A COMPARISON OF THE EFFECTS OF DIAPHRAGMATIC BREATHING EXERCISES AND YOGA PRANAYAMA TECHNIQUES ON PULMONARY FUNCTION IN INDIVIDUALS WITH EXERCISE INDUCED ASTHMA

By

Richard Serra, B.S.

A thesis submitted to the Graduate Council of Texas State University in partial fulfillment of the requirements for the degree of Master of Science with a major in Athletic Training August 2017

Committee Members:

Rod A. Harter, Chair

Christopher Russian

Lyn Litchke

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LIST OF ABBREVIATIONS

Abbreviation Description

AQLQ Asthma Quality of Life Questionnaire

BP Blood Pressure

ECT Exercise Challenge Test

EIA/EIB Exercise Induced Asthma/Exercise Induced Bronchospasm

FEF 25 – 75 Forced Expiratory Flow at 25% - 75 %

FEV₁ Forced Expiratory Volume in 1 Second

FVC Forced Vital Capacity

HR Heart Rate

HRQOLQ Heath Related Quality of Life Questionnaire

PEF Peak Expiratory Flow

QOL Quality of Life

SF-36 Short Form 36

ABSTRACT

Context: Exercise induced asthma (EIA) has known detrimental effects on both pulmonary function and human performance. Diaphragmatic breathing exercises, a nonpharmacological protocol intended to improve pulmonary function, have been identified as an adjunct treatment for persons with EIA. Yoga and subsequent breathing techniques have also been suggested to increase quality of life in individuals with asthma. **Objective:** To compare the effects of a diaphragmatic breathing exercise (DBE) program to those obtained from yoga pranayama techniques (YOGA) on pulmonary function and the incidence of EIA episodes among individuals with EIA. **Design:** Randomized controlled trial. **Setting:** Controlled laboratory setting. **Participants or Other Patients:** 22 physically active persons with EIA (17 women, 5 men); age range = 18 to 35 yrs. (mean age, 20.6 ± 1.7) were randomly assigned to 3 groups: diaphragmatic breathing exercises (DBE) (n = 6); yoga pranayama techniques (YOGA) (n = 8); and control (CONTROL) (n = 8). **Intervention(s):** Participants assigned to 1 of the 2 treatment groups performed either the DBE or YOGA protocol 4 times per week for 4 weeks. Participants randomized to the CONTROL group maintained their normal daily routines during the 4-week study period. **Main Outcome Measure(s):** Forced Expiratory Volume in 1 second (FEV1), Forced Vital Capacity (FVC), Forced Expiratory Flow at 25 and 75% (FEF 25 – 75), Peak expiratory flow (PEF), SF-36, and Asthma Quality of Life Questionnaire (AQLQ). Results: Statistically significant improvements were found with

all domains of the AQLQ scores in all groups between Week 0 and Week 4 (Total: p =

0.002, Symptoms: p = 0.006, Activity Limitations: p = 0.001, Emotional Function: p =

0.001, Environmental Stimuli: p = 0.001). No other statistically significant differences

were found for any other outcome measures (p > 0.05). Conclusion: The 4-week

intervention protocols did not provide any statistically significant improvements among

the participants with EIA in terms of pulmonary function; however, there was a clinically

relevant change in quality of life as measured by the AQLQ. Given a longer treatment

period, it is possible there can be a positive effect on health related quality of life, and

perhaps pulmonary function.

Key Words: Spirometry, pulmonary function, yoga therapy

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1. INTRODUCTION

Asthma is a chronic disease that affects 26 million individuals in the United States, affecting about 14.6 million women and almost 10 million men, including more than 7 million children. ^{1,2} Asthma was recorded to be one of the top 20 reasons for emergency department visits in 2012, reaching 1.7 million out of 136 million visits. ^{2,3} Annual asthma-related health care costs were \$56 billion nationally in 2007; in addition, asthma results in 14 million lost work days each year. ^{3,4}

The causes of asthma are not consistent among individuals, but can include environmental allergens, anxiety, stress, and/or exercise. 1,5 The exact cause of asthma is unknown, however, researchers believe genetic and environmental factors at an early age influence the development of asthma. This condition can affect any person of any age, and can be so severe as to be life threatening. When a trigger of an asthma attack is present, the bronchospasm that occurs within the bronchioles of the lungs makes it very difficult to breath. Signs and symptoms of asthma include chest tightness or pain, coughing or wheezing, and shortness of breath. Asthma is commonly controlled with a combination of prescription medications; anti-cholinergic agents, short acting β-agonists, or mast cell stabilizers have been shown to be effective against asthma symptoms. ⁶ When an individual is experiencing asthma symptoms, the bronchioles of the lungs are beginning to constrict. Anti-cholinergic agents and short acting β-agonists are used when individuals are experiencing asthma symptoms, both medications act as bronchodilators.^{7,8} Mast cell stabilizers work as a long-term medication by decreasing the sensitivity of mast cells within the body when they are exposed to an allergen. Any medication taken regularly causes medical side effects; β-agonists can increase the risk of cardiovascular disease.⁷ Since there is no cure for asthma at this time, continuous use of medication is required to control symptoms. The most recent cost of asthma per person was approximately \$3,200 per year.³ Asthma medication can cause serious cardiovascular side effects, but also have an effect on a family's annual financial situation.

Approximately 90% of the 26 million individuals suffering from asthma in the United States are affected by exercise induced asthma (EIA). Similar to asthma, EIA affects the bronchioles in the lungs; however, it is triggered by aerobic exercise. Essentially, EIA has the same effect on the respiratory system as asthma; the population of concern includes active individuals and competitive athletes. Exercise induced asthma is successfully treated with β_2 -agonists medications, which have been shown to be the most effective treatment for EIA. This type of medication can be used as either a long-term, prevention medication or a short-acting rescue medication. The long-term β_2 -agonists are typically taken prior to exercise to prevent the onset of EIA symptoms. Short-acting β_2 -agonists medications are used primarily when EIA symptoms are present and need to be reversed.

Unfortunately, excessive use of β_2 -agonists for EIA can result in an increased level of tolerance of the medication among persons with asthma. 10,12 β_2 -agonists used without combination of a corticosteroid could be unsafe, research has yet to be done on the safety of long-term use of β_2 -agonists alone. 12 However, asthma symptoms are poorly controlled, as seen by pharmaceutical refill rates of prescribed asthma medication being around 50%. 11 There is a significant amount of factors that lead to medication refill failure. A chronic disease qualifies as a chronic condition when it is persistent for more than three months. Chronic diseases require constant medication usage, unfortunately

some individuals are unable refill their medication. Some factors associated with poor medication compliance includes but is not limited to: social/economic disparities, healthcare team support or healthcare system allowance, severity of condition or level of disability, complexity of therapy (dosing frequency or form of dosage), and patients' overall attitude or knowledge about their disease.¹³

Several recent clinical studies have reported that diaphragmatic breathing exercises significantly improve quality of life (QOL) and pulmonary function among asthma patients. ¹⁴⁻²¹ Breathing exercises are utilized to allow individuals to consciously activate their abdominal muscles, which in turn expands the diaphragm to force inhalation. This type of breathing exercise focuses on active abdominal motion while limiting chest motion.

Yoga can be considered another form of breathing exercise utilized to improve respiratory health as well as overall mental and physical health. ²²Yoga practice focuses on 3 core concepts termed *pranayama*, meaning breathing exercises, *asanas*, meaning posture, and *dhyana*, meaning meditation. ²² Moderate-quality evidence was found that individuals suffering from asthma had improvements to their quality of life. ²² Since yoga is thought to be an entire body awareness practice, it is claimed to help improve stress and anxiety, ²² the presence of which are triggers for some individuals with asthma.

Yoga has been shown to improve pulmonary function in individuals suffering from respiratory condition.²³ Participants followed a yoga sequence for 7 weeks, 4 of which were supervised and 3 were at home. When compared to a physiotherapy program for improving respiration, the yoga sequence showed a significant improvement of all pulmonary functions except forced vital capacity (FVC).²³ A systematic review of

randomized control trials on the effectiveness of yoga on asthma and pulmonary function, found 4 studies of significance and 3 studies with no relative effect.²⁴

The population studied in most asthma research consists of individuals who live a sedentary lifestyle. Unfortunately, most intervention studies of breathing exercises among persons with asthma are reported to be very low levels of evidence. ²⁵ Due to low levels of evidence, there is little support of a therapeutic benefit of breathing exercises for persons with asthma. That said, many studies have shown positive effects on pulmonary outcome measures and health related quality of life questionnaires (HRQOLQ, providing a foundation for higher quality research to be conducted. ^{16,18-20} To our knowledge, no clinical study that compares the effectiveness of diaphragmatic breathing exercises and yoga pranayama exercises as therapeutic interventions for moderately active individuals with EIA has previously been conducted.

The purpose of this study was to compare the effects of two, 4-week interventions—diaphragmatic breathing techniques and a yoga pranayama exercises—on measures of pulmonary function and health related quality of life (HRLQOL) in physically-active individuals suffering from EIA.

Following the successful oral defense of this thesis, an abstract of these findings will be submitted in advance of the November 15, 2017 deadline for a peer-reviewed presentation at the 69th Annual Meeting of the National Athletic Trainers' Association, to be held in New Orleans, Louisiana from June 26-29, 2018. In the interim, the primary manuscript from this thesis will be submitted for publication to the *Journal of Athletic Training*.

2. MANUSCRIPT

Comparison of the Effects of Diaphragmatic Breathing Exercises and Yoga Pranayama

Techniques on Pulmonary Function in Individuals with

Exercise Induced Asthma

Richard Serra

Rod A. Harter

Christopher Russian

Lyn Litchke

ABSTRACT

Context: Exercise induced asthma (EIA) has known detrimental effects on both pulmonary function and human performance. Diaphragmatic breathing exercises, a nonpharmacological protocol intended to improve pulmonary function, have been identified as an adjunct treatment for persons with EIA. Yoga and subsequent breathing techniques have also been suggested to increase quality of life in individuals with asthma. **Objective:** To compare the effects of a diaphragmatic breathing exercise (DBE) program to those obtained from yoga pranayama techniques (YOGA) on pulmonary function and the incidence of EIA episodes among individuals with EIA. **Design:** Randomized controlled trial. **Setting:** Controlled laboratory setting. **Participants or Other Patients:** 22 physically active persons with EIA (17 women, 5 men); age range = 18 to 35 yrs. (mean age, 20.6 ± 1.7) were randomly assigned to 3 groups: diaphragmatic breathing exercises (DBE) (n = 6); yoga pranayama techniques (YOGA) (n = 8); and control (CONTROL) (n = 8). **Intervention(s):** Participants assigned to 1 of the 2 treatment groups performed either the DBE or YOGA protocol 4 times per week for 4 weeks. Participants randomized to the CONTROL group maintained their normal daily routines during the 4-week study period. Main Outcome Measure(s): Forced Expiratory Volume in 1 second (FEV1), Forced Vital Capacity (FVC), Forced Expiratory Flow at 25 and 75% (FEF 25 – 75), Peak expiratory flow (PEF), SF-36, and Asthma Quality of Life Questionnaire (AQLQ). **Results:** Statistically significant improvements were found with all domains of the AQLQ scores in all groups between Week 0 and Week 4 (Total: p = 0.002, Symptoms: p = 0.006, Activity Limitations: p = 0.001, Emotional Function: p = 0.0010.001, Environmental Stimuli: p = 0.001). No other statistically significant differences

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Key Words: Spirometry, pulmonary function, yoga therapy

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INTRODUCTION

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Unfortunately, excessive use of β_2 -agonists for EIA can result in an increased level of tolerance of the medication among persons with asthma. 10,12 β_2 -agonists used without combination of a corticosteroid could be unsafe, research has yet to be done on the safety of long-term use of β_2 -agonists alone. 12 However, asthma symptoms are poorly controlled, as seen by pharmaceutical refill rates of prescribed asthma medication being around 50%. 11 There is a significant amount of factors that lead to medication refill failure. A chronic disease qualifies as a chronic condition when it is persistent for more than three months. Chronic diseases require constant medication usage, unfortunately

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Yoga can be considered another form of breathing exercise utilized to improve respiratory health as well as overall mental and physical health.²² Yoga practice focuses on 3 core concepts termed *pranayama*, meaning breathing exercises, *asanas*, meaning posture, and *dhyana*, meaning meditation.²² Moderate-quality evidence was found that individuals suffering from asthma had improvements to their quality of life (QOL).²² Since yoga is thought to be an entire body awareness practice, it is claimed to help improve stress and anxiety,²² the presence of which are triggers for some individuals with asthma.

Yoga practice can also improve pulmonary function in individuals suffering from asthma and other respiratory conditions.²³ Participants followed a yoga sequence for 7 weeks, 4 of which were supervised and 3 were at home. When compared to a physiotherapy program for improving respiration, the yoga sequence showed a significant

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The population studied in most asthma research consists of individuals who live a sedentary lifestyle. Unfortunately, most intervention studies of breathing exercises among persons with asthma are reported to be very low levels of evidence. Due to low levels of evidence, there is little support of a therapeutic benefit of breathing exercises for persons with asthma. That said, many studies have shown positive effects on pulmonary outcome measures and health related quality of life questionnaires (HRQOLQ), providing a foundation for higher quality research to be conducted. Report To our knowledge, no clinical study that compares the effectiveness of diaphragmatic breathing exercises and yoga pranayama exercises as therapeutic interventions for moderately active individuals with EIA has previously been conducted.

The purpose of this study was to compare the effects of two, 4-week interventions—diaphragmatic breathing exercises (DBE) and a yoga pranayama exercises (YOGA)—on measures of pulmonary function and health related quality of life (HRQOL) in physically-active individuals suffering from EIA.

METHODS

Design

We conducted a randomized controlled trial to compare the effects of two, 4-week breathing intervention groups versus a control group to evaluate the effects of these programs on pulmonary function and quality of life (QOL). Pulmonary function outcome

measures were evaluated with a 3-way between-within ANOVA model. The three independent variables were Group (diaphragmatic breathing exercises, yoga pranayama exercises, and control), Intervention (Pre (Week 0) and Post (Week 4)), and Time (Pre-Test, Post-Test, 1 minute, 5 minutes, 10 minutes and 15 minutes). The patient-reported outcome measures were analyzed using with a 2-way between-within ANOVA. The two independent variables were Group (DBE, YOGA and Control) and Time (Week 0 and Week 4).

Six outcome measures were obtained at the beginning and end of the 4-week intervention. These measures included: forced expiratory volume in 1 second (FEV₁), forced vital capacity (FVC), pulmonary peak expiratory flow (PEF), forced expiratory flow at 25% - 75% (FEF25%-75%), the RAND SF-36 v.2, and Asthma Quality of Life Questionnaire (AQLQ). This study was approved by the Institutional Review Board at Texas State University for approval on February 7, 2017.

Participants

A total of 22 physically active women (n = 17) and men (n = 5) between the ages of 18 to 35 (mean age, 20.6 ± 1.7) were recruited via university email and flyers posted around the Texas State University campus. We operationally defined "physically active" in accordance to the American College of Sports Medicine and American Heart Association's classification of aerobic activity at least 30 minutes a day for 5 days a week, or 25 minutes of vigorous aerobic activity 3 days a week. Also, volunteers were screened for a previous diagnosis of exercise induced asthma (EIA).

Volunteers contacted the primary researcher via email or telephone for screening to determine qualifying criteria. The primary researcher conducted phone interviews to

determine qualification for the next step. See Table 1 for qualifying criteria and Appendix D for phone questionnaire prompt.

Volunteers were free of any other pulmonary disorders/diseases, free of any cardiovascular disease, free of any orthopedic injuries that will prevent them from participating in exercise, and did not participated in yoga classes more than 2 times a week for 6 months prior to the beginning of the study. Volunteers did not participate in a week or more of yoga classes 6 months prior to the beginning of this study. If volunteers reported having any of the mentioned conditions or reported to practicing yoga on a consistent weekly basis, they were not included in the study. Table 1 provides a summarized list of inclusion and exclusion criteria.

Instrumentation

Pulmonary function tests were recorded using an EasyOne Diagnostic Spirometer (ndd Medizintechnik AG, Zurich, Switzerland).

The Short Form-36 (SF-36 v.2) was utilized to obtain a general health assessment of all volunteers. The SF-36 assesses physical function, role limitations due to physical problems, bodily pain, general health perceptions, vitality, social function, role-limitations due to emotional problems, and mental health. Completion of the SF-36 took approximately 5 minutes and the test was administered as a hard copy form. The SF-36 was scored using QualityMetric Health OutcomesTM Scoring Software 5.0.

The AQLQ is a questionnaire specific to individuals who have asthma. It is sensitive to small changes overtime in patients with asthma. The questionnaire evaluates 4 domains (symptoms, activity limitations, emotional function and environmental stimuli) with 5 patient-specific domains within activity limitations. All volunteers filled

out the questionnaire prior to the Exercise Challenge Test at Week 0 and Week 4 of the study.

Risks Associated with the Study

The testing procedures came with certain risks due to the nature of the Exercise Challenge Test. The Exercise Challenge Test is conducted to produce asthma symptoms, which include shortness of breath, chest tightness, wheezing and coughing. Also, volunteers were asked to exercise at a submaximal heart rate (80 – 90% of their max heart rate) for at most 8 minutes. We excluded individuals who had a history of cardiovascular and cardiopulmonary disease to prevent exacerbation of life threatening symptoms. We excluded individuals with a musculoskeletal injury from the study in order to prevent further injury that may have been caused by the intensity of exercise.

To prevent a serious medical condition from occurring, we excluded individuals with known medical conditions. However, with any exercise testing, there is always a risk of new symptoms to arise to reportedly healthy individual. The primary researcher is a Nationally Registered Emergency Medical Technician (NR-EMT) trained in life threatening cardiac and respiratory conditions. Also, as a nationally certified (certified by the Board of Certification) and licensed (licensed by the State of Texas) Athletic Trainer (LAT, ATC) it is required to be certified in Cardio Pulmonary Resuscitation (CPR) and Automated External Defibrillator (AED). All certifications and valid and up-to-date. The primary researcher supervised all Exercise Challenge Testing and is trained in emergency situations, in the case an emergency medical situation arose. There were no adverse effects during baseline and 4-week post-testing administration of the Exercise Challenge Test.

The interventions of this study were safe and require no physical strain. However, a part of the yoga breathing intervention could possible induce hallucinations in individuals who are suffering from Type I Bi-Polar disorder.²⁸ If a person had Type II Bi-Polar disorder and is taking their prescribed medication properly, the breathing technique may not have the same effect as it does on Type I Bi-Polar disorder. However, it is recommended to have an experienced yoga practitioner working with this population, for the purpose of the study we excluded individuals with Bi-Polar disorder.²⁸ The primary researcher is not an experienced yoga practitioner. The *Kapalabhati* yoga breathing technique is the only technique which has been shown to exacerbate symptoms of Bi-Polar disorder.²⁸

Experimental Procedures

Baseline Testing

After initial phone interview screening, volunteers who qualified and wished to continue with the study were instructed to arrive in comfortable athletic clothing and athletic shoes to participate in exercise. They were also instructed to bring their rescue medication used during symptoms of an asthma attack. The first session last approximately 60 minutes and was held in 1 of 2 places: the Exercise Physiology Lab or the Biomechanics/Sports Medicine Lab in Jowers Center on the campus of Texas State University. Volunteers were instructed to abstain from using any asthma medication 48 hours prior to Exercise Challenge Test. If it was necessary to use medication, they were

Table 1. Inclusion and Exclusion Criteria.

Inclusion Criteria	Exclusion Criteria
Diagnosed with Exercises Induced Asthma (EIA)	Asthma symptoms are not exacerbated by exercise
Physically Active as defined by the American Heart Association	Inactive individuals
Between the age of 18 to 35	Practice yoga more than 2x a week; or have had weekly yoga sessions within the past 6 months
No consistent yoga practice (2x a week or more frequency) in the prior 6 months	Has a respiratory condition/disease other than asthma; has a cardiovascular condition/ disease, or an orthopedic condition/ disease exacerbated by high intensity exercise
 No consistent weekly yoga practice 	Cannot comply with the study duration or interventions
Must be free of other respiratory conditions/diseases	Diagnosed bipolar disorder or known risk of psychosis and PTSD and anxiety/panic disorders, in which they are susceptible to exacerbations
 No orthopedic injury which prevents high intensity exercising for approximately 10 minutes 	
No cardiovascular condition/disease exacerbated by high intensity exercise	
Must not have participated in diaphragmatic breathing exercises in the past 6 months	

permitted to do so; however, testing was postponed for 48 hours after medication usage to allow for clearance of the medication from the body.

Volunteers were provided informed consent which described the purpose of the study and the risks that may arise during the Exercise Challenge Test. Volunteers filled out two HRQLQ: The SF-36 v.2 and the AQLQ. After HRQLQs were administered (10 min), demographic and anthropometric measurements (height and weight) was recorded. Spirometry, heart rate (HR), and blood pressure (BP) were performed prior to exercise to obtain baseline pulmonary function, as well as resting physiological measurements (HR and BP); all measurements were conducted in a seated position.

Volunteers were tested to confirm previous EIA diagnosis by participating in an Exercise Challenge Test, ²⁹ conducted using a treadmill to achieve 80 to 90% of their predicted maximum HR (calculated as 220 – age in years). Achieved HR was maintained for approximately 4 to 6 minutes. The test ended when the volunteer had exercised for at most 6 minutes at 80 to 90% of their maximum heart rate, if they terminated the test on their own accord, or if they reached a total of 8 minutes on the treadmill. Prior to the Exercise Challenge Test, the protocol for testing was explained to the volunteer. It was made clear to the volunteer that this test is necessary to obtain a baseline measurement for data collection, however their safety was priority. In the case the patient did not feel able to continue the exercise test due to severe symptoms they were permitted and encouraged to discontinue exercise and use their rescue medication. In the event a volunteer used their rescue medication and wished to be included in the study, the

Measures of pulmonary function, FEV₁, FVC, FEF 25 – 75, and PEF were obtained for all participants at Week 0 and Week 4. FEV₁ was tested after the exercise challenge test at minutes 1, 5, 10, 15, 20 and 30. A drop of at least 10% in FEV₁ confirmed an EIA diagnosis. The American Thoracic Society suggests this protocol in assessing EIA.²⁹ Spirometry was conducted by the primary researcher, trained on the equipment by a registered respiratory therapist, following American Thoracic Society's standardization of spirometry.³⁰ Heart rate was tracked throughout the Exercise Challenge Test and post-exercise to monitor the volunteer's condition. If FEV₁ returned to baseline prior to 30 minutes, spirometry measurements were discontinued. Volunteers were dismissed after medical assessment by primary researcher to ensure no cardiovascular or cardiopulmonary issues arose.

Following a successful Exercise Challenge Test, confirming EIA, volunteers who elected to continue with the study were randomized. The volunteers were randomized into 1 of 3 groups: a diaphragmatic breathing exercise group (DBE; n = 6), a yoga group (YOGA; n = 8), a control group (CONTROL; n = 8). To accomplish randomization, the first 15 participants selected from a box of sealed envelopes that each contained a slip of paper with the word "diaphragmatic breathing" (n = 5), or "yoga" (n = 5) or "control" (n = 5). This process was repeated 2 times, as we randomize participants 1 through 15 and participants 15 to 22 to their respective groups, to ensure randomizations occurred evenly across groups.

Once randomized to a group, each participant received a packet containing information about their specific intervention, including photographs of the positions they

will be in for the exercises, descriptions of each exercise, and a log packet that was used to track their home exercise progress, and description of their home exercise programs.

The initial session of either the DBE group or the YOGA group lasted approximately 30 minutes for introduction and education of techniques. Following the initial session, all subsequent sessions remained at 20 to 22 minutes, allowing ample time for exercises and rest, refer to Table 2 for intervention group protocols. The intervention sessions consisted of 3 supervised group sessions per week for the entire 4-week period, as well as 10 unsupervised home sessions 5 times per week, twice a day, for the entire 4-week period. Participants were instructed to perform the home exercise programs twice a day for 5 out of 7 days.

All participants who completed all aspects of the study received \$50 gift card as compensation. Participants who withdrew from the study after 2 weeks received a \$10 gift card. Participants who completed the study but had a compliance rate of 80% with supervised sessions (9 supervised sessions) and 75% home exercise programs (30 unsupervised HEP), including journal entries, received a \$30 gift card. Compliance rate below 75% for the entire study (less than 49 supervised and unsupervised sessions) resulted in exclusion of participant from the study.

Of 23 participants randomized to groups, 22 completed the 4-week clinical trial, returned for post-testing, and received compensation. Nineteen participants received full \$50 compensation, attending more than 75% of the supervised sessions and complied with more than 80% of the home exercise requirements. Three participants received \$30 compensation due to their attendance of less than 75% of the supervised sessions. Only 1

participant who was randomized did not receive any compensation due to attendance of less than 50% of the supervised sessions, and did not return at Week 4 for post-testing. Diaphragmatic breathing exercises (DBE)

Participants were asked to attend 3 sessions a week, for 4 weeks. Supervised sessions were conducted in Jowers Center in an available group exercise room or lab space. Participants assigned to the diaphragmatic breathing group went through a single training session on how to breathe utilizing their diaphragm. Participants were in a supine position with their torso at a 30 to 50-degree angle, with their hips flexed to approximately 50 degrees and their knees in a comfortable flexion position (semirecumbent). Semi-recumbent position can be achieved by turning a sturdy backed chair upside down and laying on the incline of the back of the chair. The primary researcher instructed all participants to relax and place their hands on their abdomens. The next command was a slow, deep inhalation through their noses lasting about 10 seconds. The researcher described to the participants how they should physically feel with correct breathing by stating, "You should feel your stomach filling up with air like a balloon". A slow exhale followed and the researcher described the sensation to the volunteers by stating, "Use your stomach to push the air out of your stomach through pursed lips" Pursed lips was described as pressing your lips together to flatten them and allowing as little air as possible to escape during a 20 second exhale.

The breathing exercise session was continued by applying a 2.5 kg weight to the participant's abdomen, and each person was given a 1 cm in diameter by 10 cm long tube to breathe through. Participants stabilized the weight on their abdomen with one hand and held the tube steady in their mouth with the other hand. The tube mimicked pursed lips to

ensure consistent release of air throughout the session. Participants inhaled through the tube using the same concept taught prior, "filling up the balloon in their abdomen".

Participants performed 3 sets of 10 repetitions using a ratio of 1 second inhale to 2 second exhale. A 60 second rest period was given between sets. Next set of 3 consisted of 15 repetitions with a ratio of 2 second inhale to 4 second exhale. The final 3 sets consisted of 20 repetitions using a ratio of 3 second inhale to 6 second exhale. Refer to Table 2 for intervention protocol.

The participants in the DBE group were asked to refrain from practicing yoga during the 4-weeks of the study, perform their home exercise programs diligently, and log the appropriate information in the log packets provided.

Table 2. Intervention Protocols

Yoga Group
Warm up
Ujjayi (5 cycles)
Standing Forward Fold (5 cycles)
Seated forward fold (5 cycles)
Head to knee pose (5 cycles)
Pranayamas (semi-recumbent to easy
cross legged)
Adhama Svasa (abdominal
breathing)
• 3 – 5 cycles
Begin in soft belly and progress to
firm belly (2 weeks)
Kapalabhati
3 cycles of 9 breaths
Nadi Shodhana
• 3 – 5 cycles
• 2:8:4 (inhale: hold: exhale)
Progress to: 4:16:8 (2 weeks)
Postures
Supported half shoulder stand (5)
cycles)
l l

Yoga pranayama techniques (YOGA)

Participants were asked to attend 3 sessions a week for 4 weeks. Each session lasted approximately 20 minutes following a single introduction to procedures session that lasted approximately 30 minutes in length. Supervised sessions were performed in an available group exercise room or lab space.

Participants in the yoga group participated in a 20-minute yoga session. The session included 3 types of pranayama: *Adhama Svasa* (abdominal/diaphragmatic breathing), *kapalabhati* (breath of fire), and *nadi shodhana* (alternate nostril breathing), refer to Table 3 for descriptions. The yoga session began with 3 yoga postures which participants were instructed to breathe in through their nose and out through their nose. They performed 5 breath cycles (inhale through the nose and exhale through the nose = 1 cycle) before moving on to the next posture. The first posture was standing forward fold. Participants progressed to a seated position to perform seated head to knee pose and then forward fold, refer to Table 3 for descriptions of yoga postures. After warm-up postures, participants moved to a semi-recumbent position for *adhama svasa*. Participants then moved to *sukasana* (easy cross legged seated upright position) for *kapalabhati* and *nadi shodhana*. *Nadi shodhana* was completed at a beginning ratio of 2:8:4 seconds (inhale: hold: exhale), and progressed to 4:16:8 after 2 weeks and this ratio was used for the remainder of the study. Refer to Table 2 for intervention protocol.

Participants in the YOGA group were asked to refrain from participating in any further yoga practices for the duration of the study, preform their required home exercise program, and log the appropriate information in the provided log packet.

Table 3 - Yoga Breathing and Posture Descriptions.

Technique	Description
Yoga postures	
Standing Forward Fold	This posture is performed in a standing position, with knees bent slightly and comfortably. Bending at the waist, bring your upper body down so you are looking at the floor or legs (depending on flexibility). Relaxing the head, neck and shoulders.
	Modification: if positon is uncomfortable in back of legs or low back, placing hands on shins or knees is recommended. Comfort is priority in this pose.
Head to knee forward bend	This posture is performed in a seated positon on the floor with one leg straight out. The opposite leg is bent with the foot touching the inner thigh of straight leg. Bending at the waist, the goal is to bring your head to your knee. Return to a straight seated position, and switch legs. The leg that was bent should be straight, and the leg that was straight should be bent, with the foot touching the inner thigh of your straight leg. Modification: if position elicits any pain or discomfort place hands on extended leg
	in the position of most comfort. The opposite knee should be supported with pillows until comfort is felt and knee is as close to the ground as possible.
Seated Forward fold	Sitting on the floor with both legs straight, the goal of this posture is to bring body and head down towards the ground. Knees should be bent slightly for comfort. No pain or discomfort should be felt in the body.

Table 3 cont.

Cumported Half Charlden Ctand	I aving on the anound with leasure assisted
Supported Half Shoulder Stand	Laying on the ground with legs up against
	the wall and a pillow or blanket
	underneath the head and upper shoulders,
	you should push feet into the wall so they
	are flat. Knees should be bent and upper
	legs and body should be in line and
	perpendicular to the ground. Weight of
	body should be supported by shoulders.
	Hands can be supporting low back in this
	position. No weight should be on neck in
	this position.
	Progression: Advancement of this position
	requires removal of one foot from the
	wall, extending knee to be in line with rest
	of body. Further progression involves
	removal of second foot, extending both
	knees to be in line with the body, at this
	time the entirety of the body weight is
	supported by the upper shoulders, not the
	neck.
Sukasana	This position is easy cross legged in an
	upright seated position. Legs are crossed
	and feet are positioned under legs close to
	the body. Knees are relaxed and supported
	with pillows or other object for comfort.
Shavasana	This position can be accomplished by
	laying on the ground looking at the
	ceiling. Arms are extended comfortably at
	your side. Legs are extended comfortably.
	Another name for this posture is "the
	corpse pose".

Table 3 cont.

Breathing Techniques	
Adhama Svasa (abdominal breathing)	Sitting or lying, place hands on abdomen. Inhale through the nose completely, slowly, and continuously, expanding the abdomen and the lower sections of the lungs like a balloon. Pause briefly. Exhale through the nose by drawing the abdomen inwards in a continuous and slow manner. Pause again and repeat inhale. Soft belly: passive inhale/exhale keeping abdominal muscles relaxed Firm belly: passive inhale with a
	contraction of abdominal muscles during exhalation
Kapalabhati (breath of fire)	Inhale through nostrils and fill chest. Hold the chest in that "puffed up" position for the remainder of the exercise. Inhale and exhales will be performed rapidly and forcefully through nostrils. Performed at high rates for short cycle periods.
	Note: Breath of Fire has been reported to induce mania in individuals with Bi-Polar disorder. It is recommended to avoid use of this breathing technique with individuals with Bi-Polar I disorder and used with caution in individuals with Bi-Polar II disorders.

Table 3 cont.

Breathing Techniques	
Adhama Svasa (abdominal breathing)	Sitting or lying, place hands on abdomen. Inhale through the nose completely, slowly, and continuously, expanding the abdomen and the lower sections of the lungs like a balloon. Pause briefly. Exhale through the nose by drawing the abdomen inwards in a continuous and slow manner. Pause again and repeat inhale. Soft belly: passive inhale/exhale keeping abdominal muscles relaxed Firm belly: passive inhale with a
	contraction of abdominal muscles during exhalation
Kapalabhati (breath of fire)	Inhale through nostrils and fill chest. Hold the chest in that "puffed up" position for the remainder of the exercise. Inhale and exhales will be performed rapidly and forcefully through nostrils. Performed at high rates for short cycle periods.
	Note: Breath of Fire has been reported to induce mania in individuals with Bi-Polar disorder. It is recommended to avoid use of this breathing technique with individuals with Bi-Polar I disorder and used with caution in individuals with Bi-Polar II disorders.

Table 3 cont.

Nadi Shodhana (alternate nostril breathing)	The technique must begin and end with the left nostril. Begin by closing the right
	nostril with thumb and inhale through left
	nostril. Hold the breath by closing off left
	nostril with pinky. Release right nostril
	and exhale through the right nostril while
	keeping the left closed. Hold the breath
	OUT by closing right nostril with thumb
	again. Open right nostril and inhale
	through right nostril holding left closed
	with pinky still. Hold breath IN by closing
	both nostrils. Exhale through the left nostril by closing the right. This is
	considered 1 cycle. Perform this process
	for required amount of cycles.
	Tor required amount or eyeress.
	<i>Note:</i> If individuals have a deviated
	septum, this breathing technique may feel
	restricted in one nostril compared to the
	other. While no serious risk is seen with
	this condition, caution should be used to
	prevent feeling of suffocation from
	occurring.
	Nasal cycling may be occurring at the
	time of practice. Nasal cycling is a
	phenomenon of breathing out of one
	nostril naturally while the other feel
	occluded. Again, no known risk is
	associated with this phenomenon and this
	breathing technique, however, caution
	should be used.
Ujjai	Inhalation through nose, exhalation
	through nose while restricting the back of
	the throat on the exhale. Sound produced
	should be a soft snore.

Control group

Individuals assigned to the control group were instructed to maintain normal daily activities during the 4-week duration of the study. These participants were asked to refrain from participating in any form of yoga or starting any other new exercise programs during the 4-week trial period, and log the appropriate information in the log packet provided.

Home Exercise Program and Activity Log

All participants were instructed to log their symptoms and medication usage over the 4-week study. Participants were instructed to log the number of times they used their medication per day, and the activity that elicited use of the medication. In addition, participants in the intervention groups were instructed to log the day and time of completion of the unsupervised sessions.

Participants assigned to the DBE group were instructed to complete diaphragmatic breathing exercises at home up to 2 times a day (morning and evening) 5 days a week for 4 weeks. The home exercise component for the diaphragmatic breathing group was 10 minutes spent in the semi-recumbent position (as described previously) focusing on breathing with their abdomen (diaphragm). During this time, their aim was 4 diaphragmatic breaths (inhale/exhales) in a minute, continuing this practice for 10 minutes. This breathing protocol was replicated from a study conducted by Salvi et al.³¹, which found significant increases in pulmonary function after 1 week of practice.

Volunteers logged the time of day they performed their sequence and briefly log how they felt before and after their exercises. Refer to Table 4 for home exercise programs.

The YOGA group was given a packet, received on the day of group allocation, containing the yoga sequence with descriptions for home use. The yoga group was instructed to perform the same yoga sequence they performed during in supervised sessions up to 2 times a day, 5 days a week. Volunteers logged the time of day they performed their session.

All participants in the study were asked to track their medication usage throughout the study, and what activities elicited use of their medications. Participants in the 2 intervention groups were asked to record the time in which they performed their home exercise programs and had a section for reflections. Participants asked to give a brief reflection at least twice a week about how the exercises are helping their symptoms. The information in the log packets was used as anecdotal evidence to the effect of the intervention protocol.

Table 4. Home Exercise Programs

Home Exercise DBE	Yoga
	Warm up
• Semi – recumbent positon	• Ujjayi
• 3x a day (morning, afternoon, before bed)	Standing Forward Fold (5 cycles)
Techniques	Seated forward fold (5 cycles)
• 4 inhales/exhales per minute	Head to knee pose (5 cycles)
• 10 minutes total	Pranayamas (semi-recumbent to easy cross legged)
• Enter Log	 Adhama Svasa (abdominal breathing) 3 – 5 cycles Begin in soft belly and progress over time to firm belly
	 Kapalabhati 3 cycles of 9 breaths
	 Nadi Shodhana 3 – 5 cycles 2:8:4 (inhale: hold: exhale) Progress to: 4:16:8 (2 weeks) Postures Supported half shoulder stand (3-5 cycles)
	 Progress to: 4:16:8 (2 weeks) Postures Supported half shoulder stand

STATISTICAL ANALYSIS

To analyze the amount of outcome measure recorded during the serial spirometry measurements (Week 0: Pre-Exercise, Post-Exercise at 1 min, 5 min, 10 min and 15 min, and Week 4: Pre-Exercise, Post-Exercise at 1 min, 5 min, 10 min and 15 min), a 3-Way Factorial ANOVA (Intervention (2) x Group (3) x Time (5)) was used on IBM SPSS Statistics v.23. The independent variable "Intervention" was defined as Week 0 and Week 4, which was the Repeated Measure. Week 0 was considered baseline, when pulmonary function measurements and HRQLQ scores were recorded; Week 4 was posttesting for both pulmonary function measurements and HRQLQ. The independent variable "Group" was defined as the 3 experimental groups (DBE, YOGA, CONTROL). The independent variable "Time" was defined as time intervals which spirometry measurements were taken (Pre-Ex, 1 min Post-Ex, 5 min Post-Ex, 10 min Post-Ex, 15 min Post-Ex). There were 2 categories of dependent variables: Pulmonary Function and HRQLQs. Pulmonary Function included the following spirometry measurements: FEV₁, FVC, FEF 25 – 75%, and PEF. HRQLQs were broken down into 7 scoring points from the 2 HRQLQs: SF -36 was broken down to Physical Health scores and Mental Health scores, and the AQLQ was broken down into Total, Symptom, Activity Limitations, Emotional Function, and Environmental Stimuli. Since there were no significant differences found with any of the pulmonary function outcome measures among groups, a post hoc test was not required.

The results from the HRQLQs were analyzed using a 3 (Group) x 2 (Intervention) ANOVA. Group was defined as the experimental groups (DBE, YOGA, CONTROL) and

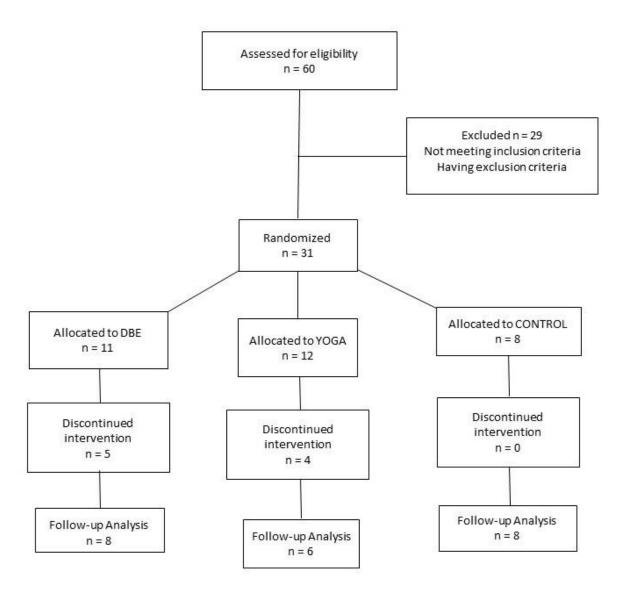
Intervention being defined as (Week 0 and Week 4). Since there were no statistically significant results with this analysis, post hoc analyses were not required.

RESULTS

Sixty (60) volunteers were screened for eligibility to be included into the study. Only 31 of the 60 volunteers (52%) screened for this study met our strict inclusion criteria and were randomized to groups. Eight of the 31 volunteers did not return after randomization to participate in the intervention. All participants complied with at least 75% of the supervised sessions and reported 100% compliance with all home exercise, except 1 participant, who failed to comply with at least 50% of supervised sessions. The 3 groups in the study had the following total of participants at Week 4: yoga breathing group (n = 8), diaphragmatic breathing group (n = 6), and a control group (n = 8). Refer to Figure 1 for a study flow chart diagram.

To determine whether the two experimental groups and the control group were statistically different at the outset of the study, we performed a 1-way ANOVA testing and Levene's Test of Equality of Error Variances on all of the pre-test variables (Week 0). Refer to Table 5. The results of these analyses indicated that our randomization process was successful in distributing the variability homogenously among the 3 groups, as no statistically significant differences were observed for any of the pulmonary function variables or HRQLQ variables among the 3 groups at the beginning of the study (p > 0.05).

Figure 1. Study flow chart.



Participants were required to attend a minimum of 9 out of 12 supervised exercise sessions (75%) to obtain full compensation. If participants attended less than 6 sessions (50%), their data were excluded from the analysis. Out of 15 participants in 2 exercise groups, 11 participated in 75% or more of the supervised sessions. Three participants attended less than 75% but were present for more than 50% of the sessions. One participant was excluded for missing more that 50% of the sessions and not returning after 4 weeks for follow up testing. The 22 participants who returned at 4 weeks for follow-up testing reported 100% compliance with their home exercise sessions.

Pulmonary Outcome Measures

Forced Expiratory Volume in 1-Second (FEV₁)

Mean FEV₁ at Week 4, prior to exercise was as follows per group: DBE = 3.16 ± 0.85 , YOGA = 3.55 ± 1.08 , CON = 3.2 ± 0.28 . Refer to Table 6 for Post-Exercise means and Table 7 for 3-way ANOVA results of primary outcome measure FEV₁. A significant main effect was found for the independent variable Time, defined as time slots which spirometry measurements were taken (Pre-Exercise, 1 min Post-Exercise, 5 min Post-Exercise, 10 min Post-Exercise, and 15 min Post-Exercise) (p = 0.001). No significant differences were found among the 3 experimental groups (p > 0.05) or from Week 0 to Week 4.

Forced Ventilatory Capacity (FVC)

Mean FVC at Week 4, prior to exercise are as follows: DBE = $3.87 \pm .95$, YOGA = 4.20 ± 1.22 , CONTROL = $3.69 \pm .23$. A significant main effect was found for the independent variable Time, defined as time slots which spirometry measurements were taken (Pre-Exercise, 1 min Post-Exercise, 5 min Post-Exercise, 10 min Post-Exercise, and

15 min Post-Exercise) (p = 0.004, partial eta sq. = 0.210, observed power = 0.908). No significant differences were found among the 3 experimental groups (p > 0.05) or from Week 0 to Week 4.

Peak Expiratory Flow (PEF)

Mean PEF at Week 4, prior to exercise are as follows: DBE = 463.17 ± 134.07 , YOGA = 451 ± 129.38 , CONTROL = 406.2 ± 39.05 . A significant main effect was found for the independent variable Time, defined as time slots which spirometry measurements were taken (Pre-Exercise, 1 min Post-Exercise, 5 min Post-Exercise, 10 min Post-Exercise, and 15 min Post-Exercise) (p = 0.000, partial eta sq. = 0.323, observed power = 0.993). No significant differences were found among the 3 experimental groups (p > 0.05) or from Week 0 to Week 4.

Forced Expiratory Flow 25 – 75 (FEF)

Mean FEF at Week 4, prior to exercise are as follows: DBE = 3.27 ± 1.5 , YOGA = 3.65 ± 1.08 , CONTROL = $3.67 \pm .78$. A significant main effect was found for the independent variable Time, defined as time slots which spirometry measurements were taken (Pre-Exercise, 1 min Post-Exercise, 5 min Post-Exercise, 10 min Post-Exercise, and 15 min Post-Exercise) (p = 0.000, partial eta sq. = 0.269 observed power = 0.977). A significant main effect was also found for the independent variable Intervention, defined as Week 0 and Week 4. (p = 0.008, partial eta sq. = 0.366, observed power = 0.814).

Table 5. 1-way ANOVA and Levene's Test of Equality of Error Variances (Week 0)

		pmuut	y voici	110 111 1	Sccond	(FEV_1)	
	N		*	Mean± SD		F	P = .05
DBE	YOGA	CON	DBE	YOGA	CON	_	
7	8	8	3.2 ±	3.3 ±	3.2 ±	.054	.948
			.82	1.12	.32		
7	8	8	3.1 ±	3.1 ±	2.8 ±	.162	.852
			.31	1.2	.82		
7	8	8	2.8 ±	3.0 ±	2.8 ±	.220	.805
			.94	1.13	.60		
7	8	8	2.8 ±	3.2 ±	2.7 ±	.640	.538
			.70	1.21	.50		
7	8	8	2.8 ±	3.1 ±	2.8 ±	.264	.771
			.95	1.20	.60		
	Forc	od Van	tilators	Canac	ity (FV	$\overline{\mathbf{C}}$	
		eu ven					D = 05
DBF		CON				Г	P = .05
						336	.719
,	0	0				.550	./19
7	0	0				165	.849
/	0	0				.103	.649
	0	0				227	725
/	8	8				.321	.725
	0	0				0.27	440
/	8	8				.837	.448
						450	
7	8	8				.650	.533
			./3	1.33	.39		
	Pea	ak Exp	iratory	Volum	e (PEF)		
	N]			F	P = .05
DBE	YOGA	CON	DBE	YOGA	CON		
7	8	8	472.4	410.6	417 ±	1.03	.375
			±	±	34.4		
7	Q	Q			363.8	700	.506
,	0	8		± 114		.707	.500
			170.9				
7	8	8	417.7	380.4	353.4	.494	.618
			±	±	± 57.1		
7	8	8			343.5	419	.663
,					±	.717	.005
			163.5	153.3	44.13		
7	8	8	383.4	380.3	362 ±	.075	.928
			±	±	53.1		
	7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	DBE YOGA 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 N N DBE YOGA 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8	DBE YOGA CON 7 8 8 8 8 8<	DBE YOGA CON DBE 7 8 8 3.2 ± .82 7 8 8 3.1 ± .31 7 8 8 2.8 ± .94 7 8 8 2.8 ± .95 Forced Ventilatory N DBE YOGA CON DBE 7 8 8 4.0 ± .96 7 8 8 3.6 ± .71 7 8 8 3.6 ± .73 7 8 8 3.6 ± .73 7 8 8 3.6 ± .73 Peak Expiratory N DBE 7 8 8 472.4 ± .115.1 7 8 8 445.4 ± .170.9 7 8 8 404.1 ± .170.9 7 8 8 404.1 ± .163.5	DBE YOGA CON DBE YOGA 7 8 8 3.2 ± 3.3 ± 1.12 7 8 8 3.1 ± 3.1 ± 1.2 7 8 8 2.8 ± 3.0 ± 9.94 ± 1.13 7 8 8 2.8 ± 3.2 ± 7.0 ± 1.21 7 8 8 2.8 ± 3.1 ± 9.5 ± 1.20 Forced Ventilatory Capace N Mean± SD DBE YOGA CON DBE YOGA 7 8 8 3.7 ± 3.8 ± 9.97 9.99 7 8 8 3.6 ± 3.9 ± 7.1 1.2 7 8 8 3.6 ± 3.9 ± 7.3 1.35 Peak Expiratory Volume N Mean± SD DBE YOGA CON DBE YOGA 7 8 8 472.4 410.6 ± ± 115.1 104.3 7 8 8 472.4 410.6 ± ± 115.1 10	DBE YOGA CON DBE YOGA CON 7 8 8 3.2 ± 3.3 ± 3.2 ± 3.2 ± 3.3 ± 3.2 ± 1.12 3.2 3.2 ± 1.12 3.2 3.2 ± 1.12 3.2 3.2 ± 2.8 ± 3.1 ± 2.8 ± 3.1 ± 2.8 ± 1.13 6.0 8 2.8 ± 3.0 ± 2.8 ± 1.12 5.0 2.8 ± 1.12 5.0 2.8 ± 2.7 ± 1.21 5.0 5.0 2.8 ± 3.2 ± 2.7 ± 1.20 6.0 2.8 ± 3.1 ± 2.8 ± 1.20 5.0 2.8 ± 3.1 ± 2.8 ± 1.20 5.0 2.8 ± 3.1 ± 2.8 ± 1.20 5.0 2.8 ± 3.1 ± 2.8 ± 1.20 5.0 2.8 ± 3.1 ± 2.8 ± 1.20 5.0 2.8 ± 3.1 ± 2.8 ± 1.20 5.0 2.8 ± 3.1 ± 2.8 ± 1.20 5.0 2.8 ± 3.1 ± 2.8 ± 1.20 5.0 2.8 ± 3.1 ± 2.8 ± 1.20 5.0 2.8 ± 3.1 ± 2.8 ± 1.20 5.0 2.8 ± 3.1 ± 2.8 ± 3.4 ± 3.	DBE

Table 6. 1-way ANOVA and Levene's Test of Equality of Error Variances for AQLQ and SF-36 (Week 0)

Quality of Life Questionnaires (AQLQ and SF-36)								
		N		l	Mean± SD			P = .05
	DBE	YOGA	CON	DBE	YOGA	CON		
AQLQ Total	7	8	8	5.48 ± .72	5.38 ± .52	5.45 ± .77	.186	.832
AQLQ SX	7	8	8	5.65 ± .70	5.55 ± .51	5.62 ± .74	.184	.833
AQLQ AL	7	8	8	5.55 ± .83	5.44 ± .61	5.53 ± .86	.160	.853
AQLQ EF	7	8	8	5.24 ± .81	5.08 ± .61	5.18 ± .86	.234	.793
AQLQ ES	7	8	8	5.20 ± .89	4.99 ± .68	5.20 ± .81	.329	.724
SF-36 PS	7	8	8	53.6 ± 1.67	53.9 ± 3.69	54.6 ± 4.18	.191	.828
SF-36 MS	7	8	8	52.5 ± 5.82	48.4 ± 11.3	55.7 ± 4.19	1.781	.194

Table 7. Week 4 Mean ± SD FEV₁

Forced Expiratory Volume in 1 Second (FEV ₁)					
		Mean± SD			
	DBE	YOGA	CON		
FEV ₁ Pre-Exercise	3.16 ± .85	3.55 ± 1.08	3.2 ± .28		
FEV ₁ 1 min Post-Exercise	3.00 ± .91	3.25 ± 1.27	3.21 ± .41		
FEV ₁ 5 min Post-Exercise	2.92 ± .97	3.4 ± 1.41	2.85 ± .55		
FEV ₁ 10 min Post-Exercise	2.89 ± .97	3.45 ± 1.40	2.73 ±.53		
FEV ₁ 15 min Post-Exercise	2.95 ± .95	3.41 ±1.41	2.86 ±.67		

Table 8. Summary of FEV₁ 3-way ANOVA Results

	F	P – value	Partial Eta	Observed
			Sq.	Power
Intervention	2.362	0.144	0.129	0.304
Time	6.085	0.000*	0.276	0.981*
Intervention/Group	0.236	0.792	0.029	0.081
Intervention/Time	0.722	0.580	0.043	0.221
Time/Group	1.433	0.200	0.152	0.598

Quality of Life Questionnaires

Short Form 36 (SF-36)

The SF-36 results were split into 2 categories, physical (PS) and mental (MS). Results for the physical and mental portion of the SF-36 showed no significant differences among the 3 experimental groups (p > 0.05).

Asthma Quality of Life Questionnaire (AQLQ)

The AQLQ results were analyzed by Total Score and in 4 subcategories: Activity Limitations, Symptoms, Emotional Function, and Environmental Stimuli. All 5 analyses showed statistically significant improvements from Week 0 to Week 4 (Total Score: p = 0.02, partial eta sq. = 0.392, Observed power = 0.913; SX: p = 0.06, partial eta sq. = 0.340, observed power = 0.844; AL: partial eta sq. = 0.433, Observed power = 0.950; EF: p = 0.001, partial eta sq. 0.442, Observed power = 0.957; ES: p = 0.001, partial eta sq. = 0.438, Observed power = 0.954); however, no significant differences were found among the experimental groups (p > 0.05). The minimal acceptable change of the AQLQ is 0.5, which is considered a clinically relevant result. The domains Activity Limitations, Emotional Function, and Environmental Stimuli had average changes of 0.6 and above in the 2 intervention groups compared to the Control group, which remained below an average of 0.4 (see Table 9).

Table 9. Mean \pm SD of AQLQ and SF-36 at Week 4

AQLQ Score Mean Change at Week 4						
	DBE	YOGA	CONTROL			
Total Score	0.65	0.51	0.38			
Activity Limitations	0.46	0.5	0.35			
Symptoms	0.79	0.57	0.43			
Emotional Function	0.76	0.6	0.42			
Environmental	0.78	0.63	0.37			
Stimuli						

Table 10. Mean Change of AQLQ scores at Week 4

Mean ± SD						
	DBE	YOGA	CON			
AQLQ Total	$6.13 \pm .45$	$5.89 \pm .66$	$5.83 \pm .71$			
AQLQ SX	6.11 ±.66	$6.05 \pm .64$	$5.97 \pm .68$			
AQLQ AL	$6.34 \pm .52$	$6.01 \pm .61$	$5.96 \pm .75$			
AQLQ EF	$6.00 \pm .56$	$5.68 \pm .58$	$5.60 \pm .81$			
AQLQ ES	$5.98 \pm .58$	$5.62 \pm .60$	$5.57 \pm .84$			
SF-36 PS	53.51 ± 4.15	55.38 ± 3.61	54.04 ± 4.5			
SF-36 MS	50.73 ± 7.98	51.46 ± 11.6	54.50 ± 3.11			

DISCUSSION

The 22 participants in this study were required to be physically active individuals who have symptoms of exercise-induced asthma (EIA). To the best of our knowledge, this is the first study to compare the ability of yoga breathing and diaphragmatic breathing techniques to improved pulmonary function and health related quality of life among persons with EIA. Previous studies that utilized diaphragmatic breathing reported positive results with populations that were not specified to be active. ^{14,17-19}

Shaw et. al.¹⁷⁻¹⁹ indicated that their population was not classified as having exercise induced asthma symptoms, since there was no decrease in their FEV₁ test values during a maximal cycle ergometer test, which is similar to the Exercise Challenge Test

that was utilized in this study. None of the studies described the activity level of their participants, which leads us to believe their focus was on the physiological effect(s) that diaphragmatic breathing exercises had on asthma symptoms in a sedentary population.¹⁷⁻

Previous studies Brandon and Ina Shaw¹⁷⁻¹⁹ have utilized aerobic training or aerobic training combined with diaphragmatic breathing as intervention groups. These studies were designed to compare the positive effects of aerobic exercise on asthma symptoms to a hypothesized equally effective method, breathing exercises. A recent Cochrane Review found 13 studies utilizing some type of breathing exercise, showed improved QOL or significant differences in lung function in individuals with asthma.²⁵ This study tried to determine if individuals with better cardiopulmonary conditioning would benefit from diaphragmatic breathing and/or yoga breathing exercise programs, since inactive participants have an increase in pulmonary function after aerobic exercise and diaphragmatic breathing.

Yoga has also been beneficial to individuals with asthma, and has been used to treat all types of ailments for centuries. ^{22-24,32-34} Quality of life and pulmonary function has been improved in participants practicing yoga; however, participants were excluded for their activity levels and previous yoga practice, due to the study criteria. ^{23,33-35} The participants in these studies were sedentary and did not have EIA, which suggests that with any type of new program they enroll in, there will be a measurable benefit with their cardiopulmonary system.

Participants in the current study met the American Heart Association's requirements to be considered "physically active". ²⁶ All of our participants indicated that

they engaged in some type of recreational biking, swimming, running, or weight lifting activities at moderate to intense levels more than 3 days a week. This criterion was chosen to insure a population with an efficient cardiopulmonary system. Our participants were also required to have a medical diagnosis of EIA, which was confirmed using an Exercise Challenge Test. This test was not a diagnosis of the condition; however, it was used to confirm a previous diagnosis.

When looking at the averages, Week 4 values of post-exercise spirometry testing show a slight increase, which suggest that the interventions could positively contribute to the time it takes for EIA symptoms to resolve; meaning recovery after experiencing asthma symptoms is shorter than normal. Anecdotally, some participants in both intervention groups reported "an easier time" with physical activity. Some participants mentioned in their log packets they experienced a quicker recovery time during periods of shortness of breath, decrease reliance on medication when other asthma stimuli were absent, and awareness of breathing throughout the day.

We also evaluated the QOL changes in the participants after the 4-week breathing exercise programs. Individuals suffering from asthma report having a low QOL; increasing their QOL is just as important as increasing pulmonary function. Asthma can affect an individual throughout the day and for no reason. Factors such as environmental stimuli (pollen, dust, smoke, etc.), weather changes, and even minor physical activity (walking upstairs, carrying groceries, etc.) can cause asthma symptoms. Since we did not find a significant change in pulmonary function in either of our experimental groups after the 4-week interventions, we hoped their collective QOL increased. Although, no statistically significant changes occurred among groups, we found a slight increase of the

QOL scores in the experimental groups. We can say there is a clinically relevant change of QOL scores. It is considered a positive effect of the interventions if medication usage decreased, individuals experienced less severe symptoms, or if they could perform activities without experiencing EIA symptoms when they normally would have; there was no quantitative data to show for these claims, but participants reported some ease in activities of daily living.

Participants completed the SF-36, a HRQLQ at two different time points (Week 0 and Week 4) in this study. The SF-36 gathers information from patients about their health in a general sense, and gives 8 individual subscales and 2 composite domains (Physical Health and Mental Health). The Physical Health domain is a more accurate representation for individuals with asthma rather than the Mental Health domain. The questions used for the Mental Health domain focus more on depression, rather than anxiety which is more common with asthma patients. However, the SF-36 is still a reliable questionnaire to utilize for asthma patients to obtain a general understanding of the quality of life with a chronic disease. The strain of the strain is a more accurate representation for individuals with asthma patients.

Grammatopoulou¹⁵ utilized the SF-36 as a secondary outcome measure to evaluate the effect of breathing retraining on asthma. That study only utilized the 2 SF-36 composite domains and found a statistically significant increase of only the Physical Heath domain (control means \pm SD: 48.15 ± 6.75 , 48.32 ± 6.76 , 48 ± 6.5 , 48.79 ± 6.31 ; experimental means \pm SD: 48.47 ± 5.29 , 53.94 ± 4.02 , 54.82 ± 3.17 , 52.30 ± 5.40). The SF-36 is not a disease-specific HRQOLQ, which may explain why the studies evaluating changes in pulmonary function or quality of life utilize the AQLQ or another standardized quality of life questionnaire specific to asthma. A study comparing 96

individuals with controlled asthma and with uncontrolled asthma utilized the SF-36 to demonstrate differences in scores. Individuals with controlled asthma scored an average of 58.9 ± 21.1 on the Physical Health (PH) component and a 59.5 ± 20 on the Mental Health (MH) component, where the uncontrolled asthma group scored 39.8 ± 22.7 and 48.5 ± 21.6 , respectively. Participants in this study had slightly lower scores in both Physical and Mental Health components, compared to Lomper et. al. (PS: DBE = 53.6 ± 1.67 , YOGA = 53.0 ± 3.69 , CONTROL = 54.6 ± 4.18 ; MS: DBE = 52.5 ± 5.82 , YOGA = 48.4 ± 11.3 , CONTROL = 48.4 ± 11.3 ,

In a similar study, Jansson et al 39 recruited 646 individuals with asthma, without asthma, with rhinitis and without rhinitis. These authors found that individuals with asthma vs. no asthma had significantly lower PH scores (p = 0.001; asthma = 44.7; no asthma = 49.4) but found no difference was found between mental health scores. 39 They also saw a higher PH score in individuals with well-controlled asthma vs. not controlled asthma (p = 0.002; controlled = 47.9; not controlled = 41.2) 39 , similar to the Lomper et al. 38 Even given the small sample size of our study, participants still scored significantly higher than individual that have uncontrolled asthma, and consistently with individuals with controlled asthma.

The AQLQ is a questionnaire that focuses primarily on how asthma symptoms effect an individual's day to day life with a 4-week recall period. There are 4 domains

and an overall score in the AQLQ; the domains are: Symptoms, Activity Limitations, Emotional Function, and Environmental Stimuli. The questions of the AQLQ aim to determine how asthma effects each domain, and therefore is a more accurate representation, compared to other HRQOLQ, of an individual's QOL with asthma. The questions are ranked from 1 to 7, with 7 being not limitations at all. According to Juniper et al⁴⁰, the minimal important change is 0.5, with a change of 1.5 being a large change.

Previous studies ^{16,20,21,33,41,42} that evaluated QOL as either the main outcome measure or a secondary outcome measure used some type of health-related quality of life questionnaires. Studies that looked at yoga and diaphragmatic breathing utilized the AQLQ had significant results with their respective intervention programs. Thomas et. al. ²⁰ reported an increase in AQLQ scores over 6 months by using an unspecified breathing retraining method compared to "asthma education" (n = 33; AQLQ average score changes: Total score = 0.79, Activity Limitations = 0.83, and Emotional Stimuli = 0.80)(citation). A later study by Thomas et. al. ²¹ reported greater increases in AQLQ scores after a 6 month breathing retraining program (n = 183; AQLQ average score changes: Total score = 1.12, Symptoms = 1.23 Activity Limitations = 0.92, Emotion Stimuli = 1.29, and Environmental Factors = 0.97).

Vempati et al.⁴¹ assessed the effects of a 2-week yoga training program on quality of life that was followed by an additional 6-week of home exercise. A significant increase in AQLQ scores was noticed after 8 weeks of the study in both their control and intervention group, but the training group saw a difference after 2 weeks compared to the control group (Training group average change, 2-week/8-week: Symptoms = 1.2/1.7, Activity Limitations = 1.1/1.8, Emotional Function = 1.1/1.8, Environmental Stimuli =

1.1/1.9, Total = 1.2/1.7; Control group average change, 2-week/8-week: Symptoms = 0.3/1.1, Activity Limitations = 0.14/0.6, Emotional Function = 0.4/.7 Environmental Stimuli = -0.2/.4, Total = 0.3/0.9) ⁴¹ The control group received "conventional care", and increased slightly compared to the experimental group, whose scores were a full point (1 point) higher in most cases than the control group. According to Juniper⁴⁰ and what is deemed, minimal important change, values greater than 1.5 represent large changes. The changes in the experimental group can be considered large and the control group considered small to moderate. ^{40,41}

Although our study did not find a significant difference among the 3 groups, we did have clinically relevant results. Both experimental groups had an increase in AQLQ scores (DBE: Total = 0.65, Sx = 0.79, AL = 0.46, EF = 0.76, ES = 0.78; YOGA: Total = 0.51, Sx = 0.57, AL = 0.5, EF = 0.6, ES = 0.63), compared to the CONTROL group, whose scores increased but did not reach the 0.5 limit to be considered a small change (Total = 0.38, AL = 0.35, Sx = 0.43, EF = 0.42, ES = 0.37). Activity Limitations was just below 0.5 in the DBE group, but only slightly. These changes show a positive trend in HRQOL scores. The previously mentioned studies had significant changes early, which remained significant compared to control groups, which means if the intervention continued for 4+ weeks, there is a possibility to have significant changes.

LIMITATIONS

Recruitment for this study began in February and ended in mid-April 2017, and only 23 of the 60 volunteers screened for this study met our strict inclusion criteria and were randomized to groups. Without delays we experienced in the IRB approval process, a longer recruitment period would have allowed us to screen a larger pool of volunteers.

We had 3 groups in this study: yoga breathing group (n = 8), diaphragmatic breathing group (n = 6), and a control group (n = 8). Our small sample size resulted in low statistical power in our analyses, and with few statistically significant findings. With a longer recruitment period, we might have increased our sample size of participants who met our inclusion criteria.

Through analysis of our data, we found small effect sizes which decreased the possibility of finding a significant difference between groups. The experimental groups had 11 (diaphragmatic breathing group) and 12 (yoga breathing group) participants randomized to them. Communicating with the participants to attend sessions was the biggest challenge which effected this sample size of this study. Two separate recruitment sessions and interventions programs were conducted over the 2-and-a-half-month period. During the first session, participants were contacted via university email, which showed to be ineffective at maintaining open lines of communication. During the second round, participants were contacted via text message on their personal cell phones. This method fared better when it came to communicating session times and participant attendance.

Participants were trusted to perform home exercise programs twice a day, 5 days a week. They were asked to record the times of day and which days they performed their exercises. There is no way of confirming their compliance other than their exercise logs. The home exercise program was designed to be shorter in length and done with equipment that can be found around the house (pillows, blankets, chairs). The home exercise program was the breathing protocol utilized by Salvi et al. 14, which had significant results after 1 week of training. The simplicity of the home exercise program may have been beneficial to a sedentary population, but an active population would

benefit more from added resistance at home, in addition to the supervised session. Future studies should provide equipment for home use to keep the diaphragmatic breathing exercises consistent.

The 4-week duration of the breathing exercise programs was the most significant limitation of this study. Most previous studies utilized intervention periods of 6 weeks or more. Three studies by Shaw and Shaw¹⁷⁻¹⁹ utilized an 8-week intervention protocol for diaphragmatic breathing. The supervised diaphragmatic breathing groups in our study were assigned the protocol utilized by Shaw and Shaw ¹⁷⁻¹⁹ This study matched the frequency and intensity of Shaw and Shaw's protocol; the main difference being sedentary vs. active participants. Two earlier studies by Thomas et al. ^{20,21} utilized a 6month period for diaphragmatic breathing and a study reviewed by Prem et al. 16 also had a 6-month intervention. The studies that looked at yoga breathing each had interventions lasting 8-weeks or greater. Bidwell et al.³⁵ utilized a 10-week session and Sodhi et al.³⁴ had an 8-week intervention. Vempati et al.⁴¹ and Singh et al.⁴³ had a different approach where they provided either 2-weeks of supervised training sessions, or 6 days supervised training sessions, then allowed the participants to practice at home for 6 weeks to 2 months with close monitoring at home. Due to the time constraints to complete this master's thesis during a time when graduate assistantship financial support was still available, the maximum duration for the interventions for this study was set at 4 weeks.

Participants in this study were active and the exercise prescription may not have been sufficient enough to challenge their pulmonary system. The diaphragmatic breathing protocol used a 1 cm by 10 cm tube for exhalation and a 5-lb weight place on the participants' abdomen. Decreasing the diameter of the tube and increasing the weight

ever week or could potentially increase the intensity of the exercise protocol. Also, the yoga intervention has room for more difficult breaths and postures. Implementing the more difficult maneuvers could essentially challenge the pulmonary system, similar to how changing the tube diameter and abdomen weight would challenge participants in the diaphragmatic group.

During the time frame of the study, we were able to allow for 2, 4-week intervention session groups, with some overlap to allow a second recruitment pool when participant numbers were less than satisfactory. Since participants were students attending the university, the majority of participants had scheduling conflicts with their class or work priorities, making it difficult for 100% program compliance.

Since asthma can be effected by many different factors, there were some instances where environmental triggers played a part in the participants' pulmonary function. Initial base-line testing was conducted towards the end of winter and concluded near the beginning of spring. The changing weather and environmental conditions could have played a big role in the pulmonary function results during testing. Participants were asked to refrain from utilizing their medications 48 hours prior to pulmonary testing to ensure there was not medications effecting their pulmonary function, but for that reason, if an environmental trigger was present, it could have decreased pulmonary function, therefore altering test results. Illness was reported by some participants, which could have negatively affected pulmonary function at Week 4 testing. Pulmonary function was tested within a week of the final intervention session.

CONCLUSIONS

Previous studies have evaluated diaphragmatic breathing and yoga breathing separately as alternative treatments for asthma. Until now, these studies have used a sedentary population with asthma as participants and have seen significant results with the treatments. This study focused on an active population suffering from EIA, and compared two alternative treatments. Although no statistically significant results on pulmonary function or quality of life were found, according to the minimal acceptable change for the AQLQ, participation in 4 week programs of diaphragmatic breathing and yoga breathing improved QOL in both groups. Further research is needed with larger scale randomized clinical trials using these breathing exercise programs with longer intervention periods. Studies of this size and duration may reveal different results—that diaphragmatic breathing and yoga breathing can be successful in reducing exercise induced asthma symptoms, and increase patients' quality of life.

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3. SUMMARY AND RECOMMENDATIONS FOR FUTURE RESEARCH

The purpose of this study was to determine whether active individuals suffering from Exercise Induced Asthma could benefit from breathing exercises which have benefited sedentary individuals with Asthma. Exercise Induced Asthma is a prevalent condition seen in the Sports Medicine field, requiring athletes to depend on medication. One hypothesis of this study was that both breathing exercise programs would increase pulmonary function and quality of life. Unfortunately, the effect size of the protocols was very small and no significance was found.

Both intervention programs were chosen because they were determined to increase pulmonary function and quality of life. Shaw and Shaw (citation) used a diaphragmatic breathing protocol involving a 5-lb weight placed on the abdomen and a 1 cm by 10 cm tube placed in the mouth. Participants were to inhale through their nose for a count of 1 second and exhale for a count of 2 second through the tube. This continued for 10 repetitions followed by a 60 second rest period and repeated 2 more times. Two (2) more rounds of 3 sets followed with breathing ratios of 2:4, 15 times and 3:6, 20 times. This group was also instructed to perform a home exercise program, used by Salvi et. al (citation). The supervised sessions were to be completed 3 days a week for 4 weeks, where the home exercise program was to be completed twice a day, 5 days a week. Both supervised and home exercise programs require full compliance and effort to be successful. Few participants maintained 100% compliance with supervised sessions, and it is impossible to ensure participants complied 100% with the home exercise program.

The yoga intervention was designed with the help of a certified yoga instructor, utilizing the "Integrative Yoga Therapy" yoga teacher training manual. This manual provides breaths and postures that are specific to certain ailments and conditions. An easy protocol for all individuals' abilities was developed with the help of the yoga instructor. The protocol lasted approximately 15 minutes per session and required common equipment, such as pillows, blankets, and chairs. The yoga group was instructed to attend 3 sessions a week for 4-weeks, and perform a home exercise program twice a day, 5 days out of the week. The home exercise program was the same as the supervised sessions program. Again, full effort and compliance is necessary to receive any benefit from the protocol.

The purpose of the two experimental programs was to create a cheap, reproducible, and easy to use protocol that can be used any place, any time, by anyone. Although we may have accomplished that, we did not determine that the protocols had a treatment effect on individuals with Exercise Induced Asthma. There are a few reasons which can explain why there was no treatment effect; duration of the study, size and compliance of the study, prescription of the exercise protocols.

The available time intervention period was 4-weeks. We were able to hold 2, 4-week intervention periods due to a lack of interest during recruitment. Most intervention studies last at least 6 to 8 weeks to determine a treatment effect. Future studies should allow for at least 8 weeks to 6 months of intervention period.

We had some specific recruitment criteria for the participants of this study.

Participants were required to be between 18 and 35, active, free of serious health

complications, and previously diagnosed with Exercise Induced Asthma. There is a

prevalence in asthma in the United States, however we narrowed down the field by requiring participants to be active and have exercise induced asthma, which reacts slightly different than normal asthma; not all individuals who have asthma, experience asthma with exercise. Also, we were limited to Texas State University student and faculty population. The participants who were randomized did not have 100% compliance due to other responsibilities (i.e. school, work, meetings, etc.). Future research should consider increasing the recruitment field to larger metropolitan areas to reach larger populations. Also, increasing the compensation would significantly motivate participants to comply with all aspects of the study.

A third limitation that could be corrected for future research was exercise protocol prescription. The protocols were based off of established protocols used on individuals who do not regularly train their cardiopulmonary system. The participants in this study were reported to be active. Intensity of the diaphragmatic breathing techniques and the yoga techniques did not change substantially throughout the 4-weeks of this study. If participants need to be challenged to not hit a training plateau, the intensity of the techniques need to be increased at least weekly. The diaphragmatic breathing techniques could change in terms of weight used on the abdomen and decreasing the size of the tube; or adding sets to each breathing cluster. The yoga techniques could also be progressed to more challenging positions or more resistive breathing techniques. Each posture or breath was performed for 5 cycles (1 inhale/ 1 exhale = 1 cycle), and could be increased for future interventions.

Recommendations for Future Research

- Increase the study duration from 4 weeks to 8 weeks to 6 months to improve pulmonary function.
- Recruiting more participants from a larger recruitment area, as well as increasing time allowed for recruitment, and adding recruitment material.
- Increase compensation to encourage participants to comply fully.
- Increase intensity and sets of exercises at more points during the intervention period.
- Obtain a more comprehensive and detailed log of medication usage 4-weeks prior to the beginning of the intervention, during the intervention period and a 4-week period after the completion of the intervention, to determine the effect on medication dependency before, during, and after interventions.
- Conduct follow-up spirometry measurements at 1 month, 3 months, 6 months, and
 1 year to determine how long treatment effects last.

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APPENDIX A

Institutional Review Board Application

Section II: General Information

1. Tittle of Study

Comparison of the Effects of Diaphragmatic Breathing Exercises and Yoga Pranayama Techniques on Pulmonary Function in Individuals with Exercise Induced Asthma

2. Investigator (Primary Research)

First Name: Richard Last Name: Serra Title: Grad Student

Degree Program/Department: Masters in Athletic Training/ Health and Human

Performance

<u>Texas State Email Address</u>: r_s327@txstate.edu <u>Phone</u>: (570) 578 – 3124

If you are a student, is this application for your thesis or dissertation research?

- Yes

3. Co-Investigator or Texas State University Sponsoring Faculty

First Name: Rod Last Name: Harter Title: Professor, Graduate Coordinator

Degree Program/ Department: Health and Human Performance

Texas State Email Address: rod.harter@txstae.edu Phone: (512) 245 – 2972

4. Project Dates

Anticipated Start Date: January 2, 2017 Anticipated End Date: May 31, 2017

5. Key Personnel

- Christopher J. Russian

cr23@txstate.edu

6. CITI IRB Training

Have you, and Co-Investigator, Student Investigator, and all other Key Personnel completed the CITI training course?

- Yes

7. Funding Information

Has external or internal funding been proposed or awarded for this project?

- No

8. Financial Conflict of Interest Disclosure

Do you or any other person responsible for the design, conduct, or reporting of this research have an economic interest in, or act as an officer or a director of, any outside entity whose financial interests would reasonably appear to be affected by the research?

- No

Section III: Risk Review

- 1. Will your research study involve any vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, cognitively impaired elderly, or minority ethnic groups?
 - No
- 2. Could public disclosure of any identifiable data you collect place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation?
 - No
- 3. Will your study involve data collection procedures other than surveys, educational tests, interviews, or observation of public behavior?
 - Yes
- 4. Will your study involve the collection of sensitive data such as: illegal drug use, alcohol abuse, victims of violence, health history, prior diagnosis of mental disorders, sexual activity, criminal activity, or personal academic history?
 - No
- 5. Will your study involve audio or video-recording research participants?
 - No
- 6. Will your study involve obtaining individually identifiable information from health care providers, clearinghouses, or plans?
 - No
- 7. Will you be collecting anonymous data (results cannot be linked to individual participants)?
 - No
- 8. Will you be using data that was previously approved by the Texas State IRB?
 - No

- 9. Will you be using data that was previously approved by a non-Texas State IRB at an another institution, organization, center?
 - No
- 10. Does this project SOLELY involve analysis of publicly available existing database?
 - No

Section IV: Research Protocol Information

1. Purpose of Study

The purpose of the study is to determine the effects of two different breathing exercises on Exercise Induced Asthma. Can breathing exercises which, strengthen the diaphragm, and breathing techniques used in the practice of yoga, be beneficial to individuals with exercise induced asthma?

2. Previous research

Yoga is one area of research in which it has been found to be beneficial to individuals with general asthma. Different studies have been conducted using different types of yoga sequences¹⁻⁹ with similar results. All studies showed an increase of quality of life scores with yoga practice in individuals with asthma; Some studies showed a positive effect on lung function with yoga practice in individuals with asthma.^{2,3,5,6,8,9}

Diaphragmatic breathing exercises have been studied less, but have promising results in the studies that have been conducted. Lung function increased in a few studies that utilized the breathing protocol that will be used in this research. Quality of life, which was the main result looked at in a few studies, was reported to significantly increase using diaphragmatic breathing exercise. 14,15

The studies have been conducted on individuals without exercise induced asthma and in sedentary individuals normally. I would like to see if it has an effect on an active population with exercise induced asthma.

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- 4. Prem V. Comparison of the effects of Buteyko and pranayama breathing techniques on quality of life in patients with asthma a randomized controlled trial. *Clin Rehabil.* 2012;27(2):133-141.
- 5. Sabina AB, Williams A, Wall HK, Bansal S, Chupp G, Katz DL. Yoga intervention for adults with mild-to-moderate asthma: a pilot study. *Ann Allergy Asthma Immunol.* 2005;94(5):543-548.
- 6. Singh S. Effect of Yoga Practices on Pulmonary Function Tests Including Trasnfer Factor of Lung for Carbon Monoxide in Asthma Patients. *Indian J Physiol Pharmacol.* 2012;56(1):63-68.
- 7. Sodhi C, Singh S, Bery A. Assessment of the quality of life in patients with bronchial asthma, before and after yoga: a randomised trial. *Iran J Allergy Asthma Immunol.* 2014;13(1):55-60.
- 8. Sodhi C. A study of the effect of yoga training on pulmonary functions in patients with bronchial asthma. *Indian J Physiol and Pharmacol.* 2009;53(2):169-174.
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- 10. Salvi D, Agarwal R, Salvi S, Barthwal BMS, Khandagale S. *Effect of Diaphragmatic Breathing on Spirometric Parameters in Asthma Patients and Normal Individuals.* 2014.
- 11. Shaw I, Shaw BS, Brown GA. Role of diaphragmatic breathing and aerobic exercise in improving pulmonary function and maximal oxygen consumption in asthmatics. *Sci Sports*. 2010;25(3):139-145.
- 12. Shaw BS, Shaw I. Pulmonary Function and Abdominal and Thoracic Kinematic Changes Following Aerobic and Inspiratory Resistive Diaphragmatic Breathing Training in Asthmatics. *Lung.* 2011;189(2):131-139.
- 13. Shaw BS, Shaw I. Static standing posture and pulmonary function in moderate-persistent asthmatics following aerobic and diaphragmatic breathing training.
- 14. Thomas M. Breathing Exercises for Asthma: A randomised controlled trial. *Thorax.* 2009;64(1):55 61.

15. Thomas M, McKinley R, Freeman E, Foy C, Prodger P, Price D. Breathing retraining for dysfunctional breathing in asthma: a randomised controlled trial. *Thorax.* 2003;58(2):110-115.

1. Recruitment of participants

- Participants will be recruited from the student/faculty population of Texas
 State University. Preferred participants include individuals between the ages of 18 -35.
- 45 participants are desired for this study. 15 participants per intervention group (3).
- There are no special requirements concerning any other demographic information that is desired specifically for recruitment of this study.
- Participants must have a current diagnosis of exercise induced asthma.
- An email, advertising flyers, and classroom announcements will be made to recruit participants.

2. Vulnerable Populations

- N/A, this study will not use vulnerable populations as research participants.

3. Informed Consent Process:

Once volunteers have been screened via phone interview to determine qualifications for the study, they will meet with the primary researcher. The primary researcher will provide an informed consent form; in which he will explain to the volunteer. If the volunteer wishes to proceed with participation in the study, and the volunteer clearly understands the information provided on the informed consent form, they may sign the form and continue with health screening. If more than one

volunteer is scheduled to meet the primary researcher at the same time, the primary researcher will explain the informed consent form to the group.

4. Procedures

Email, flyer, or announcement recruitment: (attached documents)

- The email and all subsequent advertising material will be approved by the Texas State University Institutional Review Board prior to disruption. The email will be sent out to a randomized number of Texas State students provided by the College of Education for research purposes. The email will explain the purpose of the study and benefits that may come from participation in the study. Compensation for completing the study will be included in the email.
- Flyers will be posted throughout the campus of Texas State University. The flyer will state that the researcher is looking for individuals between the ages of 18 and 35, who are physically active and have exercise induced asthma. The flyer will state that there is a possibility that breathing exercises and yoga techniques may help reduce their asthma symptoms during exercise. The possibility of compensation will also be advertised on the flyer.
- An announcement will be made in the classes which the primary research is an instructor. The announcement will proceed with a brief purpose of the study, and that interventions may help reduce symptoms of exercise induced asthma. The announcement will include volunteers must be between the ages of 18 and 35, be physically active, and have exercise induced asthma.
- All recruitment mediums will have contact information of the primary research.

Phone interview: (attached document)

Interested individuals will contact primary researcher either by phone or email. A preliminary phone interview will be conducted to determine qualification for the study. The researcher will ask questions concerning the volunteers' medical history. Some medical conditions will disqualify volunteers due to risk of exacerbating serious medical conditions. If the volunteer is approved for inclusion into the study, a meeting time and place will be scheduled for informed consent, health screening and baseline measurements. Phone interview should last no longer than 10 minutes. The volunteers who qualify, will be instructed to come wearing clothing appropriate for exercise and to bring their short acting asthma medication to the meeting.

First meeting, Health Screening and Baseline Measurements: 1 hour 20 minutes approximately

- Informed consent (attached document)
 - O Volunteers will be instructed to arrive at Jowers Center, on the Texas State

 University campus at the agreed day and time. Volunteers will arrive to
 either the Exercise Physiology Lab, the Biomechanics/Sports Medicine

 Lab, or a teaching classroom depending on the availability of space on the
 scheduled day. Room information will be given to the volunteer at least an
 hour in advance of the meeting. Volunteers may contact the primary
 researcher directly if they are having difficulty finding the correct room.

 The room of the initial screening will be empty except for volunteer(s) and
 researcher. At this point informed consent form(s) will be provided and
 explained. Once volunteers have fully understood the form and wish to

- continue they will sign the form. This process of informed consent should take no longer than 5 minutes, pending questions.
- Health Related Quality of Life Questionnaires (HRQLQ) (attached documents)
 - O Volunteers will be provided two, self-administered, HRQLQs. The volunteers will be instructed on what the forms purposes and that they are to answer the questions to the best of their ability. This process should take no longer than 20 minutes, 10 minutes per questionnaire.

- Exercise Challenge Testing

- After participants have completed the HRQLQs, they will be directed to either the Exercise Physiology Lab or Biomechanics/Sports Medicine Lab, depending on their previous location and availability of lab space. A heart rate (HR) monitor will be applied to the participant(s) to monitor HR. The participant(s) will be seated and relaxed. Resting HR, blood pressure, and pulmonary function measurements (via spirometry) will be obtained. (5 minutes)
- Once baseline is obtained, participant(s) will be asked to move to a treadmill to begin the exercise challenge test. The speed and incline will be increased incrementally to achieve a HR of 80 90% of the participant(s) maximum HR. This number will be determined by using 220 age in years. Once the desired HR is achieved they will exercise at this HR for 4 minutes. This test does not exceed 8 minutes.
- After the treadmill is stopped, the participant will be moved carefully to a seated position once again. At this time serial spirometry measurements

will be taken at 5, 10, 15, 20, and 30 minutes. HR will be monitored during this time frame, and blood pressure will be assessed every 10 minutes for safety. This process should take 30 minutes with 5 to 10 minutes of recovery for safety if necessary. **If recovery of baseline measurements does not return and the primary researcher finds it appropriate to hold the participant for their safety, this time may be extended. **

If participants qualify with exercise induced asthma, and wish to proceed in the study, the primary researcher will allow participant to randomly pick their intervention group from a box of 15 sealed envelopes (5 for each group: DBE, YOGA, CONTROL). Depending on the group they chose, the participant will be given a packet with information about the exercises they will perform and will coordinate time and days for supervised sessions.

1st intervention session: 45 minutes approximately

- Diaphragmatic Breathing Exercise group
 - O Participants will be asked to attend 3 sessions a week for 4 weeks.
 Supervised sessions will be conducted in Jowers Center in an available group exercise room or lab space. Participants assigned to the diaphragmatic breathing group will go through a training session on how to breathe utilizing their diaphragm. Participants will lie supine at a 30 to 50-degree angle, with their hips flexed to approximately 50 degrees and their knees in a comfortable flexion position (semi-recumbent). Semi-

recumbent position can be achieved by turning a sturdy backed chair upside down and laying on the incline of the back of the chair. The primary researcher (RS) will instruct all participants to relax and place their hands on their abdomens. The next command will be a slow, deep inhalation through their noses lasting about 10 seconds. The researcher will describe to the participants how they should physically feel with correct breathing by stating, "You should feel your stomach filling up with air like a balloon". A slow exhale will follow and the researcher will describe the sensation to the volunteers by stating, "Use your stomach to push the air out of your stomach through pursed lips" Pursed lips will be described as pressing your lips together to flatten them and allowing as little air as possible to escape during a 20 second exhale.

The breathing exercise session will continue by applying a 2.5 kg weight to the participant's abdomen, and each person will be given a 1 cm in diameter by 10 cm long tube to breathe through. Participants will stabilize the weight on their abdomen with one hand and hold the tube steady in the mouths with the other hand. The tube will mimic pursed lips to ensure consistent release of air throughout the session. Participants will inhale through the tube using the same concept taught prior, "filling up the balloon in their abdomen". Participants will perform 3 sets of 5 to 10 repetitions using a ratio of 1 second inhale to 2 second exhale. A 60 to 90 second rest period will be given between sets. Next set of 3 will consist of 10 to 15 repetitions with a ratio of 2 second inhale to 4 second exhale. The

- final 3 sets will consist of 15 to 20 repetitions using a ratio of 3 second inhale to 6 second exhale. Refer to Table 2.3 for intervention protocol.
- Yoga pranayama (breathing) techniques: 45 minutes approximately
 - Participants will be asked to attend 3 sessions a week for 4 weeks. Each session will last approximately 30 minutes following a single introduction to procedures session that will be approximately 45 minutes in length.
 Supervised sessions will be performed in an available group exercise room or lab space.
 - Participants in the yoga group will participate in a 30-minute yoga session. The session will include 4 types of pranayama: Adhama Svasa (abdominal/diaphragmatic breathing), kapalabhati (breath of fire), nadi shodhana (alternate nostril breathing) and ujjayi, refer to Table 2.2 for descriptions. The yoga session will begin with 3 yoga postures in which participants will be instructed to breathe in through their nose and out through their nose. They will perform 3 to 5 breath cycles (inhale through the nose and exhale through the nose = 1 cycle) before moving on to the next posture. The first posture will be standing forward fold. Participants will progress to a seated position to perform seated head to knee pose and then forward fold, refer to Table 2.2 for descriptions of yoga postures. After warm-up postures, participants will lay in a semi-recumbent position for adhama svasa. Participants will then move to sukasana (easy cross legged seated upright position) for kapalabhati and nadi shodhana. Nadi shodhana will be completed at a beginning ratio of 2:8:4 seconds (inhale:

hold: exhale), and progress to 4:16:8 after 2 weeks and this ratio will be used for the remainder of the study. Refer to Table 2.3 for intervention protocol.

Subsequent intervention sessions:

- DBE group: 30 minutes approximately
 - Participants will return for their second session and each remaining session to a predetermined location agreed upon by researcher and participants. Each session following the initial intervention session will last 30 minutes, since instructions will not need to be provided.
 - o Participants will follow the same protocols as listed above.
- Yoga group: 30 minutes approximately
 - Participants will return for their second session and each remaining session to a predetermined location agreed upon by researcher and participants. Each session following the initial intervention session will last 30 minutes, since instructions will not need to be provided.
 - o Participants will follow the same protocols as listed above.

Helpful Tables:

 Tables provide intervention protocols and exercise descriptions not provided in explanations above.

Table 3 - Yoga breathing and posture descriptions.

Technique	Description		
Yoga postures			
Standing Forward Fold	This posture is performed in a standing		
	position, with knees bent slightly and		
	comfortably. Bending at the waist, bring		
	your upper body down so you are looking		
	at the floor or legs (depending on		
	flexibility). Relaxing the head, neck and		
	shoulders.		
	Modification: if positon is uncomfortable		
	in back of legs or low back, placing hands		
	on shins or knees is recommended.		
	Comfort is priority in this pose.		
Head to knee forward bend	This posture is performed in a seated		
	positon on the floor with one leg straight		
	out. The opposite leg is bent with the foot		
	touching the inner thigh of straight leg.		
	Bending at the waist, the goal is to bring		
	your head to your knee. Return to a		
	straight seated position, and switch legs.		
	The leg that was bent should be straight,		
	and the leg that was straight should be		
	bent, with the foot touching the inner		
	thigh of your straight leg.		
	Modification: if position elicits any pain		
	or discomfort place hands on extended leg		
	in the position of most comfort. The		

	opposite knee should be supported with
	pillows until comfort is felt and knee is as
	close to the ground as possible.
	close to the ground as possible.
Control Formand fold	Citizen and a flag and the last last and the
Seated Forward fold	Sitting on the floor with both legs straight,
	the goal of this posture is to bring body
	and head down towards the ground. Knees
	should bend slightly for comfort. No pain
	or discomfort should be felt in the body.
Supported Half Shoulder Stand	Laying on the ground with legs up against
	the wall and a pillow or blanket
	underneath the head and upper shoulders,
	you should push feet into the wall so they
	are flat. Knees should be bent and upper
	legs and body should be in line and
	perpendicular to the ground. Weight of
	body should be supported by shoulders.
	Hands can be supporting low back in this
	position. No weight should be on neck in
	this position.
	Progression: Advancement of this position
	requires removal of one foot from the

	wall, extending knee to be in line with rest of body. Further progression involves removal of second foot, extending both knees to be in line with the body, at this time the entirety of the body weight is supported by the upper shoulders, not the neck.
Sukasana	This position is easy cross legged in an upright seated position. Legs are crossed and feet are positioned under legs close to the body. Knees are relaxed and supported with pillows or other object for comfort.
Shavasana	This position can be accomplished by laying on the ground looking at the ceiling. Arms are extended comfortably at your side. Legs are extended comfortably. Another name for this posture is "the corpse pose".
Breathing Techniques	
Adhama Svasa (abdominal breathing)	Sitting or lying, place hands on abdomen. Inhale through the nose completely, slowly, and continuously, expanding the abdomen and the lower sections of the lungs like a balloon. Pause briefly. Exhale

	through the nose by drawing the abdomen
	inwards in a continuous and slow manner.
	Pause again and repeat inhale.
	Soft belly: passive inhale/exhale keeping
	abdominal muscles relaxed
	Firm belly: passive inhale with a
	contraction of abdominal muscles during
	exhalation
Kapalabhati (breath of fire)	Inhale through nostrils and fill chest. Hold
	the chest in that "puffed up" position for
	the remainder of the exercise. Inhale and
	exhales will be performed rapidly and
	forcefully through nostrils. Performed at
	high rates for short cycle periods.
	<i>Note:</i> Breath of Fire has been reported to
	induce mania in individuals with Bi-Polar
	disorder. It is recommended to avoid use
	of this breathing technique with
	individuals with Bi-Polar I disorder and
	used with caution in individuals with Bi-
	Polar II disorders.
Nadi Shodhana (alternate nostril	The technique must begin and end with
breathing)	the left nostril. Begin by closing the right
	nostril with thumb and inhale through left
	nostril. Hold the breath by closing off left
	nostril with pinky. Release right nostril
	and exhale through the right nostril while
	keeping the left closed. Hold the breath

	OUT has also since with the actual with through		
	OUT by closing right nostril with thumb		
	again. Open right nostril and inhale		
	through right nostril holding left closed		
	with pinky still. Hold breath IN by closing		
	both nostrils. Exhale through the left		
	nostril by closing the right. This is		
	considered 1 cycle. Perform this process		
	for required amount of cycles.		
	Note: If individuals have a deviated		
	septum, this breathing technique may feel		
	restricted in one nostril compared to the		
	other. While no serious risk is seen with		
	this condition, caution should be used to		
	prevent feeling of suffocation from		
	occurring.		
	Nasal cycling may be occurring at the		
	time of practice. Nasal cycling is a		
	phenomenon of breathing out of one		
	nostril naturally while the other feel		
	occluded. Again, no known risk is		
	associated with this phenomenon and this		
	breathing technique, however, caution		
	should be used.		
Ujjayi	Inhalation through nose, exhalation		
- 33 - 3 -	through nose while restricting the back of		
	the throat on the exhale. Sound produced		
	should be a soft snore.		
	should be a soft shole.		

Table 2. Intervention protocols

Diaphragmatic Breathing Group

Yoga Group

Semi – recumbent position	Warm up
	• Ujjayi (5 cycles)
• 2.5 kg weight held on abdomen	• Standing Forward Fold (3 – 5 cycles)
Inhale through nostrils; exhale through 10cm x 1cm tube	Seated forward fold (3- 5 cycles)
Techniques	Head to knee pose (3-5 cycles)
 3 sets 5 – 10 repetitions 1 sec inhale: 2 sec exhale 60 – 90 second rest period 	Pranayamas (semi-recumbent to easy cross legged)
 3 sets 10 – 15 repetitions 2 sec inhale: 4 sec exhale 60 – 90 second rest period 	 Adhama Svasa (abdominal breathing) 3 – 5 cycles Begin in soft belly and progress to firm belly (2 weeks)
 3 sets 15 – 20 repetitions 3 sec inhale: 6 sec exhale 60 – 90 second rest period 	Kapalabhati3 cycles of 9 breaths
	 Nadi Shodhana 3 – 5 cycles 2:8:4 (inhale: hold: exhale) Progress to: 4:16:8 (2 weeks) Postures Supported half shoulder stand (3-5 cycles) Shavasana (5mins)

Week 4 post-testing: 1 hour approximately

- Final data collection:
 - Health Related Quality of Life Questionnaires (HRQLQ) (attached documents)
 - Volunteers will be provided two, self-administered, HRQLQs. The volunteers will be instructed on what the forms purposes and that they are to answer the questions to the best of their ability. This process should take no longer than 20 minutes, 10 minutes per questionnaire.
 - Exercise Challenge Testing
 - After participants have completed the HRQLQs, they will be directed to either the Exercise Physiology Lab or Biomechanics/Sports Medicine Lab, depending on their previous location and availability of lab space. A heart rate (HR) monitor will be applied to the participant(s) to monitor HR. The participant(s) will be seated and relaxed. Resting HR, blood pressure, and pulmonary function measurements (via spirometry) will be obtained. (5 minutes)
 - Once baseline is obtained, participant(s) will be asked to move to a treadmill to begin the exercise challenge test. The speed and incline will be increased incrementally to achieve a HR of 80 90% of the participant(s) maximum HR. This number will be determined by using 220 age in years. Once the desired HR is

- achieved they will exercise at this HR for 4 minutes. This test does not exceed 8 minutes.
- After the treadmill is stopped, the participant will be moved carefully to a seated position once again. At this time serial spirometry measurements will be taken at 5, 10, 15, 20, and 30 minutes. HR will be monitored during this time frame, and blood pressure will be assessed every 10 minutes for safety. This process should take 30 minutes with 5 to 10 minutes of recovery for safety if necessary. **If recovery of baseline measurements does not return and the primary researcher finds it appropriate to hold the participant for their safety, this time may be extended. **
- At this point, successful completion of the study will be determined and appropriate compensation will be provided to the participants.

5. Confidentiality

The information gathered from the participants in the study will be confidential.

Only the investigators will have access to the personal identifiers and to any information that may be linked with their identity. All information that is completed will have an identification number rather than their name to ensure confidentiality. All data obtained on electronic devices will be saved on a secure external device and printed out as hard copy. No identifying information other than identification number will be associated with the files or hard copy. The external files and hard copies will be locked in a secure

cabinet in the Biomechanics/Sports Medicine lab. Only investigators will have access to both forms of the data. The information will be stored for up to three years following the conclusion of the study. In the event that the results of this study are published or publicly disseminated at scientific meetings, none of your personal identifying information will be discussed.

6. Risks and benefits:

During testing procedures, symptoms of asthma may be exacerbated in individuals with exercise induced asthma. This process is necessary to confirm diagnosis of exercise induced asthma, based on the purpose of the study.

Precautions:

Volunteers will be instructed to arrive for testing with their prescribed short acting asthma medication in the event of a severe asthma attack occurs. Medication will be evaluated to ensure there are sufficient doses remaining in the event of a severe asthma attack and that the medication is no expired.

Volunteers will be informed that they are allowed to discontinue the exercise test and use their medication at any time they feel they are in severe respiratory distress. In the case that medication dosage is insufficient or expired, volunteers will be asked to return when medication has been refilled.

It is possible sever medical conditions may arise during the duration of intense exercise. Such conditions may include, but are not limited to sudden cardiac arrest and sudden respiratory distress.

Precautions:

Prior to acceptance in the study, interested volunteers will be screen for known cardiac and respiratory diseases, other than asthma, that may be exacerbated by intense exercise. Individuals who have these diseases will be excluded from the study as a precaution.

In the event of an unlikely sudden cardiac or respiratory emergency, the primary investigator, who will be present at all times during the exercise challenge test, is a Nationally Registered Emergency Medical Technician and Nationally Certified as well as Texas Licensed Athletic Trainer, with current certifications in Cardio-Pulmonary Resuscitation (CPR) and Automated External Deliberator (AED) training. The primary investigator will be able to assess and intervene as necessary. An AED will be present during testing, and in the unlikely event of an emergency situation, 911 will be contacted.

The participants will be informed that they may discontinue the exercise challenge test at any time.

During the exercise challenge test, participants with musculoskeletal injuries may experience pain or further damage.

Precautions:

Prior to acceptance in the study, interested volunteers will be asked if they have any current musculoskeletal injuries that may prevent them from participating in 8 minutes of intense exercise. If volunteers do have such injury, they will be excluded from the study for their safety.

Participants will be informed prior HRQLQs that exercise may exacerbate musculoskeletal injuries that and they may remove themselves from the study at any time.

Participants will be informed prior to exercise challenge testing, that they may stop the test at any time due to pain.

In the unlikely event of a sudden musculoskeletal injury, the primary investigator, who will be present at all times during the exercise challenge test, is a Nationally Registered Emergency Medical Technician and Nationally Certified as well as Texas Licensed Athletic Trainer, with current certifications in Cardio-Pulmonary Resuscitation (CPR) and Automated External Deliberator (AED) training. The primary investigator will be able to assess and intervene as necessary.

7. Benefits

Based on current research, yoga and diaphragmatic breathing have been shown to improve the quality of life and lung function in sedentary individuals with asthma. There is evidence that the interventions utilized in this study have a positive effect on quality of life and lung function in individuals suffering from asthma. If participants comply fully and complete the entire study, there is a good chance they will have an increase in quality of life and increase in lung function. The purpose of the study is to provide a safe, cheap, and easy to use intervention to individuals with asthma that is induced by exercise. Within the field of Athletic Training, it is common to interact with athletes who suffer from this condition. Medication that is required constantly and over long periods of time

(more than 3 months) have a strain a lot of individuals; whether it is financially, mentally, or physically. Our hopes for this study is that we can relieve some of the burden constant medication puts on their lives and improve their over-all physical health.

8. Compensation

All participants who complete all aspects of the study will receive \$50 gift card as compensation. Participants who withdraw from the study after 2 weeks will receive a \$10 gift card. Participants who complete the study but have a compliance rate of 80% with supervised sessions (9 supervised sessions) and 75% home exercise programs (30 unsupervised HEP), including journal entries, will receive a \$30 gift card. Compliance rate below 75% of entire study (less than 49 supervised and unsupervised sessions) will result in exclusion of participant from the study.

9. Publication of Results

- Academic Journal
- Academic Conference Presentation
- Thesis or Dissertation

APPENDIX B

INFORMED CONSENT



Study Title: COMPARISON OF THE EFFECTS OF DIAPHRAGMATIC
BREATHING EXERCISES AND YOGA PRANAYAMA
TECHNIQUES ON PULMONARY FUNCTION IN INDIVIDUALS
WITH
EXERCISE INDUCED ASTHMA

Principal Investigator: Richard Serra Co-Investigator/Faculty Advisor: Dr.

Rod A Harter

This consent form will give you the information you will need to understand why this research study is being done and why you are being invited to participate. It will also describe what you will need to do to participate as well as any known risks, inconveniences or discomforts that you may have while participating. We encourage you to ask questions at any time. If you decide to participate, you will be asked to sign this form and it will be a record of your agreement to participate. You will be given a copy of this form to keep.

> PURPOSE AND BACKGROUND

You are invited to participate in a research study to learn more about the effects of diaphragmatic breathing exercises and yoga breathing techniques on individuals with exercise induced asthma (EIA). The information gathered will be used to help decrease the severity and frequency of asthma attacks during exercise. You are being asked to participate because you are a physically active individual with diagnosed EIA.

> PROCEDURES

If you agree to be in this study, you will participate in the following:

- Two health related questionnaires, the Short Form 36- version 2 (SF-36 v2) and Asthma Quality of Life Questionnaire (AQLQ), taking approximately 20 to 30 minutes
- An Exercise Challenge Test on a treadmill, with exercise lasting no longer than 8 minutes.

- Repeated lung function tests measured with spirometry for a period of 30 minutes.
- If you are randomly assigned to an exercise group, 3 exercise sessions per week for 4 weeks. First session lasting approximately 45 minutes. Each subsequent session lasts approximately 30 minutes.

We will arrange a time for you to meet one of the investigators in Jowers Center. You will first be asked to complete two heath related questionnaires, an Exercise Challenge Test and lung function tests during a data collection session that will last approximately 60 minutes. This data collection process will be conducted twice--at the beginning of the study (Week 0) and at the conclusion of the study (Week 4).

> RISKS/DISCOMFORTS

The Exercise Challenge Tests that you will perform at the beginning (Week 0) and end of this study (Week 4) are required so that we can confirm your existing medical diagnosis of "exercise induced asthma". The treadmill-based Exercise Challenge Test is only 8 minutes long, but will typically result in a decrease in your pulmonary function similar to an "asthma attack". You can choose to discontinue the exercise test at any time due to discomfort.

As a safety precaution, we will require that you have your prescribed asthma medication with you at the time of the testing so that you can use it immediately if you sense an "asthma attack" coming on.

If you have any diagnosed cardiac or pulmonary disorders which could be made worse by Exercise Challenge Tests, please exclude yourself from the study.

If you have a known musculoskeletal injury that will prevent you from exercising for approximately 8 minutes at a moderate to high intensity, please exclude yourself from the study.

The graduate student investigator (RS) is a Nationally Registered Emergency Medical Technician (NR-EMT) and a nationally certified and licensed athletic trainer (AT) in Texas and can assess and intervene in the case of an emergency situation. In the unlikely event an emergency situation occurs, related to the exercise testing, local emergency medical services (EMS) will be contacted immediately.

If assigned to the yoga breathing group, one breathing exercise can potentially cause hallucinations in individuals who suffer from psychosis. We recommend that you decline to participate in this study if you have a known diagnosis of psychosis.

In the unlikely event that some of the survey or interview questions make you uncomfortable or upset, you are always free to decline to answer, or to stop your participation at any time. Should you feel discomfort after participating and you are a Texas State University student, you may contact the University Health Services for counseling services at 512-245-2208. They are located:

Texas State Counseling Center 5-4.1 LBJ Student Center 601 University Drive San Marcos, Texas 78666

> BENEFITS/ALTERNATIVES

The purpose of this study is to determine if yoga breathing and/or diaphragmatic breathing exercises have a positive effect on the frequency and severity of your EIA symptoms. Previous studies have shown that yoga practice and diaphragmatic breathing exercises can increase the quality of life, increase pulmonary function (lung function), and reduce the frequency and the severity of asthma attacks in sedentary individuals with asthma.

We are trying to determine whether the same effects will occur in physically-active individuals suffering from asthma that is brought on by exercise. We are hopeful that you will benefit from participation in this study by increasing your quality of life, increasing the functional capacity of your lungs, and reducing the frequency and severity of your asthma attacks when exercising.

> EXTENT OF CONFIDENTIALITY

Reasonable efforts will be made to keep the personal information in your research record private and confidential. Any identifiable information obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by law. The members of the research team and the Texas State University Office of Research Compliance (ORC) may access the data. The ORC monitors research studies to protect the rights and welfare of research participants.

Your name will not be used in any written reports or publications that result from this research study. Data will be kept for three years (per federal regulations) after the study is completed and then destroyed.

> PAYMENT/COMPENSATION

You will receive an HEB gift card of \$50 after completing the 4-week intervention with greater than 75% of compliance with the supervised and home exercise sessions.

You will receive an HEB gift card of \$30 after completing the 4-week intervention with less than 75% total compliance with the supervised and home exercise sessions.

You will receive an HEB gift card of \$10 if you withdraw from the study after 2 weeks of intervention.

You will not receive any compensation if you decide to exclude yourself from the study before 2 weeks.

> PARTICIPATION IS VOLUNTARY

You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time without consequences of any kind or loss of benefits to which you are otherwise entitled.

> QUESTIONS

If you have any questions or concerns about your participation in this study, please direct these to

Richard Serra (570-578-3124) at r_s327@txstate.edu or Dr. Rod Harter (512-245-2972) at rod.harter@txstate.edu.

This project #2017276 was approved by the Texas State IRB on February 2, 2017. Pertinent questions or concerns about the research, research participants' rights, and/or research-related injuries to participants should be directed to the IRB Chair, Dr. Jon Lasser 512-245-3413 – (lasser@txstate.edu) or to Monica Gonzales, IRB Regulatory Manager 512-245-2314 - (meg201@txstate.edu).

DOCUMENTATION OF CONSENT

I have read this form and decided that I will participate in the project described above. Its general purposes, the particulars of involvement and possible risks have been explained to my satisfaction. I understand I can withdraw at any time.

Printed Name of Study Participant	Signature of Study Participant	Date
Signature of Person Obtaining Consen	.+	 Date

APPENDIX C

Recruitment Mediums

Recruitment Email Message.

To: [Use this line for individual addresses or your own address if BCC line is used]

From: [Principal Investigator]

BCC: [Use this line when sending the same email message to multiple addresses]

Subject: Research Participation Invitation: Reduce Your Exercise Induced Asthma (EIA) Symptoms

This email message is an approved request for participation in research that has been approved by the Texas State Institutional Review Board (IRB).

The purpose of this study is to determine the effects of two different types of breathing exercises on exercise induced asthma. If you are an active individual who has been diagnosed with exercise induced asthma, between the age of 18 and 35 years old and would like to participate in the study, please contact graduate student researcher Richard Serra at 570-578-3124 or r_s327@txstate.edu

.

All health related information will be kept confidential, and all data collected will be reported anonymously for the study. If placed in an intervention group, you will be asked to attend three 30 minute sessions per week for one month. Volunteers who qualify and complete all aspects of this clinical trial will receive a \$50 HEB gift card at the conclusion of the study.

To participate in this study or ask questions about this research, please contact Richard Serra at (570) 578-3124 or r s327@txstate.edu

.

This project [#2017276] was approved by the Texas State IRB on February 2, 2017. Pertinent questions or concerns about the research, research participants' rights, and/or research-related injuries to participants should be directed to the IRB chair, Dr. Jon Lasser 512-245-3413 – (lasser@txstate.edu) or to Monica Gonzales, IRB administrator 512-245-2334 – (meg201@txstate.edu).



DO YOU SUFFER FROM ASTHMA WHILE EXERCISING?



Participate In On-Campus Research



Symptoms of Exercise Induced Asthma (EIA)

may be relieved with the use of yoga therapy

Requirements: Participants must experience Exercise Induced

Asthma and be between the ages of 18-35

Duration: 4 weeks

Compensation: Study participants can earn up to \$50 in HEB gift

cards

If you are interested in participating or have any questions, please contact: **Richard Serra**

570-578-3124

In class announcement script

I will be conducting a research study to determine the effects of 2 different breathing exercises on individuals with exercise induced asthma. I am looking for physically active adults between 18 and 35 who suffer from exercise induced asthma. The study will consist of a 4-week intervention program. By completing this study, there is a good possibility of an increase of quality of life and increase of lung function. Also, you will receive up an HEB gift card up to \$50, depending on your level of compliance. You will be assisting in my Graduate Level Master's thesis research, so your assistance is greatly appreciated. If you are interested, please contact me via email at r.serra78@txstate.edu. Thank you.

If announcement is to be made by other instructors:

One of the Graduate Assistants, Richard Serra, will be conducting a research study to determine the effects of 2 different breathing exercises on individuals with exercise induced asthma. He is looking for physically active adults between 18 and 35 who suffer from exercise induced asthma. The study will consist of a 4-week intervention program. By completing this study, there is a good possibility of an increase of quality of life and increase of lung function. Also, you will receive up an HEB gift card up to \$50, depending on your level of compliance. You will be assisting in Richard's Graduate Level Master's thesis research, so your assistance is greatly appreciated. If you are interested, please contact Richard via email at r.serra78@txstate.edu.

Thank you.

Appendix D

Health Related Quality of Life Questionnaires and Screening Questionnaire

Phone Questionnaire: Initial screening question

- 1. Name:
- 2. Date of Birth:
 - a. Exclude if after 1999 of today's date.
- 3. Have you ever been diagnosed for Exercise Induced Asthma? Exclude if answer is 'No'.

If so, when have you been diagnosed? And have you been prescribed medications for the EIA?

- 4. At the least, do you perform moderate-intensity aerobic exercise for approximately 30 minutes at least 5 days a week?
 - i. Examples: walking, biking, jogging, swimming, etc.)

Or: (to be asked if answer to question 4 is 'No')

Do you perform at least 25 minutes of vigorous aerobic activity at least 3 days per week for a total of 75 minutes; or a combination of moderate- and vigorous intensity aerobic activity

And:

Moderate to high intensity muscle strengthen activity at least 2 days per week for additional health benefits.

- b. Exclude if answer to all of question 4's questions are 'No'
- 5. Have you participated in yoga on a consistent weekly basis for the past 6 months?
 - a. If 'Yes'
 - i. How many times per week?
 - b. Exclude if more than 2 times per week
- 6. Have you ever been diagnosed with a cardiovascular disease which effects your ability to exercise at your submaximal heart rate?
 - a. Exclude if answer is 'Yes'
- 7. Have you ever been diagnosed with any other pulmonary or respiratory diseases/disorders?

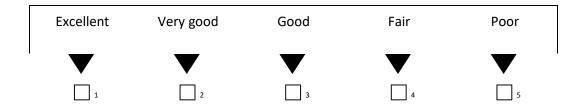
- a. Exclude if answer is 'Yes'
- 8. Have you ever been diagnosed with bi-polar disorder or Post Traumatic Stress Disorder?
 - a. Exclude if answer is yes to Bi-polar disorder
 - b. Caution volunteer of risks associated with PTSD and yoga breathing.
- 9. Do you currently have any musculoskeletal injuries that will prevent you from exercising on a treadmill to achieve 80 90% of max heart rate for at most 8 minutes?
 - a. Exclude if answer is 'Yes'
- 10. To the best of your knowledge, do you have a deviated septum?
- 11. At this time do you have any questions for me?
- 12. Would you like to participate in this study?
 - a. If 'Yes' Follow prompt A.
 - b. If 'No' Follow prompt B.
- A. Wonderful! Thank you for your interest in participating in my study. The next step is to set up a day and time to gather baseline information. My schedule shows that (available days and times) are open, Which of those best work for you?... Great, please arrive at Jowers Center on Charles Austin Dr. and City Park Rd. at (available time and day), you will go to (Biomechanics lab/Ex. Phys lab). You may give me a call at 570-578-3124, if you're unable to find you way to the lab. Please arrive in clothing and shoes for exercise, also, please come with your short-acting asthma medication on hand in case you feel the need to use it during testing. The screening will take approximately an hour and 15 minutes but may be shorter. If you are able to abstain from using your asthma medication for 48 hours prior to testing please do so, if it is absolutely necessary you may use your medication, but testing will need to be postponed. We will begin by giving you a little more information about my study, having you fill out some paper work, and then giving you an exercise test to confirm your EIA symptoms. After, if you still want to continue we will assign you a group randomly and give you further instructions. Thank you again and I'm looking forward to meeting you!
- B. I am sorry you have decided to pass on this opportunity. Thank you for contacting me. Have a wonderful day.

Your Health and Well-Being

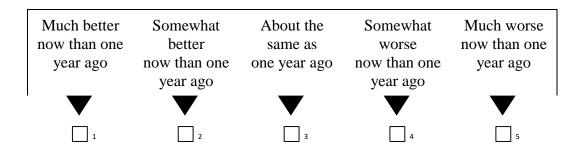
This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an \boxtimes in the one box that best describes your answer.

1. In general, would you say your health is:



2. <u>Compared to one year ago</u>, how would you rate your health in general <u>now</u>?



3.	The following questions are about activities you might do during a typical day.
	Does your health now limit you in these activities? If so, how much?

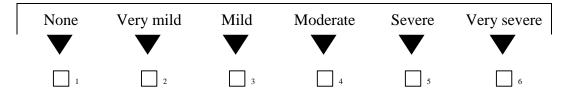
		Yes, limited a lot	Yes, limited a little	No, not limited at all
a	<u>Vigorous activities</u> , such as running, lifting heavy objects, participating in strenuous sports	1	2	
b	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c	Lifting or carrying groceries	1	2	3
d	Climbing several flights of stairs	1	2	3
e	Climbing one flight of stairs	1	2	3
f	Bending, kneeling, or stooping	1	2	3
g	Walking more than a mile	1	2	3
h	Walking several hundred yards	1	2	3
i	Walking one hundred yards	1	2	3
j	Bathing or dressing yourself	1	2	3

4. During the <u>past 4 weeks</u> , problems with your work <u>health</u> ?			-	-	
	All of the time	Most of the time	Some of the time	A little of the time	None of the time
Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
Accomplished less than you would like	1	2	3	4	5
Were limited in the <u>kind</u> of work or other activities	1	2	3	4	5
Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)	🗌 1	2] з	4	5
5. During the <u>past 4 weeks</u> , problems with your work <u>emotional problems</u> (such	k or other r	egular dai	ly activities	as a result	
a Cut down on the <u>amount of</u>			•		
time you spent on work or other activities	1	2	3	4	5
Accomplished less than you would like					
	1	2	3	4	5

6.	During the past 4 weeks, to what extent has your physical health or emotional
	problems interfered with your normal social activities with family, friends,
	neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks?



8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
1	2	3	4	5

9.	These questions are about how you feel and how things have been with you during
	the past 4 weeks. For each question, please give the one answer that comes closest to
	the way you have been feeling. How much of the time during the past 4 weeks

	All of Most of Some of A little of the None of the time the time the time the time 10.
a	Did you feel full of life? 2
b	Have you been very nervous? 1
c	Have you felt so down in the dumps that nothing could cheer you up?
d	Have you felt calm and peaceful? 1 2 3 4 5
e	Did you have a lot of energy? 1
f	Have you felt downhearted and depressed? 1 2 3 4 5
g	Did you feel worn out? 1 2 3 4 5
h	Have you been happy?
i	Did you feel tired? 1 2 3 4 5
	During
	the <u>past 4 weeks</u> , how much of the time has your <u>physical health or emotional</u> <u>problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?
	All of Most of Some of A little of None of the time the time the time the time

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely Mostly Don't Mostly Definitely true true know false false
a	seem to get sick a little asier than other people
b	am as healthy as nybody I know
с	expect my health to et worse
d	Iy health is excellent

Thank you for completing these questions!

ASTHMA QUALITY OF LIFE QUESTIONNAIRE WITH STANDARDISED ACTIVITIES (AQLQ(S))

SELF-ADMINISTERED

© 1996

QOL TECHNOLOGIES LTD.



For further information:

Elizabeth Juniper, MCSP, MSc Professor 20 Marcuse Fields Bosham, West Sussex P018 8NA, England

Telephone: +44 1243 572124 Fax: +44 1243 573680

E-mail: juniper@qoltech.co.uk

Web: http://www.goltech.co.uk

Development and validation supported by GLAXO WE-I-I-COME, INC

The Asthma Quality of Life Questionnaire with Standardised Activities (AQLQ(S)) is copyrighted and all rights are reserved. No part of this questionnaire may be sold, modified or reproduced in any form without the express permission of Elizabeth Juniper on behalf of QOL Technologies Limited

Please complete all questions by circling the number that best describes how you have been

1. STRENUOUS ACTIVITIES (such as hurrying, exercising, running up stairs, sports) Limite Limited Limite Limitatio Limitatio Limitatio Limite d
(such as hurrying, 1 2 3 4 5 6 7 exercising, running up stairs, sports) 2. MODERATE
exercising, running up stairs, sports) 2. MODERATE
up stairs, sports) 2. MODERATE
2. MODERATE
ACTIVITIES
(such as 1 2 3 4 5 6 7
walking,
housework,
gardening,
shopping,
climbing stairs)
3. SOCIAL
ACTIVITIES
(such as 1 2 3 4 5 6 7
talking, playing
with
pets/children,
visiting
friends/relative
s)
4. WORK-RELATED 6 7
ACTIVITIES
(tasks you have to 1 2 3 4 5
do at work*)
*If you are not employed or self-employed, these should be tasks
you have to do most days.
5. SLEEPING 1 2 3 7
4 5 6

HOW MUCH DISCOMFORT OR DISTRESS HAVE YOU FELT DURING THE LAST 2 WEEKS?

A Very A Great A Good Moderate Some None Very Great Deal Deal Amount Little

6. How much discomfort or distress have you felt over

1 2 3 4 5 6

7

during the last 2 weeks as a result of your asthma.

HOW LIMITED HAVE YOU BEEN DURING THE LAST 2 WEEKS IN THESE

ACTIVITIES

AS A RESULT OF YOUR ASTHMA?

the last 2 weeks as a result of

CHEST TIGHTNESS?

IN GENERAL, HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS

DID YOU:

		All of	Most	A Good		A Little	•	None
		the Time	of ethe	Bit of	of the	of the	Any of the	of the
			Time	the	Time	Time	Time	Time
7.	Feel CONCERNED			Time				
,.	ABOUT HAVING ASTHMA?	1	2	3	4	5	6	7
8.	Feel SHORT OF BREATH as a result of your asthma?	1	2	3	4	5	6	7
9.	Experience asthma symptoms as a RESULT OF BEING EXPOSED TO CIGARETTE	1	2	3	4	5	6	7
10.	SMOKE? Experience a WHEEZE in your chest?	1	2	3	4	5	6	7
11.	Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF CIGARETTE SMOKE?	1	2	3	4	5	6	7

HOW MUCH DISCOMFORT OR DISTRESS HAVE YOU FELT DURING THE LAST 2 WEEKS?

	A Very A Great A Good Moderate Some Very None Great Deal Deal Amount Little							
12. How much discomfort or distress have you felt over	1	2	3	4		7		
the	last 2 weeks	as a result	_					
of COUGHING?	aust 2 Weeks	us a resur						
IN GENERAL, HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS DID YOU: All of Most of A Good Some of A Little of Hardly Any								
the Time the Time Bit of the the Time the Time the of the Time								
Time								
13. Feel FRUSTRATED as a	1	2	3	4	5	6 7		
result of your asthma?								
14. Experience a feeling of .1 2	3 4 5 6 CHE	ST HEAV	/INESS?			7		

ASTHMA QUALITY OF LIFE QUESTIONNAIRE (S) PATIENT ID:

SELF-ADMINISTERED

DATE:

		All of the Time			Some of ethe Time	of	Any	None of the
		me rine	Time	Time	tule Tille	the Tillic	Time	Time
15	Feel CONCERNED ABOUT THE NEED TO USE MEDICATION for	1	2	3	4	5	6	7
16.	your asthma? Feel the need to CLEAR YOUR THROAT?	. 1	2	3	4	5	6	7
17.	Experience asthma symptoms as a RESULT OF BEING EXPOSED TO	1	2	3	4	5	6	7
18.	Experience DIFFICULTY BREATHING OUT as a result of your asthma?	1	2	3	4	5	6	7
19.	Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF DUST?	1	2	3	4	5	6	7
20.	WAKE UP IN THE MORNING WITH ASTHMA SYMPTOMS?	1	2	3	4	5	6	7
21.	Feel AFRAID OF NOT HAVING YOUR ASTHMA MEDICATION	1	2	3	4	5	6	7
22.	AVAILABLE? Feel bothered by HEAVY BREATHING?	1	2	3	4	5	6	7
23.	Experience asthma symptoms as a RESULT OF THE WEATHER OR AIR POLLUTION OUTSIDE?		2	3	4	5	6	7

ASTHMA QUALITY OF LIFE QUESTIONNAIRE (S) PATIENT ID:

SELF-ADMINISTERED				DATE:			
24. Were you WOKEN AT NIGHT by your asthma?	1	2	3	4	5	6	7
25. AVOID OR LIMIT GOING OUTSIDE BECAUSE OF	1	2	3	4	5	6	7
IN GENERAL HOW MUCH OF	THE TIM	TE DURIN	JG THE I	AST 2 W	EEKS	O	,

DID YOU:

THE WEATHER

OR AIR

POLLUTION?

IN GENERAL, HOW MUCH OF THE TIME DURING THE LAST 2 WEEKS DID YOU:

	All o	f Most	A	Some of	A Little	Hardly	None
		of	Good		of	Any	of
	the	the	Bit of	the	the	of the	the
Experience asthma	Time	Time	the	Time	Time	Time	Time
symptoms as a			Time				
26. RESULT OF							
BEING	1	2	3	4	5	6	7
EXPOSED -ro							
STRONG							
SMELLS OR							
PERFUME?							
27. Feel AFRAID O	_	2	3	4	5	6	7
GETTING OUT O	F						
BREATH?							
Feel you had to AVOII)						
A							
SITUATION OR							
ENVIRONMENT	1	2	3	4	5	6	7
BECAUSE OF							
STRONG SMELLS OF	R						
PERFUME?							
29.							

SELF-ADMINISTERED DATE: Has your asthma 2 3 5 7 **INTERFERE** 1 4 6 WITH GETTING A **GOOD NIGHT'S** SLEEP? 30. Have a feeling of 4 5 6 7 3 FIGHTING FOR AIR? 1 HOW LIMITED HAVE YOU BEEN DURING THE LAST 2 WEEKS? Not Slightl Very Hardl Limite Severely Very Limited Moderately Slightly d Limited Limited Limite Limite Limited At All d d Have Done Most NotSeveral Very Few All Activities Not Not Done Done Done 31. Think of the **OVERALL** RANGE OF **ACTIVITIE** S that you would have liked to have done during the last 2 weeks. 1 23 4 5 6 7 much How has your range of activities been limited by your asthma?

ASTHMA QUALITY OF LIFE QUESTIONNAIRE (S) PATIENT ID:

HOW LIMITED HAVE YOU BEEN DURING THE LAST 2 WEEKS?

Totally Extremely Very Moderate Some A Little Not at all Overall, Limited Limited LimitedLimitationLimitationLimited among ALL THE **ACTIVITIES** 32.that you have done during 2 3 4 5 1 6 7 the last 2 weeks, how limited have you been by your asthma?

DOMAIN CODE:

Symptoms: 6, 8, 10, 12, 14, 16, 18, 20, 22, 24,

29, 30

Activity Limitation: 1, 2, 3, 4, 5, 11, 19, 25, 28, 31, 32 Emotional Function: 7, 13, 15, 21, 27

Environmental Stimuli: 9, 17, 23, 26

APPENDIX E

Review of Literature

Asthma as a disease

Asthma is a chronic disease that affects 26 million individuals nationally, including more than 7 million children.^{1,2} In 2011, out of 136 million emergency department visits, asthma was recorded to be one of the 20 top reasons, reaching 1.7 million.¹ Nationally, \$56 billion in healthcare costs has been recorded in a 2007 survey; on top of national cost, asthma affecting adults can lead to millions of lost work days every year.³

When a cause of asthma is present (allergen, environmental factor, exercise), asthma creates a spasm within the bronchioles of the lungs making it difficult to breath. Signs and symptoms include chest tightness or pain, cough or wheezing, and shortness of breath. The causes of asthma are not consistent between individuals, but can include environmental allergens, anxiety or stress, or exercise. This condition can affect any person of any age and could be life threatening. Asthma can be controlled with a combination of medications; anti-cholinergic agents, short acting beta-agonists, or mast cell stabilizer have been shown to be effective against asthma symptoms. Any medication taken regularly causes medical side effects, but also leaves people with a financial burden. On average, in 2003, an individual could spend approximately \$5,000 annually on asthma. Since asthma is almost unpredictable, it is imperative to keep medication within range at all times during work, physical activity, or leisure time.

Of the 26 million individuals suffering from asthma in the United States, 90% are affected by exercise induced asthma (EIA).⁶ Similar to asthma, EIA affects the

bronchioles in the lungs; however, it is caused by aerobic exercise. Essentially, EIA has the same effect on the respiratory system as asthma; the population of concern includes active individuals, particularly, athletes. Like asthma, EIA can be treated with β_2 -agonists, which is shown to be the most effective treatment.⁷ This type of medication can be used as either a long-term, prevention medication or a short-acting rescue medication.⁸ The long-term type can be taken prior to exercise to prevent exacerbation of symptoms. Short-acting medications are used primarily when symptoms are exacerbated and need to be controlled. β_2 -agonists used in excess could cause a level of tolerance;^{7,9} tolerance to medication typically requires an increase in dosage by a physician. β_2 -agonists used without combination of a corticosteroid could be unsafe, research has yet to be done on the safety of long term use of β_2 -agonists alone.⁹ However, asthma symptoms are poorly controlled, as seen by pharmaceutical refill rates of prescribed asthma medication being around 50%.⁸

Breathing exercise programs

Diaphragmatic breathing can be performed in different ways to achieve the same goal. Professor Konstantin Buteyko claimed to be the first to identify causes of certain respiratory and related physiological diseases, also claiming he could treat those diseases, in particular asthma. The Buteyko Breathing Technique (BBT) is a common exercise used among respiratory therapists to treat patients with respiratory diseases. Buteyko hypothesized that breathing diseases revolve around hyperventilation, which, in turn, decreases CO₂ within the body. The BBT focuses on reducing hyperventilation through a series of slow breathing periods followed by breathing pauses, where the participants hold their breath for a period of time with which they feel comfortable. A review of

Buteyko breathing research tials found 4 published studies and 2 in abstract form. All of the studies, including the abstract reported a decrease in medication usage and an increase in quality of life. The outcome measures also included lung function testing, but there was no significance reported. However, despite the lack of objective data, one could say BBT can be beneficial to patients with asthma due to the increase quality of life and decrease in medication use. After all, interventions are meant to provide individuals with a sense of relief, even if it may work as a placebo effect. BBT seems to be the only standard breathing exercise reported, with other techniques utilizing a diaphragmatic focus.

More general diaphragmatic breathing exercises have studied with promising results. A 10-minute diaphragmatic breathing exercise can improve pulmonary function immediately. ¹² Individuals with and without asthma were compared to a control group to determine effects of this 10-minute protocol on pulmonary function. After 1 minute of the protocol, 10 minutes of the protocol and 7 days of the protocol, participants with asthma had a significant increase in forced vital capacity (FVC), but the healthy group had significance in all parameters. This protocol shows promise in improving pulmonary function in a population which is not sedentary and not suffering from significant respiratory disorders. The study does not provide information as to long term effects of the protocol, which could be left as an area of future research.

Three studies show significance with a resistive breathing protocol on pulmonary function. The protocol utilized in the three studies was reproduced to determine the effects on pulmonary function on moderately active individuals with exercise induced asthma. Each study compared the diaphragmatic breathing group against an aerobic

activity group in determining pulmonary function increases, with one study adding in a group which combined aerobic activity and the diaphragmatic breathing protocol. ¹⁴ This study proves that aerobic activity is affective at improving pulmonary function in an inactive population with asthma. ¹⁴ However, the purpose of this study is to determine effects on moderately active individuals, which the assumption of some aerobic training can be made. Individuals with exercise induced asthma have exacerbated symptoms during exercise, therefore adding an aerobic component might exacerbate symptoms leading to poor compliance with protocols.

The quality of evidence found on diaphragmatic breathing exercises is low, but the results of the studies mention show promise. The two most effective protocols¹²⁻¹⁵, are being combine to offer the best treatment affect possible. Pulmonary function is an important outcome measure when dealing with individuals with asthma, but any increase in quality of life has a positive effect on the same individuals.

Yoga on asthma

Yoga is reported to improve quality of life in multiple disciplines of health; from mental health to physical health, yoga could potentially help. In relation to asthma exacerbation, yoga helps to decrease tidal volume and breathing rate, which are the exact thing which may cause asthmatic symptoms. ¹⁶ Breathing exercises focus on proper breathing mechanics and posture, which is the core ethos of yoga. ¹⁶ Along with the physical changes occurring following continuous practice, yoga is theorized to assist in mind relaxation, i.e. decrease stress and anxiety, ¹⁶ which can potentially cause asthma symptoms. Yoga has been practiced for centuries for multiple reasons; it is possible to utilize components of yoga to assist with health conditions. Since its postural and

breathing awareness principles are similar to most of the diaphragmatic breathing exercises it is important to see whether it has an effect on individuals with asthma.

Evidence shows that yoga in general can improve quality of life, lung function and have some effect on physiological processes in the body, such as heart rate, breathing rate and blood pressure. 16-20 Since there are multiple different types of yoga practice, protocols that are not described are difficult to reproduce. A few studies state basic pranayamas and asanas were utilized giving exercise session durations, but not giving specifics as to which one they utilized.²¹⁻²⁴ These protocols will be referred to as "generic protocols", mainly because they are described with the Sanskrit names for breathing exercises (pranayama), postures (asanas) or cleansing (kriyas). The generic protocols, however, still showed improvements in some common outcome measures. Two studies noted a change in physiological values using generic protocols; heart rate was decreased^{21,22}, blood pressure and mean arterial pressure had decreased²¹, and respiratory rate was decreased.²² Many other studies do not use these values as outcome measures. Their importance is not any less significant when looking at chronic diseases, but many other factors (cardiovascular disease, diabetes, respiratory disorder, etc.) can effect these measures, which can lead to inconsistent or less significant findings. Although, the decrease in the values correlate with athletic population ranges. Lower resting values of heart rate, respiratory rate and blood pressure can indicate a person has better cardiovascular training, normally seen in physically active individuals.

Quality of life is another common outcome measurement when looking at individuals with asthma. Asthma has a negative effect on quality of life for many reasons. As mentioned early, it massed \$56 billion in health care costs in 2007, with

approximately \$3,200 per person per year. That alone is enough to decrease someone's quality of life. However, other factors deal with the symptoms that arise with different triggers. Individuals suffering from asthma have to avoid certain activities during different times of the years, or they have to prepare by taking long acting medications prior to the activities. Environmental allergens or even exercise can exacerbate asthma, leading to shortness of breath, wheezing, constant coughing, or chest tightness. Difficulty breathing can end a lot of enjoyable activities and force individuals to remain in doors and away from their trigger. Yoga has been shown multiple times to increase the quality of life of individuals with asthma. 18,21,24-26

The Asthma Quality of Life Questionnaire (AQLQ) is a common questionnaire which uses 4 domains to assess quality of life with asthma. Four studies which utilized the AQLQ showed yoga to improve quality of life scores. ^{18,24,26,27} Out of the four, one study showed an improvement in the activity domain. ²⁷ Two showed improvements in all domains ^{18,26} while the final study measured it as an overall outcome measure, not breaking it down by domain scores. ²⁴

Another important outcome measure to assess when dealing with asthma symptoms is pulmonary function. Pulmonary function is normally what is assessed when diagnosing asthma. ²⁸ Essentially, a decrease in FEV₁ during an asthma attack which can be reversed with a bronchial dilator is enough to confirm a suspected asthma diagnosis. ²⁸ Individuals with exercise induced asthma show the same decrease in FEV₁, however, they are tested during a bout of intense exercise. If FEV₁ is not decreased by at least 10 – 15%, a diagnosis of exercise induced asthma cannot be made. The majority of studies primarily look at individuals with asthma symptoms as a whole, they do not specify the

type of trigger of asthma. Yoga has been shown in these studies to increase pulmonary function over the intervention time frame. ^{18,24,29}

Two major factors can be noticed in the studies which have been shown to increase pulmonary function and quality of life; type of intervention and utilizing supervised verses unsupervised. As mentioned early, 4 studies utilized a generic protocol which was not explained thoroughly. The other studies which provide strong evidence go into a little more detail about the protocols utilized. The second factor which may play a role in outcome measures is the use of supervised verses unsupervised sessions.

A few similar yogic breathing techniques were noticed among multiple studies. ^{18,19,26,29} Certain techniques such as *kapalabhati* or "breath of fire", *Adhama Svasa* or abdominal breathing, *Ujjayi* -- a resistive throat breathing, and *Nadi Shodhana* -- an alternate nostril breathing can be seen throughout the studies as part of their yoga intervention groups. ^{18,19,26,29} These studies all showed significant increase in quality of life and pulmonary function. Based on information obtained from the Integrative Yoga Therapy Yoga Teacher Training Manual, the breathing techniques are utilized to improve breathing function, some being directly related to respiratory diseases such as asthma. It is not a surprise to see these breathing techniques utilized throughout multiple studies. Since the studies utilizing generic protocols do not provide specific breathing exercises, it is difficult to assume which techniques that use, or if their techniques are the reason for improvements in pulmonary function. Also, some studies use upwards of 10 different breathing techniques, which also makes it difficult to determine which one or ones have the best benefit for asthma. For this study, 3 specific breathing techniques were chosen

which directly affect diaphragmatic strength and pulmonary function in individuals with asthma, according to the Yoga Training Manual.

The duration of a study is important when trying to achieve a treatment effect of an intervention. An 8-week intervention study is generally the least amount of time acceptable to achieve a treatment effect.

Testing

An asthma diagnosis can be achieved in a variety of ways. The most accurate testing procedure for asthma is inducing bronchial spasm by using methacholine chloride. Methacholine Challenge Testing (MCT) is also a preferred method of the American Thoracic Society for asthma testing. The purpose of the test is to assess airway responsiveness to rule out a diagnosis of asthma. For the purpose of this study, an asthma diagnosis is necessary for inclusion, therefore, MCT is not an appropriate test. The required testing for this study is to confirm a previous diagnosis of exercise induced asthma (EIA). The American Thoracic Society recommends an Exercise Challenge test for diagnosing EIA.

Symptoms of asthma should be monitored over time on a daily, weekly, or monthly basis.²⁸ Measurements obtained by a peak flow meter is an inexpensive method of symptom monitoring. Measurements are obtained twice a day, usually morning and evening, for 1 to 2 weeks and are reviewed by a physician for a change in peak expiratory force (PEF),²⁸ a variation of 10% of PEF can be a diagnostic measure for asthma.

Spirometry measurements can be utilized to determine variation of pulmonary function over a sequence of visits. Forced Expiratory volume in 1 second (FEV_1) is a primary measurement for this method, however it is thought to be less accurate when

used alone.²⁸ Accuracy of spirometric measures increases when testing the pulmonary function's response to treatment.²⁸ A 12% increase of FEV₁ over a 4- week period of medication usage can support a diagnosis of asthma.²⁸

Fractional exhaled nitric oxide (FeNO) is a test for increasing the probability of asthma if conventional tests moderate probability.²⁸ Typically, nitric oxide is elevated in individuals with asthma, which can be detected with exhaled breath.²⁸ This test is not recommended and does not rule out the diagnosis of asthma if results are negative.²⁸

Screening instrumentation

Subjective, health related questionnaires are used to ascertain information not directly quantifiable from an individual. There is no gold standard when dealing with patient perceptions on their disease and disease interventions, ³³ but the use of multiple questionnaires can be used to generalize scores to certain diseases. The Shot – Form 36 (SF-36) is a generic health questionnaire that measures a patient's perception of their current disease, it is not specific to any type of disease. ³³

A quality of life (QoL) questionnaire, the Asthma Quality of Life Questionnaire (AQLQ) was developed specifically for individuals with asthma which assess 5 domains of asthma disability with a 4-week recall evaluation. The AQLQ has been studied for its reliability and validity to detect changes in individuals with asthma after interventions are conducted.³⁴⁻³⁷

Spirometry is the gold standard method in assessing respiratory diseases/disorders, specifically, COPD and asthma.³⁸ The majority of spirometry devices used require constant calibration to ensure reliability of the test measures. However, the

EasyOne portable spirometer's manufacture claims the device does not require constant calibration, in lieu of structural damages.³⁸

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APPENDIX F

Intervention Positions and Descriptions

Yoga Pranayama Pictures and descriptions

Standing Forward Fold



Description: This posture is
performed in a standing
position, with knees bent
slightly and comfortably.
Bending at the waist, bring your
upper body down so you are
looking at the floor or legs
(depending on flexibility).
Relaxing the head, neck and
shoulders. Participant should
not feel any pain in neck, back,
or legs.

Modification of Standing Forward Fold

Modification shins

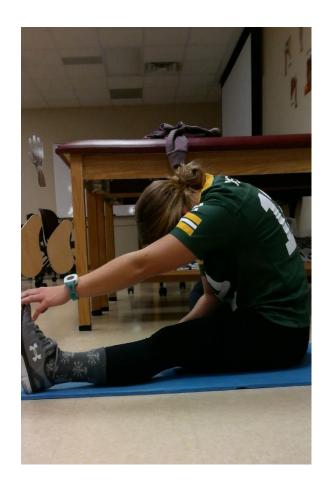
Modification knees



Modification description: if positon is uncomfortable causing discomfort or pain in neck, back or legs, rest hands on shins or knees. Neck and shoulders should remain relaxed.

Progression goal is to lower the level of hands on legs to reach the floor. Over time, practitioner should be able to touch head to knees.

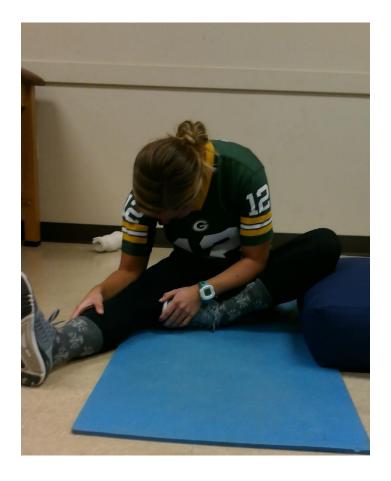




Head to knee Forward Bend

Description: This posture is performed in a seated position on the floor with one leg straight out. The opposite leg is bent with the foot touching the inner thigh of straight leg. Bending at the waist, the goal is to bring your head to your knee. Return to a straight seated position, and switch legs. The leg that was bent should be straight, and the leg that was straight should be bent, with the foot touching the inner thigh of your straight leg.

Modification of head to knee forward bend



Modification description: if position elicits any pain or discomfort place hands on extended leg in the position of most comfort. The opposite knee should be supported with pillows until comfort is felt and knee is as close to the ground as possible.

Seated Forward Fold





Description: Sitting on the flood with both legs straight, the goal of this posture is to bring body and head down towards your head, reaching for your toes. No pain or discomfort should be felt in the body.

Supported Half Shoulder Stand



Description: Laying on the ground with legs up against the wall and a pillow or blanket underneath the head and upper shoulders, you should push feet into the wall so they are flat. Knees should be bent and upper legs and body should be in line and perpendicular to the ground. Weight of body should be supported by shoulders. Hands can be supporting low back in this position. No weight should be on neck in this position.

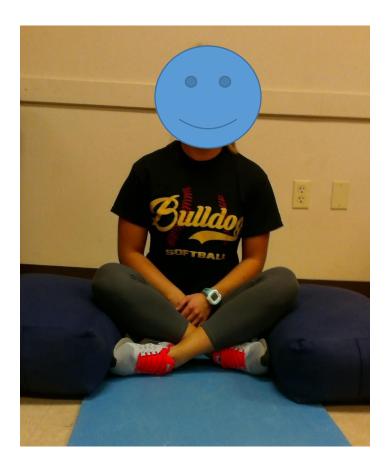
Sukasana (Easy Cross Legged)

Description: This position is easy cross legged in an upright seated position. Legs are crossed and feet are positioned under legs close to the body. Knees are relaxed.

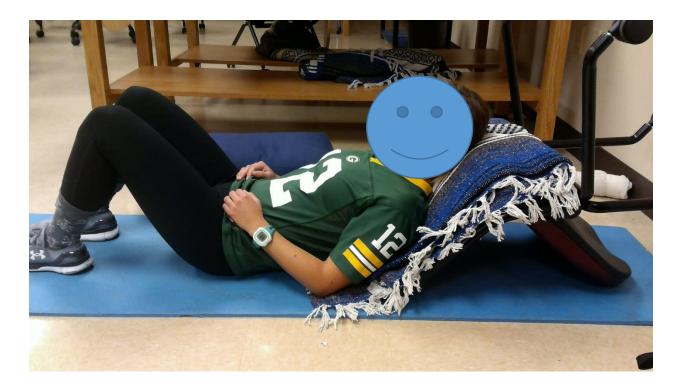


Modification of Sukasana (Easy Cross Legged)

Modification description: if pain or discomfort is felt in legs, place pillows under knees at the point before discomfort. Legs should be relaxed and resting on pillows.

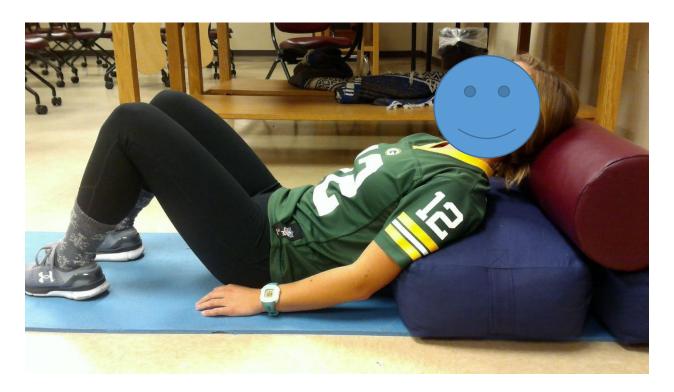


Semi-Recumbent position



Description: This position can be performed using an overturned chair or pillows. Torso should be elevated to about 30-50 degrees. Your knees and hips should be bent to about 30 degrees. Feet should be resting comfortably on the ground. Your head, neck, and back should all be resting and supported comfortably.

Using the back of an overturned chair, place a thick blanket (for comfort) on the back of the chair. Lay on the blanket and ensure your head, neck, shoulders, and back are supported comfortably.



Using multiple pillows, place two pillows down next to each other. Place a third pillow on top of the first two pillows, placing it in the middle of both. Lay on the pillows. Your head should be supported by the top pillow and your back should be supported with the bottom pillow closest to you. If the position is not comfortable, add pillows to achieve 30-50 degrees of torso elevation.

Diaphragmatic Breathing Group positions and descriptions

Semi-Recumbent position



Description: This position can be performed using an overturned chair or pillows. Torso should be elevated to about 30-50 degrees. Your knees and hips should be bent to about 30 degrees. Feet should be resting comfortably on the ground. Your head, neck, and back should all be resting and supported comfortably.



Using the back of an overturned chair, place a thick blanket (for comfort) on the back of the chair. Lay on the blanket and ensure your head, neck, shoulders, and back are supported comfortably.

Using multiple pillows, place two pillows down next to each other. Place a third pillow on top of the first two pillows, placing it in the middle of both. Lay on the pillows. Your head should be supported by the top pillow and your back should be supported with the bottom pillow closest to you. If the position is not comfortable, add pillows to achieve 30-50 degrees of torso elevation.

Semi-Recumbent position while stabilizing weight



Description: The position is achieved the same way as described above. With either your left or right hand, gently stabilize the weight on your abdomen.

