with CF by impacting many aspects of their disease; however, yoga has not previously been investigated in patients with CF.<sup>13</sup> There are several potential mechanisms by which yoga may benefit patients with CF, including improved airway clearance secondary to deep-breathing exercises and strengthening of respiratory muscles. The potential psychosomatic effects of yoga include stress reduction and an improved sense of wellbeing.

This primary aim of this study was to evaluate safety and tolerability of yoga in CF patients. We hypothesized that a standardized 8-week yoga program would be safe and well tolerated by CF patients. We also evaluated secondary exploratory outcome measures including quality of life, lung function, exercise tolerance, and weight.

## METHODS

This was a prospective, single center, pilot study of a standardized yoga program among CF patients aged

12 to 25 years. The study was done in accordance with and approved by the Seattle Children's Hospital Institutional Review Board (approval number 13424). The main objective was evaluation of safety and tolerability. Secondary exploratory outcome measures included 2 CF-specific HRQoL instruments, the Cystic Fibrosis Quality of Life instrument (CFQ-R)<sup>14</sup> and the CF Respiratory Symptom Diary (CFRSD).<sup>15</sup> Other secondary outcome measures included FEV<sub>1</sub> (forced expiratory volume in 1 sec), single breath Ease of Breathing Score (EOBS, a measure of exercise tolerance),<sup>16</sup> and weight.

Recruitment was done by the research staff by approaching patients in CF clinic and also by a mailed letter informing patients about the study. Patients aged 12 to 25 years with a diagnosis of CF were eligible to enroll if their FEV<sub>1</sub> was >40% predicted at screening (ie, mild to moderate lung disease) and if they provided informed consent. Patients were excluded if they had wheezing or oxygen saturation <90% at screening or if they had initiated antibiotic treatment for an acute respiratory infection within 2 weeks prior to screening. Patients were also excluded due to pregnancy, history of lung transplant, or current enrollment in a therapeutic clinical trial. Patients who had regularly practiced yoga ( $\geq 1$  time per week) in the month prior to enrollment also were excluded.

Eligible patients were scheduled for a 50-minute yoga session 2 times per week for 8 weeks. Each yoga session was conducted in the Pediatric Clinical Research Center (PCRC) and included only a single participant to avoid the possibility of transmission of infection, as infection among CF patients may be transmitted by contact.<sup>17</sup> The sessions were designed by the lead yoga instructor in conjunction with the CF research staff. Yoga sessions are summarized by week in Table 1. The yoga sessions included postures and breathing exercises and were conducted by 4 certified yoga instructors who followed a standardized and structured program to ensure consistency. Importantly, yoga sessions were designed to be safe for a health compromised audience. Home practice was neither encouraged nor discouraged.

Data were collected on all participants at a screening study visit before starting the yoga sessions and an

**Table 1** Yoga Sequences by Week

Week	Breathing exercises <sup>a</sup> (3-5 min)	Postures: supine, seated or standing <sup>a</sup> (35-40 min)	Breathing exercises and relaxation <sup>a</sup> (10-15 min)
1	Supine anatomical breathing	Warm-up: Supine backbends, kneeling forward bends, prone backbends (15 min)  Strengthening: Standing forward bends and gentle flows (10 min) Cool-down: Supine twist and supine forward bend (5 min)	Supine anatomical breathing and relaxation in Savasana
2	Supine anatomical breathing	Warm-up: Supine and prone backbends, kneeling forward, bends and kneeling balance (15 min)  Strengthening: Gentle/moderate flows, standing forward bends, and standing twists (15 min)  Cool-down: Supine extensions, forward bends, and twists (10 min)	Supine anatomical breathing and relaxation in Savasana
3	Supine anatomical breathing	Warm-up: Kneeling forward bends, prone backbends, gentle flow (10 min)  Strengthening: Standing forward bends, standing lateral bends, stronger flow (20 min)  Cool-down: Supine extension and supine forward bends (10 min)	Seated 2-part Krama exhale with natural pauses  Relaxation in Savasana
4	Supine anatomical breathing	Warm-up: Kneeling forward bends, prone backbends, gentle flow (10 min)  Strengthening: Standing backbends, standing forward bends, standing lateral bends, and standing balance (20 min)  Cool-down: Kneeling balance, supine extensions, supine twists, and supine forward bends (10 min)	Seated two part Krama exhale with natural pauses  relaxation in Savasana
5	Seated anatomical breathing noticing pause after exhale	Warm-up: Kneeling forward bend, prone backbends, gentle flow (10 min)  Strengthening: Standing backbends, standing forward bends, and standing twist (15 min)  Cool-down: Kneeling forward bend, supine twist, and supine forward bend (10 min)  *Note: Pause after exhale noticed in several postures	Seated 2-part Krama exhale with 2- to 3-sec pause in the middle only. Relaxation in Savasana
6	Seated anatomical breathing noticing pause after exhale	Warm-up: Kneeling balance, prone backbends, kneeling forward bends, gentle flow (10 min)  Strengthening: Standing backbends, standing forward bends standing lateral bend, standing balance, stronger flow (20 min)  Cool-down: Kneeling forward bend, supine extension, supine lateral, supine forward bend (10 min)  *Note: Pause after exhale noticed in several postures	Seated 2-part Krama exhale with 2- to 3-sec pause in the middle only  Relaxation in Savasana
7	Seated anatomical breathing noticing pause after exhale	Warm-up: Kneeling forward bends, prone backbends (5 min)  Strengthening: Standing forward bends, standing twists, stronger flow (15 min)  Cool down: Kneeling forward bend, supine backbend, supine extension, supine lateral, and supine forward bends (15 min)  *Note: Pause after exhale slightly lengthened in several postures	Seated 2-part Krama exhale with 2- to 3-sec pause in the middle and at the end of the exhale  Relaxation in Savasana
8	Seated anatomical breathing noticing pause after exhale	Warm-up: Kneeling forward bend, prone backbends (5 min)  Strengthening: Standing forward bends, standing backbends, standing balance, standing twists, stronger flow (20 min)  Cool down: Kneeling forward bend, supine twist, supine extension, supine lateral, and supine forward bends (15 min)  *Note: Pause after exhale slightly lengthened in several postures	Seated 2-part Krama exhale with 2- to 3-sec pause in the middle and at the end of the exhale  Relaxation in Savasana

<sup>a</sup> Poses are repeated for 3-8 repetitions (depending on posture) and, when appropriate, held for several breaths. Poses and breathing exercises modified depending on participants' needs.

end-of-study visit after completing 8 weeks of yoga sessions. At each of the 2 study visits, the following procedures were performed: vital signs, abbreviated physical exam, spirometry, EOBS, and CFQ-R. At screening and weekly during the intervention, each subject recorded their respiratory symptoms using the CFRSD. Before and after each yoga session, assessments of safety and tolerability were obtained.

Safety and tolerability assessment was comprised of monitoring of vital signs, patient rating of pain and dyspnea, occurrence of adverse events, and adherence to yoga sessions. Vital signs (heart rate, diastolic and systolic blood pressure, and respiratory rate) and oxygen saturation in room air were obtained at each of the 2 study visits. Vital signs and oxygen saturation in room air were also obtained before and after the first 3 yoga sessions. Before beginning each yoga session, participants completed a questionnaire asking about new respiratory symptoms. Chest pain, musculoskeletal pain, and dyspnea were assessed by pain and dyspnea scales before and after each session. If participants reported new respiratory symptoms or rated their degree of dyspnea, chest pain, or musculoskeletal pain in the severe range, the research coordinator or physician was contacted. An adverse event was defined as any medical problem experienced by a participant during the study that was an adverse change from baseline. Potential adverse events related to the practice of yoga were judged to include musculoskeletal adverse experiences including soreness or achiness as a result of the increased use of muscles, and less likely, sprains or strains. Patients with CF often mobilize secretions with activity leading to increased cough and mild dyspnea. Therefore, we felt that it was likely that participants might experience cough or dyspnea during or after a yoga session. Relatedness of any adverse event to study procedures was determined by

the principal investigator, and all adverse events were documented in the adverse event log.

Data were summarized using descriptive statistics. Reference equations of Wang<sup>18</sup> and Hankinson<sup>19</sup> were used to calculate FEV<sub>1</sub> percentage-predicted values. Differences in outcome measures between screening and end-of-study visits were analyzed by 2-sided paired sample sign tests (CFQ-R and CFRSD scores) or paired *t*-tests (lung function, EOBS, and weight). The sample size was based on feasibility constraints for a pilot study rather than statistical power considerations. Analyses were performed using Stata (Release 12.1, College Station, Texas).

## RESULTS

Eleven participants, 9 females and 2 males, were enrolled, and 10 completed the study. All were white. Mean (SD) age, FEV<sub>1</sub> percentage-predicted, and body mass index (BMI) were 20.6 (3.9) years, 86.3% (17.0), and 22.7 (2.9), respectively. Adherence to the study protocol was very good: the mean (SD) number of sessions completed was 14.2 (1.3) out of 16 sessions. There were a total of 25 adverse events reported in 8 participants. The most common adverse event reported was cough in 7 (64%) participants. Musculoskeletal pain was reported by 3 individuals. Of the 25 adverse events, only 2 were possibly related to study procedures; those were headache and calf pain and were of mild severity. There were 10 (40%) adverse events of moderate severity, all unrelated to study procedures. There were 2 (8%) serious adverse events (hemoptysis and pulmonary exacerbation); both occurred after enrollment but prior to starting yoga sessions and were unrelated to study procedures. There were no significant changes in the pain or dyspnea scales before and after yoga sessions throughout the study.

Results of the CFQ-R questionnaire at the begin-

**Table 2** CFQ-R Domain Scores at Screening and End of Study From Nine Participants With Available Data

CFQ-R Domain	Score at Screening Visit, Mean (SD)	Score at End of Study Visit, Mean (SD)	<i>P</i> value <sup>a</sup>
Physical	88.4 (9.5)	88.9 (18.8)	.45
Vitality	64.8 (9.1)	67.6 (14.7)	1.00
Emotion	73.3 (25.8)	80.0 (19.7)	.13
Eating	88.9 (19.2)	90.1 (20.4)	1.00
Treatment burden	59.3 (14.7)	56.8 (17.1)	1.00
Health perceptions	77.8 (17.6)	82.7 (16.8)	.25
Social	73.5 (12.9)	80.2 (4.9)	.29
Body image	88.9 (12.4)	86.4 (21.4)	1.00
Role <sup>b</sup>	92.7 (2.9)	88.5 (14.1)	1.00
Weight	74.1 (36.4)	70.4 (45.5)	1.00
Respiratory	67.9 (11.4)	82.1 (9.9)	.04
Digestion	86.4 (12.1)	88.9 (12.4)	.63

<sup>a</sup> *P* values are from 2-sided paired-sample sign tests testing the equality of matched pairs of observations.

<sup>b</sup> Results reflect 8 subjects; 1 subject was missing the "Role" domain score from the end-of-study visit.

Abbreviation: CFQ-R, Cystic Fibrosis Quality of Life Instrument.

ning and end of the study are summarized in Table 2. There was a significant improvement in the mean (SD) CFQ-R respiratory domain score from screening to end of study (67.9 [11.4] to 82.1 [9.9],  $P=.04$ ). There were no significant changes in the other CFQ-R domain scores, the CFRSD self-reported respiratory symptom score, FEV<sub>1</sub>, weight, or EOBs.

## DISCUSSION

To our knowledge, this is the first study to evaluate yoga in CF patients. Our primary objective was to evaluate the safety and tolerability of yoga in adolescents and young adults with CF. In this small pilot study, a standardized 8-week yoga program was safe and well tolerated. One event each of calf pain and headache were reported as possibly related to the yoga sessions but did not require intervention or result in cessation of yoga sessions. The participants' rating of dyspnea and pain did not change over the study period. Importantly, this study followed US CF Foundation infection control guidelines<sup>17</sup> prohibiting individuals with CF from being in the same room in order to prevent transmission of respiratory bacteria between patients. When considering a yoga program for patients with CF, it is of utmost importance that the sessions are individual or that no more than 1 CF patient attends a given session. In addition, this study evaluated CF patients with mild to moderate lung disease (as measured by their FEV<sub>1</sub>). Our results may not be generalizable in patients with more advanced disease.

Yoga has been shown to improve quality of life in other obstructive lung diseases such as asthma,<sup>20</sup> and quality of life has been found to be associated with other types of physical activity in CF patients.<sup>21</sup> While our study had limited power to detect an effect of yoga on outcomes, we did see a significant improvement in the Respiratory Domain of the CFQ-R health-related quality of life instrument.

An important finding of this study is that during this 8-week yoga program, the adherence to the twice-weekly yoga sessions was very good. This is at least partly due to the fact that the yoga instructors were well informed about CF prior to the study and the yoga sessions were standardized and designed to be safe.

## CONCLUSIONS

This pilot study of a standardized 8-week yoga program in CF adolescents and young adults was safe and well tolerated. Yoga may be considered for CF patients with mild to moderate lung disease. It is suggested that CF patients discuss the potential risks and benefits of yoga with their CF healthcare providers before starting a yoga program. Yoga sessions should include only 1 CF patient due to the possibility of transmitting infection. We hope that this study may be helpful to yoga instructors who are interested in working with CF patients. Larger controlled trials are warranted to determine further benefits of yoga for CF patients.

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