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Are soft tissue interventions more effective than breathing retraining interventions in decreasing asthmatic symptoms

Metropolia University of Applied Sciences

Bachelor of healthcare

Literature review

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<p>Asthma affects 5-10% of the global population and the mainstream treatment for patients involve medication's which can cause side effects. Currently, there are many alternative approaches such as breathing retraining and soft tissue interventions, however, comparative studies are lacking.</p> <p>This thesis reviewed the role of soft tissue manipulation and breathing retraining techniques on asthma patients to compare their effects and to understand their viability in the reduction of symptoms. These techniques are commonly utilized by Osteopaths and manual therapeutic branches. 8 studies were included with 7 articles which were randomized control trial studies and 1 pilot study with randomization</p> <p>Breathing retraining was found to benefit asthmatic patients in psychological measures (e.g., <i>QoL, AQLQ</i>) and had no effect on the ventilatory measure of the lungs.</p> <p>The soft tissue interventions had a beneficial impact on both ventilatory and psychological measures, but this outcome was not exclusive to all articles related to soft tissue interventions. Not enough research currently exists to give a clear answer to the research question; therefore, it cannot be stated that soft tissue techniques are superior to breathing retraining for asthmatic patients. Further research is needed to compare these mainstream alternative interventions with all appropriate measures typically associated with asthma symptoms (e.g., <i>Spirometry, QoL, AQLQ, </i>).</p>	

Keywords	Asthma, Dysfunctional breathing, manual therapy, Physiotherapy, breathing retraining, osteopathy
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Declaration of conformity

We hereby assure that we have created this present work independently and have used only the sources and aids indicated. We have submitted this nor another thesis anywhere else. Furthermore, this work does not appear in any conflict of interest with any other person or institution.

Signature,

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Abbreviations

HVS	Hyperventilation syndrome
DB	Dysfunctional breathing
BPD	Breathing Pattern dysfunction
NQ	Nijmegen Questionnaire
QoL	Quality of life
AQLQ	Asthma quality of life Questionnaire
VC	Vital capacity
FVC	Forced vital capacity
FEV	Forced expiratory volume
FEV1	Forced expiratory volume per minute
PEFR	Peak expiratory flow rate
MTrpS	Myofascial trigger points
CNS	Central nervous system
SNS	Sympathetic nervous system
OMT	Osteopathic manual therapy
RCT.	Randomized controlled trial
MET	Muscle energy technique
ATS	Advanced therapy solutions
PCLE	Pink city lung exercise

1 Background

1.1 Introduction

Asthma affects 5-10% of the global population, and currently, the mainstream treatment for patients who exhibit intolerable asthma symptoms involve inhaled bronchodilators (*containing Corticosteroids*), long-lasting beta-agonists and oral corticosteroid (Vidotto et al. , 2019). Most patients who medicate for asthma have been found to return to their previous symptoms when they cease to take them. This indicates that many asthma patients will have a dependency on their medication for a long time if not their entire lives, which often leads to corticosteroid side-effects (e.g., general muscle weakness, anxiety, osteoporosis & easy bruising (Lommatzsch and Virchow, 2021).

Mounting evidence also indicates that poor breathing control derived from asthma or other pulmonary pathologies has negative effects on patients' psychological well-being. These will often further increase their inadequate breathing function. (Laurino et al., 2012). Further analyses show increasing clinical evidence that anatomical structures and their functions change when under stress. These alterations have negative developments in musculoskeletal and connective tissues of the thoracic chest wall, abdomen, and back when the upper thoracic accessory pattern of respiration is used excessively over time. These changes occur because of fast respiration movement that are compensating mechanism for dyspnea (*air hunger*) often observed in asthmatic patients. Fast respiration decreases Full respiratory volume over time and causes shortening of vital pleural, connective tissues and musculoskeletal structure. The shortening can cause decreased functionality in ventilatory measures and cause variety of symptoms (*Hyperventilation (HVS), Dyspnea, Anxiety*) (A Pryor, 2007).

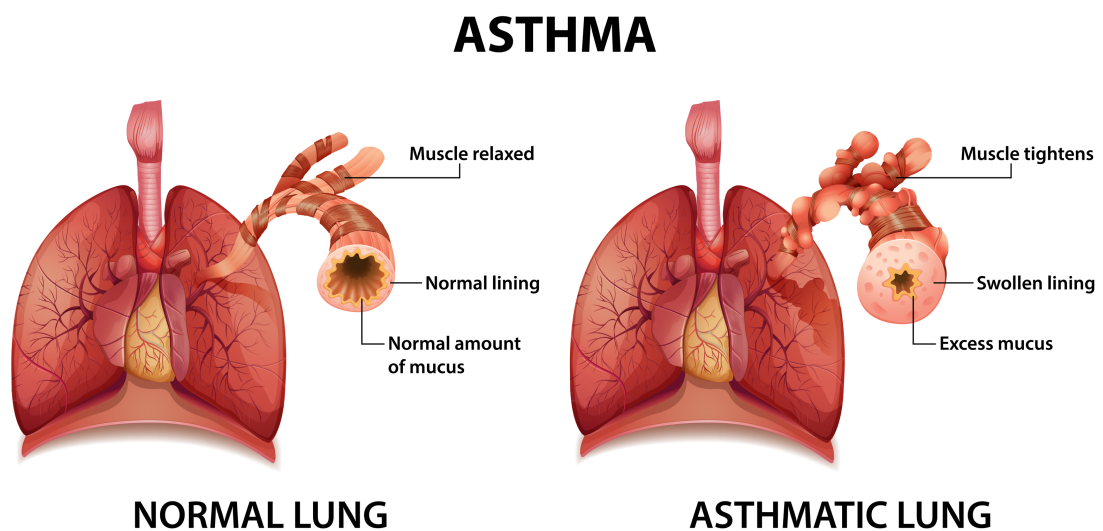
With all this in mind, alternative methods have been suggested for decreasing asthma symptoms, achieved through either alternation of tissues or breathing retraining by decreasing autonomic breathing pattern that can present as HVS. These interventions include soft tissue manipulations and breathing retraining from various manual therapeutic branches (A Kyrle MD., 2005). Therefore, in this current work the aim is to answer the following question: Do alternative therapies, such as breathing retraining or soft tissue interventions help asthmatic patients to become less dependent on their medication by reducing their asthma symptoms?

1.2 Relevant research & anatomy

1.2.1 Asthma

An estimated 235 million people worldwide are affected by asthma, leading to substantial health and economic burdens (El Deen et al., 2020). Asthma is not a single disease, but a group of disorders characterized by a chronic inflammatory condition of the airways where many different types of cellular elements are involved. At its core, however, asthma is an underlying inflammation of the airways which causes swelling and narrowing. Obstructions for flow of air is caused by excessive mucus and narrowing of smooth muscles in the bronchial tubes and physiologically shown in Figure .1. In mild stages of asthma symptoms such as, coughing, chest tightness, wheezing and Hyperventilation are the most common signs (Douglas, 2010) . Asthma can be defined Pathologically as a bronchial inflammation with prominent eosinophilic infiltration, and physiologically as a bronchial hyper-reactivity with fluctuations in lung function.

Figure .1.: The narrowing within the linings of the bronchial tubes compared to normal function. (freepic.com)



There is an increasing recognition that psychological factors affect the onset and course of asthma. Moreover, there is a significant correlation between asthma and negative emotions, especially anxiety and depression (Laurino et al., 2012).

1.2.2 Muscles of respiration & thoracic cage

The respiratory system comprises of many structures that work in unity to achieve inhalation and expiration. Muscles of respiration are unique among skeletal muscles in that they are required to work without sustained rest throughout life (McKenzie, 2006). The accessory muscles can replace the main respiratory muscles' role, which in return can increase demand on related pulmonary structures. All the respiration muscles are shown in *Table .1.*, Pulmonary dysfunctions or pathologies, such as asthma, can lead to escalated symptoms (Chaitow, 2014).

The diaphragm is the most important muscle for breathing. It serves both inhalation and expiration; among many other functions, it is also stimulated by distress through the sympathetic nervous system (Bordoni et al., 2016). Therefore, negative psychosomatic stimulation by insufficient breathing sufficiency can have adverse effects on the diaphragm or other structures and cause poor breathing patterns to occur. Reduced mobility within the thoracic cage, ribs and/or vertebra, has been associated with a decreased forced vital ability (FVC) and forced expiratory volume in the first second of expiration (FEV1), showing inadequate oxygen intake. When rigidity increases in the chest wall, there will be a direct impact on the ventilatory pumping mechanism. By decreasing rigid mobility in the thoracic area, possible improvement in lung function can occur. (M. Shams El Deen et al., 2020)

Muscles of inspiration	Structures/Muscles of expiration
Accessory muscles:	Quiet breathing structures:
Sternocleidomastoid	Expiration results from passive, elastic recoils of the lungs, rib cage.
Scalene group and pectoralis minor	Active breathing muscles:
Main respiratory muscles:	Internal intercostals, except interchondral part, abdominals, Quadratus lumborum
External intercostals, interchondral part of internal intercostals	Diaphragm
Diaphragm	

Table .1. - The key respiratory muscles & structures

1.2.3 Morphological changes

increasing evidence shows that anatomical structures and their functions change when respiratory disease's cause change in normal breathing pattern. These alterations have negative developments in musculoskeletal and connective tissues of the thoracic chest wall, abdomen, and back when the upper thoracic accessory pattern of respiration is used excessively over time. These changes occur because of fast respiration movement that are compensating mechanism for dyspnea (*air hunger*) often observed in asthmatic patients. This fast respiration pattern can have a severe decrease in full respiratory volume. Over time negative shortening of vital pleural, connective tissues, smooth muscles and musculoskeletal structure will occur, causing decreased functionality in regular ventilatory measures (A Pryor, 2007). Often, asthmatic patients exhibit upper chest respiration to compensate for air hunger (dyspnea), through hyperventilation. This imbalanced strain on anatomical structures can eventually lead to dysfunctional breathing where asthma can become more acute or cause asthma symptoms. (Vidotto et al., 2019).

1.2.4 Dysfunctional breathing mechanics in asthma

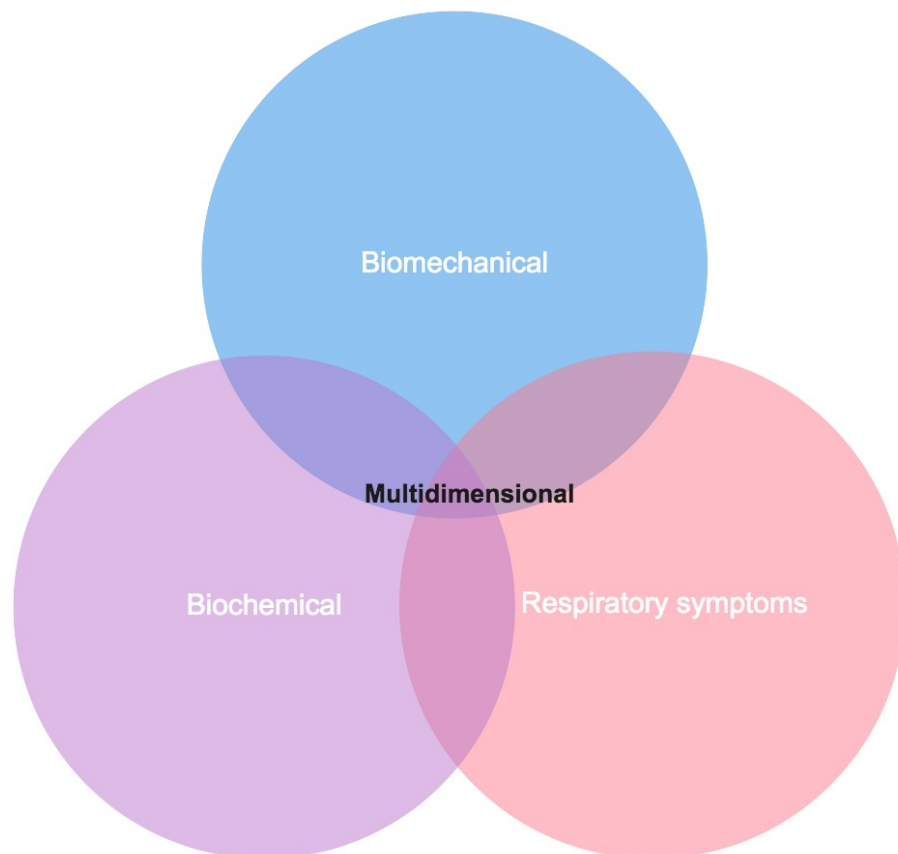


Figure .2. – Showing the multiple inputs which are affected in respiratory related dysfunctions.

Dysfunctional Breathing (DB) or Breathing Pattern dysfunction (BPD) is often used synonymously for an underlying respiration disturbance. DB is a broad topic, much like asthma, divided into three sub-areas of research: biochemical, biomechanical, and breathing-related symptoms. **Figure .2.** (Kyrle, 2005) However, these different research areas are not mutually exclusive and can overlap. For example, a disturbance in the breathing pattern can exist with or without an organic cause. It can be present in various individuals with musculoskeletal dysfunction (Biomechanical), respiratory symptoms (i.e., asthma or interstitial pulmonary disease), and psychogenic disorders (Biochemical), such as anxiety, exhaustion and depression. (Bradley et al., 2014). All dysfunctions mentioned above often occur with dyspnoea (Air hunger), which leads to hyperventilation (Boulding et al., 2016). The biomechanical alteration has been found to cause a disturbance in respiratory function, which leads to alteration in the body's biochemical state. The same applies to respiratory symptoms on the chemical and biomechanical processes of respiration. (Bradley et al., 2014) Even if dysfunctional breathing has been

observed in patients with respiratory pathologies, it can become challenging to explain its interference with breathing patterns. An extensive analysis of the subject, for example, done by Boulding et al. Fowler (2016) could not find a clear link between respiratory pathology and breathing pattern dysfunction. To explain this unclear link between DB and respiratory pathologies a fourth subarea of dysfunctional breathing could give clarification. This fourth subarea is observed in patients that have no evident symptoms that can be measured, by blood gas analysis or nitric oxide measures but still show visible symptoms such as Hyperventilation (HVS), cough, wheezing and air hunger. However, this fourth area has been thought to be an underdiagnosed psychological alteration of respiration due to unreliable diagnostic tools (Vidotto, Carvalho, Harvey and Jones, 2019). In this current work it's essential to understand that asthma and dysfunctional breathing (DB) can co-exist. Either symptom can be the causative factor of respiratory symptoms. Even if they can exist independently of each other, asthma will eventually lead to symptoms typical of DB (i.e., upper thoracic breathing, HVS, dyspnoea, anxiety). The most common tool for assessing HVS/DB is the Nijmegen questionnaire (NQ). A study evaluating symptomatic hyperventilation subjects by the NQ found that 80% of patients diagnosed with HVS/DB may have underlying Asthma (Demeter and Cordasco, 1986), potentially indicating that DB is underdiagnosed Asthma without sufficient symptoms to be detected by physiological measures. By knowing typical DB symptoms, perhaps more accessible guidelines can be followed to observe asthma in patients in clinical settings.

1.2.5 Psychogenic aspects

Anxiety, exhaustion, and panic disorders can cause alteration in the body's biochemical state and can also be stimulated or be intensified by the forced expiratory load, which leads to increased body PH, Increased alkalinity, and therefore initiating a variety of adaptive changes which produce symptoms (Chaitow, 2014). Anxiety is, however, a complex psychogenic response to the external interpretation of each individual who experiences it. Another possible influencing factor is genetic vulnerabilities (Winning, 2021).

The interoceptive awareness (i.e., awareness of inner body sensations) of an asthmatic person might lead them to have difficulties while trying to reallocate attentional focus from their breathing to external stimuli due to discomfort or irritation caused by asthma episodes and lead to symptoms such as hyperventilation, frequent deep sighing and holding their breath. In general, these patients might present with a particular form of

overactive monitoring that compromises the respiratory system's normal function due to asthma; however, these are theoretical models that are disputed and need further investigation (Vidotto et. Al., 2019).

1.2.6 Pathophysiology and pathogenesis of asthma

The immune system histopathological features of asthmatic population are primarily due to inflammatory cells infiltration; Eosinophils, lymphocytes, mast cell activation, epithelial cell damage, Neutrophils (in sudden-onset, asthma exacerbations; occupational asthma, and patients who smoke). Some patients, persistent airway structure changes occur due to sub-basement fibrosis, mucus hypersecretion, damage to epithelial cells, smooth muscle hypertrophy, and angiogenesis. These infiltrations often cause permanent changes in the lungs, which might differ in patients' symptoms depending on their anatomy and severity. These changes can lead to Bronchoconstriction, airway edema, airway hyperresponsiveness, and airway remodelling, many of which are persistent throughout life (National Heart, Lung, and Blood Institute, 2021).

1.3 Manual therapeutic interventions & assessments

1.3.1 Asthma measures

Since asthma is a multifactorial pathology that often affects a person biomechanically, physiologically, and psychologically, many assessment tools exist to measure its impact on a person's health. Psychogenic measures are the most extensive and disputed as to how accurate they are in giving precise statistics. The most common measure in mainstream healthcare is the Feno test. The test is carried out with patients breathing into a machine that measures nitric oxide, and a high amount of nitric oxide indicates inflammation factors happening in the lungs. A peak flow test is a standard measurement to see changes in patient's symptoms overtime. Patients blow into a handheld device that measures the breath rate by measuring liters of air per minute, and low peak flow values have shown narrow airways. (Asthma - Diagnosis, 2021)

Another measure used to get statistical oversight during an intervention is the spirometry measurement, which calculates FVC, FEV1, and FEV1/FVC. These values have been found to increase (decreased being less oxygen uptake) in patients during soft tissue manipulation with chronic obstructive pulmonary disease, which is similar to asthma since asthma obstructs the pulmonary system and inflammation. (M. Shams El Deen, M. et al., 2012).

When psychological measures are assessed, questionnaires are used, the most common one being Quality of Life (QoL) where 15-item instrumental questions are asked within five conceptual domains of quality of life: Material and physical well-being, relationships with other people, social, community and civic activities, personal development and fulfilment and recreation. However, this measure has been disputed since many researchers debate what questions are relevant to "know" for patients' needs and their desired outcome (Bakas et al., 2012).

Despite the QoL being used often in asthmatic psychogenic measures, another measure has been developed from the QoL more specific to asthmatic patients; Asthma Quality of Life Questionnaire (AQLQ) is similar QoL but has additional questions and is more accurate for the asthmatic population. (Asthma Quality of Life Questionnaire (AQLQ), 2021). The Nijmegen questionnaire (NQ) is often used as well to detect hyperventilation

in asthmatic patients, but it has been disputed since the NQ was developed for the detection of hyperventilation independently from asthma and to many symptoms of asthma present as hyperventilation (Dafauce et al., 2021)

1.3.2 Specific soft tissue manipulations

Many manual therapeutic soft tissue techniques have been developed to have a clinical benefit in breathing function. However, not many have done studies to examine their effect on the Asthmatic population. Osteopathic interventions have, for example, proposed to have positive outcomes for asthma patients, and some of them have been examined; Rib raising, Muscle energy techniques for rib mobility and myofascial release (A. Guiney et al., 2005, N. JULLIARD et al., 2002). The myofascial release technique aims to remove myofascial trigger points (MTrpS) within the affected Muscle by inhibiting pain signals to the central nervous system (CNS) and initiating altered proprioceptive output in surrounding tissue. Another mechanism of effect is the release of a taut band (MTrpS) which is a palpable hardening within muscle tissue; by applying direct pressure into MTrpS pump effect forces circulation into the tissue, which decreases pro-inflammatory substances and brings the muscle fibres back to normal function (Chaitow et al., 2014). Lucas et al. 2004, found that MTrpS in some regions of the body alters activation sequences of kinetic chains, causing a disturbance in the ventilation mechanism. Muscle Energy technique (MET) is an active intervention requiring the patient to perform muscle contraction, designed to improve musculoskeletal functions by stretching tight muscles, fascia, reduce pain, improve circulation and lymphatic flow. The most common form of MET is an isometric contraction, where the patient is asked to push towards a specific direction. At the same time, a therapist meets the force for 6-10 seconds; After this time, the patient relaxes. The therapist pushes the muscle into a different range of motion; this is often repeated four times until the desired result is achieved. The exact mechanism of effect in Isometric MET is mainly theoretical, and the most common theories are the Plastic changes in tissue due to direct stretch, Post-isometric relaxation through mechanoreceptors found in most skeletal muscles, which prompt positive input towards inhibitory interneurons which in return causes muscles-activating signals from the brain to relax musculoskeletal tissue. The third standard theory is Reciprocal inhibition; this theory is based on muscles spindles within skeletal muscles which are stretch-sensitive, and much like the Golgi tendon theory, isometric MET will send neurological signals by afferent nerve fibres towards the CNS where "stretch reflex" is inhibited and refers stimuli

through efferent nerve fibres towards an antagonist's muscle to with signal to relax (Waxenbaum and LU, 2020).

“Rib raising” is an osteopathic manipulative treatment used to address restricted excursion of the rib cage and modulate the sympathetic nervous system (SNS); however, physiological effects of these techniques are not well documented. The methods involve articulation of the costovertebral joints. This method is achieved by applying sufficient pressure on the area where the ribs meet the transverse processes, achieve anterior movement of the contacted tissues, and introduce rocking motion. One study examining the effects found that the OMT rib raising techniques had a positive decrease in SNS immediately following a procedure but no actual change in parasympathetic activity (Henderson et al., 2010).

1.3.3 Breathing retraining interventions

Breathing retraining therapies involve examining breathing patterns to find the best-suited techniques and habitual intervention for a better outcome. One popular therapy is called The Buteyko Method and was developed to reduce underlying unclear hyperventilation and restore proper dominant breathing patterns. The intervention itself consists of the patient holding their breath until they start to feel air hunger (dyspnea). They then take deep breaths with their nose to focus the inspiration excursion towards the abdomen and upper-thorax. Buteyko is thought to increase lung function and quality of life. However, little evidence has been found to support its effectiveness on lung function. (Cooper, 2003.). Another standard breathing retraining method involves the proper use of the diaphragm in respiration and is often carried out by professionals who guide the patient through breathing control interventions. The interventions' primary emphasis is to have slow regular breathing with the dominant use of the diaphragm consciously, which in theory should help the integration of subconscious diaphragmatic use over time; this intervention is usually followed with encouragement towards patients to train this by themselves as well. (Thomas, 2003) Speech-guided breathing retraining is a less common form of breathing retraining. Still, it indirectly influences breathing patterns through spoken combinations of syllables and rhymes adapted to patients' individual needs. The exercises have to be performed full-toned to extend and deepen respiration and make respiration rhythmical. In theory, it can reduce hyperventilation, improve sensations of stiffness and congestion in the chest and the diaphragm and, open airways through sound. (von Bonin et al., 2018)

1.4 Osteopathic relevance

Amounting evidence suggests that symptoms related to Asthma not only has affects physical dysfunction of connective tissue, joint and musculoskeletal structures (A. Pryor, 2007), but also in psychological aspects. That may be due to its chronic nature on the fundamental mechanism of breathing, where patients stimulate the sympathetic nervous system (SNS), which in return can decreases their overall quality of life (anxiety, depression) (Laurino et al., 2012). The Osteopathic principle is a holistic one. As early as when A.T. Still, the founder of osteopathy, began to formulate the osteopathic concept, he put emphasis on that "structure governs function and function determines structure", the same ideology holds today. Osteopathy could positively affect patients who experience Asthma symptoms by either direct structural manipulations or indirect by "therapeutic touch" by decreasing sympathetic innervation and potentially leading to better overall patient health (N. JULLIARD et al., 2002, A. Guiney et al., 2005). Breathing retraining programs could also be complementary alongside traditional osteopathic approaches by integrating self-sustainable breathing programs, taught by Osteopathic therapists. Potentially be beneficial to enhance lung function and quality of life in the asthma population and make them less dependent on therapies and medicine. (Thomas et al., 2017).

1.5 Problem statement

Currently, the amount of research that combines asthma symptoms, dysfunctional breathing patterns, and manual therapy is limited (*i.e.*, *Breathing retraining, muscle and joint mobilizations, and direct physical training*).

(Vidotto et al., 2019, Bradley et al., 2014)

Another problem arises with many asthma interventions. Not one soft tissue-related research can accurately answer the research question since most are independent of previously performed research. To the knowledge of this current literature review, too many interventions have been investigated without follow up research to decrease weakness in methodological approaches by different authors to expand further the validity of specific interventions such as soft tissue techniques and breathing retraining.

2 OBJECTIVE

The objective of this literature review is to examine if there are enough quality studies and research to determine if soft tissue interventions are more effective than breathing retraining for asthma symptomatic patients with either QoL measures or ventilatory measures.

2.1 Research question

- *"Does manual therapy have a positive effect on the symptoms and quality of life in asthmatic patients?"*
- *Does speech guided breathing retraining have a positive effect on the symptoms and quality of life in asthmatic patients?"*

3 METHOD

This work aims to answer the research questions defined in the previous section. This is done by conducting a literature review using PubMed, Cochrane and The Cumulative Index to Nursing & Allied health (CINAL) databases.

3.1 Keywords

Manual therapy, asthma, breathing retraining, physiotherapy, osteopathy, dysfunctional breathing.

3.2 Search Strings

The used keyword strings are as follows; "*dysfunctional breathing AND manual therapy AND asthma AND breathing retraining OR "osteopathy AND asthma" OR "physiotherapy AND asthma"*". *Dysfunctional breathing, manual therapy, asthma,* and *breathing retraining* are used to identify the topic's specific area. Another combination of keywords is added to the previous keywords "*asthma OR osteopathy*" and "*physiotherapy AND asthma*" to find articles in association with osteopathic and physiotherapy approaches for the treatment of asthmatic patients, this was done to narrow down the search. In combination with all these keywords mentioned, the term "**title/abstract**" was added to locate the articles through either the titles or the abstract fields to make relevant research visible. In general, all these combinations were set in one single search string and then it yielded the most relevant research on this review paper topic.

3.2 Inclusion criteria

- *Patients in all age groups*
- *Patients formally diagnosed with asthma*
- *Patients using asthma medications*
- *Manual therapy as a treatment method*
- *Breathing retraining techniques as treatment method*
- *Soft tissue manipulations as treatment methods*

3.3 Exclusion criteria

- *Other serious health conditions in the subjects, which could interfere with the outcomes or patient's health*
- *Articles older than 20 years*
- *Studies done on less than 10 patients*
- *Studies done on animals*
- *Studies not ethically approved.*

3.4 Analysis of data

In this current work, the PEDro scale is used for the quality assessment of the articles' methodical data since it is acknowledged as a reliable method for appraising the internal validity of randomized clinical trials (Maher et al., YEAR???). The PEDro scale consists of 11 different questions, the articles need to fulfil used in the methodological chapter need to be assessed through the questionnaire. PEDro score determined by counting the number of fulfilled questions by adding the points together (*Appendix 4*, shows detailed description of the questionnaire). If the total score of an article is less than 6 points, it will be classified as a low-quality study. If the article gets 6 points or more, it will on the other hand be classified as high-quality study. **Table.2.**

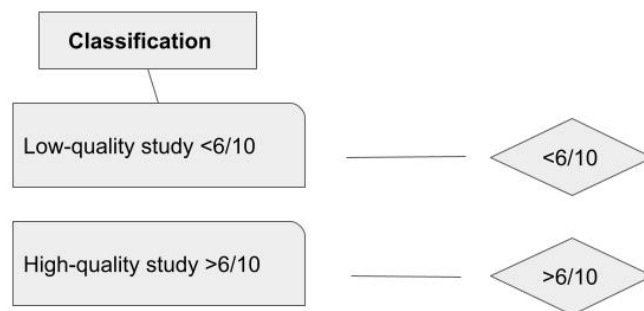


Table .2. Showing the quality score in PEDro Scale

4 RESULTS

On the 20th of February 2021, a search was conducted on PubMed, Cochrane and CINAL online databases. The keyword strings used are listed in **Table .3.**

Table .4. illustrates the outcome of the query. The search query yielded 245 articles in total. Ten of them met to the inclusion/exclusion criteria and were used for the research conducted in this work. PubMed yielded 65 articles in total of which six articles were collected. Cochrane yielded 80articles, of which ten articles were used, and CINHAL yielded 96 articles. Eight of them met the selection criteria.

However, since multiple databases were used, same articles were found on some of the databases and dealt with, respectively, towards the inclusion /- exclusion criteria. All online databases – except for Cochrane – used additional markers with randomized control trials (RCT) to see research specific to RCT. Despite this, however, some of the articles were not mutually exclusive to RCT studies in the results. Dysfunctional breathing, manual therapy, asthma and breathing retraining were combined with **AND** to unite it in one search string to make the articles more relevant to the research question. Next, Osteopathy and physiotherapy were combined with **OR** asthma to further expand the search towards more specific professions within manual interventions.

Title/abstract	“dysfunctional breathing AND manual therapy AND asthma AND breathing retraining”
Title/abstract	“osteopathy AND asthma”
Title/abstract	“physiotherapy AND asthma”

Table .3.: – *The keyword strings used as search queries in three different online databases.*

Databases:	PubMed	Cochrane	CINAL
<i>Total: 245 (many of which are the same)</i>	65	80	96
met inclusion/exclusion criteria:	5	8	7
Duplicates: 12			
Total used: 8			

Table .4.: - Results of the database search queries.

4.1 Overview

Seven articles where randomized control trial studies (Laurino et al., 2012, A. Guiney, et al., 2005, Cooper, 2003, Thomas, 2003, Thomas et al., 2017, von Bonin et al., 2018, M. Shams El Deen et al., 2020). One article was a pilot study with randomization (N. JULLIARD et al., 2002).

Two articles performed direct Osteopathic manipulative techniques on patients diagnosed with asthma, and both studies found positive outcomes (N. JULLIARD et al., 2002, A. Guiney et al., 2005). One study performed breathing retraining to examine a possible decrease in psychogenic aspects of asthma. The study found the patients had better asthma control and higher quality of life measures (Laurino et al., 2012). Two studies performed breathing retraining with no physical tissue manipulation. One research used a technique that involves breathing training called Buteyko (Cooper, 2003) and another used traditional physiotherapy guided breathing retraining (Thomas, 2003). Both of them found a slight improvement in asthmatic symptoms, and Thomas, 2003 found that the improvement in asthmatic symptoms was maintained in over 25% of the patients six months later after the intervention was conducted. One study done by Thomas et al. 2017 looked at guided breathing retraining done by a physiotherapist, either face-to-face or by educational video; the outcome was positive for both groups, showing an increase in quality-of-life measures, but no measurements were done on ventilation. Von Bonin et al., 2018 did a similar intervention with breathing retraining. Still, instead of breathing therapy, speech training was used to influence breathing pattern, the quality-of-life measures was found to improve asthma control. One study performed both breathing retraining and direct soft tissue manipulation to compare the effects of each intervention, both groups had slight positive outcomes, but the soft tissue manipulation group had a better result (M. Shams El Deen et al., 2020)

In the next section 5.2, 5.3, 5.4, there will be a further detailed description of the articles, the methods used and outcomes. Table 5. below shows further details of the studies.

Study (ref.)	Method	Length	Subjects & area	Sex & age	Interventions	Pedro scale	Outcome measures	Results
N. JULLIARD et al. 2002	OMT Rib excursion, MET, Joint mobility technique	1 day	A (N=5) , B (N=5) - Diaphragm,-Rib, - fascia	No sex mentioned, Age 35-59	immedate measure	7	Kruskal-wallis & wilcoxon signed rank test	Excursion increased for upper and lower thoracic movment
A. Guiney et al. 2005	OMT Rib excursion, MET, myofascial	1 day	A (N=90) B (N=50) -Diaphragm,-Rib, - fascia	Female - 28, male -80 Age 4-18	immedate measure	0	Peak expiratory flow rate (PEFs)	OMT group PEFs increase
Laurino et al., 2012	Subtle touch, Breathing retraining	3 months	A (N=20) B (N=18) -Respiration, - Thoracic cage	Females - 32, males - 6, age 35-45	once every 2 week for 3 months	5	PEFs, DSM-IV-R, Quality of life	Breathing retraining,subtle touch had improved in all spectrum except for Spirometry measures.
El deen et al., 2020	MET, HVLA, Breathing retraining	3 weeks	A (N=20) B (N=20) -Respiration - erector spinae	female -15, males 25, age 20-40	A = 1 a week B = 3 a week , both 3 weeks	7	FEV1, PEFs, maximum insparation, diaphragm excursion	Soft tissue manipulation was more benefical but both had positive outcomes
von Bonin et al., 2018	Breathing retraining by speech (ATS)	11 weeks	A (N=32) B (N=24) -Respiration	Females - 55, age 12 -62	trained 3 times a week, and home training 5	5	ACT, AQLQ	AQLQ improved (0.56) and ACT improved (2.96)
Thomas et al., 2017	Breathing retraining	12 months	A (N=261) B (N=132) C (N=262) -respiration	female - 419, males - 236, age 16-70	A = at least 3 times a week, B = once a week	8	AQLQ, HADS, NQ and spirometry measure	asthma quality of life measure improve but no change in lung function, inflammation
Thomas, 2003	Breathing retraining	6 months	A (N=17) B (N=16) -respiration	female - 16, males - 7, ages 17- 65	75 minutes in total, over 6 months	0	NQ and Quality of life measure	significant improvmnts in intervention group, lasting in 25% of the group 6 months after.
Cooper, 2003	Breathing retraining	6 months	A (N=30) B (N=30) C (N=29) - respiration	females - 40, males -49, ages 17-70	15 min, twice a day	9	FEV, Quality of life, use of inhalers	No change in any measures except decrease in of inhalers

Table .5. showing PEDro score, method, length, subjects, interventions, measures & results of the studies.

4.2 Manual soft tissue treatments

N. JULLIARD et al., 2002 Did a pilot study where the aim was to see the immediate effects of osteopathic manipulative techniques (OMT) on patients diagnosed with asthma. Ten patients were recruited from local primary care. All of them had to be over 18 years old, symptomatic of asthma and with no other pathologies which could interfere with the measures. All patients were put through both sham intervention and osteopathic manipulative intervention. The sham group had interventions unrelated to manual respiratory techniques. The leading intervention group had four OMT respiratory techniques performed, in theory to improve respiratory function. Randomization between both procedures was performed to observe the immediate effect of each method. Measurements of upper thoracic and lower thoracic forced respiratory excursions statistically increased after the OMT intervention compared to the sham procedures. No change was in peak flow rate, and little statistical difference was in asthma symptoms.

A. Guiney et al., 2005 conducted RCT to find the therapeutic effect of OMT in the paediatric asthma population. A Group of 140 patients at the age of 5- 17 years were recruited from a local asthma clinic. Ninety subjects were placed in the OMT intervention group, and 50 subjects were assigned to control groups, group 1 (OMT) got treatment on rib mobility, MET on rib elevation, and myofascial release. Group 2 (control group) got treatment on unrelated structures, and measures were taken to decrease therapeutic touch responses. All patients had a peak expiratory flow rate (PEF) measurements taken before and after the procedures. The results showed an increase in PEF from 7L to 9L per minute, and the results suggest that OMT has treatment value in pediatric asthma patients.

4.3 Breathing retraining

Cooper, 2003 performed RCT breathing retraining exercises to see if there is a positive outcome for asthma patients by breathing retraining. One hundred seventy-eight patients participated in the experiment. The ages of the subjects were 18-70, all of whom had a diagnosis of asthma from the local clinic where they were currently being treated. All now were taking their asthma medications symptoms over the intervention phase. All pathologies were excluded that could interfere with the outcome. The measurements were taken before and after the spirometry device, and measures such as FEV and forced vital capacity (FVC) were taken. Quality of life questionnaires, Asthma symptom diary, and asthma medication was recorded throughout the intervention in the psychological spectrum. The intervention consisted of a control group with a respiratory resistance device called PCLA, and a control group for the PCLA group used a respiratory resistance device with no resistance. The primary intervention group had 15 minutes of breathing intervention two times a day called Buteyko, were diaphragmatic, holding breath, and instructors taught nose breathing. All intervention groups were kept in this routine for six months. The intervention group's outcome that got the Buteyko showed a reduction in bronchodilator use, but no change was found in the bronchial responsiveness or FEV, FVC. The group which brought the PCLE intervention had no change in any of the measures taken.

Thomas, 2003 did an RCT where breathing retraining for Dysfunctional breathing in asthma experimented on 33 patients at the age of 17-65, all of which were taking medication for asthma and had a diagnosis of asthma. The patients had an NQ score of >23, which suggests Dysfunctional breathing/hyperventilation in asthma. Volunteers were randomized alphabetically to assign them into trial groups where one group was to get breathing retraining from a physiotherapist. The other group (control) had asthma education from an asthma nurse. The study used a self-completed Asthma Quality of Life Questionnaire (AQLQ) and the NQ questionnaire before 1 and 6 months after concluding the intervention. The physiotherapist did sessions with the patients at 1-2-week intervals with 15-minute sessions. The subjects were encouraged to practice slow 10-minute diaphragm breathing; the nursing education had 60-minute small group sessions where asthma education was given. The outcome showed significant improvement in asthma control and in AQLQ. Furthermore, the improvements were followed for six months, and 25% of the leading intervention group still maintained the improvement.

Thomas et al., 2017 did an RCT study to see if virtual breathing retraining is as beneficial as face-to-face asthma sessions. Therefore, two interventions were carried out virtual and face-to-face sessions. Six hundred fifty-five asthmatic patients at the ages of 16-70 participated in the study, all of which took medication for asthma and had a proper diagnosis before the examination. The patients were divided into DVD taught breathing retraining group (n=261), physiotherapist guided breathing retraining (n=132) and control (usual care by medication) (n=262). All patients were evaluated by an asthma quality of life questionnaire (AQLQ), NQ and HADS (anxiety & depression scale) before, over and after the intervention. The physiotherapists and researchers carrying out the treatments were blinded. The outcome showed that the patients getting face-to-face sessions had more engagement and were more enthusiastic towards the therapy, but that did not affect the result since both groups had the statistically identical improvement in NQ, AQLQ and HADS score. Still, the underlying pathophysiology was not changed (i.e., respiratory tract inflammation, FEV).

Von Bonin et al., 2018 performed an RCT study with speech-guided breathing retraining. Sixty-three patients age 12 - 60 participated in the study and all of which had a proper diagnosis of their asthma and were currently medicated for it. Participants were randomly allocated in a 1:1 allocation ratio to receive the intervention or wait as the control group. None of the researchers was blinded or the participants during the study. All of the patients were measured with SF-36 Quality of life and AQLQ and asthma control test (ACT) before and after the study. The intervention consisted of Anthroposophical therapeutic speech (ATS), which aims to directly affect respiratory function by potentially decreasing inflammatory factors, strengthening the diaphragm, and reducing the respiratory rate and minute volume. ATS was carried out three times a week for five months, patients with poor asthma control scores showed significant improvement in asthma control and Quality of life measures. However, lung function was not measured, and therefore no observation was made there.

4.4 Breathing retraining & soft tissue manipulation comparative studies

Laurino et al., 2012 did a study where Thirty-eight asthmatic patients with anxiety symptoms entered a case-controlled study and were randomly assigned into two groups, one group that got breathing retraining (n=20) a control group that got light touch therapy called Subtle touch. For three months the same physiotherapist performed all of the treatments on both groups. Before, during, and after the experiment Asthma symptoms diary, peak flow measures, anxiety scale, Quality of life questionnaire and spirometry was used. Despite two different interventions, both groups had significantly improved in psychological measures, group one (breathing retraining) had a statistically better outcome, both groups had no change in Spirometry measure.

M. Shams El Deen et al., 2020 performed a Pilot study to examine if breathing retraining guided by physiotherapy had a better outcome than soft tissue targeted manipulations on asthmatic symptoms. Forty patients at the ages 20 - 40 with a proper diagnosis of asthma, currently taking medication for it, and with no pathologies which could interfere with the outcome participated in the study. Patients were divided into two groups. A soft-tissue group (n=20) and breathing retraining (n=20) group. All of the patients were measured with a spirometry device before and after the study to observe their FEV1 in one second and Peak expiratory flow (PEF) and their Inspiratory muscle strength was calculated with maximum inspiratory pressure device. At the same time, their diaphragmatic excursion was evaluated by an X-ray device. The soft tissue group received soft tissue manipulation, one session a week for three weeks, and the breathing retraining group received training three times a week. both breathing retraining and soft tissue manipulation interventions showed improvement in diaphragm excursion and spirometry measures, however, the soft tissue manipulation group had better outcomes than the breathing retraining.

5 Discussion

5.1 Discussion of method

Obvious weaknesses exist in the methodology due to certain factors and therefore explanation for this weakness will be addressed below.

5.1.1 Breathing retraining & soft tissue comparative studies

Throughout the background investigation of this literature review, it became clear that a variety of manual therapeutic professions has made attempts at treating Asthmatic patients with non-medical interventions. The papers' apparent weakness was the measurements since most articles use various measures and often exclude important ones such as psychological measurement (QoL, NQ, AQLQ) and lung function measurements (Spirometry). The soft tissue manipulation articles in treating asthma predominantly measured lung function and rarely combined psychology measures. Investigation of breathing retraining intervention primarily investigated psychological outcomes without lung function measures except for Thomas et al., 2017. Both measures are essential towards clinical outcome since many articles have proposed and shown that psychosomatic response is just as critical as the physical improvement in asthmatic patients. Finding consistency in papers investigating specific interventions or improving their methods with already existing articles was challenging to find. Therefore, the articles' methodology sections have various breathing retraining interventions with different names, such as diaphragmatic breathing retraining, speech therapy, or Buteyko breathing therapy. At the core of the breathing retraining interventions, most aimed to address breathing pattern through the use of diaphragmatic breathing by slow, conscious breathing control, potentially leading to decreased negative psychosomatic stimuli and poor lung function.

Soft tissue intervention used multiple techniques, such as muscle energy techniques (MET), Rib excursion, myofascial release, and light touch chest therapy. These soft tissue interventions aimed to increase ROM in the thoracic cage's costovertebral joints, causing relaxation inhibition of the diaphragm and indirectly decrease sympathetic stimulation by therapeutic touch (light touch). However, this could prove inaccurate in statistical outcome since many of these techniques are theoretical interventions that lack background research to prove their effectiveness on asthmatic patients and combining different interventions, and comparing their results could have a misleading outcome.

5.1.2 Inclusion -/exclusion criteria & keywords

In gathering information to answer the current research question, it became clear that few articles exist which specify the onset of the bronchial hypersensitivity in asthma patients; this made the inclusion of specific asthma onset impossible to narrow down in the databases searches; this could have been a critical marker since asthma, in general, is broad pathophysiology with multiple causes leading to symptoms such as bronchial inflammation. Another downside is that all currently diagnosed patients in this literature review who underwent manual treatments remained on cortical inhalers during their treatments, possibly interfering with pulmonary function measuring outcomes. The formation of the search strings used in the online databases gave many search results, many of which were irrelevant to the research questions. Possibly because of imprecise keywords or the topic has had few quality RCTs studies performed. So despite multiple attempts of including or excluding specific keywords to find articles, it remained difficult, which perhaps suggests that more research is needed. There is also the possibility that there are existing articles on different databases not available to this literature review and or not known by the authors, then this present review paper could be irrelevant.

5.1.3 Use of PEDro quality on all papers

PEDro is a quality measurement tool for randomized control trial studies (RCT) (shown in section 3.4 - appendix 4) and has been proven reliable to hinder BIAS among data scoring. However, the limitation of using RCT based articles is obvious in this current literature review, evident by the limited number of articles available to answer the research question by this quality measure. A search was not conducted on any of the online databases without RCT based markers and therefore possible articles could exist which would help expand the answer further.

5.2 Discussion of results

5.2.1 Methodical analysis

All eight articles included by the present thesis were analysed using PEDro scale (*table .2. - section 3.4*).

Five of the articles were randomized control studies which scored as High-quality studies, scoring more than six out of eleven quality evaluation questions (A. Guiney, Chou, Vianna and Lovenheim, 2005, Cooper, 2003, Thomas et al., 2017, N. JULLIARD, SING

LO, HUANG and M. SHETH, 2002, M. Shams El Deen et al., 2020, Thomas, 2003) Two articles were pilot studies with randomization but could not be fully assessed with the PEDro scale since they lacked proper control to be thoroughly evaluated by the PEDro scale (M. Shams El Deen et al, 2020 and Laurino et al., 2012)

None of the eight articles did blinding procedures on all their subjects, therapists, and accessories. Only one study blinded their subjects (A. Guiney et al., 2005), and one study blinded all assessors who measured the key outcomes (N. JULLIARD et al., 2002). The downside of a study failing to use blinding methods could have a placebo effect on subjects. It could affect the results because all current literature subjects have asthma, which may impair their quality of life or ventilation. This could affect the expectation of subjects and cause them to desire a positive outcome from the intervention, which is especially relevant since the subjects' asthmatic symptoms have impaired them for an average of 1-20 years. When therapists are not blinded, their enthusiasm or lack of it could impact the results. The same principle could affect the primary measures if taken by accessories that are not overwhelmed.

All the studies included psychological measures, except for two (Guiney et al., 2005, M. Shams El Deen et al., 2020). The value of using psychological measure is essential since it can directly affect respiratory function. Therefore, failure to collect psychological data (before, during and after an intervention) could prove little value for a better quality of life for asthmatic patients.

Two studies performed experiments without randomly allocating subjects. (M. Shams El Deen et al., 2020 and Laurino et al., 2012), which can impact the outset of their experiment since the comparison of statistical outcomes becomes less accurate when there is no control group to compare the results. All eight of the studies included patients who were currently being treated for asthma. Some did not explicitly explain their medication routine, which can interfere with measures such as ventilation measure and psychological measure because asthma medication has an impact on both mental and physical data by decreasing dyspnea (Air hunger) and HVS, which has been shown to have a direct effect on the whole system of respiration. Two of the studies used subjects that expanded from 4-75 years old (Cooper, 2003, Thomas, 2003), which is a weakness since asthma has multiple causes; for example, it's more likely that older patients have morphological changes which cause or have made their asthma worse and the psychological impact on a person who has experienced asthma symptoms for 10-40 years will perhaps

have more significant relief from the intervention than an adolescent patient who has not fully grasped the severity of their asthma. Four of the studies performed breathing retraining (Cooper, 2003, Thomas, 2003, Thomas et al., 2017, von Bonin et al., 2018), while two performed soft-tissue interventions (A. Guiney et al., 2005, N. JULLIARD, et al., 2002) and another two performed both to estimate which of the interventions would be more effective (M. Shams El Deen et al., 2020, Laurino et al., 2012). The method used by this current literature review could possibly affect the statistical outcome of the research question because the researchers, practitioners, interventions and measures are different from each other. Therefore, an accurate "scientific" controlled result could be distorted, and potential bias could be presented by this literature, despite the best efforts to deliver actual outcomes of the articles used.

Narrowing down the research based on a statistical methodological approach is problematic since no two articles use the same combination of measure. The same problem was found in the interventions. Further studies with specific assessments and interventions extracted from existing research and used with better control, randomization, blinding could hopefully give this valuable question a better answer.

5.2.2 Summary of results

N. JULLIARD et al., 2002 found that the total expenditure of the lower and upper "thoracic forced excursion" statistically increased after Osteopathic intervention. Still, the measures of peak expiratory flow rate (PEFs) and asthma symptoms were insignificant, this contradicts the outcome by A. Guiney et al. 2005 were they found a significant change in peak expiratory rate or 7L to 9L after OMT intervention, the difference could be due to ages of the participants since the interventions were the same.

Three articles examined the effect of breathing retraining without physical intervention (Thomas, 2003, Thomas et al., 2017, von Bonin et al., 2018), and all of them found positive outcomes in both Quality of life measures related to asthma and the Nijmegen questionnaire (NQ), one article found no improvement (Cooper, 2003). However, all the papers could not find change significant change in exacerbation peaks, spirometry value, bronchial inflammation or decrease in inhaler use.

Two studies performed breathing retraining and direct physical techniques to investigate if one of the approaches had more effect than the other. M. Shams El Deen et al., 2020 found that both were effective, but the soft tissue manipulations were far more effective

than breathing retraining. Laurino et al., 2012 found that breathing retraining was more effective than physical manipulation. However, they used much less invasive techniques than M. Shams El Deen et al. 2020, where light touch was used on the anterior thoracic cage. The difference with these outcomes could be due to different methods performed and BIAS's aim of either researcher trying to promote interventions.

5.2.3 Differential outcome from Breathing retraining and soft tissue treatments

Breathing retraining seems to have a better outcome in quality of life measures since four out of five articles investigating QoL with breathing retraining before and after treatment found statistical improvement (Laurino et al., 2012, von Bonin et al., 2018, Thomas et al., 2017 & Thomas, 2003) while soft tissue manipulation interventions had a better outcome in lung function score (PEFs and Spirometry). This outcome is perhaps affected because not all the articles used QoL /or psychological measures on patients. For example, M. Shams El Deen et al., 2020 performed soft-tissue intervention and regular physiotherapy breathing retraining to compare each effect through spirometry measures. Possibly there is a flaw in their approach not using QoL; however, Spirometry is a reliable assessment tool for asthma patients. It can be speculated that the patients did experience some improvement in their QoL but that remains to be compared with both values. The same trouble is seen within research done by A. Guiney, Chou, Vianna and Lovenheim, 2005 where soft tissue osteopathic intervention was performed, only the PEFs measure is taken, which shows improvement from 7L per minute ventilation to 9L per minute ventilation and the author also assumes these measures correlate with decreased asthmatic symptoms. One study found an increase in both upper and lower thoracic forced respiratory excursion after OMT intervention and no change in PEFs (N. JULLIARD et al., 2002); however, unlike the previously mentioned soft tissue articles, they used asthma symptom measures and found no improvement in that spectrum, possibly, disproving that spirometry improvements give any relief in QoL for asthmatic patients.

5.3 Osteopathic relevance

When A.T. Still, the founder of osteopathy, began to proselytize the osteopathic concept, he emphasized the relationship between structure and function in the human body. Much of the mechanisms within the human body are interrelated and becomes noticeably observable in Asthma patients; for example, patients with poor control of Asthma have ap-

parent disruptions of normal homeostasis, mainly by aggravating the sympathetic nervous system and psychological sensitization, which is often thought to cause impairments within the pulmonary system, musculoskeletal, pleural, fascia and joints.

Even if Asthma is a chronic illness that often follows a person through their entire life, it is still relevant to maintain proper function and quality of life to hinder the escalation of asthma symptoms or illness associated with Asthma. Osteopathy can be an appropriate intervention by addressing Asthma systemically due to its holistic perspective. Anatomical structures can change due to insufficient biomechanical load. By using direct techniques, OMT could potentially enhance the patient's life to some extent by allowing a greater range of motion of soft tissue and joints to affect the total expenditure of the thoracic space, hence decreasing air hunger, alkalinity, and indirect OMT techniques could decrease sympathetic drive caused by dyspnea, anxiety, depression and hyperventilation in Asthma. But at its core, Asthma is an inflammatory disorder in the bronchial tubes. In many onsets of inflammation, it can never truly be cured by an osteopathic approach, but symptoms can be made tolerable for the quality of daily life.

6 Conclusion

Not enough research currently exists to give a clear answer to the research question, therefore, it cannot be stated that soft tissue techniques are superior to breathing retraining for asthmatic patients. Further research is needed to compare these mainstream alternative interventions with all appropriate measures typically associated with asthma symptoms (e.g., *Spirometry*, *QoL*, *AQLQ*,).

6.1 Ethical declaration

All eight articles had approval from ethical committees and written consent from their patients before the studies were conducted Templeton .1.

(N. JULLIARD et al., 2002, A. Guiney et al., 2005, Cooper, 2003, Thomas, 2003, Thomas et al., 2017, von Bonin et al., 2018, M. Shams El Deen et al., 2020, Laurino et al., 2012).

One study got written approval from the parents of the participants since all participants were under the age of 18 (Cooper, 2003). However, one study did not mention if the written consent from the parents of the participants was acquired before the study (M. Shams El Deen et al., 2020) therefore could be considered unethical since some of the participants were younger than 18. None of the articles mentioned if the patients had their confidentiality concealed, this could make patients less comfortable around their examiners during the procedures and potentially make them less open about relevant data which could affect their psychological analysis. None of the participants were asked to stop taking asthma medication during the interventions which could affect the analysis and if they would have stopped their medication It could have serious repercussions. Two articles failed to interview their patients after the interventions, which could possibly have negative or positive feedbacks regarding experience of the interventions they participated in (M. Shams El Deen et al., 2020, von Bonin et al., 2018).

All articles excluded dangerously acute asthma since the therapeutic interventions could have negative treatment reactions and cause them harm. The articles also excluded other serious pathologies which could cause statistical analysis to be disturbed. No Conflict of interest was found in any of the articles.

	<i>N. Juliard at al. 2002</i>	<i>A. Guiney at al. 2005</i>	<i>Cooper, 2003</i>	<i>Thomas, 2003</i>	<i>Thomas et al., 2017</i>	<i>Von bonin et al., 2018</i>	<i>El Deen et al., 2020</i>	<i>Lauriono et al., 2012</i>
<i>Confidentiality of data</i>								
<i>Approval from ethics committee</i>	x	x	x	x	x	x	x	x
<i>Patients approval</i>	x	x	x	x	x	x	x	x

Template .1. – Template showing which articles had their confidentiality concealed, approval of ethics committee and patient’s approval. (X marks positive)

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Appendix 1

Quality of life measures the generic questionnaire often used in assessing asthmatic patients.

**QUALITY OF LIFE INDEX®
GENERIC VERSION - III**

PART 1. For each of the following, please choose the answer that best describes how *satisfied* you are with that area of your life. Please mark your answer by circling the number. There are no right or wrong answers.

HOW SATISFIED ARE YOU WITH:	Very Dissatisfied	Moderately Dissatisfied	Slightly Dissatisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied
1. Your health?	1	2	3	4	5	6
2. Your health care?	1	2	3	4	5	6
3. The amount of pain that you have?	1	2	3	4	5	6
4. The amount of energy you have for everyday activities?	1	2	3	4	5	6
5. Your ability to take care of yourself without help?	1	2	3	4	5	6
6. The amount of control you have over your life?	1	2	3	4	5	6
7. Your chances of living as long as you would like?	1	2	3	4	5	6
8. Your family's health?	1	2	3	4	5	6
9. Your children?	1	2	3	4	5	6
10. Your family's happiness?	1	2	3	4	5	6
11. Your sex life?	1	2	3	4	5	6
12. Your spouse, lover, or partner?	1	2	3	4	5	6
13. Your friends?	1	2	3	4	5	6
14. The emotional support you get from your family?	1	2	3	4	5	6
15. The emotional support you get from people other than your family?	1	2	3	4	5	6

HOW SATISFIED ARE YOU WITH:	Very Dissatisfied	Moderately Dissatisfied	Slightly Dissatisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied
16. Your ability to take care of family responsibilities?	1	2	3	4	5	6
17. How useful you are to others?	1	2	3	4	5	6
18. The amount of worries in your life?	1	2	3	4	5	6
19. Your neighborhood?	1	2	3	4	5	6
20. Your home, apartment, or place where you live?	1	2	3	4	5	6
21. Your job (if employed)?	1	2	3	4	5	6
22. Not having a job (if unemployed, retired, or disabled)?	1	2	3	4	5	6
23. Your education?	1	2	3	4	5	6
24. How well you can take care of your financial needs?	1	2	3	4	5	6
25. The things you do for fun?	1	2	3	4	5	6
26. Your chances for a happy future?	1	2	3	4	5	6
27. Your peace of mind?	1	2	3	4	5	6
28. Your faith in God?	1	2	3	4	5	6
29. Your achievement of personal goals?	1	2	3	4	5	6
30. Your happiness in general?	1	2	3	4	5	6
31. Your life in general?	1	2	3	4	5	6
32. Your personal appearance?	1	2	3	4	5	6
33. Yourself in general?	1	2	3	4	5	6

(Please Go To Next Page)

Appendix 2

The Asthma quality of life measure (AQLQ) with more specific questions to further assess asthma.



Name: _____ Date: _____

Asthma Quality of Life Questionnaire with Standardized Activities AQLQ (S)

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

	Totally Limited	Extremely Limited	Very Limited	Moderately Limited	Some Limitation	A little Limitation	Not at all Limited
1. STRENUOUS ACTIVITIES (such as hurrying, exercising, running upstairs, sports)	1	2	3	4	5	6	7
2. MODERATE ACTIVITIES (such as walking, housework, gardening, shopping, climbing stairs)	1	2	3	4	5	6	7
3. SOCIAL ACTIVITIES (such as talking, playing with pets/children, visiting friends relatives)	1	2	3	4	5	6	7
4. WORK RELATED ACTIVITIES (tasks you have to do at work) *if you are not employed or self-employed, these should be tasks you have to do most days.	1	2	3	4	5	6	7
5. SLEEPING	1	2	3	4	5	6	7

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

	A very great deal	A great deal	Very Limited	Moderate limitation	Some limitation	A little limitation	No limitation
6. How much discomfort or distress have you felt over the last 2 weeks as a result of CHEST TIGHTNESS?	1	2	3	4	5	6	7

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

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
7. Feel CONCERNED ABOUT HAVING ASTHMA?	1	2	3	4	5	6	7
8. Feel SHORT OF BREATHE 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 SMOKE?	1	2	3	4	5	6	7
10. Experience 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 great deal	A great deal	Very Limited	Moderate amount	Some	Very little	None
12. How much discomfort or distress have you felt over the last 2 weeks as a result of COUGHING?	1	2	3	4	5	6	7

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

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
13. Feel FRUSTRATED as a result of your asthma?	1	2	3	4	5	6	7
14. Experience a feeling of CHEST HEAVINESS?	1	2	3	4	5	6	7

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

	All the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
15. Feel CONCERNED ABOUT THE NEED TO USE MEDICATION for your asthma?	1	2	3	4	5	6	7
16. 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 DUST?	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 MEDICAITON AVAILABLE?	1	2	3	4	5	6	7
22. 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?	1	2	3	4	5	6	7
24. Were you WOKEN AT NIGHT by your asthma?	1	2	3	4	5	6	7
25. AVOID OR LIMIT GOING OUTSIDE BECAUSE OF THE WEATHER OR AIR POLLUTION?	1	2	3	4	5	6	7

Appendix 3

The Nijmegen Questionnaire (NQ) used in diagnosing hyperventilation of asthmatic patients and to monitor any change before and after procedure.

	Never	Rare	Sometimes	Often	Very Often
Chest pain	0	1	2	3	4
Feeling tense	0	1	2	3	4
Blurred Vision	0	1	2	3	4
Dizzy spells	0	1	2	3	4
Feeling confused	0	1	2	3	4
Faster or deeper breathing	0	1	2	3	4
Short of breath	0	1	2	3	4
Tight feelings in the chest	0	1	2	3	4
Bloated feeling in the stomach	0	1	2	3	4
Tingling fingers	0	1	2	3	4
Unable to breathe deeply	0	1	2	3	4
Stiff fingers or arms	0	1	2	3	4
Tight feelings round mouth	0	1	2	3	4
Cold hands	0	1	2	3	4
Palpitations	0	1	2	3	4
Feeling of anxiety	0	1	2	3	4
Column Totals	0				

Grand Total

Appendix 4

PEDro scale

1. eligibility criteria were specified	no <input type="checkbox"/> yes <input type="checkbox"/> where:
2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no <input type="checkbox"/> yes <input type="checkbox"/> where:
3. allocation was concealed	no <input type="checkbox"/> yes <input type="checkbox"/> where:
4. the groups were similar at baseline regarding the most important prognostic indicators	no <input type="checkbox"/> yes <input type="checkbox"/> where:
5. there was blinding of all subjects	no <input type="checkbox"/> yes <input type="checkbox"/> where:
6. there was blinding of all therapists who administered the therapy	no <input type="checkbox"/> yes <input type="checkbox"/> where:
7. there was blinding of all assessors who measured at least one key outcome	no <input type="checkbox"/> yes <input type="checkbox"/> where:
8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no <input type="checkbox"/> yes <input type="checkbox"/> where:
9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no <input type="checkbox"/> yes <input type="checkbox"/> where:
10. the results of between-group statistical comparisons are reported for at least one key outcome	no <input type="checkbox"/> yes <input type="checkbox"/> where:
11. the study provides both point measures and measures of variability for at least one key outcome	no <input type="checkbox"/> yes <input type="checkbox"/> where:

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (*Verhagen AP et al (1998). The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology, 51(12):1235-41*). The list is based on "expert consensus" not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to "weight" scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (ie RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "generalisability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the "validity" of a study's conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the "quality" of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999

Notes on administration of the PEDro scale:

- All criteria **Points are only awarded when a criterion is clearly satisfied.** If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
- Criterion 1 This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
- Criterion 2 A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
- Criterion 3 *Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was “off-site”.
- Criterion 4 At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups’ outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
- Criteria 4, 7-11 *Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
- Criterion 5-7 *Blinding* means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be “blind” if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
- Criterion 8 This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
- Criterion 9 An *intention to treat* analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
- Criterion 10 A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group \times time interaction). The comparison may be in the form hypothesis testing (which provides a “p” value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
- Criterion 11 A *point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.