THE EFFECT OF ONE NOSTRIL INHALATION, ADDED TO STANDARD PHYSIOTHERAPY MANAGEMENT, ON HOSPITAL LENGTH OF STAY AND PULMONARY COMPLICATIONS IN PATIENTS WITH THORACIC TRAUMA: A RANDOMISED TRIAL

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DECLARATION

I, Sameer Tootla, declare that this Dissertation is my own, unaided work. This dissertation is being submitted for the Degree of MSc Physiotherapy at the University of the Witwatersrand, Johannesburg. This work has not been submitted before for any degree or examination at this or any other University.

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20th day of March 2024 in Lenasia, Johannesburg.

ABSTRACT

Background: Trauma is the second most common cause of mortality in South Africa. Thoracic trauma encompasses a wide variety of injuries that contributes to morbidity and mortality. It can vary from a simple blunt injury to complex penetrating injuries. South Africa has a high prevalence of thoracic injury, indicating a significant burden. Physiotherapists play an important part in the management of patients with thoracic trauma to reduce pain, prevent pulmonary complications, and improve physical function. One nostril inhalation (ONI) is a type of resistance breathing with limited use in physiotherapy clinical practice. Its function is to decrease inspiratory flow and rate and regain breathing control for patients who are experiencing pain.

Objectives: To describe the profiles (demographic and clinical) of patients who sustained thoracic trauma and were admitted to the trauma wards at Chris Hani Baragwanath Academic Hospital. To investigate the effects of ONI, added to standard physiotherapy management of patients with thoracic trauma, on their primary (hospital length of stay and incidence of pulmonary complications) and secondary (level of pain, functional status, exercise capacity and rate of adverse events) clinical outcomes.

Design: A single-centre, single-blinded, randomised trial was conducted.

Methods: Potential participants were recruited from CHBAH trauma wards through consecutive sampling and written informed consent was obtained. Participants were allocated to one of two groups through 1:1 allocation using a computer-generated randomisation sequence. Group one received standard physiotherapy care and group two received standard physiotherapy plus ONI. Participants in group two performed ONI under supervision during physiotherapy treatment sessions and were also instructed to perform ONI independently every second waking hour and when experiencing pain. The ONI technique was taught as slow and deep inspirations with the mouth and one nostril closed by hand. The participant was informed to perform sets of 10 deep breaths every second waking hour of the day and, in addition, when experiencing pain. Their training was recorded in their given ONI diary. Re-enforcement of the ONI technique was done each day by the treating physiotherapist reminding the participant to continue the technique and to document in the ONI diary when it was done. Participants' hospital length of stay, and incidence of pulmonary complications was recorded. Pain, physical function, exercise capacity and rate of adverse events was assessed on days 1, 3, 5, 7, 10, 15, 20, 25, and 30 or until hospital discharge. Patient recruitment started in April 2022 and was concluded in May 2023. Descriptive statistics were used to summarise the data and inferential statistics were used for group comparisons. Significance was reported as p-value <0.05.

Results: One hundred and fifty participants (mean age 32.6 (SD 8.1); group one mean age 31.4 (SD 7.4); group two mean age 33.9 (SD 8.6)) were recruited from the trauma wards. The groups were comparable as no significant between group differences for demographic and clinical characteristics existed at baseline. Majority were male (n=139, 93%). Majority had penetrating thoracic trauma (n=120, 80%) while others had blunt thoracic trauma (n=30, 20%). The most common cause of thoracic trauma was assault (n=124, 83%). In group one, 84% (n=63) had no rib fractures, 12% (n=9) had 1-3 ribs fractured on the left side, 4% (n=3) had 1-3 ribs fractured on the right side. No participants who had more than 3 ribs fractured bilaterally. In group 2, 76% (n=57) had no rib fractures, 18.7% (n=14) had 1-3 ribs fractured on the left side, 4% (n=3) had 1-3 ribs fractured on the right side and 1.3% (n=1) had more than 3 ribs fractured bilaterally Fifty-eight percent (n=82) participants had a unilateral pneumothorax and 43% (n=64) had a unilateral haemo-/haemopneumothorax. Almost all participants (n=149, 99%) were managed with an intercostal drainage system. The ONI group had a significantly longer length of stay (0.49 days) (p-value 0.008) than the standard care group. None of the participants in either group developed pulmonary complications during their hospital stay. Pain decreased for both groups over time and was not significantly different between groups. There were no significant differences in the functional outcomes assessed (FSS-ICU mobility scale, 10-meter walk test and the TUG test) and the exercise capacity (one-minute sit to stand test) between group 1 (standard treatment) and group 2 (ONI). There were, however, gradual improvements in both the functional outcomes and exercise capacity through the days of assessment in both groups. There were no reports of adverse events that occurred during physiotherapy sessions for both group 1 (standard treatment) and group 2 (ONI). All the participants in group 1 (standard treatment) and group 2 (ONI) were discharged home, with none requiring a follow up outpatient appointment, according to the treating physiotherapists. Conclusion: The findings from this study suggest that ONI added to standard physiotherapy management in patients with thoracic trauma does not influence clinical outcomes.

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- “My ability is only from Allah. Only on Him do I rely on and to Him do I return”. Quran 11:88

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LIST OF ABBREVIATIONS

ACBT	- Active Cycle Breathing Technique
ANB	- Alternate Nostril Breathing
CHBAH	- Chris Hani Baragwanath Academic Hospital
ICD	- Intercostal Drain
ICU	- Intensive Care Unit
MV	- Mechanical Ventilation
MVA	- Motor Vehicle Accidents
ONI	- One Nostril Inhalation
PE	- Pulmonary Embolism
PVA	- Pedestrian Vehicle Accidents
WHO	- World Health Organization

CHAPTER 1

1. INTRODUCTION TO THE STUDY

This chapter serves as an introduction and provides the justification for and significance of this study.

1.1 INTRODUCTION

Traumatic injuries constitute a major public health problem globally and contributes significantly to a high rate of mortality and morbidity. Injuries, both intentional and unintentional claim the lives of approximately 4.4 million people around the world yearly which makes up nearly eight percent of all deaths (WHO, 2021). Injuries and violence put an enormous weight on economies, requiring countries to pay billions of US dollars in medical expenses annually (WHO, 2021). 3.6 million people lose their life from unintentional injuries and 1.25 million die from injuries connected to violence annually. (WHO, 2021). Three of the top five causes of death for children and young adults between the ages of five and 29 are road traffic injuries, homicide, and suicide (WHO, 2021). Every year, tens of millions more people sustain non-fatal injuries that require care from general practitioners, hospital stays, or casualty visits. This frequently leads to either a temporary or permanent disability, necessitating long-term care and rehabilitation for both physical and mental health (WHO, 2021).

In every country, injuries and violence rank highly among the leading causes of death. They are, however, unequally distributed across and within countries in terms of socioeconomic status and gender (WHO, 2021). Young males from low-income backgrounds are more likely to be injured and to be either the victim or the attacker of physical violence (WHO, 2021). Males are killed twice more than females as a result of injuries and violence (WHO, 2021). Globally, three quarters of road traffic deaths and four-fifths of homicides involve men (WHO, 2021). The risk of injury and violence is increased by poverty. Ninety percent of fatalities resulting from injuries happen in low- and middle-income nations (WHO, 2021). People from lower-income backgrounds are more likely to suffer fatal and non-fatal injuries in both high- and low-income countries (WHO, 2021). The majority of traffic fatalities worldwide (93%) take place in middle- and low-income nations (WHO, 2020).

Trauma is the leading cause of death among young adults in South Africa, and it is the second most prevalent cause of death overall. (Moodley, 2016). In South Africa, penetrating injuries to the thorax are commonly seen according to a study done in

Pietermaritzburg by Clark et al. (2011). Over a three-year period, individuals who suffer penetrating thoracic trauma and sustain stab wounds have a death rate of 30% and 52% respectively (Clarke et al. 2011). Controlling pain greatly affects morbidity and mortality in patients with thoracic trauma (Jain and Waseem, 2018). Injury to the thorax leads to pain which causes splinting of the thoracic cage and worsening of respiratory mechanics. In many cases, splinting can lead to pneumonia (Jain and Waseem, 2018). Pneumonia is the most common complication that develops post thoracic injury (Chrysou et al. 2017). Atelectasis and poor lung compliance are among other common complications (Yin et al. 2021). The frequency and psychosocial impact of pain can worsen the prognosis of patients recovering from thoracic trauma (Kahloul et al. 2020). It is recommended that a multi-disciplinary approach, including physiotherapy, is used in pain management of patients with thoracic trauma (Unsworth et al. 2015).

Physiotherapists play an important part in the multidisciplinary team management of patients with thoracic trauma. The aims of physiotherapy in these patients are to improve clinical outcomes such as decreasing the occurrence of complications and contributing to the reduction of mortality, improving lung volumes and oxygenation, optimising mobilisation, reducing pain and decreasing hospital length of stay (Van Aswegen, 2020). Some of the strategies used as part of daily physiotherapy management of patients with thoracic trauma are education on pain management, breathing exercises, active coughing, arm mobilisation exercises, thoracic mobility exercises, active cycle of breathing technique (ACBT) and mobilisation (Van Aswegen, 2020). Breathing techniques performed by patients with thoracic trauma such as pursed lip breathing, active expiration and incentive spirometry, are reported to be beneficial in reducing hospital stay and contributing to better pulmonary recovery (Valenza-Demet et al. 2014); however, the effect of nasal breathing on patient outcomes has not been reported.

One nostril inhalation (ONI) is a type of cost-free resistance breathing, for which no equipment is needed. It has been introduced as a modality to decrease inspiratory flow and rate and regain breathing control for patients who are experiencing pain. This breathing strategy is currently being tested, in an ongoing study, on patients with pulmonary embolism (PE) to evaluate the effect of a treatment, in patients with respiratory-associated acute pain due to PE (ClinicalTrials.gov Identifier: NCT03375723 - J Danielsbacka). There is a dearth of literature and research into this area, however, what is known is that ONI is done with the mouth and one nostril closed and provides some resistance to inhalation, as compared to normal two nostril inhalation that adds no additional resistance to inhalation.

1.2 PROBLEM STATEMENT AND JUSTIFICATION FOR RESEARCH

Worldwide, traumatic injuries are a major problem for public health. It has been connected to high rates of illness and mortality in both industrialized and developing nations (WHO, 2014, 2021). Admissions into the intensive care unit (ICU) at Chris Hani Baragwanath Academic Hospital (CHBAH) show that since the year 2000, 50% of the adult admissions were trauma related (CHBAH, n.d.).

A study conducted in 2020 analyzed the factors affecting the outcome of thoracic trauma in a trauma center in Bielefeld risk, Germany and it was found that chest physiotherapy and optimal pain control resulted in good outcomes; however, the specific physiotherapy management procedures were not highlighted (Beshay et al. 2020). A global review on the management of patients with significant thoracic trauma with physiotherapy revealed that active coughing, body positioning, deep breathing exercises and early mobilisation were the most common practices though the frequency, intensity, and the impact on patients during hospitalisation was not mentioned (Van Aswegen et al. 2019). Two clinical studies were conducted in South Africa in the 1990s to describe the impact of physiotherapy on the outcomes of patients with penetrating thoracic trauma (Senekal and Eales, 1994; Ngubane, De Charmoy and Eales, 1999). These authors reported that physiotherapy initiated within nine hours of insertion of an intercostal drainage system significantly decreased the drainage time of the haemopneumothoraces and hospital length of stay (Senekal and Eales, 1994; Ngubane, De Charmoy and Eales, 1999). Treatment interventions used in these two studies included deep basal breathing, diaphragmatic breathing, active coughing, active shoulder and trunk range of motion exercises, brisk walking and stair climbing.

Neither of the studies mentioned above utilised nasal breathing against resistance as a strategy to reduce pain in order to prevent secondary pulmonary complications and hence reduce hospital length of stay. Considering the South African context, the amount of literature that exists regarding physiotherapy management of patients with thoracic trauma consist of a limited number of clinical trials and other related studies are dated. ONI is a novel breathing strategy and is cost free. It does not require any apparatus or equipment. The effects of ONI in patients with thoracic trauma regarding their clinical outcomes has not yet been tested.

1.3 SIGNIFICANCE OF RESEARCH

Given the small number and quality of clinical studies available on physiotherapy management thoracic trauma and its effects on patient outcomes, further high-quality clinical trials are strongly recommended (Russo et al. 2017).

With this study, preliminary findings will be provided on the effectiveness of ONI on clinical outcomes of patients with thoracic trauma, admitted to the trauma unit of a single hospital. If ONI is effective in shortening hospital length of stay and causes a reduction in the incidence of pulmonary complications for this patient population, recommendations can be made to include it in the daily standard physiotherapy care that patients receive at the study site. The findings of this preliminary clinical trial form the foundation on which future clinical research in this patient population can be modelled.

1.4 RESEARCH AIM

To describe the effect of ONI, added to standard physiotherapy management, on clinical outcomes of patients with thoracic trauma.

1.5 RESEARCH OBJECTIVES

- To describe the profiles (demographic and clinical) of patients who sustained thoracic trauma and were admitted to the trauma wards at CHBAH.
- To investigate the effects of ONI, added to standard physiotherapy management of patients with thoracic trauma, on their primary clinical outcomes (e.g. hospital length of stay, and incidence of pulmonary complications) and to compare this with the clinical outcomes of patients with thoracic trauma who did not receive ONI.
- To investigate the effects of ONI, added to standard physiotherapy management of patients with thoracic trauma, on their secondary clinical outcomes (e.g. level of pain, functional status, exercise capacity, and rate of adverse events) and to compare this with the same outcomes of patients with thoracic trauma who did not receive ONI.

1.6 STUDY DESIGN

A single-centre, single blinded, randomised trial was done to answer the study objectives.

1.7 CONCLUSION OF CHAPTER 1

The aims, objectives, and rationale for conducting this study have been highlighted in chapter 1. Chapter 2 provides a summary of the existing evidence related to the study topic.

CHAPTER 2

2. LITERATURE REVIEW

Sources covered in identifying relevant articles for inclusion in this literature review included textbooks as well as journal articles. Google Scholar, CINAHL, PEDro, PubMed, and Scopus were among the databases that were searched. Between January 1990 and February 2024, studies published in English or translated into the language were taken into consideration. Among the search terms used were: blunt thoracic trauma, penetrating thoracic trauma thoracic trauma/injury, thoracic trauma, physiotherapy for thoracic trauma, pneumonia, atelectasis, lung compliance, pneumothorax, haemothorax, anatomy of the thoracic wall, pain, breathing, one nostril inhalation, one nostril breathing and physiology of thoracic trauma.

2.1 INCIDENCE AND PREVALENCE OF THORACIC TRAUMA

Trauma contributes massively to global morbidity and mortality rates (WHO, 2021). Globally, life years lost due to traumatic injuries is equal to the life years lost from HIV, cancer and cardiovascular disease put together (El-Manyar et al. 2014). More males sustain thoracic injuries than females (El-Manyar et al. 2014). Thoracic trauma encompasses a wide variety of injuries that contributes to morbidity and mortality. It can vary from a simple blunt injury (e.g. rib fracture) to complex penetrating injury resulting in sternal fractures and/or cardiovascular and pulmonary injuries (Ludwig and Koryloss, 2017). Each type of thoracic injury can result in one or more parts of the body being injured such as the thoracic wall, heart, lungs, diaphragm, tracheo-bronchial tree, and other major vessels (Ekpe and Eyo, 2014). Patients who have been subjected to thoracic trauma have an increased risk of morbidity and mortality. Possible reasons for this are the severity of the injury sustained or secondary complications (e.g. pneumonia, atelectasis and respiratory failure) that develop (Kim and Moore, 2020).

Approximately 66% of the world's trauma related injuries include thoracic trauma with severity varying from case to case (Ludwig and Koryloss, 2017). Worldwide 20%-25% of these thoracic injuries are fatal (Dippenaar and Wallis, 2019). Motor vehicle accidents (MVAs) account for 80% of blunt thoracic injuries in the United States (Edgecombe et al. 2018). In a study done in Nigeria in 2018, the prevalence of blunt thoracic injuries was directly proportional to the number of MVAs (Okonta and Ocheli, 2018). In Niger, blunt thoracic trauma constituted 70% of thoracic trauma while penetrating thoracic trauma accounted for 30% of cases (Ekpe and Eyo, 2014).

Clarke et al. (2018) examined the epidemiology of thoracic trauma in a major trauma centre in Cape Town. The researchers found that thoracic trauma accounted for 35% of all major trauma cases, indicating a significant burden. Ten-point four percent of trauma cases result in death in KwaZulu Natal, South Africa. Twenty-seven percent of those deaths were thoracic trauma (Dippenaar and Wallis, 2019). Moodley et al. (2020) conducted a study investigating the prevalence and outcomes of blunt thoracic trauma in a regional trauma unit in South Africa. They reported a prevalence of 23% among their study population. Another study in South Africa focused on penetrating thoracic trauma and reported a prevalence of 32% in their study population (Kong et al. 2019). These studies highlight the considerable prevalence of thoracic trauma and its associated injuries globally and in South Africa.

2.2 ANATOMY AND PHYSIOLOGY OF THE THORAX AND ITS RELATION TO THORACIC TRAUMA

Thoracic trauma indicates injury to structures of the thoracic cavity (Ullah et al. 2010). The thoracic wall consists of three parts namely the rib cage, costal cartilage and intercostal muscles (Edgecombe et al. 2018). The intercostal artery, vein and nerve that runs under each rib make up the innervation and blood supply of the thoracic wall (Edgecombe et al. 2018). In cases of trauma, such as a penetrating injury, blunt force impact, or fracture of the rib, these vessels can be damaged, leading to bleeding or hematoma formation. High speed MVAs are linked to thoracic aortic injuries. Hyperextension of the thorax and pulling on blood vessels have been hypothesised as additional mechanisms of injury to the vessels of the thoracic wall (O'Connor et al. 2009). The intercostal nerves are located below the intercostal arteries and veins and run along the bottom edge of each rib. These nerves provide sensation to the thoracic wall, and they also participate controlling thoracic wall movement during breathing (Fazekas et al. 2022). In thoracic trauma, these nerves can be injured or compressed, leading to pain, sensory disturbances, or even impairing respiratory function if the motor nerves are affected (Edgecombe et al. 2018).

The intrathoracic structures are covered by a layer of visceral pleura. The pleural space is the name given to the potential space between the visceral and parietal layers which generally contains a small amount of pleural fluid (Edgecombe et al. 2018). The fluid acts as a lubricant to make it possible for the two pleura layers to pass one another without encountering any resistance when breathing. The sub-atmospheric pressure of the pleural fluid maintains the negative pressure necessary for inhalation and prevents the lungs from collapsing (D'Agostino et al. 2018).

One of the thoracic wall's main functions is to facilitate respiration (Edgecombe et al. 2018). In health, intrathoracic volume increases, decreasing intrathoracic pressure by contraction of the intercostal muscles and diaphragm during inspiration which allows passive flow of air into the lungs (Edgecombe et al. 2018). The opposite happens during expiration. Air is forced out of the lungs and intrathoracic volume and pressure are increased as the diaphragm and intercostal muscles relax. (Edgecombe et al. 2018). Disruption of the thoracic cage due to trauma can significantly impact respiration and intra-thoracic pressures (Dogrul et al. 2020). It can cause severe pain, limiting the ability to take deep breaths. This pain can result in shallow breathing or reluctance to expand the thorax fully, reducing the amount of air moved in and out of the lungs (Dogrul et al. 2020). Trauma to the thoracic cage can disrupt these pressure changes. A penetration injury can create a pathway for air to enter the pleural cavity, disrupting the normal pressure balance and leading to lung collapse (Sahota and Sayad, 2022).

The thoracic cage serves as a means of protection for the intrathoracic structures from external injury. The anterior thorax receives additional structural support from the clavicles and sternum (Edgecombe et al. 2018). They require a large force to fracture and serve as an attachment point for various muscles. The scapulae which lie posteriorly also provide additional protection to the contents of the thorax (Edgecombe et al. 2018). Fractures in the ribs or penetrating injuries to the thoracic cage can directly expose internal organs, such as the lungs, heart, and major blood vessels, to external trauma. This can increase the risk of injury or damage to these vital structures (Dogrul et al. 2020). Significant energy can be transmitted to the internal organs by blunt force trauma to the thoracic cage, leading to contusions, lacerations, or other injuries. The ability of the thoracic cage to absorb and distribute external forces might be compromised due to trauma, increasing the risk of damage to underlying organs (Knottenbelt and Cosford, 2011)

The mediastinum is comprised of many vital structures including the heart, trachea, essential nerves and great vessels (Stoddard et al. 2021). The aorta is the structure that is most injured due to blunt thoracic injury while in penetrating trauma the structures are equally susceptible to injury (Edgecombe et al. 2018).

The placement of an intercostal drainage (ICD) system involves creating an incision in the thoracic cage, usually in the intercostal space between ribs, to insert the drain into the pleural space for draining excess air, fluid, or blood. This procedure, like any surgical intervention, carries the potential risk of affecting the nearby intercostal vessels and nerves (Kong et al. 2014). The ICD itself may come into contact with or compress the intercostal nerves, especially if it is not optimally positioned or secured. This compression may lead to nerve irritation and pain. Irritation or compression of these nerves can lead to pain with each breath, limiting deep breathing and affecting overall respiratory function (Dalton et al. 2022). Patients may be hesitant to engage in physical activities due to the pain caused by the ICD placement. This limitation can impede the patient's ability to participate in daily activities (Dalton et al. 2022).

2.3 MECHANISMS AND TYPES OF THORACIC TRAUMA

The sites and mechanisms of an injury can be used to categorize the injury sustained. Trauma to the thoracic region can be categorized as visceral, skeletal, cardiac and greater vessels of the thorax, pulmonary or diaphragmatic injury. The mechanism may be blunt or penetrating (van Aswegen and Morrow, 2015).

2.3.1 Blunt Thoracic Trauma

Blunt trauma constitutes injury to the thoracic cage, lungs, heart, diaphragm and/or abdominal organs, although the skin on the walls of the thorax and abdomen does not break (Van Aswegen, 2020). Blunt injuries can occur from MVAs, PVAs, assault with a blunt object and fall from heights (Stewart et al. 2005). Other causes of blunt thoracic trauma are acts of violence (Moodley et al. 2016), falls and work-related accidents (Okonta and Ocheli, 2018). The mechanisms of blunt thoracic trauma vary from place to place depending on the location, economic and social influences (Sakran et al. 2012). The age distribution of the population affects the mechanism of harm as well. Falls have been reported to be one of the most frequent causes of traumatic injuries in the elderly (El-Manyar et al. 2014).

The most frequent thoracic injury brought on by blunt thoracic trauma is a rib fracture (Chrysou et al. 2017). According to Pharaon et al. (2015) and Chrysou et al. (2017), there are many types of rib fractures, including simple rib fractures, multiple rib fractures, and flail thoracic injuries that cause respiratory failure. Single, non-displaced rib fractures are referred to as simple rib fractures (Ekpe and Eyo, 2016).

Simple rib fractures are serious in the elderly population and in those who have a reduced pulmonary reserve (e.g. patients who have restrictive lung disease and chronic obstructive pulmonary disease) in whom coughing, or impairment of ventilation may lead to pneumonia (Ekpe and Eyo, 2016). Pulmonary reserve is “the volume of air remaining in the lungs after maximum forceful expiration. It is the volume of air that cannot be expelled from the lungs and is responsible for keeping the alveoli open at all times”. During complications like pneumonia or atelectasis, the lungs experience increased demand for oxygen and work harder to clear secretions. Pulmonary reserve allows the lungs to manage this extra demand more effectively, preventing respiratory failure (O'Donnell DE and Laveneziana, 2006).

Numerous rib fractures are the trademark of severe thoracic trauma and result from a high energy transfer with a large amount of force (Ekpe and Eyo, 2016). The mortality and morbidity risk increases as the number of ribs fractured increases (Chien et al. 2017). It is known that complications following blunt thoracic trauma are directly proportional to displaced fractures and the total number of ribs fractured (Chien et al. 2017). The number of ribs fractured is also directly related to patients’ length of stay in hospital (Hashemzadeh et al. 2018). A flail injury is the most pressing of thoracic cage injuries (Ekpe and Eyo, 2016) and is diagnosed when in two locations three or more ribs are fractured making a rib segment that is independent and moves paradoxically from the rest of the thoracic cage (Naidoo et al. 2017).

By managing these fractures correctly, complications and mortality can be reduced (Kim and Moore, 2020). A pneumothorax or haemothorax are two thoracic injuries that frequently accompany rib fractures (Manay et al. 2017).

2.3.2 Penetrating Thoracic Trauma

According to Van Aswegen (2020), penetrating trauma occurs when an object penetrates the thoracic wall's soft tissue and skin. Penetrating thoracic trauma is less common than blunt thoracic trauma, yet it can still be fatal (Jain et al. 2021). It is paramount that the mechanism of injury is known so that management can be appropriate (Jain et al. 2021). The common mechanisms for penetrating thoracic trauma are stab injuries, gunshot injuries and blasts (Ullah and Shah 2010).

The most typical aetiology of penetrating trauma in the United States are gunshots and stabbings making up 10% and 9.5% respectively (Jain et al. 2021). Despite having a lower incidence than blunt thoracic trauma, 15% to 30% of patients with penetrating trauma require surgical intervention and has a higher rate of mortality (Edgecombe et al. 2018). The incidence of penetrating trauma is reliant on various factors, one being geographical location, where a higher rate is found in urban areas and areas prone to violence and conflict (Edgecombe et al. 2018). The incidence of gunshots and stabbings varies from country to country, where in war torn countries, the incidence is as high as 95% (Jain et al. 2021). In KwaZulu Natal, South Africa, 89% of injuries to the thorax are penetrating in nature (Dippenaar and Wallis, 2019). In South Africa 75% of patients who need ICD insertion were victims of penetrating thoracic injury (Kong et al. 2014). According to the authors, of the 1050 ICDs implanted during a four-year period, 32% were for hemopneumothorax, followed by haemothorax (30%), simple pneumothorax (25%), tension pneumothorax (8%), and open pneumothorax (5%) (Kong et al. 2014).

Thoracic trauma frequently results in life-threatening complications such as severe hemorrhage, flail chest, open pneumothorax, tension pneumothorax, and cardiac tamponade. (Ullah and Shah, 2010).

2.4 COMPLICATIONS THAT DEVELOP DUE TO THORACIC TRAUMA

2.4.1 Pneumothorax

A pneumothorax is “an accumulation of air outside the lung but inside the pleural cavity. It occurs when air is trapped in the chest between the parietal and visceral pleurae. The buildup of air can compress the lung and cause it to collapse and result in a decrease in lung volumes” (McKnight and Burns, 2017). An open thoracic wound is a consequence of penetrating trauma but may happen in association with blunt trauma (Ullah and Shah, 2010). A negative intra-thoracic pressure is necessary for normal ventilation. When a significant open thoracic wall defect occurs, the air preferentially flows through it, causing severe hypoxia (van Aswegen and Morrow, 2015). A simple pneumothorax is when air enters the pleural space without mediastinal shift (Ullah and Shah, 2010).

2.4.2 Tension Pneumothorax

A tension pneumothorax is the diagnosis of thoracic trauma which can be rapidly lethal with patients developing respiratory distress and hypotension (Edgecombe et al. 2018). Clinical signs such as decreased breath sounds on the affected side and tracheal deviation from the affected side can allude to this (Edgecombe et al. 2018). A fault in the thoracic wall forms a link between the external environment and the pleural space. A wound big enough to surpass the laryngeal cross-sectional area creates an alternate pathway for air which has less resistance than what the normal tracheobronchial tree has. Minor wounds can form a one-way valve which can allow air to be pushed into the thoracic wall during inspiration which gives rise to a tension pneumothorax (Ulla and Shah, 2010). Decompression of the pleura is the most important issue in the treatment of a tension pneumothorax (Kim and Moore, 2020). This is done via needle decompression or finger thoracostomy and placement of a drain follows (Kim and Moore, 2020).

2.4.3 Massive Haemothorax

A massive haemothorax can be defined as larger than 1500mL of blood in the pleural space (Edgecombe et al. 2018). Penetrating trauma such as gunshot wounds and stabbing injuries can also result in a massive haemothorax. This can cause damage to major blood vessels, such as the aorta, subclavian arteries, or intercostal arteries, leading to significant bleeding into the thoracic cavity (Karmy-Jones et al. 2004). The presence of a large amount of blood within the thoracic cavity can compress the lungs and compromise their ability to expand, resulting in respiratory distress (Karmy-Jones et al. 2004). Multiple rib fractures accompanied with lacerated intercostal arteries are the most typical reason for a haemothorax in blunt thoracic trauma. This can also be caused by lung parenchymal lacerations which is usually accompanied with an air leak (Edgecombe et al. 2018). An ICD is inserted in the pleural area to restore intrapleural negative pressure and allows the lungs to re-expand.

2.4.4 Cardiac Tamponade

Cardiac tamponade is most commonly caused by a penetrating thoracic injury but can sometimes be caused by blunt thoracic injuries. In blunt thoracic injuries it is caused by myocardial rupture, ascending dissection of an aortic tear or coronary arterial laceration (Ulla and Shah, 2010). Blood in the pericardial sac, typically as a result of penetrating injuries, causes cardiac tamponade, which stops normal cardiac activity. The patient may present with reduced atrial pressure, muted heart sounds, and raised venous pressure (van Aswegen and Morrow, 2015).

2.4.5 Flail Chest

A direct hit to the thoracic cage results in a flail chest. A section of the chest wall that moves and is “free-floating" is caused by two or more neighbouring ribs that are fractured at two or more points and this section moves opposite to the normal thoracic cage motion with respiration. This causes pain, reduced thoracic cage movement and the underlying pulmonary contusion causes atelectasis and decreased lung compliance (van Aswegen and Morrow, 2015).

2.4.6 Pulmonary Contusion

An injury to the lung parenchyma without a laceration is called a pulmonary contusion. It is a condition that can be fatal and has an insidious onset. The oedema fluid and interstitial haemorrhage seep into the alveoli, reducing pulmonary compliance and resulting in atelectasis and hypoventilation. Bleeding into parts of the lung that were intact at the time of injury may result in bronchospasm, which exacerbates lung dysfunction (van Aswegen and Morrow, 2015).

2.4.7 Post Traumatic Empyema

Posttraumatic empyema may result from blunt or penetrating thoracic trauma. a retained hemothorax that is mostly linked to the development of posttraumatic empyema and is frequently brought on by rib fractures. Trapped blood in the pleural space prevents it from being absorbed by the body and provides an ideal environment for bacteria to proliferate (van Aswegen and Morrow, 2015). When an ICD is implanted and a retained haemothorax becomes contaminated, empyema may ensue.

Other injuries because of thoracic trauma may include a myocardial contusion, disruption of the aorta, diaphragmatic rupture, tracheobronchial injury and oesophageal trauma.

2.5 MANAGEMENTS OF PATIENTS WITH THORACIC TRAUMA

2.5.1 Pneumothorax or Haemothorax

The ICD system consists of a set of chambers below the thoracic level, one or more thoracic tubes or drains, and a water seal to keep air out of the thorax. The drainage system may be self-contained, movable, and disposable. It may also include a suction or vacuum assistance (Mathew, 2019). In order to control pnuemo or hemothoraces, intercostal drains are employed to remove pressure from the pleural space. It can be necessary to use high pressure, low volume suction to encourage a collapsed lung's re-expansion (Paramasivan and Bodenham, 2007). Quick blood flow out of the pleural space is vital in both adults and children with haemothoraces since fibrous scar tissue may replace the haematoma as it organizes, leading to lung entrapment, which predisposes the patient to persistent atelectasis, V/Q mismatch, pneumonia or empyema (van Aswegen and Morrow, 2015). Additionally, drainage offers a way to gauge and track the amount and pace of blood loss. For direct closure of the wound, a thoracotomy may be necessary if low-pressure, high-volume suction is not successful (van Aswegen and Morrow, 2015). A massive haemothorax is usually an indication for operative intervention. The operative intervention indicated is a thoracotomy (Edgecombe et al. 2018). However, less invasive techniques using video-assisted thoracoscopic surgery (VATS) have been used more in hemodynamically stable patients after both blunt and penetrating thoracic trauma.

2.5.2 Soft Tissue Injuries of the Thoracic Cage

Entrance and exit wounds of gunshot and stab injuries are debrided in detail. For wounds involving a significant loss of thoracic cage integrity, reconstructive surgery may be indicated (van Aswegen and Morrow, 2015).

2.5.3 Pulmonary Contusion

Treatment for all patients with pulmonary contusions should include thorough bronchial cleanliness, precise fluid management, and control of pain arising from the thoracic cage. Patients who have a severe pulmonary contusion need to be continuously monitored to make sure there is sufficient organ perfusion and oxygenation (van Aswegen and Morrow, 2015). Intermittent positioning in prone can be used to improve oxygenation (Cohn and DuBose, 2010).

2.5.4 Pain in Thoracic Trauma

Pleural and intercostal nerve pain can occur as a result of various medical interventions, including the placement of intercostal drains for the management of pleural effusions, pneumothorax, or hemothorax (DeMaio and Semaan, 2021). While intercostal drains are essential in evacuating air or fluid from the pleural space, they can inadvertently cause discomfort or pain due to their proximity to sensitive nerve structures within the chest wall (DeMaio and Semaan, 2021). The origin of the intercostal nerves is from the thoracic spinal nerves and course along the intercostal spaces between the ribs, innervating the chest wall, pleura, and surrounding tissues. During intercostal drain insertion, these nerves can be inadvertently injured, compressed, or irritated, leading to various types of pain (DeMaio and Semaan, 2021). Early pain management is a crucial aspect of care and is the most critical intervention for patients with thoracic trauma (Flarity et al. 2017). Pain following rib fractures has been found to be the biggest obstacle to recovery post hospitalisation (Pharoan et al. 2015). The management of pain substantially affects morbidity and mortality in patients with thoracic trauma. Pain decreases the ability to cough which leads to the retention of secretions (Jain et al. 2021). It can affect ventilation and respiratory function (Ekpe and Eyo, 2016). Severe pain while having and ICD greatly affects the patient's quality of life and causes serious pathophysiological conditions (Mergner, 2017). Pain management improves patient comfort and reduces the risk of secondary complications such as pneumonia, atelectasis, and respiratory failure (May et al. 2016). Analgesia can also help reduce complications by maintaining pulmonary function, weaning from the ventilator and assist with secretion clearance (Witt and Bulger, 2017). Pain control therefore promotes improvement in respiratory function as well as physical activity following thoracic trauma (Pharoan et al. 2015). It allows for the patients to do deep breathing as well as coughing, thoracic physiotherapy and mobilisation (Bilalee et al. 2017).

Kinesio taping can be used to relieve pain in people with rib fractures in addition to analgesic medicines. Clinical benefits of Kinesio taping include pain alleviation, correction of skin discoloration, and support for lymphatic drainage from the fracture site (van Aswegen and Morrow, 2015).

2.5.5 Posttraumatic Empyema

Treatment options for posttraumatic empyema include thoracotomy for decortication and re-expansion of the afflicted lung, less invasive video-assisted thoracoscopy, and intrapleural injection of fibrinolytic medications such as streptokinase or urokinase (van Aswegen and Morrow, 2015).

2.6 PHYSIOTHERAPY MANAGEMENT OF PATIENTS WITH THORACIC TRAUMA

Physiotherapy plays major role in the management of patients with thoracic trauma (Kourouche et al. 2018). The inclusion of physiotherapy in the care of patients with thoracic trauma has beneficial results such as decreased length of stay, decreased rates of secondary complications and decreased rates of morbidity and mortality (van Aswegen, 2020). Cardiopulmonary physiotherapists aim to improve the patient’s breathing pattern, increase their oxygen saturation, optimise lung ventilation, remove and clear excess retained secretions from the airways, reduce the work of breathing, decrease pain, reduce joint stiffness, restore out of bed mobility, and to rehabilitate patients to their highest level of function following a traumatic injury (van Aswegen and Morrow, 2015).

2.6.1 Mobilisation

Early mobilisation is one of the most critical aspects of physiotherapy in the management of patients with blunt thoracic trauma including ventilated patients (Battle et al. 2013). It is one of the key factors in reducing complications like respiratory failure, atelectasis and thromboembolism (Unsworth et al. 2015). Patients with thoracic trauma have reduced physical activity due to the pain inflicted by such injury and the attachments connected to them from various monitoring and therapeutic devices. Side-effects experienced from the medication they receive may also impact on their level of physical activity. Immobility and bed rest can lead to the development of muscle weakness and raises the chance of contracting an infection (Zomorodi et al. 2012). Early mobilisation improves peripheral and respiratory muscle strength (Pathmanathan et al. 2015) and may reduce the rates of cognitive impairment in patients admitted to acute care settings due to injury (Patel et al. 2023). Available evidence shows that tidal volumes increase significantly in ICU ventilated patients post abdominal surgery who receive early mobilisation (Zafiropoulos et al. 2004).

Mobilisation can refer to multiple interventions such as rolling in bed actively or passively, performing active exercise therapy and mobilisation out of the bed (Pathmanathan et al. 2015). Mobilisation improves ventilation and ventilation-perfusion matching thus optimising oxygenation (Pathmanathan et al. 2015). Progressing mobilisation can be from rolling in the bed to sitting at the edge of a bed, transferring between bed and chair, standing, walking on the spot, and walking in the ward with or without an assistive device. These can be further progressed by increasing the number of repetitions or by increasing the duration of the mobilisation depending on the patient's level of tolerance. According to a global survey done by van Aswegen et al. (2020), 98% of physiotherapist use mobilisation as a treatment method for patients with major thoracic trauma. A study done at Ngwelenaza Hospital in KZN and at the Hillbrow hospital in South Africa incorporated brisk walking and running up and down stairs and showed a significant improvement in patient outcomes and an earlier discharge from hospital (Ngubane et al. 1999; Senekal and Eales, 1994). Mobilisation forms part of standard physiotherapy care provided to patients with thoracic trauma at CHBAH.

2.6.2 Exercise Therapy

Numerous positive impacts on both mental and physical health are linked to exercise therapy. Physical activity has been found to improve mood and anxiety levels, as well as satisfaction in life, emotions of well-being, and mental performance, whilst inactivity has been linked to the development of mental diseases such as depression and anxiety (van Aswegen and Morrow, 2015). Aerobic exercises have a variety of benefits to the cardiovascular system such as decreasing blood pressure, increasing stroke volume, decreasing heart rate, and improving insulin sensitivity (van Aswegen and Morrow, 2015). Exercise therapy also increases maximum oxygen intake which reduces the energy needed to perform activities of daily living (ASLs) and improves the level of quality of life (van Aswegen and Morrow, 2015). Upper limb and trunk range of motion exercises are extremely important in patients who have an ICD or after thoracic surgery. These exercises are to prevent abnormal postures and joint range limitations (van Aswegen and Morrow, 2015). Strengthening exercises should also be carried out to prevent any decreases in muscle strength and promote a faster recovery. Exercise therapy in the form of upper limb and trunk range of motion exercises are a standard of practice in South Africa and was used in two studies by Ngubane et al. (1999) and Senekal and Eales (1994). Exercise therapy is still being used around the world in the form of trunk and upper limb range of motion and strengthening exercises as shown in a global study done in 2020 (van Aswegen et al. 2020). This is also still used at CHBAH as standard physiotherapy care.

2.6.3 Education

The primary purpose of education in this context is to empower the patient with a comprehensive understanding of their condition and the rehabilitative process. By explaining the anatomical and physiological aspects of thoracic trauma, physiotherapy aims to simplify the recovery process. Education also encompasses teaching patients the importance of performing their prescribed exercises, breathing techniques, and lifestyle modifications to expedite healing and prevent complications (van Aswegen and Morrow, 2015).

If there is an ICD bottle inserted, it should be kept below the level of entry into the thorax. It is recommended to carry the ICD bottle by its strings and held near to the body during mobilization to avoid tangling with any objects in the ward setting (van Aswegen and Morrow, 2015). These education strategies are used globally by physiotherapists (van Aswegen et al. 2020).

Patients find it difficult to cough properly and to take deep breaths after thoracic trauma or surgery. There is anecdotal evidence that providing support to an unstable thoracic cage or surgical incision when coughing lowers pain and may ease patients’ anxiety about the wound reopening (van Aswegen and Morrow, 2015). Education plays a vital role in physiotherapy and is used in the daily treatment of thoracic trauma patients at CHBAH.

2.6.4 **Breathing Exercises**

Deep breathing exercises can be used simultaneously with other treatments or by itself in the management of patients with thoracic trauma. Patients are taught to breath basally by relaxing their shoulder girdle and breathing with their diaphragm instead of the respiratory accessory muscles (Pathmanathan et al. 2015). Deep breathing exercises have many benefits such as increasing oxygenation, tidal volumes and functional residual capacity, alveolar recruitment, and the reversal of atelectasis (Pathmanathan et al. 2015). Slow deep breathing exercises are thought to help in the reduction of pain (Joseph et al. 2022). In the early 1900s, methods for re-expanding portions of atelectasis included upper extremity exercise, lateral costal expansion activities, and localized thoracic expansion procedures (van Aswegen and Morrow, 2015). In the 1990s, patients with thoracic trauma were treated with physiotherapy using unilateral lateral costal breathing, posterior basal breathing, diaphragmatic breathing, blowing up a balloon, and coughing (Ngubane et al. 1999; Senekal and Eales, 1994). The forced expiratory technique, coughing, deep breathing exercises, and the active cycle of breathing technique are some of the most widely utilized respiratory physiotherapy procedures in use today worldwide. (van Aswegen et al. 2020). These approaches, along with other forms of breathing exercises, are still utilized today at CHBAH, particularly in non-ventilated patients and those who can obey directions and cooperate willingly (van Aswegen and Morrow, 2015).

2.6.4.1 **Active cycle breathing technique (ACBT)**

Active cycle breathing technique (ACBT) is a combination of breathing techniques that is now utilized by many physiotherapists for patients suffering from secretion retention and lung volume loss (van Aswegen and Morrow, 2015). ACBT is an “airway clearance method that uses a cycle of techniques to loosen airway secretions, which includes breathing control, thoracic expansion exercises and forced expiration technique. The ACBT focuses on normalizing the respiratory pattern, promoting airway clearance, and reducing work of breathing” (Thorat et al. 2019). For patients with thoracic trauma, 83% of physiotherapists globally employ ACBT (van Aswegen et al. 2019). Additionally, it has been demonstrated that ACBT helps rib fracture patients feel less pain (Grammatopoulou et al. 2010). At CHBAH, this method is also included in the routine physiotherapy treatment.

2.6.4.2 **Breath-stacking**

Another technique to facilitate deep breathing, improve vital capacity and cough effort is breath-stacking. This technique involves stacking breaths on top of each other using a mask with a one-way valve that allows for inspiration only which results in increasing lung volumes. The breath is held for two to three seconds, the mask removed, and the breath is let out through the mouth (van Aswegen and Morrow, 2015). The breath stacking method is not part of standard physiotherapy care provided to patients with thoracic trauma at CHBAH.

2.6.4.3 **Incentive spirometry**

Incentive spirometry is a technique used in postoperative patients to stimulate deep breathing. It gives visual feedback on volume obtained during a deep breath and may thus be a beneficial supplement to deep breathing exercises (van Aswegen and Morrow, 2015). Incentive spirometers are used to improve airway clearance and prevent atelectasis by recruiting atelectatic or collapsed portions of the lung and increase lung volume (Pathmanathan et al. 2015). Incentive spirometry is used by 54% of physiotherapists globally in their management of those with thoracic trauma (van Aswegen et al. 2020). Not all patients with thoracic trauma receive an incentive spirometer in CHBAH.

2.6.4.4 **Intermittent positive pressure breathing (IPPB)**

In IPPB, positive airway pressure is given during both inspiration and expiration, the patient's airway pressure returns to atmospheric levels. Intermittent positive pressure breathing provides symptom relief for patients experiencing greater effort required to breathe as a result of respiratory muscle weakness or exhaustion, as well as for those breathing at decreased lung volumes due to pain post operatively. Intermittent positive pressure breathing has the potential to improve secretion clearance and stimulate the expansion of collapsed lung regions by increasing tidal volume and decreasing respiratory work (van Aswegen and Morrow, 2015). Intermittent positive pressure breathing is used frequently by 20% and infrequently by 40% of physiotherapists globally (van Aswegen et al. 2020). This, however, does not form part of the standard physiotherapy care provided to patients with thoracic trauma at CHBAH.

2.6.4.5 **Respiratory muscle training**

When it's necessary to strengthen the expiratory or inspiratory muscles which may have been compromised by thoracic trauma, respiratory muscle training is employed. This can be achieved with a spring-loaded resistance device (Martin et al. 2011). The device applies resistance to either inspiration or expiration and in turn strengthens the muscles of the thoracic cage. Respiratory muscle training is used frequently by 22%

of physiotherapist and infrequently by 26% globally (van Aswegen et al. 2020). This device is not used routinely in thoracic trauma patients at CHBAH.

2.6.5 One Nostril Inhalation (ONI)

Eastern cultures have been practicing breath control for thousands of years with the goal of improving or enhancing their health (Upadhyay-Dhungel and Sohal, 2013). For example, Yoga breathing, also known as pranayama, is a well-known, traditional breathing technique that is believed to provide spiritual and health-improving benefits (Upadhyay-Dhungel and Sohal, 2013). There are several types of pranayama, including double, single, and alternating nostril breathing. Since then, there has been a growth in interest in holistic and wellness approaches to healthcare, which has led to the popularity of breathing exercises. The scientific and medical sectors have been interested in them and have encouraged research into the field due to their claimed health benefits and ability to treat a variety of medical ailments (Russo et al. 2017).

Breathing through one nostril at a time while manually closing the other is known as alternate nostril breathing (ANB). It is performed once a day for 15 minutes. Based on parasympathetic or sympathetic tone, the nasal tissue experiences alternating stages of congestion and decongestion during a typical nasal cycle. Restoring autonomic nervous system equilibrium can be accomplished by breathing alternatively through each nostril (Ghiya, 2017).

According to Dhungel et al., (2008) in a study on the effect of alternate nostril breathing exercise on cardiorespiratory functions, ANB showed an increase in peak expiratory flow rate and pulse pressure. It also showed a decrease in heart rate, respiratory rate and diastolic blood pressure. Similarly, Srivastava et al. (2005) reported decreases in heart rate, respiratory rate and systolic blood pressure and an increase in peak expiratory flow rate (Srivastava et al. 2005). It has been demonstrated that breathing through one's alternate nostrils increases focus and lowers both systolic and diastolic blood pressure (Telles et al. 2017).

One nostril inhalation is a type of cost-free resistance breathing, for which no equipment is needed. It has been introduced as a modality to decrease inspiratory flow and rate and regain breathing control for patients who are experiencing pain (Danielsbacka, 2017). One nostril inhalation is thought to balance the autonomic nervous system by stimulating the parasympathetic response, which is associated with relaxation and reduced stress (Kanojia et al. 2013). One nostril inhalation encourages deeper and more controlled breathing, which can improve lung capacity and oxygen exchange, benefiting overall respiratory health (Bhavanani et al. 2014). One nostril inhalation is slow but deep breaths through only one nostril to decrease inspiratory flow and rate and regain breathing control. One nostril inhalation (done with mouth closed) provides some resistance to inhalation as compared to normal two nostril inhalation that adds no additional resistance to inhalation. It can also increase inspiratory volume and decrease the level of pain experienced (Upadhyay-Dhungel and Sohal, 2013).

While recordings during extended slow breathing practice are uncommon, short-term spontaneous and controlled slow breathing performances in a controlled setting have been the focus of most studies on a number of physiological characteristics. There is a lot of scientific interest in the long-term repercussions of slow breathing. It has been demonstrated that practicing rhythmic slow breathing on a regular basis can lower chemoreflex activation and increase baroreflex sensitivity (Turankar et al. 2013). It can also lower mean, diastolic, and systolic blood pressure as well as heart rate variability in hypertensive individuals (Turankar et al. 2013). Slow breathing increases arterial oxygenation and ventilation efficiency through the recruitment of alveoli, alveolar distension, and the decrease of alveolar dead space. It also increases venous return which improves cardiac output (Russo et al. 2017).

2.7 ADVERSE EVENTS THAT OCCUR DURING PHYSIOTHERAPY

Physiotherapy interventions such as percussion, coughing techniques, and deep breathing exercises may exacerbate pain in patients with chest trauma, especially those with rib fractures or soft tissue injuries. Physiotherapy interventions that involve body position changes or out-of-bed mobilization may precipitate changes in blood pressure or heart rate, leading to adverse cardiovascular events such as hypotension or cardiac arrhythmias (Ringer and Lappin, 2023). In such cases a patient may be at risk of developing dizziness and/or fainting and falls. Opioid administration is also linked with a greater risk of fall events in adults of all ages, especially within the first four weeks of administration (Hopkins et al. 2024). Care must be taken as to not dislodge the ICD or any intravenous lines during mobilisation (van Aswegen and Morrow, 2015). Another precaution is to monitor for a decrease in oxygen saturation during treatment, to ensure breathing control is done during chest physiotherapy techniques to avoid any desaturation (van Aswegen and Morrow, 2015).

2.8 LENGTH OF HOSPITAL STAY OF PATIENTS WITH THORACIC TRAUMA

Patients with thoracic trauma may require varying lengths of hospital stays, depending on several factors, including the severity of the injury, presence of associated injuries or complications, effectiveness of treatment, and an individual patient's response to therapy (Gonzalez et al. 2023). It's important to note that advancements in trauma care, including early interventions, improved pain management, and enhanced rehabilitation protocols, contribute to reducing the length of hospital stay for some patients with chest trauma. In a study conducted by Senekal and Eales (1994) in South Africa, patients who received physiotherapy within nine to twelve hours post ICD insertion had a mean length of stay of 78 hours (4 days). Results from a study done at the Ngwelezana Hospital show that thoracic trauma patients who received physiotherapy immediately after ICD insertions had an average hospital length of stay of two days and patients who received physiotherapy 12 to 24 hours post ICD insertion had an average length of stay of six days (Ngubane et al. 1999).

2.9 CONCLUSION

The aim of this chapter was to provide a thorough background and foundation regarding thoracic trauma and the medical, surgical and physiotherapy management of patients recovering from such injury. Thoracic trauma is a massive contributor to the global morbidity and mortality rate. The anatomy of the thoracic wall as well as its functions have been highlighted in this chapter. Many complications such as a pneumothorax, tension pneumothorax, massive pneumothorax, pulmonary contusion, and cardiac tamponade are caused by blunt and penetrating thoracic trauma. In most cases an ICD system is needed to assist in re-expansion of the lungs. One of the hallmark symptoms of thoracic trauma is the pain that is associated with it. Pain management is one of the most crucial aspects in the management of these patients. Adequate pain management reduces the rate of morbidity and mortality significantly. It reduces the risk of an increased length of stay in hospital and a reduction in developing secondary complications such as pneumonia, atelectasis, and respiratory failure. Physiotherapy plays a vital role in the management of these patients. The aim of physiotherapy is to rehabilitate patients to their highest level of function following a traumatic injury. This is done through mobilisation, exercise therapy, education and beathing exercises. Breathing exercises play an important role in pain management which in turn reduces the risk of complications. One nostril inhalation is a cost-free resistance breathing technique that has been introduced to reduce pain. There is a lack of research on the effect of ONI on the clinical outcomes of patients with thoracic trauma. Therefor investigation of the ONI technique and its effects on patient outcomes, in the context of thoracic trauma, is justified.

CHAPTER 3

3. METHODOLOGY

3.1 STUDY SETTING

The study setting was the Chris Hani Baragwanath Academic Hospital (CHBAH) in Soweto, Johannesburg. It is the third largest hospital in the world (CHBAH, n.d.). It houses approximately 3200 beds and has roughly 6700 staff. The trauma wards of CHBAH participated in this study. This comprises of a 60-bed trauma ward and a further two (32 and 60 bed) outlier wards. Tertiary level patient care is provided at this government sector hospital in South Gauteng province. Yearly, about 128 000 inpatients are registered as accident and emergency cases in CHBAH (CHBAH, n.d.) At CHBAH the standard physiotherapy management of patients with thoracic trauma consists of deep breathing exercises, ACBT, positive expiratory pressure in the form of glove blowing, mobilisation away from the bedside, stair climbing, education on pain management, shoulder and trunk range of motion exercises and cycling on a stationary bicycle. The education given to thoracic trauma patients at CHBAH include the importance of breathing exercises and its effects on pain management and improvement in pulmonary function. It also includes the importance of early mobilisation and the benefits of exercise therapy. A ward exercise programme is given to each patient to follow when the physiotherapist leaves for the day which consists of the above-mentioned techniques. All of which is performed once daily supervised by the treating physiotherapist.

3.2 STUDY DESIGN

A single-centre, single blinded randomised trial was done. Reporting for this study was done using the CONSORT statement and checklist (Appendix N). This study forms part of a larger project titled ‘Physiotherapy management of patients who sustained thoracic trauma: a multi-centre study’ for which ethics clearance was obtained (see section 3.3). This study is phase 2 of the larger project.

3.2.1 Study Hypotheses

- One nostril inhalation, added to standard physiotherapy care, does not reduce the hospital length of stay or incidence of pulmonary complications for those who suffered thoracic trauma.
- One nostril inhalation, added to standard physiotherapy care, does not decrease the level of pain experienced by those who suffered thoracic trauma.

- One nostril inhalation, added to standard physiotherapy care, does not improve the functional status or exercise capacity of those who suffered thoracic trauma.

3.2.2 Study Participants

Patients who suffered thoracic trauma and were admitted to the trauma wards of CHBAH, were screened for possible participation in the study and recruited using a consecutive sampling technique.

3.2.3 Inclusion Criteria

Participants were eligible to participate in the study if they were:

- Adult (18 years and older) male and female patients
- Diagnosed with traumatic injury to the thorax and breathing spontaneously (without assistance from a mechanical ventilator)
- Standardised 5 questions (S5Q) score of 4-5/5 (indicates close to full or full cooperation)

3.2.4 Exclusion Criteria

Participants were excluded from the study if they had any of the following:

- Accompanying acute or previously diagnosed spinal cord injury or traumatic brain injury.
- Accompanying complex fractures of the pelvis or lower limbs that restrict active mobilisation.
- Amputation of the lower limb/s.
- Accompanying extensive abdominal trauma (repeated laparotomy procedures) that required prolonged immobilisation.
- Extensive data missing from the data capturing forms.

3.2.5 Study Population and Sample Size Estimation

The primary outcome measure for this study was hospital length of stay. In phase 1 of the larger project, hospital length of stay was observed in patients with thoracic trauma at CHBAH. The average hospital length of stay observed over a three-month period (January – March 2021) was 126.85 hours (5.3 days) with a standard deviation of 95.75 hours (3.98 days). Using the sample size calculator for continuous data suggested by Noordzij et al. (2010), to detect a minimal clinically relevant difference of 48 hours decrease in hospital length of stay for the group receiving ONI plus standard physiotherapy care, a sample size of 74 patients per group was necessary for this randomised trial (alpha set at 0.05, power at 0.80 (beta at 0.20) and taking into consideration 10% non-compliance and 10% drop out rate). On average, 30 patients are admitted to CHBAH with thoracic trauma monthly. The data collection period for this project was therefore 14 months (beginning of April 2022 to end of May 2023).

3.2.6 Variables

3.2.6.1 Independent Variable

- ONI added to standard physiotherapy care.

3.2.6.2 Dependant Variables

- Hospital length of stay
- Incidence of pulmonary complications during hospital stay (e.g. pneumonia, loss of lung volume or atelectasis, respiratory distress necessitating high flow oxygen therapy or NIV; respiratory failure necessitating intubation and MV)
- Level of pain experienced.
- Physical function.
- Exercise capacity.
- Adverse events that occurred during physiotherapy sessions (e.g. falls, dislocation of lines, dizziness or fainting, desaturation).

3.2.7 Outcome Measures/Instrumentation

- The primary outcomes were hospital length of stay and incidence and type of pulmonary complications developed. This was captured on a study specific data capture form (Appendix A).

Table 3.1: Outcome Measures

Outcome Measure	What it Assesses	Reliability and Validity	Previously used in the Trauma Setting
Functional Status Score for ICU (FSS-ICU) (Appendix B)	This tool assesses levels of physical function in patients with acute illness (Huang et al. 2016). A difference in scores of 2-5 is a minimal clinically important difference (MCID) in level of physical function (Huang et al. 2016).	This instrument is reported to be a valid and responsive tool to assess levels of physical function in patients with acute illness (Huang et al. 2016).	Yes (Huang et al. 2016)
10-meter walk test (Appendix C)	This tool is a test of functional ability and walking speed in older adults	This test is reported to be an acceptable test of functional ability and walking speed in older adults (Holland et al. 2011; Chen et al. 2018).	No. This test was included in this study as participants from the Swedish cohort (part of the larger study into which this study feeds) are generally older. This is to allow for data comparison between

Outcome Measure	What it Assesses	Reliability and Validity	Previously used in the Trauma Setting
			South Africa and Sweden.
Timed Up and Go (TUG) Test (Appendix D)	This test is a test of functional balance and walking speed.	The TUG test is a widely used reliable and valid tool for the assessment of functional balance in a variety of patient populations (Steffen, Hacker & Mollinger 2002)	No. This test was included in this study as participants from the Swedish cohort (part of the larger study into which this study feeds) are generally older. This is to allow for data comparison between South Africa and Sweden.
One minute sit to stand test (Appendix E)	This test is a test of muscular strength and endurance (Trija Vaidya et al. 2016).	This test is an acceptable test of muscular strength and endurance (Trija Vaidya et al. 2016).	No. This test was included in this study as participants from the Swedish cohort (part of the larger study into which this study feeds) are generally older. This is to allow for data comparison between South Africa and Sweden.
Wong-Baker FACES pain rating scale (Appendix F)	Pain	The scale is valid for use with people of ages three and older, not limited to children (Garra et al. 2009)	No.

3.2.8 Procedures

The researcher met with all clinical physiotherapists who work in the CHBAH trauma wards to discuss the aim and objectives of the study and educated them on how ONI should be taught and administered to participants. This education session happened during a staff meeting and was repeated by the researcher when new physiotherapy staff joined the physiotherapy trauma team as they rotated into this area every three months.

The chief physiotherapist that oversees the trauma wards at CHBAH was responsible for recruiting participants for the study, according to the set inclusion and exclusion criteria, as they screened the wards and units daily for new admissions. It is the daily standard procedure for the chief physiotherapist to screen the trauma ward admissions and allocate patients to their staff in the wards. On receipt of participants' written consent (Appendices J and K), the chief physiotherapist assigned each participant to either the standard care group (as described in section 3.1 above) or the ONI plus standard care group (experimental group) according to the ward they are recruited from. The study supervisor and the chief physiotherapist at CHBAH Trauma Unit determined prior to participant recruitment, which ward would be allocated as the experimental ward and which ward would continue with standard physiotherapy care of patients admitted with thoracic trauma. This was overseen by the supervisor who monitored the project and was therefore not blinded. The wards were swopped in terms of experimental or standard care group to accommodate the different types of patients in both groups until the required sample size was met. A computer-generated randomisation list (www.randomiser.org) was used to determine ward allocation and allocation was 1:1 (Appendix L). Randomization of wards was repeated every three weeks until the end of participant recruitment.

The chief physiotherapist allocated each participant who consented to the trial to the clinical physiotherapists working in that specific trauma ward or participating outlier ward for management according to the study requirements. The clinical physiotherapists administered either standard physiotherapy care or ONI plus standard physiotherapy to each participant as per ward allocation. The researcher was responsible for continued assessment of patient outcomes as per study procedures. The researcher remained blinded to participant allocation as he assessed and re-assessed participant outcomes during the trial. The participants were informed prior to being assessed that they should not inform the assessor which group they were in to avoid any researcher bias. The researcher performed all test procedures (outcome measures) on the participants in the afternoon on days 1, 3, 5, 7, 10, 15, 20, 25, and 30 or until discharge. The last assessment was on the day before discharge or day 30, as relevant for each specific participant. Data was captured on a study specific data capture form (Appendix A).

The ONI technique was taught as slow and deep inspirations with the mouth and one nostril closed by hand (Appendix H). The participant was informed to perform sets of 10 deep breaths every second waking hour of the day and, in addition, when experiencing pain. Their training was recorded in their given ONI diary (Appendix G). Re-enforcement of the ONI technique was done each day by the treating physiotherapist reminding the participant to continue the technique and to document every two hours when it was done in the ONI diary. This treatment continued until discharge from hospital. Participants in the experimental group were informed that there was no consequence for not ticking the diary when not doing ONI and that in doing so did not affect their care given in the hospital.

The researcher was responsible for data capturing, cleaning, and data analysis with guidance from the research supervisor.

3.2.9 Statistical Analysis

Data captured in Excel was imported to IBM® SPSS® Statistics version 29 software to assist with statistical analysis. Descriptive statistics were used to present the data and inferential statistics were used for comparison of outcomes between the standard care and ONI plus standard care groups.

Table 3.2: Statistical Analysis

Study Objective	Type of Data Obtained	Statistical Test
To describe the profiles of patients who sustained thoracic trauma and were admitted to the trauma wards at CHBAH.	Nominal, ordinal, and interval/ratio	Categorical variables (e.g. type of injury, mechanism of injury, etc.) were summarised using frequencies and percentages. The distribution of continuous data was tested using the Shapiro Wilk test. Continuous variables (e.g. age) were summarised using means and standard deviations (SD) for normally distributed data, and medians and interquartile ranges (IQR) for non-normality distributed data. Baseline comparisons between groups was done using an independent t-test and Chi-squared test.
To investigate the effects of ONI, added to standard physiotherapy management of patients with thoracic trauma, on the incidence of pulmonary complications (pneumonia, atelectasis).	Nominal	Categorical variables were summarised using frequencies and percentages. Chi-squared test was used to perform between group comparisons.
To investigate the effects of ONI, added to standard physiotherapy management of patients with thoracic trauma, on participants' hospital length of stay.	Interval/ratio data	The distribution of data was tested using the Shapiro Wilk test. Continuous variables were summarised using means and standard deviations (SD) for normally distributed data, and medians and interquartile ranges (IQR) for non-normality distributed data. Between group comparisons was done using independent t-test.
To investigate the effects of ONI, added to standard physiotherapy management of patients with thoracic trauma, on their secondary clinical outcomes (physical function	Nominal, ordinal, and interval/ratio data	Categorical variables were summarised using frequencies and percentages. Chi-squared test was used to perform between group comparisons.

status, physical performance and adverse events).		Continuous variables will be summarised using means and standard deviations (SD) for normally distributed data, and medians and interquartile ranges (IQR) for non-normality distributed data. Between group comparisons was done using independent t-test.

Throughout testing was done at the 5% level of significance ($p<0.05$).

Any data capture forms with extensive missing data were excluded from data analysis.

3.3 ETHICAL CONSIDERATIONS

This study forms part of a larger multi-centre trial, as mentioned earlier, titled 'Physiotherapy management of patients who sustained thoracic trauma: a multi-centre study' which received ethics approval from the University of the Witwatersrand Human Research Ethics (Medical) committee on 26 June 2020 (Clearance certificate number: M200222 – see Appendix I). Permission to conduct this project was obtained from National Health Research Database Gauteng on 21 August 2020. This study forms part of phase two of the larger project.

This study was conducted at a single site namely Chris Hani Baragwanath hospital when phase one of the umbrella study at Chris Hani Baragwanath hospital concluded in October 2021. The phase one study describes physiotherapy management of patients recovering from thoracic trauma. The trauma unit manager, head of nursing services in the trauma unit, head of the trauma unit and head of the physiotherapy department at CHBAH were informed when this clinical trial phase of the larger project (Phase 2) commenced.

The researcher familiarised himself with the principles of conducting research in an ethical fashion by completing Module 1 (Introduction to Research Ethics) of the TRREE ethics online course at https://elearning.trree.org/ prior to commencement of the project. The certificate of completion was submitted to the study supervisor (Appendix M). The ethical principles related to conduct of research on human subjects as outlined in the Declaration of Helsinki was observed for the duration of this trial. The first priority of this study was to promote the health and well-being of patients involved. The rights and interests of participants were always the main priority and always took precedence over this study maintaining privacy, confidentiality, and autonomy.

This protocol was registered on the Pan African Clinical Trials Registry (PACTR) (trial registration number PACTR202201706227234) (Appendix N) prior to commencement of data collection.

CHAPTER 4

4. RESULTS

Results obtained are reported in figures, tables and text format.

4.1 STUDY POPULATION

The number of participants admitted into the trauma wards during the period April 2022 until May 2023 and the recruitment of participants to the study is summarised in the flow diagram below (Figure 4.1).

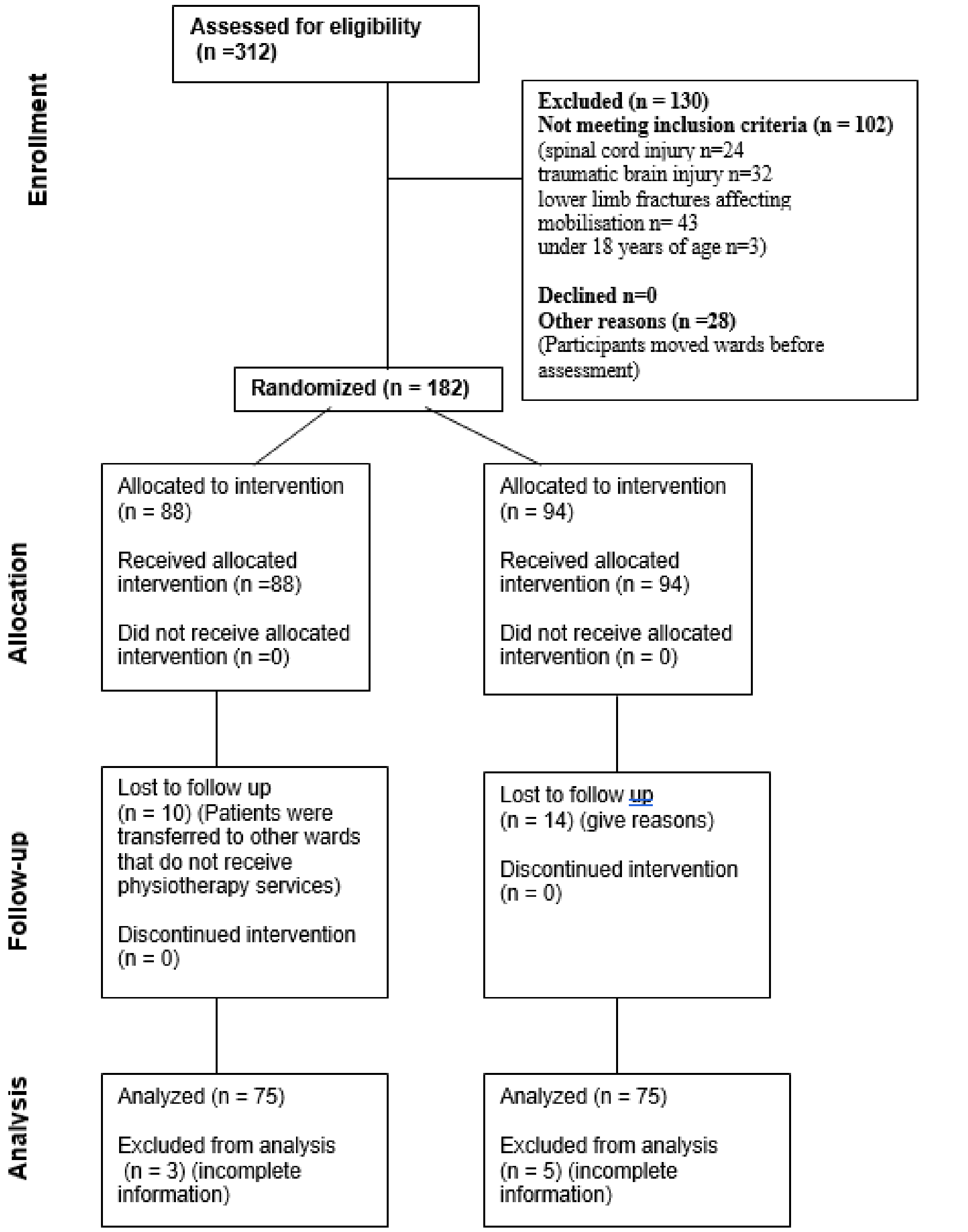

Figure 4.1: Flow Chart Summary of Participant Recruitment for the ONI Study at CHBAH

4.2 DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE STUDY POPULATION0

The median age for the total cohort was 31 (IQR 26-39) years with the minimum age being 18 years, and the maximum age being 50 years (Table 4.1). Majority of participants were male (n=139, 92.7%) and less than half of the cohort were smokers (n=60, 40%). Most participants in both groups sustained penetrating trunk trauma and the most common mechanism of injury was assault (Table 4.1).

Table 4.1: A Between-Group Comparison of Participants' Baseline Characteristics (n=150)

Variable	Total cohort	Group 1 (standard treatment) (n=75)	Group 2 (ONI) (n=75)	p-value
Age (years) (median, IQR)	31 (26-39)	30 (26-37)	34 (26-41)	0.054
Height (m) (median, IQR)	1.71 (1.64-1.74)	1.71 (1.65-1.74)	1.7 (1.63-1.72)	0.156
Weight (kg) (median, IQR)	68 (61-72)	68 (61-74)	67 (60-71)	0.253
Body mass index (kg/m^2) (median, IQR)	23 (21.9-24.9)	23 (22.5-24.9)	23 (21.8-25.1)	0.793
Sex (n, %) - Male - Female	 139 (92.7%) 11 (7.3%)	 68 (90.7%) 7 (9.3%)	 71 (94.7%) 4 (5.3%)	0.347
Smoking status (n, %) - Non-smoker - Smoker	 90 (60%) 60 (40%)	 48 (64%) 27 (36%)	 42 (56%) 33 (44%)	0.317
Type of injury (n, %) - Blunt - Penetrating	 30 (20%) 120 (80%)	 13 (17.3%) 62 (82.7%)	 17 (22.7%) 58 (77.3%)	0.414
Mechanism of injury (n, %) - Assault - Attempted suicide - MVA - PVA	 124 (82.7%) 2 (1.3%) 22 (14.7%) 2 (1.3%)	 66 (88%) 1 (1.3%) 8 (10.8%) 0 (0%)	 58 (77.3%) 1 (1.3%) 14 (18.7%) 2 (2.7%)	0.245

IQR, interquartile range; m, meters; kg, kilograms; kg/m^2, kilograms per meter squared; MVA, motor vehicle accident; PVA, pedestrian vehicle accident.

None of the participants reported having a chronic respiratory disease prior to hospital admission. Participants allocated to the ONI group were slightly older (34 years vs 30 years), more were smokers (44% vs 36%) and more were involved in MVAs and PVAs (19% vs 11% and 3% vs 0%, respectively) than those in the standard care group. Despite these subtle differences, the groups were comparable at baseline as no significant differences were observed for between-group comparisons.

4.2.1 Mechanism of Injury

The mechanisms of injury for the total cohort consisted of 8582.7% (n=124) assaults, 14.7% (n=22) MVAs, 1.3% (n=2) attempted suicide and 1.3% (n=2) PVAs. The most common mechanism of injury in group 1 (standard treatment) was assaults (88%, n=66), followed by MVAs (10.8%, n=8), and attempted suicide (1.3%, n=1). There were no PVAs in group 1 (Figure 4.2). The most common mechanism of injury in group 2 (ONI) was assaults (77.3%, n=58), MVAs (18.7%, n=14), PVAs (2.7%, n=2) and attempted suicide (1.3%, n=1) (Figure 4.3).

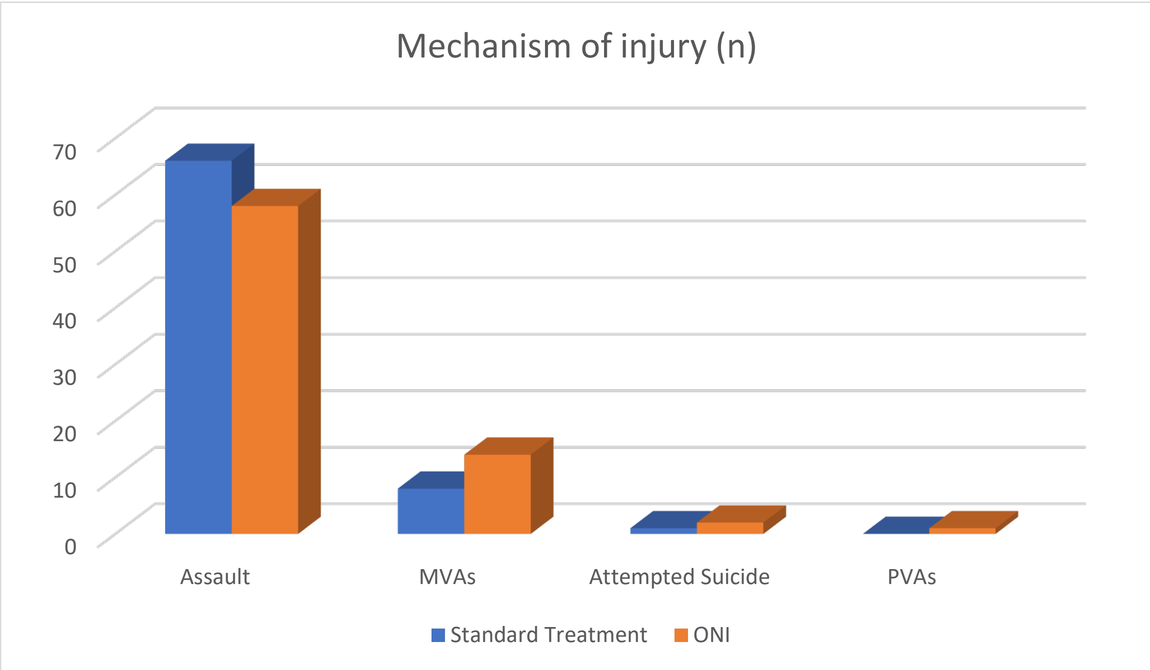

Figure 4.2: Mechanism of Injury in Both Groups

4.3 THORACIC TRAUMA PROFILE OF PARTICIPANTS AT BASELINE COMPARISON

4.3.1 Thoracic Cage Injury

Eighty percent (n=120) of the total cohort (n=150) had no rib fractures, 15.3% (n=23) had 1-3 ribs fractured on the left side, 4% (n=6) had 1-3 ribs fractured on the right side and 0.7% (n=1) had more than 3 ribs fractured bilaterally. In group 1 (standard treatment) 84% (n=63) had no rib fractures, 12% (n=9) had 1-3 ribs fractured on the left side, 4% (n=3) had 1-3 ribs fractured on the right side. There were no participants who had more than 3 ribs fractured bilaterally (Figure 4.4). In group 2 (ONI) 76% (n=57) had no rib fractures, 18.7% (n=14) had 1-3 ribs fractured on the left side, 4% (n=3) had 1-3 ribs fractured on the right side and 1.3% (n=1) had more than 3 ribs fractured bilaterally (Figure 4.5). None of the participants had sternal fractures. The p-value for between group comparison was 0.496.

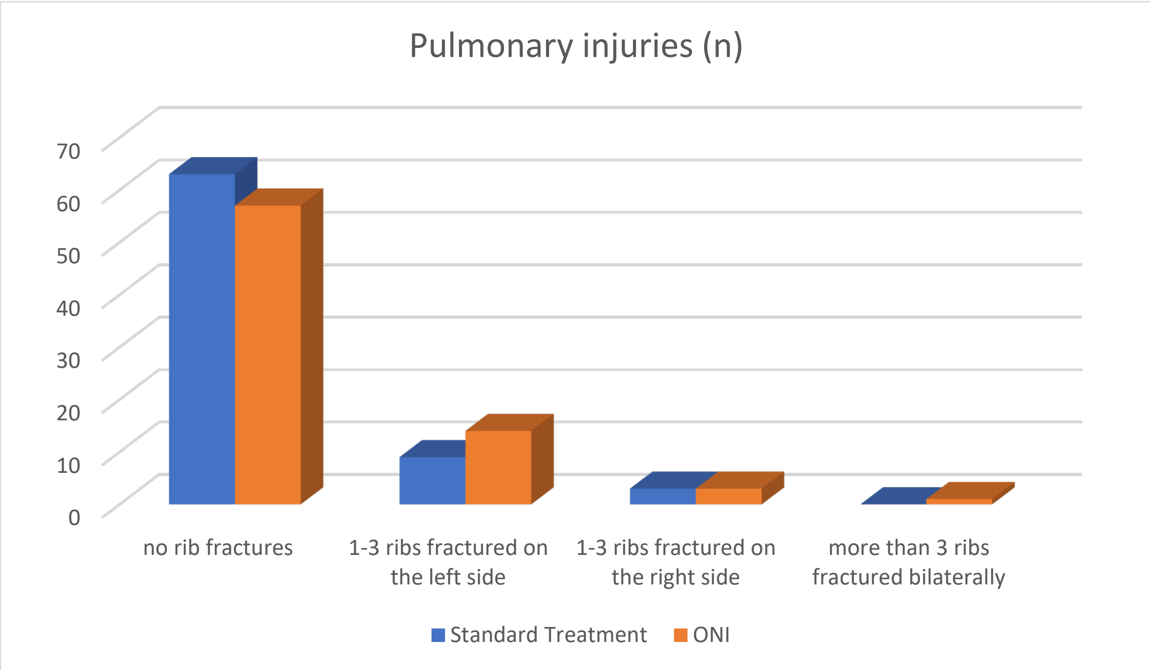

Figure 4.3: Pulmonary Injuries in Both Groups

4.3.2 **Intrapleural Abnormalities**

In the total cohort (n=150), 54.7% (n=82) participants had a unilateral pneumothorax, 42.7% (n=64) had a unilateral haemo-/haemopneumothorax and 2.7% (n=4) had a bilateral haemo-/haemopneumothorax. In group 1 (standard treatment), 49.3% (n=37) participants had a unilateral pneumothorax, 49.3% (n=37) had a unilateral haemo-/haemopneumothorax and 1.3% (n=1) had a bilateral haemo-/haemopneumothorax (Figure 4.6). In group 2 (ONI), 60% (n=45) participants had a unilateral pneumothorax, 36% (n=27) had a unilateral haemo-/haemopneumothorax and 4% (n=3) had a bilateral haemo-/haemopneumothorax (Figure 4.7). The p-value for between group comparison was 0.188.

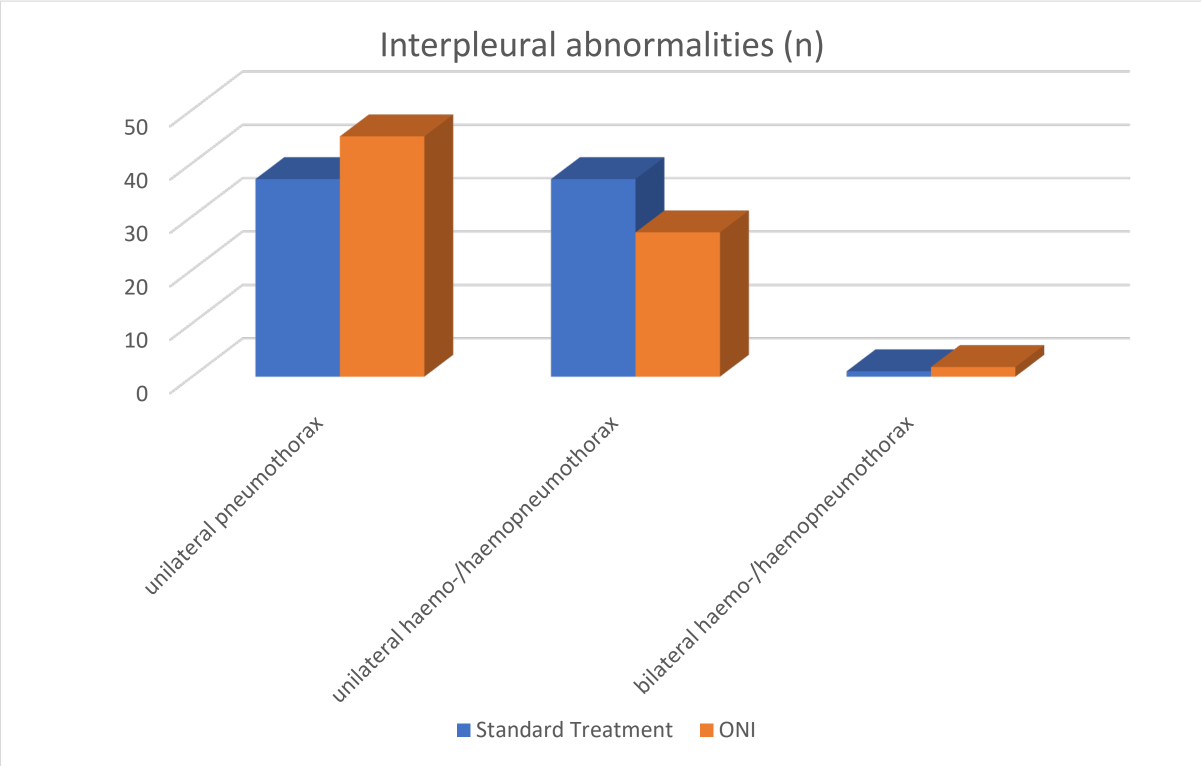

Figure 4.4: Intrapleural Abnormalities in Both Groups

4.3.3 Pulmonary Contusion

There was only one participant in the study who had a pulmonary contusion and they fell into group 1 (standard treatment).

4.3.4 Diaphragm Rupture

One of the participants in group 2 (ONI) had a diaphragm rupture.

4.4 OTHER INJURIES SUSTAINED IN ADDITION TO THORACIC TRAUMA

A small number of participants sustained other injuries in addition to their thoracic trauma. These findings are summarised in table 4.2.

Table 4.2: A Between-Group Comparison of Participants' Other Injuries (n=150)

Variable	Total Cohort (n=150)	Group 1 (Standard) (n=75)	Group 2 (ONI) (n=75)	P-Value
Ortho Injuries (n, %)				0.316
- Yes	1 (upper limb fracture) (0.7%)	0 (0%)	1 (upper limb fracture) (1.3%)	
- No	149 (99.3%)	75 (100%)	74 (98.7%)	
Internal organ injuries (n, %)				0.316
- Yes	1 (spleen injury) (0.7%)	0 (0%)	1 (1.3%)	
- No	149 (99.3%)	75 (100%)	74 (98.7%)	

There were no significant between-group differences for other injuries sustained.

4.5 MEDICAL AND SURGICAL MANAGEMENT RECEIVED BY PARTICIPANTS

Forty-three percent of the total cohort received some form of analgesia at the time of first physiotherapy assessment (Table 4.3). None of the participants received any type of sedation. Most participants had a unilateral ICD in place and only a few participants (n=2, 2.7%) in the ONI group needed additional surgery and underwent a laparotomy (n=1 for splenic injury; n=1 for diaphragm rupture). None of the participants were on any form of oxygen therapy at the time of recruitment. None of the participants underwent rib fixation surgery. Between-group comparisons are presented in table 4.3.

Table 4.3: A Between-Group Comparison of Participants' Medical and Surgical Management (n=150)

Variable	Total Cohort (n=150)	Group 1 (Standard) (n=75)	Group 2 (ONI) (n=75)	P-Value
Analgesia (n, %)				1
- Yes	64 (42.7%)	32 (42.7%)	43 (57.3%)	
- No	86 (57.3%)	43 (57.3%)	32 (42.7%)	

Variable	Total Cohort (n=150)	Group 1 (Standard) (n=75)	Group 2 (ONI) (n=75)	P-Value
Sedation - Yes - No	 0 150	 0 75	 0 75	
O2 Therapy - Yes - No	 0 150	 0 75	 0 75	
ICD present (n, %) - Yes - No	 149 (99.3%) 1 (0.7%)	 74 (98.7%) 1 (1.3%)	 75 (100%) 0 (0%)	0.316
ICD site (n, %) - None - Unilateral - Bilateral	 1 (0.7%) 144 (96%) 5 (3.3%)	 1 (1.3%) 72 (96%) 2 (2.7%)	 0 (0%) 72 (96%) 3 (4%)	0.549
Other surgery (n, %) - Yes - No	 2 (1.3%) 148 (98.7%)	 0 (0%) 75 (100%)	 2 (2.7%) (Laparotomy) 73 (97.3%)	0.155

ICD; intercostal drain

No significant between-group differences were found for any of the listed parameters.

4.6 PHYSIOTHERAPY TREATMENT RECEIVED AND ADHERENCE TO ONI TRAINING

The median number of physiotherapy contact sessions during their hospital stay for group 1 (standard treatment) was 4 (IQR 3-4) and the median for group 2 (ONI) was 4 (IQR 3-5). The days on which patients did not receive physiotherapy sessions were the weekends and/or public holidays.

Group 2 (ONI) adherence to the ONI training was recorded in the ONI diaries. Forty-five percent (n=34) of the ONI group completed 75% or more of the training sessions between the initial physiotherapy session and the date of discharge. Fifty-five percent of the ONI group completed less than 75% of the training sessions between the initial physiotherapy session and the date of discharge.

4.7 PRIMARY CLINICAL OUTCOMES

4.7.1 Hospital Length of Stay

The mean length of stay for group 1 (standard treatment) was 4.47 (SD 1.19) days and 4.96 (SD 1.28) days for group 2 (ONI). The p-value for the length of stay is 0.008 with 95% confidence interval of 4.51 to 4.92. Participants who received ONI plus standard physiotherapy care therefore had a longer length of stay by 0.5 days compared to those who only received standard physiotherapy care.

4.7.2 Pulmonary Complications

None of the participants in the two groups were reported to develop the predetermined pulmonary complications for this study namely loss of lung volume or atelectasis, pneumonia, respiratory distress necessitating NIV or high flow oxygen therapy, or respiratory failure requiring intubation and MV.

4.8 SECONDARY CLINICAL OUTCOMES

4.8.1 Pain

Pain was assessed with the Wong-Baker FACES Pain Rating Scale. The mean amount of pain felt on day 1 for group 1 (standard group) (n=75) was 5.6/10 (SD 1.62) and 5.6/10 (1.9) for group 2 (ONI) (n=75) (p=0.292). On day 3 it was 3.4/10 (SD 1.78) for group 1 (standard treatment) (n=63) and 3.7/10 (SD 2) for group 2 (ONI) (n=66) (p=0.407). On day 5 it was 3.2/10 (SD 1.4) for group 1 (standard treatment) (n=19) and 2.1/10 (SD 1.6) for group 2 (ONI) (n=30) (p=0.075). This is represented in the bar chart below (Figure 4.8). No statistically significant differences were observed between the two groups. For both groups pain decreased over time and the small differences in pain scores reported by participants in each group over time are not clinically significant.

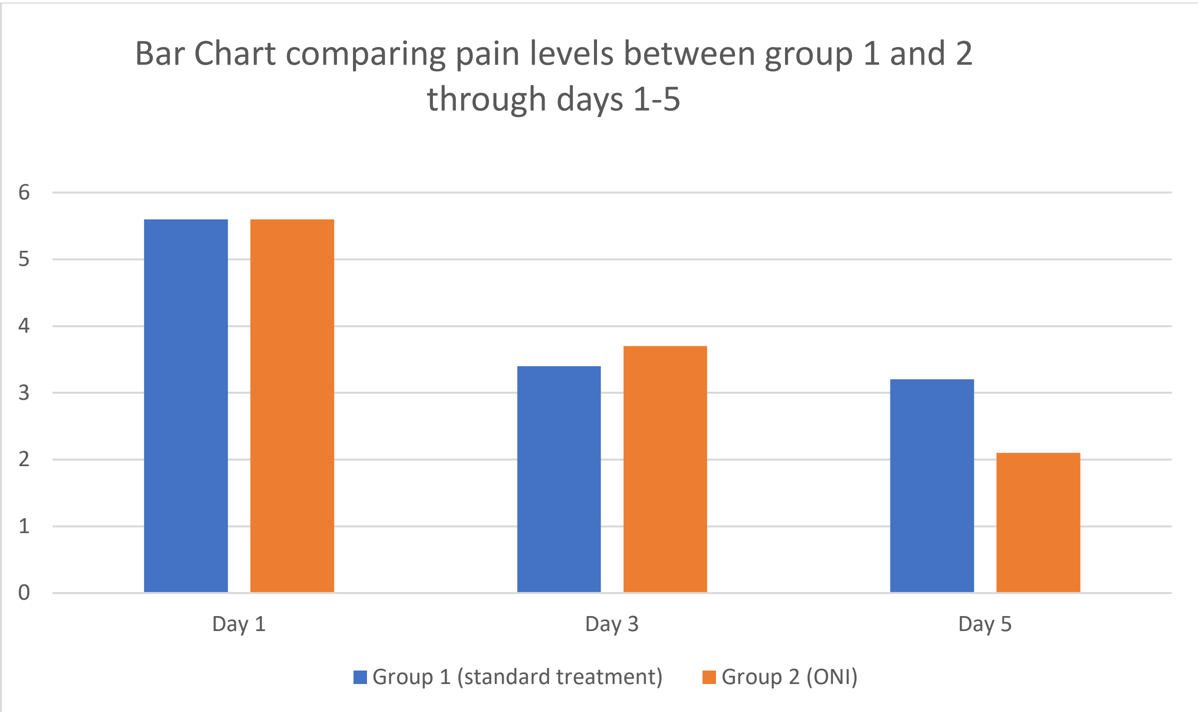

Figure 4.5: A Comparison of Pain Levels Reported by Participants in Groups 1 and 2 through Days 1-5 of Hospitalisation

4.8.2 Functional Status

Participants’ physical function abilities were assessed using the FSS-ICU mobility scale, 10-meter walk test and the TUG test. There were no significant differences in the functional outcomes assessed between group 1 (standard treatment) and group 2 (ONI). There were, however, gradual improvements through the days of assessment in both groups (Table 4.4).

None of the participants presented with any prior walking impairments at recruitment to the study. None of the participants in either group needed physical assistance to complete the 10-meter walk test at a comfortable or face pace at any of the assessment days.

The planned air-test was not recorded as none of the participants in either group were receiving oxygen therapy at the time of assessment.

The FSS-ICU score was not analysed as all of the participants had a score of 35/35 on all days of assessment.

Table 4.4: A Comparison of Functional Outcomes Assessed between Groups on Days One to Five of Hospital Stay (n=150)

Variable	Day 1			Day 3			Day 5		
	Group 1 (standard treatment) (n=75)	*Group 2 (ONI) (n=75)*	*p-value*	*Group 1 (standard treatment) (n=63)*	*Group 2 (ONI) (n=66)*	*p-value*	*Group 1 (standard treatment) (n=19)*	*Group 2 (ONI) (n=30)*	*p-value*
10m-walk test (m/s) median (IQR)									
- Comfortable pace	1.21 (1.2-1.28)	1.21 (1.2-1.28)	0.592	1.3 (1.23-1.31)	1.28 (1.22-1.31)	0.427	1.28 (1.24-1.3)	1.3 (1.24-1.34)	0.841
- Fast pace	1.51 (1.45-1.59)	1.51 (1.47-1.58)	0.630	1.57 (1.48-1.62)	1.54 (1.48-1.61)	0.317	1.59 (1.46-1.62)	1.57 (1.5-1.64)	0.430
TUG (seconds) median (IQR)	12.3 (12.1-13.1)	12.3 (12.1-13.12)	0.263	11.45 (11.1-12.3)	11.4 (11.1-12.3)	0.291	11.4 (11.1-12.1)	11.35 (10.9-12.15)	0.568

4.8.3 **Exercise Capacity**

Participants' ability to perform exercise was assessed using the one-minute sit to stand test. There were no significant differences in the exercise capacity assessed between group 1 (standard treatment) and group 2 (ONI). There were, however, gradual improvements through the days of assessment in both groups (Table 4.5). All participants (n=150) were able to walk away from the bedside on day one of physiotherapy treatment for both groups.

Table 4.5: A Comparison of Exercise Capacity Assessed between Groups on Days One to Seven of Hospital Stay (n=150)

Variable	Day 1			Day 3			Day 5		
	Group 1 (standard treatment) (n=75)	***Group 2 (ONI) (n=75)***	***p-value***	***Group 1 (standard treatment) (n=63)***	***Group 2 (ONI) (n=66)***	***p-value***	***Group 1 (standard treatment) (n=19)***	***Group 2 (ONI) (n=30)***	***p-value***
Sit-to-stand in one minute (repetitions) median (IQR)	17 (12-22)	16 (11-19)	0.600	24 (12-26)	21 (12-25)	0.597	19 (14-24)	21 (16-24)	0.109

4.8.4 Rate of Adverse Events during Physiotherapy Sessions

The predetermined adverse events that were monitored for during physiotherapy treatment included dizziness and/or fainting, disconnection of lines, and falls. There were no reports of any adverse events that occurred during physiotherapy sessions for both group 1 (standard treatment) and group 2 (ONI).

4.8.5 Discharge Information

All the patients (n=150) in both group 1 (standard treatment) and group 2 (ONI) were discharged home. None of the participants were transferred to another facility or hospital for further management. The treating physiotherapists did not deem it necessary for any of the patients to receive out-patient physiotherapy follow-up after post discharge.

CHAPTER 5

5. DISCUSSION

This chapter entails interpreting the findings set out in the preceding section against the available evidence on this topic. The challenges and limitations of the study as well as recommendations for further research are discussed towards the end of the chapter.

This study describes the effect of ONI, added to standard physiotherapy management, on clinical outcomes of patients with thoracic trauma.

5.1 CHARACTERISTICS OF THE STUDY COHORT

The participants in this study were predominantly male (n=139, 92.7%) and had a median age of 31 (IQR 26-39) years. This is in accordance with various studies on the incidence of trauma between males and females as according to El-Manyar et al. (2013) and Lundin et al. (2022). El-Manyar et al. (2013) reported that among 5118 cases admitted to the section of trauma surgery in Qatar, 94% of the patients were male and 6% were female. The mean age reported in the study also showed similarities with this study as their mean age was 33 years old. Lundin et al. (2022) identified patients through the Karolinska Trauma Register in Scandinavia and found that majority of their patients were male, making up 71% of the total cohort. They, however, had a higher mean age of 46 when compared to the current study (Lundin et al. 2022). In India it was found that 92% of patients that suffered a blunt thoracic injury were male and 8% were female (Verma et al. 2023) This also coincides with the findings of this study. In a study conducted by Ngubane et al. (1999) on the treatment of stabbed chests in KwaZulu Natal, South Africa, they reported a mean age of 25.5 and 31.85 in their groups which is in line with the findings of this study. Ngubane et al. (1999) had a 100% male study cohort as did Senekal and Eales (1994) when looking for the optimal physiotherapeutic approach to penetrating stab wounds of the chest. Kong et al. (2014) reported that according to their study in South Africa where they reviewed ICD complications in a major trauma service, 91% were male and 9% were female, having a median age of 24.The characteristics of the study cohort are also in similarity with a study conducted in 2023, KwaZulu Natal, South Africa where 93% of the patients who suffered traumatic haemothoraces were male and 7% were female (Kithuka et al. 2023).

Among young adults, particularly those aged 18-35, thoracic injuries are predominantly associated with high-energy mechanisms, such as motor vehicle accidents, sports injuries, and violent encounters. This age group is generally more active and engages in riskier behaviours, leading to a higher likelihood of sustaining traumatic injuries (Peterson et al. 1994). Additionally, lifestyle factors such as smoking, and alcohol consumption contribute to the prevalence and severity of thoracic injuries in this age group. Work-related injuries are a significant cause of thoracic trauma among adults, particularly in industries involving manual labour and heavy machinery. Motor vehicle accidents remain a leading cause, with seat belt use and airbag deployment being critical factors in reducing injury severity (Dembe et al. 2004).

Age significantly impacts recovery after trauma, influencing various physiological, psychological, and social factors. Older adults typically have reduced physiological reserves, which can impair their ability to respond to and recover from trauma. This includes decreased cardiac output, reduced pulmonary function, and diminished renal function (Evans et al. 2012). Aging affects the body's healing processes, leading to slower wound healing and recovery. This can result in prolonged hospital stays and increased risk of complications. Older patients often have multiple comorbidities, such as hypertension, diabetes, and cardiovascular diseases. These conditions can complicate the management of trauma and delay recovery (Gould et al. 2015). Older adults may face more significant challenges in rehabilitation due to decreased muscle mass, joint stiffness, and reduced mobility. This can impact their ability to regain independence and return to pre-injury functional levels. Studies show that older trauma patients have higher mortality rates compared to younger patients. This is due to the combined effects of physiological decline, comorbidities, and complications (Perdue et al. 1998). This could be seen in the study population as the median age for the standard group was 30 and the median age for the ONI group was 34. Both groups had a young median age which improves their ability to recover from thoracic injury at a faster rate and can be seen in the improvement of their functional outcomes.

Biological dissimilarities between males and females play a significant role in their susceptibility to trauma. Evolutionary perspectives suggest that males have historically engaged in riskier behaviours due to their role as protectors and providers in society. Testosterone, a hormone predominantly found in males, has been linked to increased aggression and risk-taking tendencies, potentially predisposing men to participate in activities with higher rates of trauma, such as physical altercations and dangerous sports (Archer, 2006). Furthermore, societal pressures to conform to masculine ideals of strength and invulnerability may compel males to engage in riskier behaviours to validate their masculinity, thereby increasing their exposure to traumatic events (Levant and Richmond, 2008). Additionally, men are overrepresented in occupations and activities with inherent risks, such as military combat, law enforcement, and construction work, amplifying their likelihood of encountering trauma-inducing circumstances (Tolin and Foa, 2006). Conversely, females may exhibit more cautious behaviours and seek out protective strategies, reducing their exposure to traumatic events.

In this study, it was reported that 40% of the total cohort were smokers and 60% were non-smokers. Smoking history can have several implications in relation to thoracic trauma. Smoking impairs wound healing due to its effects on blood flow and oxygenation. This can be particularly relevant in the context of thoracic trauma, where healing of thoracic wall injuries, lung contusions, or surgical wounds might be compromised (Hawn et al. 2011). Smokers are at a higher risk of developing infections, including pneumonia, after sustaining thoracic trauma (Hawn et al. 2011). This can complicate recovery and increase morbidity and mortality. Smokers are more likely to have pre-existing lung conditions such as COPD. This can complicate the management of thoracic trauma, as these patients may have reduced pulmonary reserve and are more susceptible to respiratory failure (Celli et al. 2015). Even in the absence of overt lung disease, smokers often have compromised lung function, which can worsen the prognosis of thoracic trauma. Studies have shown that smokers have higher rates of complications and worse outcomes following traumatic injuries, including thoracic trauma. This can include prolonged hospital stays, increased need for intensive care, and higher rates of mortality (Calfee et al. 2011). Although this is how smoking can have several implications in thoracic trauma, this study did not have any follow up post discharge to see if the smokers in the study population developed any complications to wound healing. This however could have affected the length of stay as 44% of the participants were smokers in the ONI group while in the standard treatment group 36% were smokers.

Penetrating thoracic trauma was the most prominent type of injury in this study cohort, having a prevalence of 80%. While blunt thoracic trauma had a prevalence of 20%. Similarly, Kithuka et al. (2023) reported that penetrating injuries made up 91.5% while blunt thoracic trauma made up only 8.5% of their study cohort. Dippenaar and Wallis (2019) also reported the like with a prevalence of 88.8% for penetrating thoracic trauma and a prevalence of 11.2% for blunt thoracic trauma. Comparatively Kong et al. (2014)

resonated with these findings by reporting that most of their South African study cohort had suffered penetrating thoracic injury at 75% and the remaining 25% sustained blunt thoracic trauma. Blunt thoracic trauma is more common among MVAs according to Okonta and Ocheli (2018) and this can be seen in this study as MVAs made up 14% of the total cohort. Penetrating thoracic trauma often occurs in contexts where individuals are exposed to violence, accidents, or armed conflicts. These high-risk environments, such as war zones, urban areas with high rates of crime, or during interpersonal conflicts, elevate the chances of encountering penetrating trauma (Edgecombe et al. 2018). This can be seen in South Africa where a high crime rate exists, and assault cases are large in number.

Assault was the most prominent mechanism of injury in thoracic trauma in this study. According to Statistics South Africa, particularly in Soweto the high rate of violent crimes can help explain the prevalence of thoracic trauma seen in the local hospitals and clinics (statisticsSA n.d). This resonates with the South African Police Service statistics where in the 2022/2023 year there were over 185 000 cases of common assault (SAPS n.d). South Africa is ranked as the country with the highest stabbing deaths in the world with 16.95 per 100 000 (wisevoter n.d). This is in conjunction with this study as assault cases made up 82.7% of the total cohort. This can also be seen in the study conducted in South Africa in 2023 where assault in the form of a stab wound was in 64.4% of the study cohort, and gunshot wounds made up 22.9% (Kithuka et al. 2023). Motor vehicle accidents made up 22% of this study's total cohort and PVAs along with attempted suicides made up 1.3% each. A reason for this is that in this study patients with accompanying lower limb fractures, spinal cord and traumatic brain injuries were excluded from the study. Previous studies have not documented the prevalence of MVAs and PVAs in thoracic trauma. It is however reported as polytrauma as a result of MVAs and PVAs.

The intrapleural abnormalities in this study were similar to the study cohort by Kong et al. (2014). This study had a majority unilateral pneumothorax followed by haemo/pneumothorax while Kong et al. (2014) had a majority of haemopneumothorax followed by pneumothorax. These statistics were found in a retrospective study review of ICD complications in a major trauma service in South Africa. These findings are also in line with previous findings of the most common type of thoracic trauma being pneumothorax and haemothorax (Edgecombe et al. 2018).

Forty-three percent of the total cohort in this study received some form of pain management in the form of analgesia. Pain management is one of the most crucial aspects of care in the management of patients with thoracic trauma (Flarity et al. 2017). In a study conducted by Schaffer et al. (2022) on the pain management of a trauma service in the United States of America, 64% of patients received multimodal pain therapy. The higher the injury severity score, the more pain therapy was required (Schaffer et al. 2022). This study did not use the Injury severity score therefore it is of the assumption that this study cohort were not severely injured as only 43% required analgesia as pain management. None of the patients in this study were mechanically ventilated or needed oxygen therapy. In addition, only two participants had undergone other surgeries (laparotomy). There was only one participant who had a diaphragm rupture and another who had a pulmonary contusion, further adding to the assumption that this cohort was not severely injured. Additionally, a possible reason for this study population having a low injury severity is that it had a low number of rib fractures (20%, n=30). According to Kim and Moore (2020) the severity of thoracic injury is proportional to the number of ribs fractured and in turn contributes to the prevalence of complications.

5.2 PRIMARY OUTCOMES

One of the primary clinical outcomes of this study was hospital length of stay. The ONI group had a longer length of stay by half a day compared to the standard care group. This was statistically significant. The p-value for the length of stay is 0.008 with 95% confidence interval of 4.51 to 4.92, but its clinical significance is debatable. Possible explanations for this finding are related to procedures in the trauma wards at the participating study site. One possibility is the time that it takes from ordering of a patient's chest x-ray prior to discharge to establish safety for discharge versus the time it actually takes for patients to having their chest x-ray taken and their results reported. This can be attributed to the high patient numbers at the study site that require radiological investigations on a daily basis (CHBAH, n.d.). Another possibility may be the available time that trauma surgeons have to order patient discharges for the day, depending on their capacity and workload. At CHBAH there are three junior registrars and one senior registrar on call on a daily basis. Discharges typically happen in the late afternoon at the participating study site and, together with the administrative processes related to patient discharge, may have inadvertently impacted on individual participants' hospital length of stay.

Possible explanations for the longer length of stay for participants in the ONI group are related to the characteristics of the group. Participants in the ONI group were slightly older, more were current smokers, and more had rib fractures than those in the standard physiotherapy care group. The ONI group also had a participant with upper limb fractures, one with splenic injury, and one with a diaphragm rupture that necessitated surgery, in addition to thoracic trauma. A limitation of this study is that data was not gathered on the development of other complications within the two groups. It is possible that complications related to fractures (e.g. delayed time to theatre due to thoracic injury) or to surgery (e.g. wound infection, delayed removal of surgical drains) may have developed but were not recorded. Such complications could have influenced length of stay for participants in the ONI group.

The effect of ONI on hospital length of stay in patients with thoracic trauma has not been described by others and therefore no comparisons of findings can be drawn with the current findings. Earlier studies reported an average of four (Senekal and Eales, 1994) and six (Ngubane et al. 1999) days of hospital stay for South African patients with thoracic trauma. Participants in this study therefore had similar durations of hospital stay.

Another one of the primary clinical outcomes of this study was the prevalence of pulmonary complications. In this study there were no reported cases of any pulmonary complications in either of the groups, while in previous studies pneumonia and a retained haemothorax were the most common complications found in patients with thoracic trauma reported by İliklerden et al. (2022) and Stuart and Corneille (2008). İliklerden et al. (2022) found that 15% of thoracic trauma patients in Turkey developed long-term complications. A retained haemothorax was the most common complication found in penetrating thoracic trauma and pneumonia was the most common complication found in blunt trauma to the thorax. Stuart and Corneille (2008) found that respiratory failure, pneumonia and pleural sepsis as a result of a retained haemothorax were the most common complications. The authors also stated that age and the severity of the injury is closely related to the development of complications post thoracic trauma. The older and more severe the thoracic trauma is, the higher the chances of developing complications (Stuart and Corneille, 2008). In this study the mean age being 31 and the assumption of the total cohort having a low injury severity contributes to the low incidence of any pulmonary complications. In this study over 40% (n=64) of the total cohort received analgesia which also possibly assisted in the reduction of pain experienced and reduced incidence of complications.

This study's pulmonary complication incidence was similar to the study conducted by Senekal and Eales (1994) where there were no reports of empyema or wound sepsis. There were differences in that the authors found a total of seven patients who had spiking temperatures while in this study, temperature changes were not recorded. This study's findings are in agreement with a previous study conducted by Ngubane et al. (1999) where only four patients developed complications in the form of empyema.

Another limitation of this study is that data was not collected regarding re-admission rates of participants with complications such as empyema. Therefore, it is not possible to make assumptions about the possible long-term impact of ONI breathing on patient outcomes.

5.2.1 **Secondary Outcomes**

In previous studies of patients with thoracic trauma, pain was not recorded during physiotherapy treatment, but, in this study, there were no significant differences in pain experienced by participants between the two groups. For both groups pain decreased over time and the small differences were not significant. The management of pain plays a vital role in morbidity and mortality in patients with thoracic trauma and if controlled well, improves patient outcomes (Kim and Moore, 2020). If rib fracture pain is not treated in a timely manner, complications such as death, increased hospital length of stay and increased use of hospital resources may result (Unsworth et al. 2015). Pain however does not always come from rib fractures and can be ascribed to pain caused by the ICD position in the thoracic wall. Pleural pain arises from irritation or inflammation of the parietal pleura, the membrane lining the inner surface of the chest wall (DeMaio and Semaan, 2021). When an intercostal drain is inserted, it may come into contact with the parietal pleura, causing discomfort or sharp pain, especially during deep breathing or movement. Pleural pain is typically localized to the site of drain insertion and may be described as sharp or stabbing in nature (Mergner, 2017). Intercostal nerve pain results from injury or irritation of the intercostal nerve and may be exacerbated by movement, coughing, or palpation of the chest wall and can persist beyond the initial post-procedural period (DeMaio and Semaan, 2021). These types of pain can be associated with this study population as almost all (n=149) participants had an ICD inserted.

Deep breathing exercises assist with pain management (Joseph et al. 2022). Deep breathing exercises activate the parasympathetic nervous system, promoting the relaxation response and counteracting the body's stress response (Ma and Teasdale, 2004). This physiological shift from sympathetic dominance to parasympathetic activation induces a state of calmness and reduces muscle tension, thereby diminishing the perception of pain (Brown and Gerbarg, 2005). In this study the reduction in pain in both groups can be associated with the deep breathing exercises performed by both groups during their physiotherapy sessions. Though the breathing exercises may have differed slightly between groups, this together with analgesia may have helped in the management of pain.

The ONI diary was completed by the participant themselves. It was found that 45% of the participants in the ONI group completed 75% or more of the ONI exercise and 55% completed under 75%. This brings about the concern for compliance with the ONI exercise. Previously Frost et al. (2016) reported that individual diary data may be valid but there is a dearth in the literature with regards to current rehabilitation adherence measures. The author reported that patients were compliant with rehabilitation, but no measures were in place to monitor this. Stone et al. (2002) assessed the compliance of patients with paper diaries compared to electronic diaries. It was noted that participants who used the paper diaries indicated a high level of faked compliance in that study. Patients who used the electronic diary however had a much higher compliance rate. It can be assumed however that patients were truthful with the ONI diary in this study due to the daily reminders from treating physiotherapists to complete the ONI therapy and document each session in the diary.

Pain from thoracic trauma influences physical function abilities (Suss, 2017). Pain control therefore promotes physical activity following thoracic trauma (Pharoan et al. 2015). Changes in physical function were assessed with the FSS-ICU, 10-meter walk test and TUG test. The scores from the FSS-ICU indicate that the total cohort in this study had complete independence in all functional activities from day one of assessment. The total cohort scored a value of 35/35 when using the FSS-ICU indicating complete independence. This can also be attributed to the assumption of the patients in this study having a low injury severity since all were independent in their daily activities. The FSS-ICU mobility scale was not used in the studies conducted by Senekal and Eales (1994) nor Ngubane et al. (1999), however, the physiotherapy interventions that were given to the patients in both studies show comparativeness to this study. Senekal and Eales (1994) had incorporated brisk walking as well as running up and down stairs which could be compared to a high functional independence and thus comparable with the physical function of this population. Similarly, Ngubane et al.

(2019) had also included brisk walking and running up and down stairs in the physiotherapy management of patients on day one of admission, which indicates high physical function in their study population as well. The FSS-ICU was not sensitive to detect changes in physical function as the participant population were independent and scored the maximum score from day one of assessment. Therefore, progress or changes in the improvement could not be assessed using the FSS-ICU.

The 10-meter walk test was selected to assess functional ability and walking speed. This outcome measure was chosen as there is a death of evidence that reports on the effect of physiotherapy interventions on clinical outcomes of patients who sustained thoracic trauma, and this is the first study to report on this outcome measure in the thoracic trauma population. This test was included in this study as participants from the Swedish cohort (part of the larger study into which this study feeds) are generally older. This is to allow for data comparison between South Africa and Sweden. The normal values for 30–39-year-olds is 1.34-1.43 m/s. The median for group 1 (standard treatment) on day one of assessment was 1.21 m/s, on day three was 1.3 m/s and on day five was 1.28 m/s. The median for group 2 (ONI) on day one of assessment was 1.21 m/s, on day three was 1.28 m/s and on day five was 1.3 m/s. This showed gradual improvements in both groups through the days of assessment. The same was seen when assessing walking speed at a fast pace. The normal values for 30–39-year-olds is 2.45 m/s. The median for group 1 (standard treatment) on day one of assessment was 1.51 m/s, on day three was 1.57 m/s and on day five was 1.59 m/s. The median for group 2 (ONI) on day one of assessment was 1.51 m/s, on day three was 1.54 m/s and on day five was 1.57 m/s. There were no significant differences at either of the assessment days. There was improvement from the first day of assessment to the last day of assessment. In the current study there were no significant difference between the two groups at the day 1, day 3, or day 5 when walking speed was assessed. The walking speed stayed below normal by day 5. It can be assumed that patients may need more time to recover from the thoracic trauma so that their functional outcomes may be normalised. Patients are still experiencing pain on all days of assessment, and this could be a contributing factor for them not able to reach the norm. The surgeries that the two patients underwent in the ONI group affects their walking speed as they would have gone to theatre which delays the recovery process and possibly adds to their pain. This indicates that this outcome measure is useful and sensitive within thoracic trauma patients as it was able to assess their walking speed and their progress thereof. The 10-meter walk test also assesses the influence of the physiotherapy interventions given to each group, by decreasing pain and improving the physical function of patients.

The TUG test was used as an assessment of functional balance and walking speed. This test was included in this study as participants from the Swedish cohort (part of the larger study into which this study feeds) are generally older. This is to allow for data comparison between South Africa and Sweden. To the knowledge of the author this outcome measure has however not been used in the trauma population and this is the first study to assesses this. The normal values for community dwelling adults are 13.5 seconds (Shumway-Cook et al. 2000). On day one of assessment group 1 (standard treatment) had a median score of 12.3 and on day three had a median score of 11.45 and on day five had a median score of 11.4. Group 2 (ONI) had a median score of 12.3 on day one of assessment, 11.4 on day three and 11.35 on day 5 of assessment. The TUG scores for both groups also showed improvement but do not show any significant difference between the groups on either of the days. These findings can be supported by Kim et al. (2018) who assessed for any vestibular concerns in trauma patients and found that particularly with thoracic injuries almost all of the patients did not experience any dizziness which is often contributed to balance and fall risk (Kim et al. 2018). The TUG was a sensitive outcome measure as it was able to detect change in physical function between the two groups as it shows an improvement throughout the days of assessment in time taken to complete the test.

Exercise capacity was assessed using the one-minute sit to stand test. This test was included in this study as participants from the Swedish cohort (part of the larger study into which this study feeds) are generally older. This is to allow for data comparison between South Africa and Sweden. This outcome measure has not been used in the trauma population prior to this. According to Bohannon and Crouch (2019), the norm for this test in young men had an average of 50 repetitions in one minute. The one-minute sit to stand test did not show a significant difference between group 1 (standard treatment), which had a median number of 16 and group 2 (ONI) which had a median number of 24. The values for the test had shown an increase in both groups throughout the duration of hospital stay but the reason for the below the normal value could be due to uncomfortable nature of the ICD insertion as well as the pain the patients were experiencing. In the ONI group two patients who had undergone laparotomies would have had an increased pain and recovery time further explaining the below norm results.

The study hypothesis is therefore accepted in that ONI, added to standard physiotherapy care, does not reduce the hospital length of stay or incidence of pulmonary complications for those who suffered thoracic trauma. The ONI group had a significant longer hospital length of stay but may be attributed to many factors and not specifically the ONI technique. Both groups also did not have any participants who experienced pulmonary complications.

The study hypothesis is also accepted that ONI, added to standard physiotherapy care, does not decrease the level of pain experienced by those who suffered thoracic trauma as there were no significant differences between group 1 (standard treatment) and group 2 (ONI). Both groups experienced a decrease in pain over the time period.

The study hypothesis is also accepted that ONI, added to standard physiotherapy care, does not improve the functional status or exercise capacity of those who suffered thoracic trauma. There were no significant differences between group 1 (standard treatment) and group 2 (ONI) for any of the functional outcomes assessed nor for the exercise capacity assessed.

There was general improvement in outcomes in both groups of the study. This could be attributed to the impact of age and injury severity on recovery from thoracic trauma. In this study the average age of the study population was 31 years old. Being younger generally has a positive impact on recovery from thoracic trauma due to several factors that enhance the body's ability to heal and adapt after injury (Sikander et al. 2020). This resilience enables quicker recovery from thoracic trauma. Younger bodies generally heal faster due to more efficient cell regeneration and repair mechanisms. This includes the healing of bone fractures, soft tissues, and damaged organs (Van De Kerkhof et al 1994). Younger patients are less likely to have chronic conditions such as heart disease, diabetes, or chronic obstructive pulmonary disease (COPD), which can complicate recovery (Battle et al. 2012). The absence of these conditions generally allows for a more straightforward healing process. Youth is often associated with better physical fitness, including stronger muscles and higher endurance. This functional reserve helps in coping with the physical stress of trauma and the demands of rehabilitation. Studies have shown that younger patients with thoracic trauma tend to have lower mortality rates compared to older patients (Qaqish et al. 2018).

The severity of the thoracic injury, including the number of ribs fractured, lung contusions, or the presence of flail chest, directly correlates with the complexity and duration of recovery (Battle et al. 2012). More severe injuries often require more intensive medical intervention, which can prolong hospital stays and recovery times. Severe thoracic injuries are more likely to result in complications such as acute respiratory distress syndrome (ARDS), pneumothorax, or haemothorax. These complications can significantly delay recovery and increase mortality risk (Sikander et al. 2020). In cases of severe thoracic trauma, surgical intervention may be required, which adds additional risks and extends recovery time. Surgical trauma and anaesthesia effects can further stress the body, particularly in older patients. Severe injuries often lead to greater functional impairment, impacting respiratory function, mobility, and overall quality of life. Recovery often involves prolonged rehabilitation, which can be particularly challenging for older individuals. Those with more severe injuries generally experience longer and more complicated recovery periods (Qaqish et al. 2018).

5.2.2 Study Limitations

During this study the main trauma ward had undergone renovations and the unit moved from a 60-bed ward to a smaller 40-bed ward. The patients who were admitted over and above the 40 beds in the new ward, moved to a separate building that was initially used for the management of COVID-19 patients. This ward was however not serviced by the physiotherapy department of CHBAH. This prolonged the data collection phase as well as patients were not recruited, lost to follow up or had extensive data missing in their forms.

On days where the physiotherapy department were short staffed and had a high patient load, participant recruitment decreased especially on weekends as there were only a limited number of physiotherapists working per weekend and assessment of study participants was only done during working hours which lead to patients being lost over the weekend to transfer to other wards.

During the education of the ONI technique, the participants were not reminded to clean or blow their nose prior to doing the technique.

CHAPTER 6

6. CONCLUSION

The research question that this study attempted to answer was does the application of ONI, added to standard physiotherapy care of patients with thoracic trauma influence their clinical outcomes. A single centre, single blinded, randomised trial was conducted, and participants were recruited over a 14-month period using a consecutive sampling technique.

One hundred and fifty participants were recruited in this study. The majority were male (n=139, 92.7%) and had a median age of 31 (IQR 26-39). Penetrating trauma had a prevalence of 80% and blunt trauma had a prevalence of 20%. The most common mechanism of injury was assault (n=124, 82.7%), followed by, MVAs (n=22,14.7%), PVAs (n=2,1.3%) and attempted suicide (n=2, 1.3%).

The first primary objective was to investigate the effects of ONI, added to standard physiotherapy management of patients with thoracic trauma, on their primary clinical outcomes (e.g. hospital length of stay, and incidence of pulmonary complications) and to compare this with the clinical outcomes of patients with thoracic trauma who did not receive ONI. Results showed that ONI added to standard physiotherapy management of patients with chest trauma does not influence their primary outcomes. The mean length of stay for group 1 (standard treatment) was shorter than for group 2 (ONI). Though the length of stay was significantly longer in the ONI group, there are a multitude of factors that may have affected the results such as the time taken from ordering an x-ray to the x-ray being done and results reported. The time trauma surgeons have to order patient discharges for the day depending on their workload. Another factor would be the compliance of performing the ONI exercise as only 45% completed most training sessions between the initial physiotherapy session and the date of discharge None of the participants developed any pulmonary complications in either group.

The second primary objective was to investigate the effects of ONI, added to standard physiotherapy management of patients with thoracic trauma, on their secondary clinical outcomes (e.g. level of pain, functional status, exercise capacity, and rate of adverse events) and to compare this with the same outcomes of patients with thoracic trauma who did not receive ONI. Results confirmed that pain decreased over time in both groups but did not have a significant difference. Functional status was assessed using the FSS-ICU mobility scale, 10-meter walk test and the TUG test. All participants had a FSS-ICU score of 35/35 upon first assessment. There were no significant differences in the functional outcomes assessed between group 1 (standard treatment) and group 2 (ONI). There were, however, gradual improvements through the days of assessment in both groups. None of the participants presented with any prior walking impairments at recruitment to the study. None of the participants in either group required any physical assistance to complete the 10-meter walk test at a comfortable or face pace at any of the assessment days. Exercise capacity was assessed using the one-minute sit to stand test and there were no significant differences in the exercise capacity assessed between group 1 (standard treatment) and group 2 (ONI). Both groups showed gradual improvement through the days of assessment.

Other objectives included describing the profiles (demographic and clinical) of patients who sustained thoracic trauma and were admitted to the trauma wards at CHBAH. Eighty percent (n=120) of the total cohort (n=150) had no rib fractures, while 19.3% (n=29) had 1-3 rib fractures on either side. Only one participant had more than three rib fractures bilaterally. Majority of the participants had a unilateral pneumothorax (54.7%, n=82), followed by unilateral haemo-/haemopneumothorax (42.7%, n=64). Almost all the participants (n=149) had an ICD inserted and two participants had an additional laparotomy, one for a diaphragm rupture and one for a spleen injury. Analgesia was only given to 43% of the total cohort.

The current study is the first study comparing the effect of ONI on hospital length of stay in patients with thoracic trauma. ONI is a new type of breathing technique that has been introduced to decrease inspiratory flow rate and regain breathing control for patients who are experiencing pain. The findings from this study suggest that ONI added to standard physiotherapy management in patients with thoracic trauma does not influence clinical outcomes.

6.1 RECOMMENDATIONS

6.1.1 Recommendations for Clinical Practice

It is recommended that deep breathing exercise continue to be a part of the physiotherapy management of thoracic trauma patients. Deep breathing exercises have many benefits such as increasing oxygenation, tidal volumes and functional residual capacity, alveolar recruitment, and the reversal of atelectasis (Pathmanathan et al. 2015). Deep breathing exercises are thought to help in the reduction of pain (Joseph et al. 2022). This in turn allows for early mobilisation, coughing and improves the well-being of patients (Mergner, 2017). It can also improve patient comfort and reduce the risk of secondary complications such as pneumonia, empyema, atelectasis, and respiratory failure (May et al. 2016).

6.1.2 Recommendations for Research

This study highlighted an area where there is a dearth of literature around the physiotherapy management of thoracic trauma and its effect on clinical outcomes. The preliminary results form a good bases for future research. It is recommended that further research of a similar nature be conducted at more clinical sites in patients with thoracic trauma to establish comparative results for the effect of ONI. It is recommended based on the fact that the population was young and not severely injured so one would like to see what the effect would be on an older population with complex thoracic trauma injuries. It is also recommended that further research to establish the clinometric properties of functional outcome measures for this patient population that are more sensitive to detect changes in scores e.g. responsiveness of outcome measures be done.

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APPENDIX A

- **THORACIC TRAUMA PHYSIOTHERAPY STUDY**

PATIENT INFORMATION CAPTURE FORM

Patient Hospital Number:

Date of Injury:

Date of Admission:

Location in Hospital (please tick off)
- Casualty ward ____
- Trauma ward ____
- High care unit ____
- Intensive care unit ____

Patient Information

Age ___	Height ____	Smoker: Yes/No
Gender ___	Weight ____	Chronic resp disease: Yes/No

Type of Chest Trauma Sustained

- Mechanism/type of injury
  - Blunt injury to thorax Yes / No
  - Penetrating injury to thorax Yes / No
  - Assault Yes/No
  - Attempted suicide Yes/No
  - Motor vehicle accident Yes/No
  - Pedestrian vehicle/cycle accident Yes/No
  - Other: __________________ Yes/No
- Rib fractures *(tick appropriate option/s)*
  - None ____
  - 1-3 ribs fractured Left side ____
  - 1-3 ribs fractured Right side ____
  - 4-6 ribs fractured Left side ____
  - 4-6 ribs fractured Right side ____
  - >3 ribs fractured bilaterally ____
  - Flail chest Left side ____
  - Flail chest Right side ____
- Intra-pleural abnormality *(tick appropriate option/s)*
  - None ____
  - Pneumothorax ____
  - Haemo-/haemopneumothorax unilateral ____
  - Haemo-/haemopneumothorax bilateral ____
- Pulmonary contusion Yes / No
- Specify if pulmonary contusion present *(tick)*
  - Unilateral contusion ____
  - Bilateral contusion ____
- Lung laceration Yes/No
- Diaphragm rupture Yes/No
- Sternal fracture Yes / No
- Other orthopaedic injuries Yes / No
- Specify other orthopaedic injuries if present

  ____
- Internal organ injury Yes / No
- Specify which organ/s were injured

  ____
- Neurological injury Yes / No
- Specify type of neurological injury if present

  ____

Medical Management (circle or tick)

- Analgesia Yes/No
- Sedation Yes/No
- Mechanical ventilation Yes/No
  - Date initiated ______
  - Date removed from MV ______
- Non-invasive ventilation (CPAP/BiPAP) Yes/No
  - Date initiated ______
  - Date removed from NIV ______
- Cough-Assist therapy Yes/No
  - Date initiated ______
  - Date removed from therapy ______
- High flow nasal cannulae (O_2 therapy) Yes/No
  - Date initiated ______
  - Date removed ______
- Spontaneous breathing Yes/No
  - On O_2 mask or cannulae Yes/No
    - Date initiated ______
    - Date removed ______
  - On room air Yes/No
    - Date initiated ______
- Other management received

  ____
  ____
  ____

Procedures Performed on Patient (circle or tick)

- Intercostal drain/s inserted

  Yes / No

  If yes: Unilateral ____

  Bilateral ____
- Surgical rib fixation done

  Yes/No

  If yes, date ______________

  Type of fixation ______________
- Other surgery received

  Yes/No

  If yes, date ______________

  Type of surgery ______________

Exercise Endurance Assessment

- Any walking impairments prior to hospital admission? Yes/No If Yes, describe: ____________
- Test used to assess exercise endurance

  Please specify: ____
- Results of first exercise endurance test assessment (HR, RR, SpO2 – before, immediately after, 3 mins after test)

  ____
  ____
  ____
- On which day since hospital admission was the first exercise endurance test done?

  ____
- Results on day of discharge from physiotherapy (HR, RR, SpO2 – before, immediately after, 3 mins after test)

  ____
  ____
  ____
- If no exercise test was performed, please explain the reasons for this:

  ____

Outcomes Assessed							
	Day 1	**Day 3**	**Day 5**	**Day 7**	**Day 10**	**Day 15**	**Day 20**
No physiotherapy treatment given (please supply reason for no physiotherapy)							
Level of pain at rest (The Wong-Baker FACES pain rating scale)							
Level of physical function (FSS-ICU)							
10-meter walk test ave comfortable walking speed							
10-meter walk test ave fast walking speed							
10-meter walk test level of assistance (comfortable walking speed)							
10-meter walk test level of assistance (fast walking speed)							
TUG test time (secs)							
Number of sit to stands in one minute							
Air Test							
Did adverse events occur during the session?	Yes/No Specify if yes	Yes/No Specify if yes	Yes/No Specify if yes	Yes/No Specify if yes	Yes/No Specify if yes	Yes/No Specify if yes	Yes/No Specify if yes

Outcomes Assessed							
	Day 25	**Day 30**					
No physiotherapy treatment given (please supply reason for no physiotherapy)							
Level of pain at rest (The Wong-Baker FACES pain rating scale)							
Level of physical function (FSS-ICU)							
10-meter walk test ave comfortable walking speed							
10-meter walk test ave fast walking speed							
10-meter walk test level of assistance (comfortable walking speed)							
10-meter walk test level of assistance (fast walking speed)							
TUG test time (secs)							
Number of sit to stands in one minute							
Air Test							
Did adverse events occur during the session?	Yes/No Specify if yes	Yes/No Specify if yes					

Complications

Did the patient develop any pulmonary complications during their stay in hospital? Yes/No

If yes, on which day of hospital stay was it diagnosed? ________________________________

What type of complication developed?

- Loss of lung volume or atelectasis Yes/No
- Diagnosed pneumonia Yes/No
- Respiratory distress necessitating NIV or high flow O2 therapy Yes/No
- Respiratory failure necessitating intubation and MV Yes/No

Discharge

- Date of discharge from in-patient physiotherapy services: ________________________________
- Date of discharge from hospital: ________________________________
- Does this patient need follow up in the out-patient physiotherapy department? Yes / No
- Was this patient discharged home OR to a rehabilitation centre OR to another hospital?

  ____

APPENDIX B

- **FSS-ICU**

Date: ________________ Patient No. ________________________

FUNCTIONAL STATUS SCORE FOR THE INTENSIVE CARE UNIT (FSS-ICU)

(Thursh, Rozek & Dekerlegand (2012), Parry et al. (2015), Main & Denehy (2016)

Functional activity	Score
Rolling	
Supine to sit	
Sitting on edge of bed	
Sit to stand	
Walking	
Total Score	

<u>Scoring system for rolling to sit to stand:</u>

0 – Unable to perform
1 – Total assistance
2 – Maximum assistance
3 – Moderate assistance
4 – Minimal assistance
5 – Supervision
6 – Moderate independence
7 – Complete independence

<u>Scoring system for walking:</u>

- Is the patient unable to attempt or complete the task of ambulation due to weakness? *If yes, score 0.*
- Can the patient walk less than 50 feet (15 m) with the assistance of one person *or* requires the assistance of two people to physically assist with any ambulation distance? *If yes, score 1.*
- Can the patient walk at least 50 feet (15 m) with the assistance of only one person? *If yes, score 2.*
- Can the patient walk a minimum of 150 feet (45 m) with moderate assistance of only one person (defined as the patient being able to perform between 50 to 74% of the walking effort)? *If yes, score 3.*
- Can the patient walk a minimum of 150 feet (45 m) with minimum assistance of only one person (defined as the patient being able to perform 75% or more of the walking effort)? *If yes, score 4.*
- Does the patient require only supervision or cueing in order to walk 150 feet (45 m) without physical help (the patient may use an assistive device as need)? *If yes, score 5.*

- Can the patient walk 150 feet (45 m) but requires the use of an assistive device such as a cane, walker, crutches, or use of a brace or prosthesis? *If yes, score 6.*
- Can the patient walk 150 feet (45 m) without using an assistive device such as a cane, walker, crutches, or use of a brace or prosthesis? *If yes, score 7.*

APPENDIX C

- **10-METER WALK TEST**

Date: ______________________ Patient No: ____________________________

10-meter walk test:

Objective parameters:

	Instruction to patient	Total time to complete 6m (secs)*	Walking speed (m/s)**	Level of assistance provided	Type of assistive device or bracing used
Comfortable walking speed – Trial 1	*"Walk at your own comfortable walking pace and stop when you reach the far mark"*				
Comfortable walking speed – Trial 2	*"Walk at your own comfortable walking pace and stop when you reach the far mark"*				
Fast walking speed – Trial 1	*"Walk as fast as you can safely walk and stop when you reach the far mark"*				
Fast walking speed – Trial 2	*"Walk as fast as you can safely walk and stop when you reach the far mark"*				

**The time is measured for the middle 6 m to allow for patient acceleration and deceleration.*
The time is started when any part of the leading foot crosses the plane of the 2-m mark.
The time is stopped when any part of the leading foot crosses the plane of the 8-m mark.
***6 m is divided by the total time (in seconds) taken to ambulate and recorded in m/s*

Average comfortable walking speed: __________ m/s
Average fast walking speed: __________ m/s

The level of physical assistance documented using an ordinal 7- point scale is described below. 1 = total assistance [patient performs 0%-24% of task]*
2 = maximum assistance [patient performs 25%-49% of task]
3 = moderate assistance [patient performs 50%-74% of task]
4 = minimum assistance [patient performs 75%-99% of task]
5 = supervision [patient requires stand-by or set-up assistance; no physical contact is provided]
6 = modified independent [patient requires use of assistive devices or bracing, needs extra time, mild safety issues]
7 = independent
*Note: if your patient requires total assistance, a score of 0 should be documented

Subjective parameters:

Pain at completion of test: Yes Δ No Δ
Shortness of breath (Modified Borg Scale) at completion of test: Yes Δ No Δ

APPENDIX D

- **TIMED UP AND GO TEST (TUG) - SCORING SHEET**

Patient Number : ______________________

Date : ___________

Time (seconds) : ___________

Assistive Device Used:

None : ____

Cane : ____

Walker : ____

Other : ____

Other:

stopped to rest : ____

impaired cognition : ____

Risk for Falls:

High Risk (>13.5 seconds) : ____

None/low/moderate: (<13.5 seconds) : ____

APPENDIX E

- **ONE MINUTE SIT TO STAND TEST**

Date: ______________________ Patient Number: ________________________

Number of sit to stand repetitions in one minute: _______

APPENDIX F

- **WONG-BAKER FACES PAIN RATING SCALE**

Date: _____________________ Patient Number: _______________________

APPENDIX G

- **ONI DIARY**

ONI Diary (Please tick when you have done your ONI breathing today)

Patient No. __________________

Day 1	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 2	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 3	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 4	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 5	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 6	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 7	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 8	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 8	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 9	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 10	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 11	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 12	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 13	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 14	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 15	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 20	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 25	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____
Day 30	06:00 ____	08:00 ____	10:00 ____	12:00 ____	14:00 ____	16:00 ____	18:00 ____	20:00 ____

APPENDIX H

- **ONI TECHNIQUE AND SHOULDER GIRDLE RELAXATION EXERCISES**

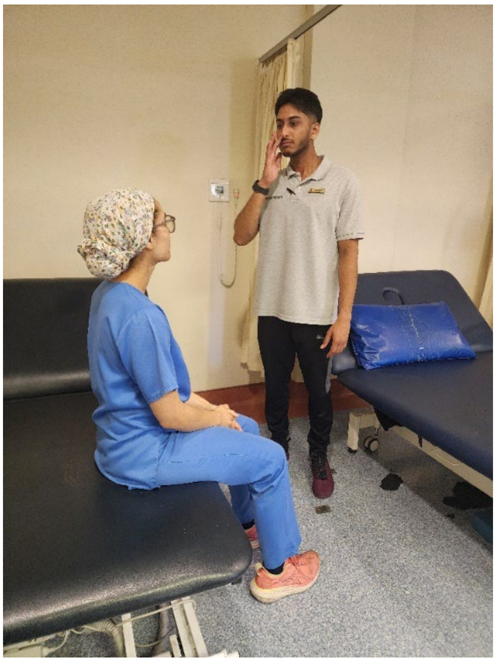

Figure 3.1: Physiotherapist teaching the model how to perform the ONI technique

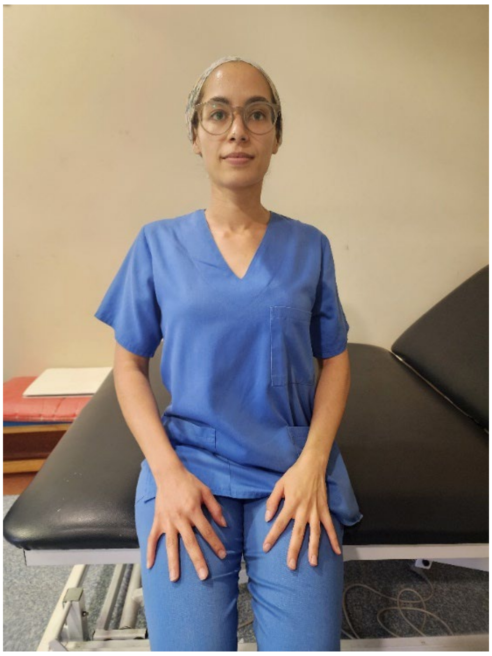

Figure 3.2: Model performing shoulder girdle relaxation exercises prior to ONI

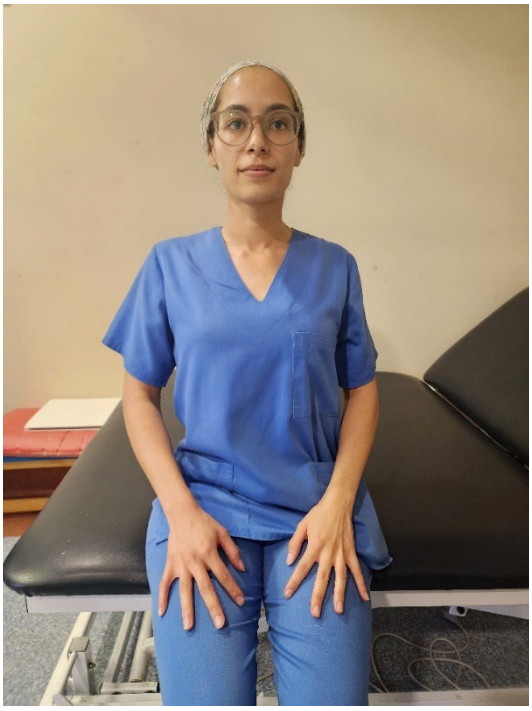

Figure 3.3: Model performing shoulder girdle relaxation exercises prior to ONI.

Figure 3.4: Model practicing the ONI technique.

APPENDIX I

- **HUMAN RESEARCH ETHICS (MEDICAL) COMMITTEE CLEARANCE CERTIFICATE**

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

R14/49 Prof. Heleen Van Aswegen

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M200222

NAME: (**Principal Investigator**)	Prof Heleen Van Aswegen
DEPARTMENT:	Physiotherapy
PROJECT TITLE:	Physiotherapy management of patients who sustained thoracic trauma: a multi-centre study.
DATE CONSIDERED:	28/02/2020
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	N/A
APPROVED BY:	CB Penny Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	27/06/2020

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions.Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in **June** and will therefore be due in the month of **June** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature   Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX J

- **STUDY INFORMATION SHEET (RANDOMISED TRIAL)**

Study Title: The effect of one nostril inhalation, added to standard physiotherapy management, on hospital length of stay and pulmonary complications in patients with thoracic trauma: a randomised trial.

Good day,
I, Sameer Tootla, am conducting research on the effect of one nostril inspiration (ONI) on the clinical outcomes of patients who sustained thoracic trauma. Research is a process used to answer a specific question and gain new knowledge. In this study, I want to review what effect ONI as a rehabilitation strategy has on the clinical outcomes of patients who sustained an injury to their thorax due to trauma. I am therefore asking/ inviting you to participate in this research study.

What does the study involve?
If you consent to participate in this research study, you will be assigned to a specific treatment group. The standard care group will receive standard physiotherapy treatment. This could include getting up out of bed, walking, cycling, and exercising in the ward while taking deep breaths. The study participants assigned to the ONI plus standard care group will receive standard physiotherapy treatment and will also be taught how to perform ONI. The treating physiotherapists daily will review your level of pain and level of physical function. This assessment could take 10 minutes. On the first, third and fifth day of your hospital admission the physiotherapist will also ask you to do two walking tests and a sit to stand test to determine your walking ability, walking speed, balance, strength, and endurance. The two walking tests could take an additional 10 minutes to perform and are called the 10-meter walk test, the Timed Up and Go Test and the one-minute sit to stand test. The research assistant or a researcher will review your clinical records to see whether you developed any lung complications such as a chest infection during your hospital stay. In addition, I will review how many days you were in hospital and whether you spend days in the intensive care unit.

Are there any risks involved when you participate in the study?
If you are part of the treatment group that includes ONI, you might become a little bit dizzy when taking too many deep breaths. If you stop and rest for a few minutes the dizziness should go away.

Please note that you are not obliged to take part in this study, it is voluntary. Refusal to take part in the study will not affect your care given in the hospital.

Are there any benefits of participating in the study?
There are no added benefits to you participating in this research study if you are part of the control group but if you are part of the ONI group the added breathing exercise, (ONI) may improve your lung volumes. You will not receive payment for agreeing to take part in the study.

Will my information be kept confidential?

Your personal information that can identify you e.g., hospital number will be treated in the strictest confidence and will only be available to the researchers. The information collected during the study will be stored safely (locked away) in the physiotherapy department at the University for two years. Data analysis will be done on the information collected and your information will be anonymous, as your information will be processed with a specific study code. The final findings of the research study will be published as an article in an academic journal and will be made available to study participants on request.

If you need to get in touch with the researchers during the study period, please use the details provided below.
Sameer Tootla
0832878813

This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg. A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

Thank you for reading this Study Information Sheet.
Date: June 2021

APPENDIX K

- **SUBJECT CONSENT FORM (RANDOMISED TRIAL)**

Study Title: The effect of one nostril inhalation, added to standard physiotherapy management, on hospital length of stay and pulmonary complications in patients with thoracic trauma: a randomised trial.

<u>**Informed Consent**</u>

- I hereby confirm that I have been informed by the researcher/ research assistant about the nature, conduct, benefits, and risks of this study.
- I have also received, read, and understood the above written information document regarding the research study.
- I am aware that the results of the study, including personal details regarding my gender, age and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researchers/ research assistants on their behalf.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

PARTICIPANT:

______________	__________________________	____________
Printed Name	Signature / Mark or Thumbprint	Date and Time

I, researcher/ research assistant herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

RESEARCHER/ RESEARCH ASSISTANT:

______________	__________________________	____________
Printed Name	Signature	Date and Time

APPENDIX L

- **COMPUTER-GENERATED RANDOMISATION LIST (WWW.RANDOMISER.ORG)**

Randomisation sequence - Phase 2 Chest trauma project (CHBAH) - Sameer Tootla RCT

Intervention allocation: ONI = Group 1, Standard Physio = Group 2

August 2022: Ward 1 = H3; ward 6 = outliers in wards 8 & 10

Weeks	Ward ID	Allocation of intervention	
1	1	Group 1	
	6	Group 1	
4	1	Group 1	
	6	Group 1	
7	1	Group 1	
	6	Group 1	
10	1	Group 2	
	6	Group 1	
13	1	Group 2	1 August 2022 onwards
	6	Group 2	
17	1	Group 1	
	6	Group 1	
20	1	Group 1	
	6	Group 1	
23	1	Group 2	
	6	Group 1	
26	1	Group 1	
	6	Group 1	
29	1	Group 2	
	6	Group 1	
32	1	Group 1	
	6	Group 2	
35	1	Group 2	
	6	Group 2	
38	1	Group 2	
	6	Group 2	
41	1	Group 1	
	6	Group 1	
44	1	Group 1	
	6	Group 1	
47	1	Group 1	Updated 13 March 2023
	6	Group 1	
50	1	Group 1	
	6	Group 2	
53	1	Group 2	
	6	Group 2	
56	1	Group 1	
	6	Group 2	
59	1	Group 1	
	6	Group 1	
62	1	Group 2	
	6	Group 2	
65	1	Group 1	
	6	Group 2	

APPENDIX M

- **INTRODUCTION TO RESEARCH ETHICS CERTIFICATE**

TRREE

Zertifikat

Certificado

Certificat

Certificate

Promouvoir les plus hauts standards éthiques dans la protection des participants à la recherche biomédicale
Promoting the highest ethical standards in the protection of biomedical research participants

Clinical Trials Centre
The University of Hong Kong

Certificat de formation - Training Certificate

Ce document atteste que - this document certifies that

Sameer Tootla

a complété avec succès - has successfully completed

Introduction to Research Ethics

du programme de formation TRREE en évaluation éthique de la recherche
of the TRREE training programme in research ethics evaluation

Release Date: 2021/05/18
CID : CXpy9VzgFB

Professeur Dominique Sprumont
Coordinateur TRREE Coordinator

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[REV : 20170310]

APPENDIX N

- **PAN AFRICAN CLINICAL TRIALS REGISTRY (PACTR) CONFIRMATION LETTER**

14 January 2022

To Whom It May Concern:

RE: The effect of one nostril inhalation, added to standard physiotherapy management, on hospital length of stay and
pulmonary complications in patients with thoracic trauma: a randomised trial.

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR202201706227234.**

Please be advised that you are responsible for updating your trial, or for informing us of changes to your trial.

Additionally, please provide us with copies of your ethical clearance letters as we must have these on file (via email or post or by uploading online) at your earliest convenience if you have not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.org Project Manager
+27 021 938 0835

PACTR
PAN AFRICAN CLINICAL TRIALS REGISTRY

The South African Medical Research Council
Cochrane South Africa | PO Box 19070, Tygerberg, 7505
Tel: +27 (0)21 938 0438 | Email: cochrane@mrc.co.za | Web: www.southafrica.cochrane.org

APPENDIX O

- **THE CONSORT 2010 CHECKLIST**

Section/topic	Item number	Checklist item	Page Number
Title and abstract	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions	ii
Introduction			
Background and objectives	2a	Scientific background and explanation of the rationale	1
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	24
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	25
	4b	Settings and locations where the data were collected	24
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	27
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	26
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined?	25
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomization			
Sequence generation	8a	The method used to generate the random allocation sequence	28
	8b	Type of randomization; details of any restriction (such as blocking and block size)	28
Allocation concealment mechanism	9	The mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	28
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	28
Blinding	11a	If done, who was blinded after assignment to interventions (e.g., participants, care providers, those assessing outcomes) and how	28
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	28
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned received intended treatment and were analyzed for the primary outcome	31
	13b	For each group, losses and exclusions after randomization, together with reasons	31
Recruitment	14a	Dates defining the periods of recruitment and follow-up	31
	14b	Why the trial ended or was stopped	31
Baseline data	15	A table showing the baseline demographic and clinical characteristics for each group	32
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	31
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	38
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, the multiplicity of analyses	54
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	48
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	48
Other information			
Registration	23	Registration number and name of trial registry	30
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as the supply of drugs), the role of funders	N/A

APPENDIX P

- **TURN-IT-IN REPORT**

Sameer Tootla Dissertation

ORIGINALITY REPORT

14%	11%	9%	3%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

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