THE USE OF THE CPAX TOOL IN A SOUTH AFRICAN INTENSIVE CARE UNIT: CLINICAL OUTCOMES AND PHYSIOTHERAPISTS' PERCEPTIONS

Megan Whelan

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DECLARATION

I, Megan Whelan, declare that this research report is my own work. It is being submitted for the degree of Masters of Science in Physiotherapy at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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Megan Whelan

ABSTRACT

Background: There is limited research available on the use of outcome measures in intensive care units (ICU) in a South African setting.The Chelsea Critical Care Physical Assessment tool (CPAx) is a measure of morbidity related to physical function and assesses respiratory function and functional abilities of critically ill patients.

Objectives: The objectives of this study were to establish the effect of the use of the CPAx tool on ICU and hospital length of stay (LOS) in the care of critically ill patients; to establish the usefulness of the CPAx tool according to patient admission diagnosis; to determine if a relationship exists between CPAx scores and severity of illness or general morbidity during ICU admission; and to establish physiotherapists' perceptions and views towards the use of the CPAx tool in their daily clinical practice in ICU.

Design: The study consisted of two parts. Part one was a quasi-experimental design with a historical matched control group. Part two was a survey-based design.

Methods: The study took place in a South African public sector hospital. Twenty six participants each were recruited into the experimental and control groups. Participants from the control group were matched with participants in the experimental group according to age, gender, diagnosis and acute physiology and chronic health evaluation (APACHE) II scores. CPAx scores and sequential organ failure assessment (SOFA) scores were calculated for participants in the experimental group on alternate weekdays during their ICU stay. Comparisons of ICU and hospital LOS between the study participants and historical control group were done using an independent t-test. Pearson's correlation coefficient was used to determine if a relationship existed between CPAx scores, APACHE II scores or SOFA scores. A p-value ≤ 0.05 was deemed statistically significant. A questionnaire was developed and was completed by the research assistants who administered the CPAx tool to participants in the experimental group in order to determine their perceptions of the tool.

Results: The mean age for the CPAx group was 37.88 (±13.37) years and for the control group was 37.81 (±12.21) years. The CPAx group consisted of 14 (53.8%) participants who underwent surgical procedures and 12 (46.2%) participants with traumatic orthopaedic injuries. The control group consisted of 14 (53.8%) participants who underwent surgical procedures and 12 (46.2%) participants with traumatic orthopaedic injuries. The mean initial SOFA score for the CPAx group was 2.42 (±1.79) and for the control group was 4.15 (±2.6). A p=0.03 indicates that there was a statistically significant

difference between the two groups with regards to initial SOFA scores. The mean SOFA score at ICU discharge for the CPAx group was 1.80 (±0.42) and for the control group was 2.87 (±1.81). A p=0.05 indicates that there was a statistically significant difference between the two groups with regards to SOFA scores at ICU discharge.

The mean initial CPAx score for the experimental group was 29.73 points (±14.81) and the mean CPAx score at ICU discharge was 36.15 (±8.33). The mean CPAx scores changed by 9.45 points between admission and discharge from ICU for participants who underwent surgical procedures and the mean CPAx scores changed by 3.9 points between admission and discharge from ICU for participants who sustained traumatic orthopaedic injuries. The mean ICU LOS for the CPAx group was 5.84 days (±7.43) and for the control group was 4.56 days (±5.25). The mean hospital LOS for the CPAx group was 17.43 (±16.68) days and for the control group was 19.31 days (±15.79); however, in both cases differences were not statistically significant.

APACHE II scores had a very weak negative correlation with initial CPAx scores. APACHE II scores had a very weak positive correlation with CPAx scores at ICU discharge. There was a statistically significant difference between the two groups with regards to initial SOFA scores (p=0.05). Initial SOFA scores had a statistically significant moderate negative correlation with initial CPAx scores (r=-0.45, p=0.02). Initial SOFA scores had a weak negative correlation with CPAx scores at ICU discharge. Initial CPAx scores had a moderate positive correlation with SOFA scores at ICU discharge. CPAx scores at ICU discharge had a very strong statistically significant positive correlation with SOFA scores at ICU discharge (r=0.80, p=0.05).The CPAx tool proved to be more responsive in a surgical population than in a trauma population. Clinicians had positive perceptions of the CPAx tool in the management of critically ill patients.

Discussion: Participants in the CPAx group were well matched with those in the historical control group with regards to age, gender, diagnoses and severity of illness. Those in the CPAx group had lower extent of organ dysfunction than those in the control group which might account for their shorter period of hospitalisation. Patients with a higher risk for mortality on admission into the ICU displayed lower functional abilities and, in turn, lower CPAx scores were measured. A greater change in CPAx scores was observed for participants recovering from surgical interventions compared to those recovering from traumatic orthopaedic injuries. Participants with low morbidity at the time of ICU admission seemed to have a greater ability to perform functional activities during their ICU stay. Limitations of the study included a small patient sample, a limited number of research assistants as well as lack of content validation of the questionnaire used. A multi-centre trial on the use of CPAx in ICU patient management

could yield a wider perception of physiotherapists regarding the usefulness of the tool in daily clinical practice. Measuring the effect of the CPAx tool on participants' length of mechanical ventilation could also be an interesting clinical outcome to consider.

Conclusion: The data presented in this study show that the use of the CPAx tool does not have an influence on ICU and hospital LOS in a small sample of surgical and trauma participants. The tool appears to be more useful when used in the care of patients who are recovering from surgical procedures rather than those who sustained complex traumatic injuries. Physiotherapy clinicians that participated in the study supported the use of the CPAx tool in this single-centre trial and generally had positive perceptions towards the use of the tool.

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LIST OF ABBREVIATIONS

ACIF	- Acute Care Index of Function
APACHE	- Acute Physiology and Chronic Health Evaluation
AusTOMs	- Australian Therapy Outcome Measure
CCU	- Critical Care Unit
CI	- Confidence Interval
CIM	- Critical Illness Myopathy
CIP	- Critical Illness Polyneuropathy
CPAx	- Chelsea Critical Care Physical Assessment
FIM	-Functional Independence Measure
FSS-ICU	- Functional Status Score for the Intensive Care Unit
GCS	- Glasgow Coma Scale
ICC	- Intra-Class Correlation Coefficient
ICU	- Intensive Care Unit
ICU-AW	- Intensive Care Unit Acquired Weakness
IMS	- Intensive Care Unit Mobility Scale
LOS	- Length of Stay
ORIF	- Open Reduction Internal Fixation
PFIT	- Physical Function in Intensive Care Unit Test
PFIT-s	- Physical Function in Intensive Care Unit Test-Scored
SAPS	- Simplified Acute Physiology Score
SF-36	- 36 Item Short Form Health Survey
SD	- Standard Deviation
SOFA	- Sequential Organ Failure Assessment
SPPB	- Short Physical Performance Battery
SPSS	- Statistical Package for Social Sciences
TREND	- Transparent Reporting of Evaluations with Nonrandomised Designs
URACE	-University of Rochester Acute Care Evaluation
VAP	- Ventilator Acquired Pneumonia

CHAPTER 1

1. INTRODUCTION

1.1 BACKGROUND

Recently there has been a growing worldwide trend towards early rehabilitation of patients in the intensive care unit (ICU) (Bailey, et al., 2007; Thomsen, et al., 2008; Truong, et al., 2009).This has been implemented in order to combat the negative effects associated with critical illness (Bailey, et al., 2007). There are very few rehabilitative outcome measures that can be used in ICU to measure patients' functional abilities as the majority of them are not applicable in a critical care setting (Corner, 2012). The Chelsea Critical Care Physical Assessment tool (CPAx) is an outcome measure that assesses respiratory function as well as functional abilities of critically ill patients (Corner, et al., 2013). The aim of this study is to explore whether the use of CPAx in critically ill patients has an effect on their clinical outcomes. The second aim of this study is to determine physiotherapists' perceptions towards the use of the CPAx tool in a South African ICU setting.

Intensive care unit acquired weakness (ICU-AW) is a common debilitating condition associated with prolonged critical illness (Saxena and Hodgson, 2012). Risk factors include multiple organ dysfunction, sepsis and prolonged length of mechanical ventilation (Saxena & Hodgson, 2012). Common complications linked with ICU-AW include difficulty with weaning from mechanical ventilation, increased hospital length of stay (LOS), long term functional impairments and disability as well as reduced health-related quality of life (Corner, 2012).

Marques et al. (2006) states that outcome measures are vital in order to determine patients' responses to treatment given, to evaluate the usefulness of the treatment given as well as to make a comparison between different treatment interventions. In a study performed by Maher and Williams (2005) that examined factors influencing physiotherapists' use of outcome measures in the management of patients who underwent a lung transplant, it was found that 83% of physiotherapists do not use outcome measures as part of their routine patient management due to time constraints as well as lack of equipment. Although there are many rehabilitation tools used to measure physical disability, functional outcome measures are not commonly used by physiotherapists in critical care settings (Corner, 2012). Most rehabilitation tools are time consuming to use, lack specificity and are not appropriate for patients in the ICU (Corner, 2012).

The CPAx tool is an outcome measure designed to assess 10 domains of physical ability including: respiratory function, cough, bed mobility, supine to sitting on the edge of the bed, dynamic sitting, sit to stand, standing balance, transferring from bed to chair, stepping and grip strength (Corner, et al., 2013). Each domain is graded from 0 (complete dependence) to 5 (complete independence) (Corner, et al., 2014). A total score out of 50 is then obtained and is depicted in pictorial form on a “radar” or “spider diagram” chart. The tool is simple to use and was designed as a bed-side scoring system in order to monitor patients’ functional abilities and identify problem areas daily (Corner, et al., 2013). Once problem areas have been identified, a specific rehabilitation programme can be designed to meet the needs of the patient (Corner, et al., 2013).

Although it is important to measure function in the ICU, it is also vital to be able to measure patients’ risk for morbidity and mortality. The Acute Physiology and Chronic Health Evaluation (APACHE II) score was designed to assess a patient’s physiological state and is used as a predictor of mortality in critically ill patients in the first 24 hours following admission into the ICU (Dosset, et al., 2009; Mica, et al., 2013; ClinCalc.com, 2015). Numerical scores are assigned to different clinical and biochemical domains including white cell count, Glascow Coma Scale (GCS), temperature, mean arterial blood pressure, haematocrit, heart rate, respiratory rate, oxygenation, arterial pH, serum potassium, serum sodium and serum creatinine (Dosset, et al., 2009; ClinCalc.com, 2015). High scores indicate an increased illness severity and therefore a higher risk for mortality (Dosset, et al., 2009). The Sequential Organ Failure Assessment (SOFA) score is commonly used to determine the degree of organ dysfunction and sepsis severity of patients in intensive care units (Bale, et al., 2013). The SOFA score assesses function of six t organ systems namely the respiratory, coagulation, renal, liver, cardiovascular and neurological systems (Bale, et al., 2013). The tool is a useful predictor of morbidity in critical care (Bale,et al., 2013; ClinCalc.com, 2014).

In a validation pilot study performed by Corner et al. (2013), CPAx was shown to have a significant negative correlation with patients’ SOFA scores. This suggests that as patients’ CPAx scores increase, so their risk for organ dysfunction is reduced (Corner, et al., 2013). The study also revealed that the higher patients’ CPAx scores are, the shorter the length of mechanical ventilation becomes (Corner, et al., 2013). This information may be the building block for this study which looks to assess whether the use of CPAx in the treatment of critically ill patients has an effect on length of stay (LOS) in ICU and in the hospital.

1.2 STATEMENT OF PROBLEM AND JUSTIFICATION FOR RESEARCH

To date rehabilitation-based outcome measures have not been well utilised in South African physiotherapy ICU practice. This may be due to time constraints and high patient caseloads but this has not been confirmed through research. It is important to identify a suitable outcome measure that is easy to administer to patients in ICU and assists physiotherapy clinicians to identify individual patient needs and develop appropriate goal-directed physiotherapy interventions to improve the clinical outcomes of patients in a South African ICU setting. By assessing physical function of critically ill patients, goal-orientated early mobilisation and rehabilitation is encouraged. The CPAx tool seems to be a user-friendly and an easily understandable tool to use in the ICU setting.

1.3 RESEARCH QUESTIONS

1.3.1 Does the use of the CPAx tool in the care of critically ill patients have an influence on their clinical outcomes?

1.3.2 What are physiotherapists' perceptions and views towards the use of the CPAx tool in the care of critically ill patients?

1.4 SIGNIFICANCE OF RESEARCH

There is evidence that shows that early mobilisation of patients in ICU significantly reduces the harmful effects of prolonged critical illness (Bailey, et al., 2007; Thomsen, et al., 2008; Truong, et al., 2009). Use of the CPAx tool as part of physiotherapy patient management in ICU has been shown to have a negative correlation with length of mechanical ventilation and morbidity (Corner, et al., 2013). The CPAx is easy to use and assists physiotherapy clinicians to assess physical function of patients in a general intensive care unit setting (Corner, et al., 2013). By measuring patients' functional progress objectively through assessment of CPAx scores, patient specific rehabilitation goals can be created to ensure appropriate progression of rehabilitative care which may improve clinical outcomes such as ICU and hospital LOS. This study investigates the effect of the CPAx tool on the clinical outcomes of patients who underwent surgical procedures or who sustained traumatic injury and were admitted to ICU. The incidence of trauma in South Africa is high and a large number of patients with trauma-related injury or surgery are regularly admitted to the critical care division of Chris Hani Baragwanath Academic hospital. If it is found that the use of the CPAx tool as part of physiotherapy management of patients in these ICUs impacts positively on patients' clinical outcomes and is perceived to be easy to administer, its use in other South African ICU populations may be encouraged.

1.5 RESEARCH AIMS

- To determine if the use of the CPAx tool in the care of critically ill patients has an influence on their clinical outcomes.

- To determine physiotherapists' perceptions and views towards the use of the CPAx tool in the care of critically ill patients.

1.6 RESEARCH OBJECTIVES

- To establish the effect of the use of the CPAx tool on LOS in ICU and in the hospital in the care of critically ill patients.

- To establish the usefulness of the CPAx tool according to patient admission diagnosis.

- To determine if a relationship exists between scores obtained from the CPAx tool and those obtained from the APACHE scoring system.

- To determine if a relationship exists between scores obtained from the CPAx tool and those obtained from the SOFA scoring system.

- To establish physiotherapists' perceptions and views towards the use of the CPAx tool in their daily clinical practice in ICU.

1.7 TYPE OF STUDY

The study consisted of two parts. Part one was a quasi-experimental design with a historical matched control group. Part two was a survey-based design.

CHAPTER 2

2. LITERATURE REVIEW

Information shared in this literature review was identified through searches performed on the following search engines: Google Scholar, Science Direct, Clinical Key, EBSCO Host (CINAHL Plus), PubMed, Springer Link and Scopus. The following search terms were used: 'CPAx', 'Chelsea Critical Care Physical Assessment tool', 'early mobilisation in ICU', 'benefits of early mobilisation in ICU', 'intensive care unit acquired weakness', 'ICU-AW' 'APACHE', 'SOFA', 'SAPS', 'injury severity scores', 'physiotherapy + outcome measures + ICU' 'rehabilitation outcome measures in ICU', 'organ dysfunction scores in ICU'. English language articles were sourced and used.

The burden of disease in developing countries such as South Africa is a growing concern. As patient management improves, there are more survivors of critical illness than there were in the past (Schweickert & Kress, 2011). This in turn has resulted in the emergence of conditions such as intensive care unit acquired weakness which leads to severe long-term functional impairments (Schweickert & Kress, 2011). We are constantly searching for ways to improve provision and monitoring of health care services in our country. Where resources and funds allow, physiotherapists in South Africa seem to be following trends in current research especially with regards to management of patients in the intensive care unit. Although early mobilisation in the ICU has been researched in this country, the number of studies in this area is limited. Outcome measures are tools that are under-utilised in South African hospitals particularly in the public sector. To the researcher's knowledge, there are no South African studies available that examine the use of rehabilitative outcome measures in the management of critically ill patients.

2.1 COMPLICATIONS OF BED REST AND CRITICAL ILLNESS

Immobility has been associated with many complications including those of the respiratory system (Goldhill, et al., 2007). The respiratory complications experienced by immobile patients in the ICU include pneumonia, atelectasis, pulmonary emboli and acute respiratory distress syndrome (Goldhill, et al., 2007).

Intensive care unit acquired weakness is also a well-known complication of critical illness associated with severe short term and long term functional limitations (Schweickert and Kress, 2011; Thrush, et al., 2012; Wieske, et al., 2015). Due to increasing numbers of ICU survivors, more health care workers are being exposed to patients with ICU-AW outside of the ICU (Kress

& Hall, 2014). This means that more post-ICU rehabilitation is taking place (Kress & Hall, 2014). Intensive care unit acquired weakness can be defined as generalised muscle weakness that has developed in the absence of any condition or diagnosis aside from the underlying critical illness (Stevens, et al., 2009). Intensive care unit acquired weakness affects skeletal muscle including the diaphragm (Li, et al., 2013). Intensive care unit acquired weakness has been associated with risk factors such as poor glycaemic control, sepsis, multi-organ failure, mechanical ventilation, glucocorticoid use and exposure to neuromuscular blocking agents (Stevens, et al., 2009). Assessment of patients with ICU-AW reveals symmetrical limb and diaphragm weakness and decreased muscle tone (Stevens, et al., 2009). Deep tendon reflexes may be normal, reduced or absent; however, cranial nerves are normally spared (Stevens, et al., 2009). These patients often suffer from associated respiratory failure and are generally difficult to wean from mechanical ventilation (Stevens, et al., 2009; Kress and Hall, 2014).

Critical illness polyneuropathy (CIP) and critical illness myopathy (CIM) are pathological processes associated with ICU-AW. Patients that are diagnosed with CIP have the same symptoms as those diagnosed with ICU-AW as well as electrophysiological evidence of a sensorimotor axonal polyneuropathy (Stevens, et al., 2009). Such evidence includes reduced amplitude of compound muscle action potentials and sensory nerve action potentials with normal or slightly decreased conduction velocity of the nerves (Batt, et al., 2013). Primary axonal degeneration of peripheral nerve sensory and motor fibres occurs in CIP (Batt, et al., 2013). Creatine kinase levels are normal in these patients (Kress & Hall, 2014). Patients with CIP present with distal loss of pain, temperature, proprioception and vibration sensation; and deep tendon reflexes are either absent or reduced (Stevens, et al., 2009; Batt, et al., 2013). Critical illness myopathy has been described as a form of skeletal muscle dysfunction that occurs as a result of reduced muscle mass and impaired contractility combined (Batt, et al., 2013). Muscle atrophy occurs as a result of a discrepancy between muscle proteolysis and protein synthesis with a remarkable loss of myosin relative to actin (Batt, et al., 2013). Problems with muscle contractility and force generating capacity in CIM may occur due to oxidative stress, mitochondrial dysfunction, lack of mucous membrane excitability and impaired excitation-contraction coupling (Batt, et al., 2013). Patients with CIM have elevated serum creatine kinase levels, weak and flaccid limbs, reduced or normal deep tendon reflexes and difficulty in weaning from mechanical ventilation; however the patient's sensation is spared (Batt, et al., 2013) It has been suggested that CIM and CIP do not occur in isolation but form rather an integral part of the processes associated with multiple organ dysfunction (Batt, et al., 2013).

In a study by Wieske et al. (2015), the authors compared post-ICU mortality and physical functional levels between patients with and without ICU-AW at six months post discharge. Intensive care unit acquired weakness was associated with lower functional abilities and higher mortality rates at six months following ICU discharge (Wieske, et al., 2015).

Intensive care unit acquired weakness is a multi-factorial process and it has strong associations with prolonged bed rest and immobility (Li, et al., 2013). Historically, mechanically ventilated patients are kept in bed partly due to the severity of their underlying illness as well as sedation protocols that are followed (Li, et al., 2013). Early mobilisation of critically ill patients is a concept in its infancy that is becoming a global trend in an effort to combat the negative effects of bed rest and immobility (Amidie, 2012). It could potentially be used to prevent ICU-AW provided that the patients are physiologically stable and that there are no contraindications to early mobilisation (Hanekom, et al., 2011; Amidie, 2012).

2.2 EARLY MOBILISATION OF PATIENTS IN ICU

There have been multiple studies published investigating the safety, practicality and benefits of early mobilisation of critically ill patients (Bailey, et al., 2007; Morris, et al., 2008). Bailey et al (2007) investigated the feasibility of early activity in patients with respiratory failure that required mechanical ventilation and also considered the safety associated with it. The results of their prospective cohort study showed that early mobilisation is a candidate therapy that can be used to prevent the neuromuscular complications associated with critical illness (Bailey, et al., 2007). After performing a prospective cohort study, Morris et al. (2008) concluded that early rehabilitation is safe and feasible, does not increase hospital costs and is also associated with reduced ICU LOS and hospital LOS. Clark et al. (2013) suggested that early mobilisation of patients in a trauma/burns population is also safe and effective. This rehabilitation strategy can also lead to reduced airway, pulmonary and vascular complications (Clark, et al., 2013).

Hanekom et al. (2011) used 28 draft algorithm statements to develop an evidence-based clinical management algorithm for early rehabilitation and mobilisation of critically ill patients. The authors achieved this using an electronic three round Delphi process (Hanekom, et al., 2011). The algorithm was developed by an international inter-professional panel, is the first of its kind and has been cited by many researchers since its publication (Hanekom, et al., 2011).

Introduction of an early rehabilitation team in a European ICU was associated with improved patient mobility at ICU discharge, decreased mechanical ventilator days, reduced ICU length of

stay and reduced hospital length of stay (McWilliams, et al., 2015). Schweickert et al. (2009) established that early physiotherapy and occupational therapy combined with breaks in sedation are associated with better functional outcomes, shorter period of delirium and shorter duration of mechanical ventilation. It has also been shown that early rehabilitation of critically ill patients is safe and well tolerated with few adverse incidents (Bailey, et al., 2007; Schweickert, et al., 2009). Although early mobilisation strategies in ICU are part of a growing global clinical and research trend, the use of functional/rehabilitation outcome measures in ICU is minimal(Corner, 2012). The efficacy of early mobilisation of critically ill patients in specific patient populations needs to be further researched using appropriate outcome measures and instrumentation (Li, et al., 2013).

2.3 REHABILITATION OUTCOME MEASURES IN ICU

Outcome measures are used to evaluate the effectiveness of patient management (Maher & Williams, 2005). Maher and Williams (2005) examined the outcome measures used by physiotherapy clinicians in the care of patients who underwent lung transplants in Australia and New Zealand. The authors also investigated the factors that have an influence on the use of outcome measures in this patient group (Maher & Williams, 2005). A cross-sectional, descriptive qualitative design was used to survey the clinicians working with the above-mentioned patients (Maher & Williams, 2005). Results of the study showed that time constraints, lack of reliability and validity and equipment requirements were the most commonly reported problems with outcome measure use in the study (Maher & Williams, 2005). The most commonly reported outcome measures were those used to assess exercise tolerance, dyspnoea and the ability to carry out activities of daily living (Maher & Williams, 2005).

According to Corner (2012) and Bisset et al (2016), there is a wide variety of outcome measures available to assess physical disability; however, these are problematic when used in a population of critically ill patients. These tools lack specificity as they were not designed for patients in a critical care setting (Corner, 2012). There are a few measures available; however, most of the current tools are yet to be tested for validity or reliability (Corner, 2012). Intensive care unit acquired weakness significantly contributes to disability in the critical care population which results in many of the available outcome measures having a significant “floor effect” (Corner, 2012). This means that most of the tools available are not able to identify changes in patients that have lower functional levels (Corner, 2012). A valid and reliable outcome measure designed for the critical care population should be able to detect small changes in patients’ functional abilities (Corner, 2012). To date there is no ‘gold standard’ to measure exercise capacity in

critically ill patients (Skinner, et al., 2009). There is currently a need for a bedside tool that can facilitate assessment, guide rehabilitation strategies and help to monitor patients' progress during their stay in ICU (Corner, 2012).

The ICU mobility scale (IMS) is an assessment tool that was designed to enable physiotherapists to report on their patients' functional abilities (Hodgson, et al., 2014). The tool is unique as it assesses various levels of function as well as describing the amount of assistance that the patient required in order to successfully complete a functional task (Hodgson, et al., 2014). Hodgson et al. (2014) found that the tool is effective and feasible to measure functional abilities of critically ill patients and has strong inter-rater reliability for recording patients' maximum levels of mobility during the day. The authors admitted that validation of the tool in future research is needed (Hodgson, et al., 2014). The IMS is quick to administer and is simple to understand; however, it has been described as having floor effects when used in the assessment of critically ill patients (Hodgson, et al., 2014; Parry et al., 2015).

The Functional Independence Measure (FIM) is a tool created to achieve a more general functional assessment of a patient (Corner, 2012). The tool tests patients on 18 different functional cognitive tasks and requires input from all members of the multidisciplinary team (DiCicco and Whalen, 2010; Corner, 2012). The psychometric properties of the tool have been tested in a population with varying diagnoses including multiple sclerosis, stroke and general rehabilitation groups (Corner, 2012). It has been proved to be a valid and reliable outcome measure in a general population; however, its use in a critical care setting has not been substantially investigated (DiCicco and Whalen, 2010; Corner, 2012). The tool is also time consuming to administer which can be problematic in a busy ICU (Corner, 2012). The tool does not account for changes in a patient's medical condition nor the interruptions by other health professionals that commonly occur (DiCicco & Whalen, 2010). DiCicco and Whalen (2010) described the significant floor effects of the FIM as it is unable to detect small improvements in function in critically ill patients. Another downfall of the FIM is that it does not account for patients who are not yet physiologically stable for activity and mobilisation (DiCicco & Whalen, 2010).

The University of Rochester Acute Care Evaluation (URACE) was designed with efficiency in mind (DiCicco & Whalen, 2010). The tool consists of activities that would normally be included in a standard physiotherapy assessment so no extra time would be required to administer it to the patients (DiCicco & Whalen, 2010). These activities include moving from supine to sitting, transfers, locomotion and stair climbing (DiCicco & Whalen, 2010). Scoring is achieved by simply

circling the correct score for each assessed activity; however, the tool has no total score which means it cannot be statistically compared to other outcome measures (DiCicco & Whalen, 2010). Although the tool is useful in a critically ill patient population, it has not been validated to date and its reliability has not been tested (Pawlik & Kress, 2013). The tool does not account for basic bed mobility assessment criteria such as rolling in the bed and is not suitable for patients that are not able to mobilise into sitting (DiCicco and Whalen, 2010; Pawlik and Kress, 2013).

The Functional Status Score for the Intensive Care Unit (FSS-ICU) is a novel measure based on the scoring structure of the FIM (Zanni, et al., 2010). The tool consists of five functional tasks: rolling, transferring from supine to sitting, sitting on the edge of the bed, sit to stand and ambulation (Zanni, et al., 2010). Each activity is scored from one to seven with one representing total assistance and seven representing total independence with a higher score indicating a higher level of function (Zanni, et al., 2010; Thrush, et al., 2012). The FSS-ICU was first used in a small pilot study to describe functional deficiencies of patients receiving rehabilitation in ICU (Zanni, et al., 2010). Thrush et al. (2012) investigated the clinical utility of the FSS-ICU in a long term acute care setting and also examined the association between FSS-ICU score and discharge location. Results of the study showed that the FSS-ICU is able to discriminate between different discharge settings and is able to successfully document functional changes in patients in a long term acute care setting (Thrush, et al., 2012).

The Physical Function in Intensive Care Test (PFIT) was designed specifically for the critical care population as these patients may never have the ability to perform sub-maximal exercise testing while they are still in ICU (Nordon-Craft, et al., 2014). The tool was designed to identify endurance, muscle strength, cardiovascular capacity and functional ability (Skinner, et al., 2009). The assessment includes sit-to-stand, marching on the spot, shoulder flexion for as long as possible and muscle strength testing for knee extension and shoulder flexion (Skinner, et al., 2009). The PFIT demonstrates responsiveness to change over time provided that it is used in conjunction with a rehabilitation programme (Skinner, et al., 2009). It is easy to administer and is reliable when used in a critically ill population (Skinner, et al., 2009). The PFIT has been said to demonstrate face validity; however, it is difficult to formally validate the tool (Skinner, et al., 2009). The PFIT requires the patient to be awake and able to follow instructions.

The Short Physical Performance Battery (SPPB) test was designed to assess physical function in the elderly population (Gomez, et al., 2013). It is a valid and reliable measure to assess physical performance in elderly people. It is also easy to administer and safe to use (Gomez, et

al., 2013). The SPPB consists of three measures: gait speed over a four metre course, time taken to complete five chair raises without the use of arm rests and a standing balance test (Chmelo, et al., 2015). Although it is responsive to change, the SPPB has floor effects which may limit its effectiveness in assessment of elderly patients in ICU (Parry, et al., 2015). The SPPB has not been validated for use across a wider age-range of patients (Gomez, et al., 2013).

Parry et al. (2015) found that the FSS-ICU, IMS and the SPPB had high criterion validity when compared to the Physical Function in Intensive Care Test-scored (PFIT-s). In the same study it was found that patients that had higher PFIT-s scores on awakening in ICU were more likely to be discharged home directly (Parry, et al., 2015). Parry et al. (2015) suggested that both the FSS-ICU and the PFIT-s are promising outcome measures that should be considered as part of a standard ICU assessment.

The Acute Care Index of Function (ACIF) was designed to measure the physical function of people with neurological injury; however, it may demonstrate usefulness in other patient populations (Bisset, et al., 2016). The tool consists of four domains namely mental status, bed mobility, transfers and mobility (Bisset, et al., 2016). The tool was shown to have good construct validity, is easy to administer and requires minimal training of healthcare professionals before its use (Bisset, et al., 2016). Bisset et al. (2016) investigated the use of the ACIF in an ICU population as well as the relationship between the ACIF and the FIM. The ACIF demonstrated excellent inter-rater reliability in a cohort of mixed surgical/medical/trauma ICU patients and strongly correlates with the FIM (Bisset, et al., 2016). Acute Care Index of Function scores can also be used by physiotherapists to describe the functional improvements of their patients especially those with a prolonged ICU stay (Bisset, et al., 2016). The tool is yet to be validated for its use in a critically ill population (Bisset, et al., 2016).

The Chelsea Critical Care Physical Assessment (CPAx) tool was developed by Evelyn Corner and is one of the newest outcome measures designed for the assessment of physical morbidity in critically ill patients (Corner, 2012). The tool is a numerical and illustrative scoring system that evaluates ten different components of physical function including respiratory function, cough effort, bed mobility, supine to sitting on the edge of the bed, sitting balance, sit to stand, transfers from bed to chair, standing balance, stepping and grip strength (Corner, 2012; Corner, et al., 2014; Corner, et al., 2015). Each component is scored from zero to five on a Guttman scale with zero representing full dependence and five full independence (Corner, 2012; Corner, Soni, Handy, and Brett, 2014; Corner, et al., 2015). A total score out of 50 is acquired (Corner, 2012).

The scores are depicted on a radar chart giving a quick pictoral indication of the patient's functional ability as well as clearly indicating functional components that can be considered problematic (Corner, et al., 2014). The tool was specifically designed to detect changes in low functioning patients (Corner, et al., 2015). What makes the CPAx unique is that it includes assessment of cough effort and respiratory parameters and not just general functional activities like the other rehabilitation outcome measures described above. In light of the respiratory complications that often occur in critically ill immobilised patients, CPAx would therefore appear to be the outcome measure of choice.

Corner et al. (2013) performed a proof-of-concept pilot study in the United Kingdom in order to test the validity of the CPAx tool. The study consisted of four parts: development of the CPAx tool, a focus group, content validity indices (CVI) questionnaire and an observational cohort study component (Corner, et al., 2013). The observational study was performed to test construct validity of CPAx against the Medical Research Council (MRC) score for muscle strength, peak cough flow, Australian Therapy Outcome Measure (AusTOMs) score, Glasgow Coma Scale score, Bloomsbury sedation score, Sequential Organ Failure Assessment (SOFA) score, 36 Item Short Form Health Survey(SF-36) score and mechanical ventilator days (Corner, et al., 2013). The prospective cohort consisted of 33 general and trauma patients in the critical care unit (CCU) (Corner, et al., 2013). The author of the study did not elaborate on the specific type of trauma that the participants had sustained prior to admission into the CCU. The results of the study showed strong inter-rater reliability and internal consistency (Corner, et al., 2013). The CPAx tool demonstrated significant negative correlation with the SOFA score and the duration of mechanical ventilation as well as moderate to strong positive correlation with GCS score, sedation score, muscle strength, AUSTOMs score, peak cough flow score and the SF-36 score (Corner, et al., 2013). The combination of these results suggests validity of the CPAx tool in the assessment of physical morbidity (Corner, et al., 2013).

A strong association between CPAx scores at discharge from ICU and hospital discharge setting was established in a study in 2014 which implies construct validity of the tool (Corner, et al., 2014). When designing the study, the authors hypothesised that higher CPAx scores on ICU discharge would be associated with improved functional outcomes indicated by discharge location (Corner, et al., 2014). Following the study it was also established that CPAx has a limited floor and ceiling effect in the management of general ICU patients (Corner, et al., 2014).

The CPAx tool was also shown to be effective in the management of specialist trauma patient populations such as burns (Corner, et al., 2015). Corner et al. (2015) performed an observational study to analyse the responsiveness of CPAx in the adult burns population. The study was performed at a small specialist burns ICU in central London (Corner, et al., 2015). The CPAx scores of 52 patients with burn injuries in intensive care were taken retrospectively at pre-admission into ICU, prospectively at ICU admission, ICU discharge and hospital discharge (Corner, et al., 2015). Scores were not taken over the weekends due to the logistics of teaching non-specialist clinicians in the use of the CPAx tool (Corner, et al., 2015). Results showed that CPAx is effective in detecting variations in physical function and that it has a limited floor and ceiling effect when used in critically ill patients with burn injuries (Corner, et al., 2015). It was concluded that a change in CPAx score of more than six represents the minimal clinically important amount of progress made by patients (Corner, et al., 2015). The authors admitted that further research is needed in order to test the validity of CPAx in the burns population in a larger cohort of patients across multiple locations (Corner, et al., 2015).

2.4 ORGAN DYSFUNCTION SCORES

Organ dysfunction scores are used to predict patients' severity of illness and to statistically describe the extent of their injuries (Giannoni, et al., 2013). Severity scores are also used in research to demonstrate equivalency of control and study participants (Zimmerman, et al., 2006).

The SOFA score quantifies daily organ dysfunction by measuring 14 physiological variables from six organ systems namely the respiratory, renal, cardiovascular, liver, haematological and neurological systems (Ulvik, et al., 2007). Each system is given a score ranging from zero to four according to the degree of dysfunction (Bhattacharyya, et al., 2011). The SOFA score is used to evaluate the degree of organ dysfunction over time (Ferreira, et al., 2001). The tool is said to be a useful predictor of morbidity and mortality (Ferreira, et al., 2001; Fueglistaler, et al. 2010). The Sequential Organ Failure Assessment is based on fewer physiological parameters than other scores such as the Simplified Acute Physiology Score (SAPS) and the APACHE score and also does not include information on the reason for admission into the ICU or co-morbidities (Minne, et al., 2008). Bhattacharyya et al (2011) stated that patients who obtain lower SOFA scores are more likely to be weaned from mechanical ventilation. This in turn suggests that SOFA scores can be useful in predicting the outcome of mechanically ventilated patients (Bhattacharyya, et al., 2011). Moreno et al. (1999) investigated the performance of the total maximum SOFA score and a derived measure (delta SOFA). Results of their study suggested that the total maximum SOFA score and the delta SOFA score (total maximum SOFA score minus admission total SOFA

score) can be used to calculatethe degree of organ dysfunction at ICU admission, the amount of dysfunction during the patient's hospital stay as well as the cummulative injuries suffered by the patient (Moreno, et al., 1999).

Ferreira et al. (2001) investigated the usefulness of the SOFA score to predict mortality of critically ill patients in ICU. The authors found that the SOFA score is a good prognostic indicator and that an increase in the SOFA score during the first 48 hours of admission into the ICU is able to predict a mortality rate of 50% (Ferreira, et al., 2001). Arts et al. (2005) performed a prospective study with 30 randomly selected patient cases and 20 ICU doctors to examine the accuracy and reliability of the SOFA scoring system. Results of the study showed that the accuracy and reliability of the SOFA score amongst physicians in the ICU is good (Arts, et al., 2005).

Minne et al. (2008) completed a systematic review to assess the performance of the SOFA score for predicting mortality in a critically ill patient population. According to their results, the authors concluded that performance models based on the SOFA score is comparable with that of other organ failure scores (Minne, et al., 2008). Minne et al. (2008) advocated the use of a traditional score based on information obtained during the first 24 hours of admission into ICU (e.g. APACHE) with sequential scores (such as SOFA) across the entire ICU stay.

Nair et al. (2016) performed a study to determine if the initial SOFA score is a superior predictor of mortality than the SAPS score. Simplified Acute Physiology Score measures 14 biological and clinical variables to predict mortality of patients admitted into ICU (Le-Gall, et al., 1984). Results of the study showed that SOFA was found to be a more superior mortality predictor (Nair, et al., 2016). When compared with the SOFA score, the SAPS was found to lack sensitivity whereas the initial SOFA score was found to be sensitive and specific (Nair, et al., 2016).

The APACHE is an injury prediction score that was designed according to the theory that the severity of acute disease can be established by quantifying the degree of irregularity of multiple organ systems (Knaus, et al., 1985). The APACHE II system was designed as a revised version of the APACHE system (Knaus, et al., 1985). The score was designed as a way to predict mortality (Minne, et al., 2008) and the maximum score attainable is 71 (Knaus, et al., 1985). The system assigns numerical values to 12 physiological parameters including: mean arterial blood pressure, haematocrit, temperature, heart rate, respiratory rate, oxygenation, arterial pH, serum sodium, serum potassium, serum creatinine, white blood cell count and GCS (Dossett, et al., 2009). The APACHE II utilises the worst physiological parameters recorded during the first 24

hours following admission into the ICU (Dossett, et al., 2009). It should be noted that the APACHE II score is an accurate predictor of clinical outcomes in critically injured trauma patients (Dossett, et al., 2009). The APACHE II score has not been validated for use outside of the first 24 hours following admission into the ICU (Ferreira, et al., 2001).

The APACHE II scores have been used as a mechanism to match participants in previous studies (Beattie, et al., 2012). In a study published in 2012, the authors performed a retrospective review to describe the population of people who developed ventilator acquired pneumonia (VAP) bundles (Beattie, et al., 2012). The study also aimed to assess the degree to which VAP bundle compliance limited the risk of acquiring VAP (Beattie, et al., 2012).Ten cases were examined and each case was matched with two controls according to age, gender, APACHE II score and number of ventilator days (Beattie, et al., 2012). With regards to matching of participants, cases were matched according to APACHE II scores within a range of five points (Beattie, et al., 2012).

Dossett et al. (2009) revisited the validation of the APACHE II score in a prospective study that examined a population of critically injured patients. Severity scores were collected and in-hospital mortality was predicited (Dossett, et al., 2009). When compared with the Trauma Injury Severity Score and the Injury Severity Score, the APACHE II was found to be a greater predictor of mortality in critically ill trauma patients that required longer than 48 hours stay in the intensive care unit (Dossett, et al., 2009). This could be due to the fact that the APACHE II is a more generalised scoring system with a significant physiologic basis when compared to traditional trauma scores (Dossett, et al., 2009).

Polderman et al. (2001) examined the accuracy and reliability of the APACHE II scoring system in a retrospective review. The authors found that various causes of error and extensive variability exist when the APACHE II is used in everyday patient management (Polderman, et al., 2001). The APACHE II was shown to lack reliability in this study (Polderman, et al., 2001). It should also be noted that the APACHE II score tends to overestimate mortality risk in ICU patients (Polderman, et al., 2001). In the ICU at Chris Hani Baragwanath Academic hospital, the APACHE II is the scoring system used to predict injury severity on admission into the unit. It is on this basis that the APACHE II was used in the current study.

2.5 CONCLUSION

There is little literature available on early mobilisation of critically ill patients in South African intensive care units. There is also currently a gap in the literature with regards to the use of valid

and reliable rehabilitative outcome measures in the ICU, especially in the South African context. Prolonged hospital and ICU LOS results in impaired physical function of patients and increased costs to the hospital involved. There is a need to examine the use of outcome measures, such as the CPAx tool, in order to determine if it will aid in reducing patients' ICU and hospital LOS. It is also vital to find a functional outcome measure that is cost effective, quick to administer and user-friendly when used in a critically ill patient population.

CHAPTER 3

3. METHODOLOGY

The methodology discussed in this chapter is based on the findings of the literature review discussed in Chapter 2. The study design, sample population, inclusion and exclusion criteria as well as instrumentation and data collection procedure used during the study are discussed in detail. An explanation of the pilot study, its aims, methodology and its implications on the main study procedure is given. The methods for data analysis are given as well as the ethical considerations that were taken into account when the study was conducted.

3.1 STUDY DESIGN

For the first part of the study a quasi-experimental design with a historically matched control group (Portney & Watkins, 2009) was used to determine the effect of the CPAx tool on patients' clinical outcomes. Participants assessed with the CPAx tool were compared to carefully matched data (age, gender, admission diagnosis, severity of illness) of previous admissions into the same ICU. A comparison was made with regards to ICU and hospital LOS between the groups.

For the second part of the study, a survey-based design was used. A questionnaire was developed and used; quantitative data were collected to determine the perceptions and views of physiotherapists towards the use of the CPAx tool in clinical practice in the intensive care unit.

3.2 SUBJECTS

3.2.1 Sample Selection and Demographics

Participants for the study (patients and physiotherapists) were selected from Chris Hani Baragwanath Academic hospital. This hospital is a tertiary institution in Soweto Johannesburg. The ICU has two floors with nine beds on each floor. The lower floor is reserved for patients with medical conditions or who underwent general surgical procedures and the second floor is reserved for admission of patients with traumatic injuries. There are four therapists that work in the ICU (two on each floor). Two therapists work permanently in the ICU and the other two rotate through different work areas on a quarterly basis. All four therapists have an additional workload outside the ICU in the medical and surgical wards. Subject recruitment started in October 2015 and data collection was completed in February 2016.

3.2.1.1 Inclusion criteria

All male and female patients admitted into the trauma ICU and surgical patients admitted into the general ICU were considered for inclusion in the first part of the study.

All physiotherapists working in the trauma ICU and general ICU were considered for inclusion in the second part of the study.

3.2.1.2 **Exclusion criteria**

The following patients were excluded from participation in the first part of the study:

- Patients who were bedridden prior to admission to ICU due to orthopaedic, neurological or neuromuscular conditions.

- Patients placed on bed rest in ICU as a result of complex orthopaedic and/or spinal injuries sustained.

- All patients admitted to the general ICU and trauma ICU one month prior to the start of the pilot study (clinicians familiarised themselves with the CPAx tool during this time).

The following people were excluded from participation in the second part of the study:

- Physiotherapists working in the paediatric ICU as the CPAx tool has only been validated for use in the adult ICU population to date.

- Physiotherapy technicians and assistants as it is beyond their scope of practice to work in an ICU setting.

3.2.2 **Sample Size**

Patient admission information from the general ICU and trauma ICU was reviewed from December 2014 to February 2015 in order to calculate patients' average ICU LOS. This information was used to calculate the sample size for the study. A sample size of 26 patients per group (width of C/I ± 3.7) was determined to yield 90% power to detect a difference of 12 hours in ICU and hospital LOS if a SD of 9.399 was used with alpha set at 5%, non-compliance at 10% and drop out (including mortality) at 38%.

3.2.3 **Variables**

3.2.3.1 **Independent variable**

The independent variable for the first part of the study was the CPAx score.

3.2.3.2 **Dependent variables**

The dependent variables for the first part of the study were:

- ICU and hospital length of stay
- APACHE II scores
- SOFA scores

3.3 **STUDY PROCEDURES**

3.3.1 **Instrumentation**

3.3.1.1 **APACHE II score**

The APACHE II score (on-line calculator) was used to match injury severity and risk for mortality of participants in the experimental group with that of participants in the historical control group (Mica, et al., 2013; ClinCalc.com, 2015). The APACHE II has been shown to be a valid tool in predicting mortality in critically injured trauma patients when compared to other scoring systems (Dosset et al., 2009). The reliability of the APACHE II has been questioned as it has been shown to overestimate mortality risk (Polderman, et al., 2001).

3.3.1.2 **SOFA score**

The SOFA score (on-line calculator) was used to measure patients' degree of organ dysfunction (Bale et al., 2013). The SOFA score has been shown to be an accurate and reliable measure (Arts, et al., 2005) as well as a good predictor of morbidity and mortality in critically ill patients (Ferreira, et al., 2001). Nair et al. (2016) found the SOFA score to be sensitive and specific.

3.3.1.3 **Hand-grip dynamometer**

A Smedley digital hand-grip dynamometer (Figure 3.1) was used to assess patients' grip strength as required for the CPAx tool (Corner, et al., 2013). The dynamometer was obtained from Physio and Wellness Warehouse situated in Johannesburg, South Africa.

Figure 3.1: Smedley Digital Hand-Grip Dynamometer

3.3.1.4 **The Chelsea critical care physical assessment tool**

The CPAx tool was used to assess patients' functional abilities and respiratory function (Corner, et al., 2014) (see Figure 3.2 and Appendix 1). A maximum score of 50 indicates normal functional ability and respiratory function and no physical morbidity. The CPAx tool has been shown to be a valid tool in the assessment of physical morbidity (Corner, et al., 2012) and has been proven to be effective in detecting changes in physical function (Corner, et al., 2015). The CPAx tool is also useful as it has a limited floor and ceiling effect (Corner, et al., 2015). Reliability testing has shown that CPAx has strong internal consistency and inter-rater reliability between five different testers (Corner, et al., 2013).

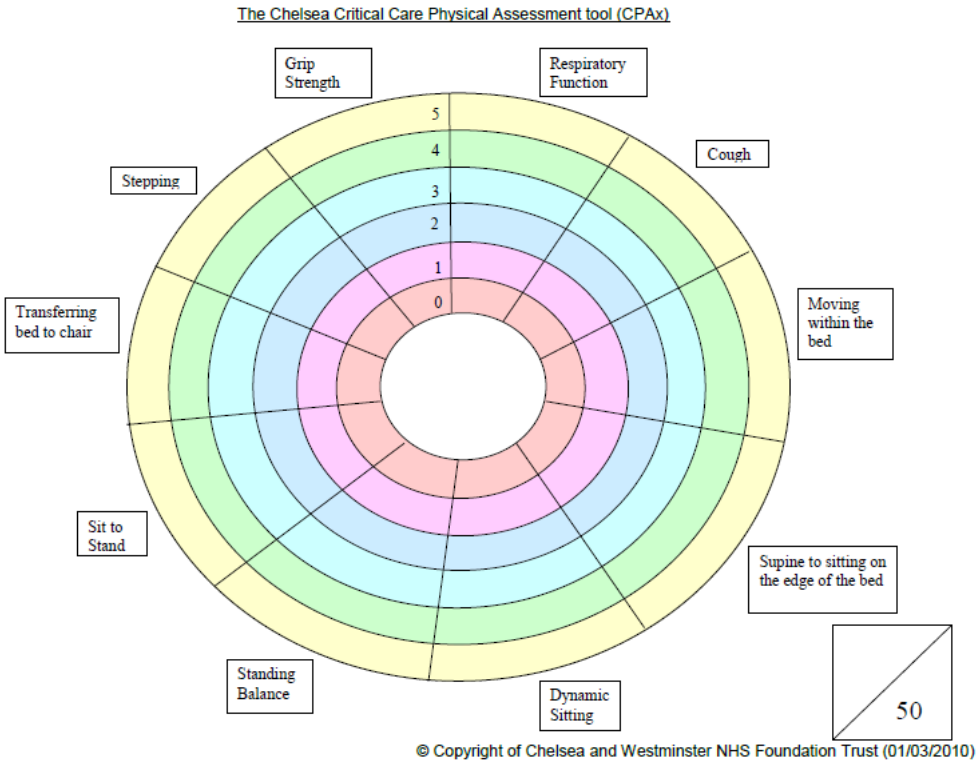

Figure 3.2: Chelsea Critical Care Physical Assessment tool

3.3.1.5 **Individual Participant Record Sheets**

These were used to capture demographic information, admission dates, discharge dates and other relevant information (Appendix 2).

3.3.1.6 **Questionnaire**

A questionnaire was developed in order to establish clinician's perceptions towards the use of the CPAx tool. It was administered to all suitable physiotherapy clinicians who used the CPAx tool during the first part of the study (Appendix 3). The questionnaire was administered to physiotherapy clinicians in part two of this study.

3.3.2 **Data Collection Procedure**

3.3.2.1 **Part one of the study**

3.3.2.1.1 Procedures prior to the pilot study

All physiotherapy clinicians who work in the general ICU and trauma ICU of Chris Hani Baragwanath Academic hospital were required to complete the online CPAx training module (cpax.ocbmedia.com) developed by E. Corner. This training module had to be

completed by the clinicians before they were allowed to administer the CPAx tool to the study participants. The online programme issues a certificate if an individual successfully passes the training module. Clinicians were only allowed to participate in the study if they were able to produce their certificate of completion. Copies of the certificates have been kept by the researcher (Appendix 4). These physiotherapists acted as research assistants for the duration of the first part of the study. Following completion of the CPAx training module, the clinicians were given one month to familiarise themselves with using the tool during patient assessment and re-assessment in ICU in preparation for the pilot study and main study. The researcher gave advice to the research assistants during the pilot study when questions arose in order to ensure that they were comfortable using the tool.

3.3.2.1.2 Pilot study

A pilot study was performed on five participants in ICU. Five participants were selected as this equates to approximately ten percent of the total study population. The aim of the pilot study was to determine the inter-rater reliability of CPAx tool scores obtained between the research assistants for the pilot study participants. The two research assistants assessed the five participants together but decided on the patients' CPAx scores separately. After completion of the pilot study, results obtained were analysed and discussed between the researcher and the study supervisor (view results of pilot study in Chapter 4). Good inter-rater reliability was demonstrated which meant that no changes were implemented for the data collection procedure of the main study. Data obtained from the five pilot study participants were included in the main study data set. Their CPAx scores were recorded as the sum of the two scores obtained by the research assistants divided by two.

3.3.2.1.3 Main study

Patients admitted to the general ICU as well as the trauma ICU were screened consecutively by the researcher and research assistants against the inclusion and exclusion criteria for the study, to determine their suitability for participation in the study. Once suitable participants were identified, the researcher approached the patients and explained the aims of the study to them to obtain informed consent (Appendix 5). Temporary informed consent forms were kept available in case the patients were not conscious or orientated in order for the researcher to approach the patients' parents/spouses in the presence of the ICU nurse or ICU doctor (face-to-face or

telephonically) to explain the aims of the study to them to obtain temporary informed consent for their relative to be included in the study. The director/deputy director of critical care at Chris Hani Baragwanath Academic hospital was approached to obtain temporary consent in the event that the patient's family could not be located or in the event that the patient's identity could not be confirmed (Appendix 6). However, participants that were recruited into the CPAx (experimental) group were approached when they were orientated to person, place and time with a GCS of 10/10 or 15/15. This resulted in temporary consent from a caregiver or the director/deputy director of critical care not being required.

Once informed consent was obtained, the researcher informed the research assistants of such. Research assistants were assigned patients according to the daily patient loads and logistics in the ICUs at the time of the study. No randomisation of participant allocation to research assistants took place. The research assistants assessed each participant according to the CPAx tool criteria (Appendix 1). Following this, the participants received their physiotherapy treatment daily (or bi-daily if required) according to problem areas identified with the CPAx tool. Treatment was provided by all physiotherapists working in the ICU. In other words, patient management was not restricted to the research assistants only. Treatment of study participants was given according to the plan laid out by the research assistants after CPAx assessments were performed. Subsequent assessments using CPAx tool were performed by the research assistants for all included participants every second weekday of their stay in ICU (Monday, Wednesday and Friday) and progression of treatment was performed according to the ongoing CPAx assessment findings. CPAx assessments were performed on alternate weekdays in order to mimic the study performed by Corner et al. (2014). In the above-mentioned study, participants were assessed at least three times per week using the CPAx tool.

Data was captured on individual patient record sheets. Date and time was recorded for ICU/hospital admission and discharge. Following discharge from the ICU, the participants continued to receive physiotherapy in the ward as required but use of the CPAx tool was terminated at patient discharge from ICU.

The researcher matched information of each included participant in the CPAx group to the ICU patient record data bases of the general and trauma ICUs in order to identify

suitable historical controls for the study. Intensive care unit charts were used to determine information of patients in both the historical control and CPAx (experimental) groups. Matching was performed according to the following criteria:

- Age: Control participants were considered a potential match if they fell into the same age category as the participant recruited into the CPAx group. Age categories were defined as follows: a) 20-29 years, b) 30-39 years, c) 40-49 years, d) 50-59 years and e) 60-69 years.

- Diagnosis: Surgical patients were matched according to the surgical procedure that they underwent (for example laparotomy). Trauma patients were matched according to the nature of injury (blunt versus penetrating) and as far as possible they were matched according to the types of injuries sustained as well as the surgical procedures that they underwent for management of injuries.

- Gender: Male and female participants were matched accordingly.

- APACHE II score: Historical control participants were considered a potential match if their APACHE II score was within three points of the APACHE II score for the participant recruited into the CPAx group.

Participants were matched according to all four criteria mentioned above. The matching variables and processes performed were designed based on those used in a study by Beattie et al. (2012). Beattie et al. aimed to describe the population of patients who acquired ventilator-associated pneumonia (2012). A retrospective case note review was conducted where cases were each matched with two controls (Beattie et al. 2012). Cases were matched according to age (within ten years), gender (male or female), APACHE II score (within five points) and number of ventilator days (Beattie et al. 2012).

Patients admitted to the general and trauma ICUs in the month prior to the start of the pilot study were not considered for inclusion in the historical control group as clinicians would have been using the CPAx tool, for the purpose of familiarisation, already during this time which would have resulted in skewed data. Historical controls were selected from patients that were admitted into the ICUs during the period 1 January 2014 to 30 June 2015.

The researcher entered information obtained into the on-line APACHE II calculator to determine risk for mortality for study participants in the CPAx group and for historical control participants. It is not standard practice for all patients to have APACHE II scores calculated on admission to the general or trauma ICU at Chris Hani Baragwanath Academic hospital, therefore APACHE II scores were calculated by the researcher and research assistants for subjects in both the CPAx and control groups. All information required was easily accessible on the ICU charts as well as from the database where blood results are stored. APACHE II scores for participants in the CPAx group were calculated on admission. APACHE II scores for the historical control group were calculated once historical patients were identified as potential matches for participants in the CPAx group. In other words, once it was established that the potential control participants matched the CPAx participants according to age, gender and diagnosis then admission information for these participants was used to calculate APACHE II scores thus determining if they were appropriate matches or not. The matching process used is reproducible. The results were documented on the individual patient record sheets designed for this study.

The researcher also entered information obtained for participants in the CPAx group and for historical controls into the on-line SOFA calculator (re-assessed on alternate weekdays during their ICU stay) to determine risk for organ dysfunction and captured the results on the individual patient record sheets. The SOFA score was re-assessed for all study participants on every second weekday of their ICU stay and recorded accordingly (see Appendix 2).The on-line SOFA and APACHE II calculators were used during the period October 2015 to March 2016. The researcher tracked and recorded ICU LOS and hospital LOS for each participant in the CPAx and historical control groups.

3.3.2.2 **Part two of the study**

3.3.2.2.1 <u>Procedures prior to the pilot study</u>

A questionnaire was drawn up by the researcher and her supervisor prior to the study. The aim of the questionnaire was to establish physiotherapists' perceptions of the CPAx tool when used in a surgical and trauma patient population (Appendix 3).

3.3.2.2.2 <u>Main study</u>

For the second part of the study, the researcher approached all physiotherapy clinicians that were involved in the first part of the study and gave them a printed copy of the questionnaire to complete in their own time (Appendix 3). A clearly labelled box was placed in the physiotherapy department of Chris Hani Baragwanath Academic hospital into which completed questionnaires were deposited.

All information obtained during part one and part two of this study was entered by the researcher, in consultation with her supervisor, on Excel spreadsheets in preparation for data analysis.

3.4 ETHICAL CONSIDERATIONS

Ethical clearance for the study was obtained from the University of the Witwatersrand Human Research Ethics (Medical) Committee (Appendix 7). Permission was obtained from the Medical Advisory Committee, the Chief Executive Officer, the Director of Critical Care and the Assistant Director of Physiotherapy at Chris Hani Baragwanath Academic hospital to perform this study (Appendices 8, 9 and 10). A comprehensive information sheet was given to the patients/caregivers as well as the clinicians recruited (Appendices 11and 12) and written consent was obtained from the patients/caregivers prior to enrolment of participants into the first part of the study (Appendices 5 and 6). Participants were allowed to withdraw from the study at any time without any penalty to them or any consequences to their continued care while in hospital. All information obtained about study participants was coded to preserve the participants' identity. A separate coding list was kept on which the participant's name and allocated subject code was documented. This list was password protected and stored on the researcher's computer. Any information obtained was used for statistical purposes only and no personal information was disclosed about the patients. This study was registered with the South African National Clinical Trials Registry through the Department of Health (trial registration number: DOH-27-0816-5496).

3.5 STATISTICAL ANALYSIS

3.5.1 Part one of the study:

The data obtained was nominal and interval in nature. Data was captured on an Excel spreadsheet. The IBM® Statistical Package for Social Sciences (SPSS) version 24 for Windows was utilized to analyse data collected. Descriptive statistics were used to present the data. Categorical data were summarized as frequencies and percentages in the text as well as in illustrative tables or pie charts. Continuous data were presented as means and standard

deviations (SD) in the text as well as in tables and graphs. Comparisons of ICU and hospital LOS between the study participants and historical control group were done using an independent t-test. Pearson's correlation coefficient was used to determine if an association existed between CPAx scores, APACHE II scores or SOFA scores. A p-value ≤ 0.05 was deemed statistically significant.

3.5.2 Part two of the study:

The data obtained in the second part of the study was descriptive in nature. Results were reported in narrative form.

CHAPTER 4

4. RESULTS

Results for phase one of this study are reported in the format of the Transparent Reporting of Evaluations with Nonrandomised Designs (TREND) statement for nonrandomised experimental trials. Results for phase two of the study are reported in narrative form towards the end of this chapter.

4.1 PART ONE OF THE STUDY: INTER-RATER RELIABILITY BETWEEN RESEARCH ASSISTANTS

The pilot study was performed on two research assistants and five participants, three of which were participants who underwent surgical procedures and two were participants with traumatic injuries.

The data for the CPAx tool is continuous in nature. Therefore in order to determine inter-rater reliability for the CPAx tool between the two raters, the intra-class correlation coefficient (ICC) was calculated. The results showed ICC = 0.999 (95% confidence intervals (CI) = 0.994-1). This demonstrated excellent inter-rater reliability between the two raters. In 95% of cases the inter-rater reliability between these two raters was therefore likely to fall between 0.994 and 1.

4.2. STUDY POPULATION FOR PART ONE STUDY

The number of patients admitted into the two ICUs during the period 19 October 2015 to 29 February 2016 and the recruitment of participants to the study is summarised in the flow diagram in Figure 4.1. During the study period 30 participants were recruited into the CPAx group. Four participants were excluded from this group as the researcher was unable to find appropriate historical control matches for them. One participant in the CPAx group died during his stay in the ICU.

Twenty six participants were recruited into the historical control group. Two participants died in the wards following their discharge from the ICU and one was transferred to another hospital following his discharge from the ICU.

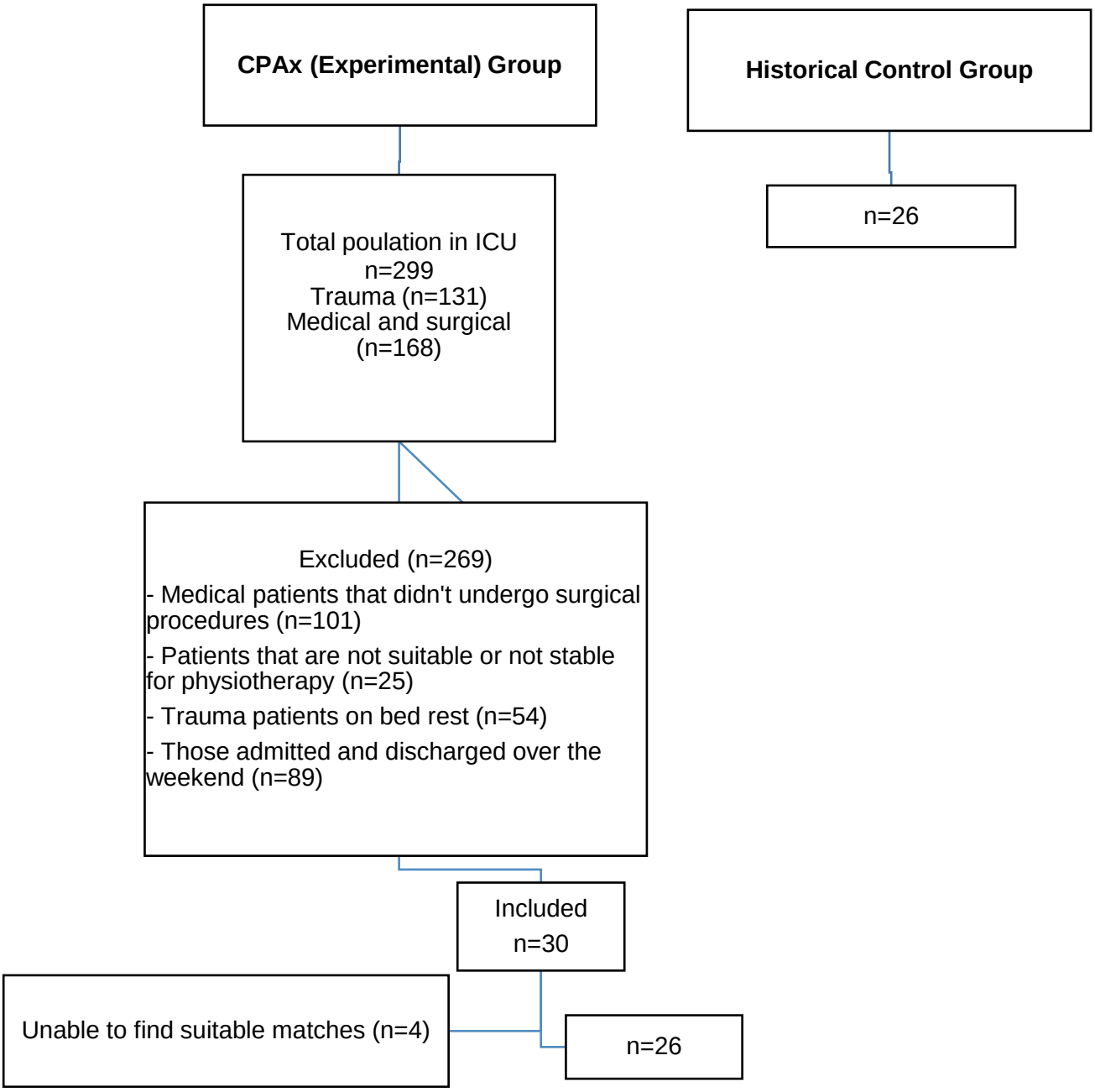

Figure 4.1: Summary of Patient Recruitment for the Study

4.2.1 Baseline Characteristics of the Study Population

4.2.1.1 Age

The mean age for the CPAx group was 37.88 (±13.37) years with the minimum age being 21 years and the maximum age being 68 years. The mean age for the control group was 37.81 (±12.21) years with the minimum being 21 years and the maximum being 66 years. There was

no statistically significant difference in age between the two groups (p=0.7) which shows that the groups were well matched.

4.2.1.2 **Gender**

The patient population consisted of 65.4% (n=34) male and 34.6% (n=18) female participants. The CPAx group consisted of 17 (65.4%) male participants and nine (34.6%) female participants (Figure 4.2). The control group consisted of 17 (65.4%) male participants and nine (34.6%) female participants (Figure 4.3). There was no difference in gender between the two groups (p=1).

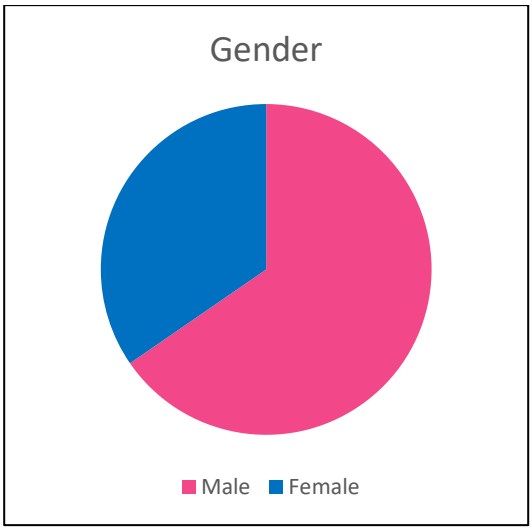

Figure 4.2: Gender Distribution of CPAx Group

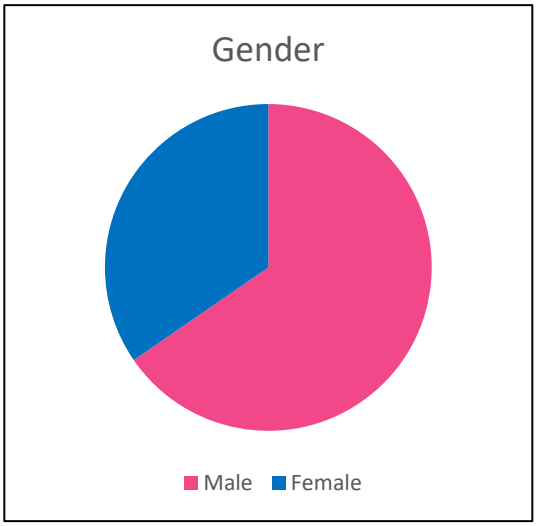

Figure 4.3: Gender Distribution of Control Group

4.2.1.3 **Severity of illness on admission (APACHE II score)**

The mean APACHE II score for the CPAx group was 11.58 (±5.16) with a minimum score of 2 points and a maximum score of 24 points. The mean APACHE II score for the control group was 11.96 (±4.99) with a minimum score of 2 points and a maximum score of 21 points. There was no statistically significant difference in APACHE II scores (p=0.81) between the two groups which shows that the groups were well matched.

4.2.1.4 **Diagnosis**

The patient population consisted of 28 (53.8%) participants who underwent surgical procedures and 24 (46.2%) participants with traumatic injuries. The CPAx group consisted of 14 (53.8%) participants who underwent surgical procedures and 12 (46.2%) participants with traumatic injuries. The control group consisted of 14 (53.8%) participants who underwent surgical

procedures and 12 (46.2%) participants with traumatic injuries. There was no difference in diagnosis between the two groups (p=1).

Five participants from the CPAx group sustained more than one traumatic injury whereas seven sustained single traumatic injuries. Eleven of the 12 participants with traumatic injuries in the CPAx group sustained penetrating injuries whereas only one participant sustained blunt trauma. The specific trauma and surgical diagnoses are listed in Table 4.1below.

Table 4.1: Diagnoses of participants in the experimental group

ID	Diagnosis 1	Diagnosis 2	Trauma/Surgical
1	Caesarean section		Surgical
2	Sternotomy	Flexor tendon injury	Trauma
3	Thoracotomy		Trauma
4	Head and neck extensive surgery		Surgical
5	Head and neck extensive surgery		Surgical
6	Exploratory laparotomy for gunshot wound		Trauma
7	Exploratory laparotomy for gunshot wound		Trauma
8	Neck exploration		Trauma
9	Thoracotomy	Sternotomy	Trauma
10	Clavicle fracture	Rib fractures	Trauma
11	Exploratory laparotomy for gunshot wound	Ulna fracture	Trauma
12	Exploratory laparotomy for gunshot wound		Trauma
13	Exploratory laparotomy for gunshot wound		Trauma
14	Neck exploration	Sternotomy	Trauma
15	Multiple stab wounds		Trauma
16	Laparotomy for adrenal mass resection		Surgical
17	Caesarean section		Surgical
18	Debridement for necrotising fasciitis		Surgical
19	Caesarean section		Surgical
20	Caesarean section		Surgical
21	Nephrectomy		Surgical
22	Laparotomy for total colectomy		Surgical
23	Whipples procedure		Surgical
24	Caesarean section		Surgical
25	Laparotomy for complicated appendicectomy		Surgical
26	Caesarean section		Surgical

Four participants from the historical control group sustained more than one traumatic injury whereas eight sustained single traumatic injuries. Eleven of the 12 participants with traumatic injuries in the control group sustained penetrating injuries whereas only one participant sustained blunt trauma. The specific trauma and surgical diagnoses are listed in Table 4.2 below.

Table 4.2: Diagnoses of participants in the control group

ID	Diagnosis 1	Diagnosis 2	Trauma/Surgical
50	Caesarean section		Surgical
51	Sternotomy	Flexor tendon injury	Trauma
52	Thoracotomy		Trauma
53	Head and neck extensive surgery		Surgical
54	Head and neck extensive surgery		Surgical
55	Exploratory laparotomy for gunshot wound		Trauma
56	Exploratory laparotomy for gunshot wound		Trauma
57	Neck exploration		Trauma
58	Sternotomy		Trauma
59	Tibia-fibular fracture (ORIF done)	Rib fractures	Trauma
60	Exploratory laparotomy for gunshot wound	Gunshot wound to the face	Trauma
61	Exploratory laparotomy for gunshot wound		Trauma
62	Exploratory laparotomy for gunshot wound		Trauma
63	Neck exploration	Sternotomy	Trauma
64	Multiple stab wounds		Trauma
65	Laparotomy for tumour removal (pancreatic cancer)		Surgical
66	Caesarean section		Surgical
67	Debridement for necrotising fasciitis		Surgical
68	Caesarean section		Surgical
69	Caesarean section		Surgical
70	Nephrectomy		Surgical
71	Laparotomy for bowel disease		Surgical
72	Whipples procedure		Surgical
73	Caesarean section		Surgical
74	Laparotomy for bowel disease		Surgical
75	Caesarean section		Surgical

4.2.1.5 **Initial extent of organ dysfunction (SOFA score)**

The mean initial SOFA score for the CPAx group was 2.42 (±1.79) with a minimum score of 0 points and a maximum score of 8 points. The mean initial SOFA score for the control group was 4.15 (±2.6) with a minimum score of 0 points and a maximum score of 11 points. A p=0.03 (Mann-Whitney test: p=0.01) indicates that there was a statistically significant difference between the two groups with regards to initial SOFA scores. This suggests that the historical control group had a higher degree of organ dysfunction at the start of the trial when compared to the CPAx group.

4.2.1.6 **Extent of organ dysfunction at ICU discharge (SOFA score)**

There were 25 participants who had SOFA scores measured at ICU discharge (10 participants in the CPAx group and 15 participants in the control group). Only 25 SOFA scores were available at ICU discharge for the whole study population because some patients only had one SOFA

score calculated during their ICU stay. In the above-mentioned cases, the score was recorded as the 'initial SOFA score' and these participants did not have a SOFA score measured or recorded at ICU discharge.

The mean SOFA score at ICU discharge for the CPAx group was 1.80 (±0.42) with a minimum score of 1 point and a maximum score of 2 points. The mean SOFA score at ICU discharge for the historical control group was 2.87 (±1.81) with a minimum score of 1 point and a maximum score of 8 points. A p=0.05 (Mann-Whitney test: p=0.05) indicates that there was a statistically significant difference between the two groups with regards to SOFA scores at ICU discharge. This suggests that the control group had a higher degree of organ dysfunction at ICU discharge when compared to the CPAx group (Figure 4.4).

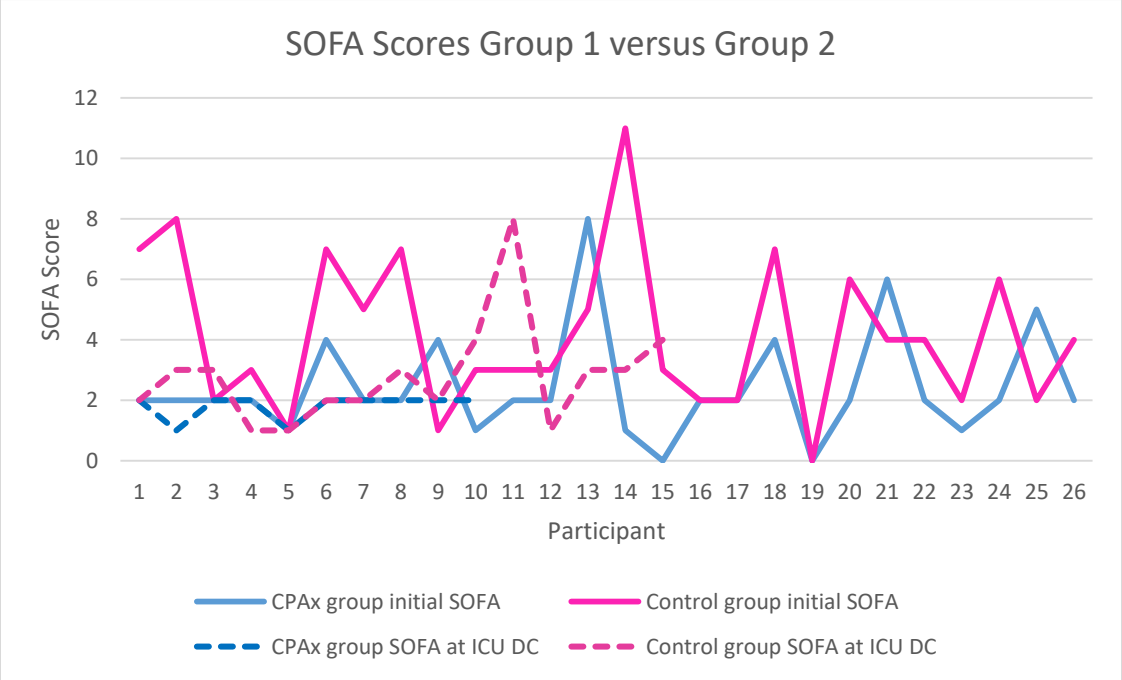

Figure 4.4: Graph Depicting the Initial SOFA Scores and SOFA Scores at ICU Discharge of CPAx Group and Control Group

4.2.2 Clinical Outcomes

4.2.2.1 **ICU length of stay**

The mean ICU LOS for the CPAx group was 5.84 days (±7.43) with a minimum 0.79 days and a maximum of 34.21 days. The mean ICU LOS for the control group was 4.56 days (±5.25) with a minimum of 0.58 days and a maximum score of 21.08 days. Although the CPAx group had a greater mean ICU LOS than the historical control group, a p=0.54 (Mann-Whitney U test: p=0.27) suggests that there was no statistically significant difference in ICU LOS between the two groups.

4.2.2.2 **Hospital length of stay**

One participant from the CPAx group died during his stay in ICU which means that there was hospital LOS data for 25 of the 26 participants initially recruited into the CPAx group. Two participants from the historical control group died during their hospital stay and one was transferred to another hospital following his discharge from the ICU. This means that hospital LOS was measured for 23 of the 26 participants initially recruited into the historical control group.

The mean hospital LOS for the CPAx group was 17.43 (±16.68) days with a minimum of 4.71 days and a maximum of 79.13 days. The mean hospital LOS for the control group was 19.31 days (±5.79) with a minimum of 5.08 days and a maximum score of 59.71 days. Although the historical control group had a greater mean hospital LOS than the CPAx group, a p=0.80 (Mann-Whitney test: p=0.42) suggests that there was no statistically significant difference between the two groups.

4.2.2.3 **Physical morbidity (CPAx scores)**

CPAx scores were measured for participants in the CPAx group on alternate days during the patients' ICU LOS. One participant died during his stay in the ICU. If participants only had two CPAx scores taken during their stay in the ICU, then these scores were recorded as 'initial CPAx score' and 'CPAx score at discharge' respectively. There were 26 initial CPAx scores measured, four CPAx scores measured at midway and 10 CPAx scores measured at discharge from the ICU. Only 10 CPAx scores were available at ICU discharge because some patients only received one CPAx assessment during their ICU stay. In the above-mentioned cases, the score was recorded as the 'initial CPAx score' and these participants did not have a CPAx score measured or recorded at ICU discharge. Any participants that received three or more CPAx scores would have had a midway score recorded.

The mean initial CPAx score for the CPAx group was 29.73 points (±14.81) with a minimum score of 2 points and a maximum score of 49 points. The mean midway CPAx score was 10.75 (±14.36) with a minimum score of 2 points and a maximum score of 32 points. The mean CPAx score at ICU discharge was 36.15 (±8.33) with a minimum score of 23 points and a maximum score of 46 points. The mean difference in CPAx scores between ICU admission and ICU discharge was 6.42 for the CPAx group.

The mean initial CPAx score for all participants who underwent surgical procedures was 32.75 (±14.16) with a minimum score of 2 points and a maximum score of 46 points. The mean initial CPAx score for all participants with traumatic injuries was 26.21 (±15.39) with a minimum score of 23 points and a maximum score of 39.5 points. The difference in mean CPAx scores on ICU admission between participants who sustained traumatic injuries and those who underwent surgical procedures was 6.54.A p=0.27 (Mann-Whitney test: p=0.35) indicates that there was no statistically significant difference in initial CPAx scores between the surgical and trauma participants.

There were 10 participants who had CPAx scores measured at ICU discharge. Five participants (50%) were trauma cases and five participants (50%) were surgical cases. The mean CPAx score at ICU discharge for all participants who underwent surgical procedures was 42.20 (±4.09) with a minimum score of 7 points and a maximum score of 49 points. The mean CPAx score at ICU discharge for all participants with traumatic injuries was 30.10 (±6.91) with a minimum score of 23 points and a maximum score of 39.5 points. The difference in mean CPAx scores at ICU discharge between participants who sustained traumatic injuries and those who underwent surgical procedures was 12.10 .A p=0.01 (Mann-Whitney test: p=0.03) indicates that there was a statistically significant difference in CPAx scores at ICU discharge between the surgical and trauma participants (Figure 4.5).

The mean CPAx scores for participants who underwent surgical procedures changed by 9.45 points between admission and discharge from ICU. The mean CPAx scores for participants who sustained traumatic injuries changed by 3.9 points between admission and discharge from ICU. From this it can be postulated that the CPAx tool is more useful to detect change in physical function in surgical participants than in participants with traumatic injury.

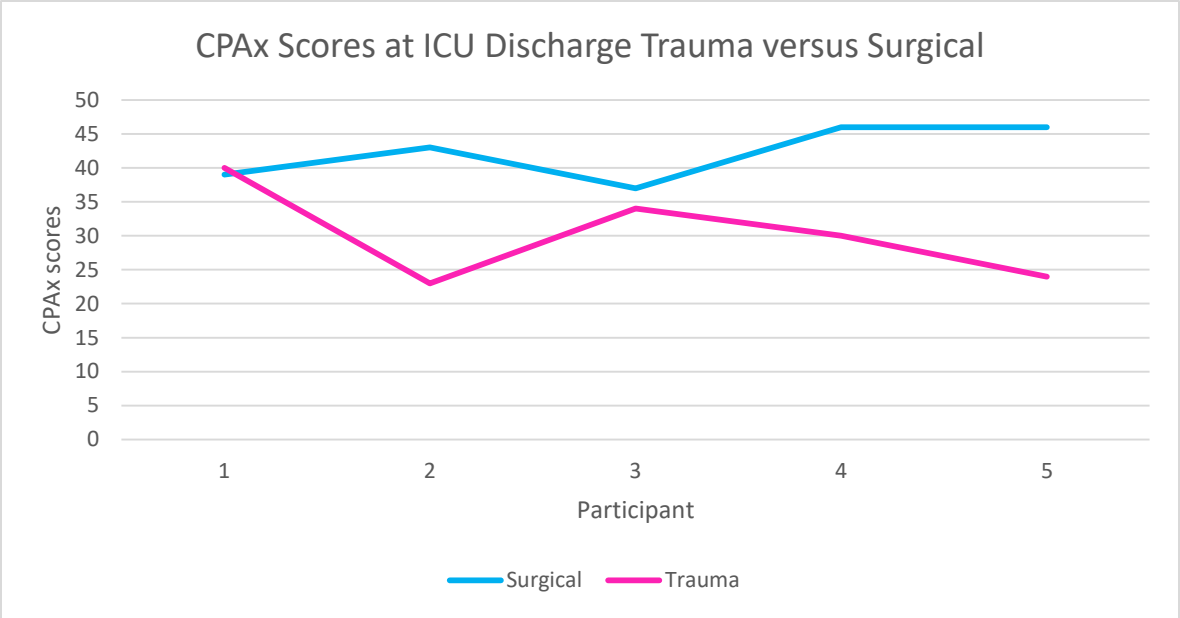

Figure 4.5: Figure Depicting the Difference in CPAx Scores at ICU Discharge between Participants with Different Admission Diagnoses

4.2.2.4 **Association between severity of illness and physical morbidity scores on admission into the ICU**

A Pearson correlation coefficient was computed in order to determine the association between APACHE II scores and initial CPAx scores for subjects in the CPAx group (n=26). Results indicated that APACHE II scores had a very weak negative correlation with initial CPAx scores (r=-0.07). This association was not statistically significant (p=0.74).

4.2.2.5 **Association between severity of illness and physical morbidity scores at ICU discharge**

A Pearson correlation coefficient was computed in order to determine the association between APACHE II scores and CPAx scores at ICU discharge for subjects in the CPAx group (n=10). Results indicated that APACHE II scores had a very weak positive correlation with CPAx scores at ICU discharge (r=0.06). This finding was not statistically significant (p=0.87).

4.2.2.6 **Association between extent of organ dysfunction and physical morbidity scores on admission into the ICU**

A Pearson correlation coefficient was computed in order to determine the association between initial SOFA scores and initial CPAx scores for subjects in the CPAx group (n=26). Results indicated that initial SOFA scores had a moderate negative correlation with initial CPAx scores

(r=-0.45) (Figure 4.6). This suggests that a smaller extent of organ dysfunction on admission to ICU may result in a reduction in physical morbidity as a higher initial CPAx score indicates better physical function. The results were statistically significant (p=0.02).

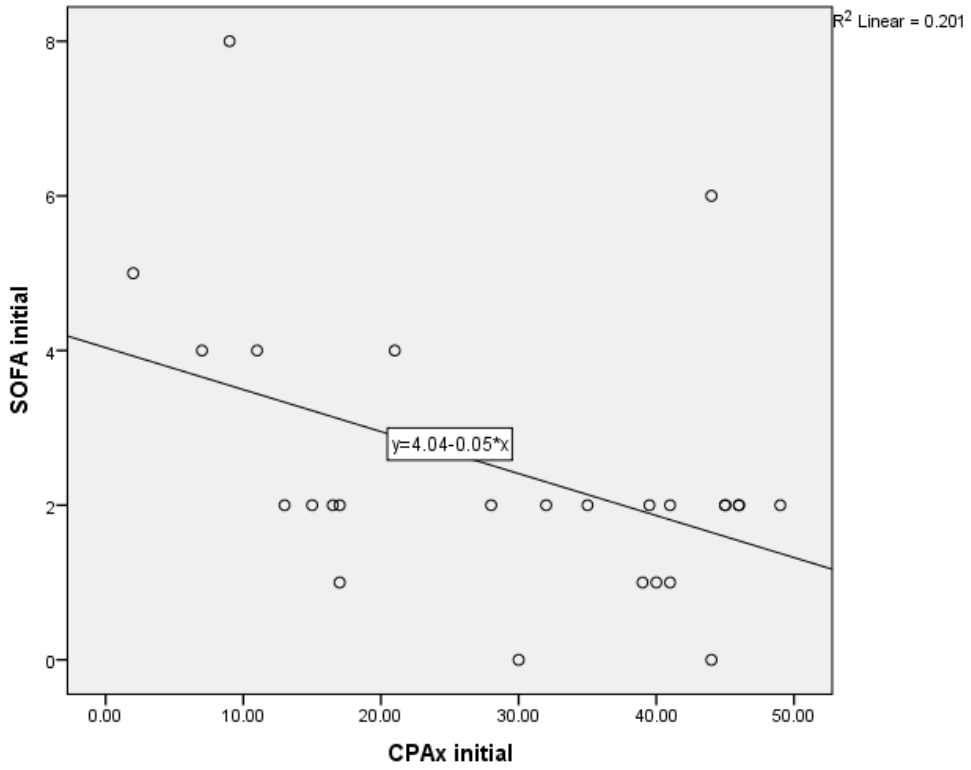

Figure 4.6: **Graph Depicting the Relationship between Extent of Organ Dysfunction and Physical Morbidity Scores on Admission into the ICU**

4.2.2.7 **Association between extent of organ dysfunction on admission and physical morbidity at ICU discharge**

A Pearson correlation coefficient was computed in order to determine the association between initial SOFA scores and CPAx scores at ICU discharge for the CPAx group (n=10). Results indicated that initial SOFA scores had a weak negative correlation with CPAx scores at ICU discharge (r=-0.24). The results were not statistically significant (p=0.51).

4.2.2.8 **Association between physical morbidity at admission and extent of organ dysfunction at ICU discharge**

A Pearson correlation coefficient was computed in order to determine the association between initial CPAx scores and SOFA scores at ICU discharge for the CPAx group (n=10). Results indicated that initial CPAx scores had a moderate positive correlation with SOFA scores at ICU discharge (r=0.47). The results were not statistically significant (p=0.17).

4.2.2.9 **Association between physical morbidity at ICU discharge and extent of organ dysfunction at ICU discharge**

A Pearson correlation coefficient was computed in order to determine the association between CPAx scores at ICU discharge and SOFA scores at ICU discharge for the CPAx group (n=10). Results indicated that CPAx scores at ICU discharge had a very strong positive correlation with SOFA scores at ICU discharge (r=0.80) (Figure 4.7). This suggests that as the extent of organ dysfunction increases, a reduction in physical morbidity may be observed (higher CPAx scores represent less physical morbidity). The results were statistically significant (p=0.05). Similar results were found when doing the Spearman correlation test (r=0.70, n=10, p=0.03).

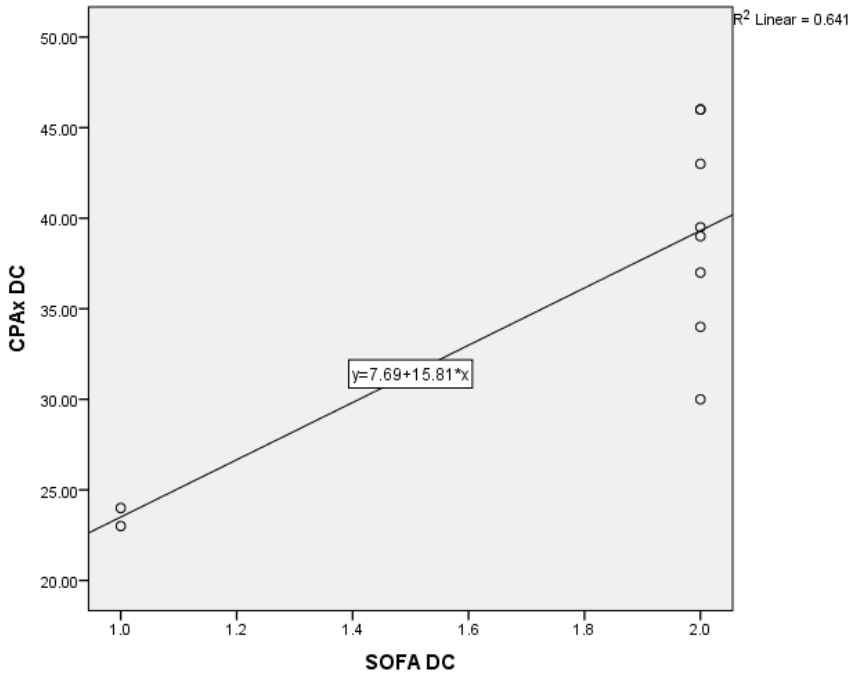

Figure 4.7: **Graph Depicting the Relationship between Physical Morbidity at ICU Discharge and Extent of Organ Dysfunction at ICU Discharge**

4.3 PART TWO OF THE STUDY: PHYSIOTHERAPISTS' PERCEPTIONS OF THE CPAX TOOL

All clinicians who were working in the ICU during the data collection period were considered for recruitment into the study. There were five clinicians (other than the researcher) working in the ICU at the time; all of which volunteered to participate in the study. Due to logistical reasons, three of the clinicians were excluded from the study. This allowed them to take care of the other patients in the ICU that were not recruited into the study and assist with the workload in other areas. Two clinicians were therefore recruited into the study. Please see Figure 4.8 below.

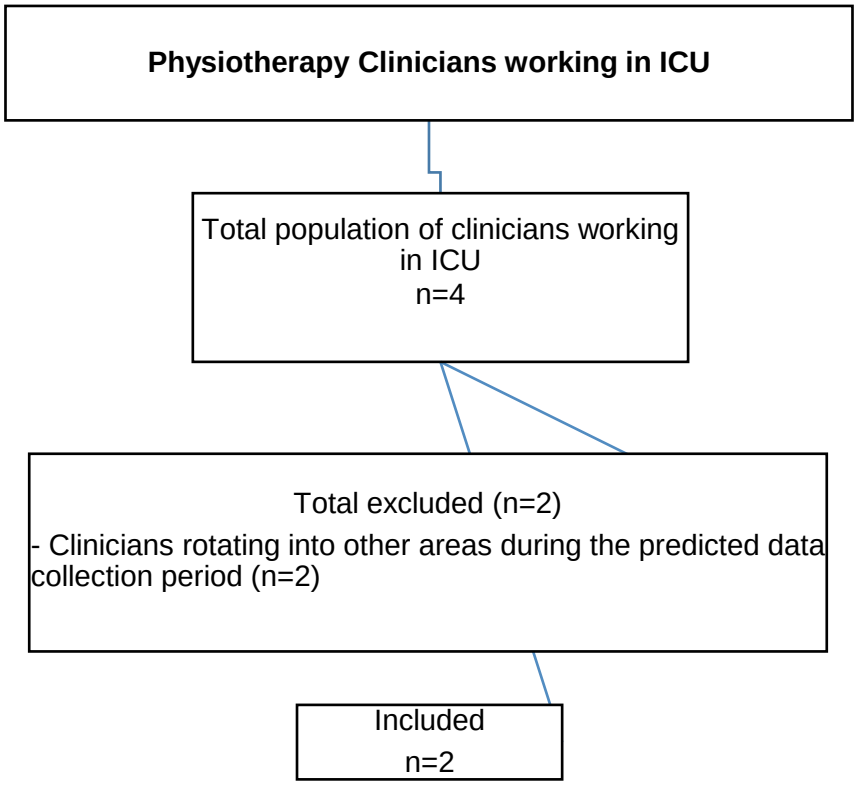

Figure 4.8: Summary of Clinician Recruitment for the Study

Two research assistants were recruited into the study to assist with data collection for participants in the CPAx group. They completed questionnaires to assess their perceptions of the CPAx tool. The results are as follows:

4.3.1 **Demographics of Participants**

Both research assistants had undergraduate (Bachelor of Science in Physiotherapy) qualifications and the preferred area of clinical work for both was in cardiopulmonary/ICU settings. Both had less than five years' experience working as a physiotherapist. The first clinician had more than three years of experience working in the ICU setting whereas the second clinician had less than three years of work experience in ICU. The first clinician worked between 11 and 15 hours per week in the ICU and had an average patient load in the ICU of four to six patients whereas the second clinician worked between five and 10 hours per week in the ICU and had a patient load in the ICU of seven to nine patients. Both had a daily average patient load of more than nine patients outside of the ICU. The first clinician reported to the occasional use of outcome measures to assess patients' responses to treatment; however, the second clinician reported infrequent use of outcome measures.

4.3.2 **Use of the CPAx Tool**

Neither clinician had ever heard of the CPAx tool prior to the start of this study nor were they aware of any other tool that measured physical morbidity in the ICU. Neither clinician answered the question asking to give further comments if they prefer not to use outcome measures in their daily clinical practice.

4.3.3 **Perceptions of Participants regarding the CPAx Tool**

Both clinicians found that the CPAx tool enhanced their accuracy of patient assessment. The first clinician agreed that the CPAx tool was not appropriate when used with patients with certain admission diagnoses (especially patients with multiple traumatic injuries) whereas the second clinician did not agree with this statement. Both clinicians felt that the tool assisted with patient care and planning, evaluating patient progression, motivating patients to partake in treatment, enhancing communication with patients as well as motivating physiotherapists regarding patient treatment.

The clinicians both agreed that the tool was not time consuming to use or difficult to interpret. They also established that the tool did not consist of variables that were difficult to interpret and did not require too much effort than proved necessary. The statement “did not require too much effort than proved necessary” suggests that effort taken to administer the tool was worth the time it took to administer it. Both clinicians agreed that the CPAx tool was comprehensive enough to be administered independently. The term "comprehensive enough to be administered independently" suggests that the CPAx tool assesses all areas necessary to complete a thorough functional assessment of the patients.

CHAPTER 5

5. DISCUSSION

This chapter involves interpretation of the results laid out in the previous chapter. The challenges and limitations of the study are also discussed here.

This study is the first in South Africa to assess the effects of the CPAx tool on patient outcomes in a critical care setting and to assess physiotherapists' perceptions about the CPAx tool. Participants in the CPAx and historical control groups were well matched with regards to age, gender, admission diagnosis and APACHE II scores. It is important to note that participants in the control group had a statistically significant higher mean SOFA score on admission and at discharge from the ICU when compared with those in the CPAx group. This suggests that historical control participants had a larger extent of organ dysfunction and risk for mortality on admission into the unit as well as on discharge from the unit when compared with participants in the CPAx group.

5.1 THE EFFECT OF THE USE OF THE CPAX TOOL ON LENGTH OF STAY IN ICU AND IN THE HOSPITAL IN THE CARE OF CRITICALLY ILL PATIENTS

It was assumed that the use of the CPAx tool for objective assessment of patients' functional abilities during ICU stay would result in more goal-directed physiotherapy patient management resulting in changes in ICU and hospital LOS. A recent survey of physiotherapy practice in South African ICUs showed that majority of respondents used exercise therapy and out-of-bed mobilisation as part of their daily management of patients in ICU (Lottering & Van Aswegen, 2016). Intensive care unit LOS and hospital LOS were measured in this study as these are outcomes that have been assessed in many other studies based on early rehabilitation strategies (Morris et al., 2008; Engel et al., 2009; Malkoc et al.,2009). Results from three studies showed that patients in the experimental groups who received physiotherapy that included early mobilisation strategies had a significantly shorter LOS in the ICU or in the hospital (Morris et al., 2008; Engel et al., 2009; Malkoc et al., 2009).

Results of the current study showed that the mean ICU LOS for participants in the CPAx group was 5.84 days and the control group was 4.56 days. Corner et al. investigated the relationship between CPAx scores and hospital discharge location (Corner et al., 2014). The authors found

that the mean ICU LOS of their whole study population was 11.54 days (Corner et al., 2014). This study took place in an ICU in the United Kingdom (Corner et al., 2014). All participants recruited into their study received CPAx assessments and the target was a minimum of three CPAx assessments per week (Corner et al., 2014). A similar frequency of CPAx assessment was performed in the current study. The patient population recruited into the study by Corner et al (2014) was a mixed medical and surgical population whereas the current study had a mixed trauma and surgical population. This may account for the differences in ICU LOS between Corner et al.'s (2014) study and this study.

It also appears that the ICU at Chris Hani Baragwanath Academic hospital in South Africa has a very high turnover of patients at any given time when comparing ICU LOS data for the CPAx group and the historical control group for this study to that described by Corner et al. (2014). There is a constant demand for ICU beds at Chris Hani Baragwanath Academic hospital which often leads to patients being discharged to the wards when they are still ill and would otherwise still require critical care if there were more beds available. This may offer another explanation for the differences in ICU LOS reported for this study and that of Corner et al. (2014).

At the start of the current study it was hypothesised that participants in the historical control group would have a longer mean ICU LOS than those in the CPAx group as participants in the CPAx group might have received more goal-directed physiotherapy interventions. On completion of the study, it was however established that the CPAx group had a longer mean ICU LOS than the historical control group but this finding was not statistically significant. The difference in ICU LOS cannot be attributed to the patients' risk for morbidity and mortality on admission into the ICU as the groups had similar APACHE II scores and the historical control group had higher initial SOFA scores than the CPAx group. A possible explanation could be the fact that one participant in the CPAx group had an extended LOS in the ICU (34.21 days) whereas the maximum LOS for participants in the control group was only 21.08 days. Another contributing factor may be the reduction in sample size by the time of ICU discharge in this study.

It was also hypothesised that participants in the control group would have a longer mean hospital LOS than those in the CPAx group. Results confirmed that participants in the control group had a longer mean hospital LOS than those in the CPAx group; however, the difference in hospital LOS was not statistically significant. Participants in the CPAx group had lower degrees of organ dysfunction than those in the control group which might account for their shorter period of hospitalisation. It is possible that the CPAx group had a shorter hospital LOS due to the fact that

the participants were more functional when they were discharged from ICU as a result of the goal-directed physiotherapy treatment that they received in ICU. This may have resulted in these participants spending less time in the ward than the historical control group participants resulting in a shorter hospital LOS.

It is important to note that although early mobilisation of critically ill patients can improve other functional outcomes such as bed mobility, exercise tolerance and muscle strength (Stiller, 2013), unfortunate circumstances such as wound sepsis and multi-organ dysfunction may occur regardless of whether the patient was mobilised early or not. This patient population consisted of critically ill individuals who might have spent prolonged periods of time in the ICU and in the hospital for reasons that could not be influenced by physiotherapy interventions.

5.2 THE USEFULNESS OF THE CPAX TOOL ACCORDING TO PATIENT ADMISSION DIAGNOSIS

It is interesting to note that the mean midway CPAx scores were lower than the mean initial CPAx scores. One would expect the midway scores to be higher than the initial scores. A possible explanation is the fact that only four midway scores were recorded (due to patient discharge from ICU as explained in Chapter 4) whereas 26 initial CPAx scores were documented.

In this study, participants who underwent a surgical procedure had a greater change in CPAx scores from ICU admission to ICU discharge when compared to change in CPAx scores in participants who had sustained traumatic orthopaedic injuries. From this it would appear that the CPAx tool is more useful to detect changes in physical morbidity/physical function in surgical populations than in trauma populations.

Corner et al. (2015) found that CPAx was responsive to change from ICU admission until hospital discharge in patients who had sustained burn injuries. Patients with burn injuries are comparable to patients who undergo surgical procedures and therefore the results from the current study seem to support the usefulness of the CPAx tool as reported by these authors.

Corner et al (2015) also discussed the fact that a change in CPAx score of six or more can be considered a clinically relevant change in physical function in a burns ICU population. One could hypothesise that in the current study, the mean difference in CPAx scores observed from ICU

admission to ICU discharge in the surgical group suggests a clinically relevant finding. This suggests that the surgical participants were more functional at discharge from the ICU than they were on admission into the unit; however, the current study was not performed in a burns cohort.

Traumatic injuries in a South African context are often severe and consist of a combination of pedestrian-and-motor-vehicle accidents, interpersonal violence including penetrating and blunt trauma (Norman et al., 2007) as well as burn injuries. Norman et al. (2007) described the exceptionally high burden from injuries related to violence and road traffic injuries in South Africa. It is easy to hypothesise that patients (in a South African context) who have sustained multiple traumatic injuries may find it more difficult to mobilise while they are being cared for in the ICU. Although patients who sustained unstable pelvic or vertebral fractures were excluded from the study, there were five participants who had sustained more than one traumatic injury. One could hypothesise that multiple injuries would involve higher levels of pain experienced by patients and thus more difficulty to perform physical activities. Patients with multiple injuries may find it more difficult to progress with functional activities in which case the CPAx tool may be deemed less appropriate or effective to detect changes in physical function in these instances.

5.3 THE RELATIONSHIP BETWEEN PHYSICAL MORBIDITY AND DISEASE SEVERITY

Corner et al. (2014) found an association between age, APACHE II score and ICU LOS with discharge location; however, the authors did not investigate the relationship between APACHE II scores and CPAx scores.

In this study, the CPAx scores for participants on admission into ICU demonstrated a weak inverse association with APACHE II scores. This inverse association can be interpreted by the fact that patients with a higher risk for mortality on admission into the ICU would have lower functional abilities and in turn lower CPAx scores measured. This was an expected finding even though it was not statistically significant.

The CPAx scores on discharge from the ICU had a weak linear association with APACHE II scores on admission into the ICU. This suggests that patients with higher APACHE II scores on admission may have higher physical function scores on discharge from the ICU. One would expect that all CPAx scores would have a negative correlation with APACHE II scores and therefore this finding was unexpected. A possible explanation for this finding could be the low number of CPAx scores available at ICU discharge which might have skewed the results.

5.4 THE RELATIONSHIP BETWEEN PHYSICAL FUNCTION AND EXTENT OF ORGAN DYSFUNCTION

Corner et al. (2013) found that CPAx had a significant negative correlation with SOFA scores in her mixed cohort of 33 general and trauma participants. Similar results emerged in this study where a statistically significant inverse association of moderate strength was found between initial SOFA scores and initial CPAx scores as well as a weak inverse association between initial SOFA scores and CPAx scores at ICU discharge. This negative association shows that participants with a higher degree of organ dysfunction on admission into the ICU would have lower functional abilities and in turn lower initial CPAx scores measured on admission. Similarly, the participants with higher SOFA scores on admission are more likely to have lower CPAx scores on discharge from the ICU as a result of higher degree of injury severity; although in this study there was a weak association between these variables at the time of ICU discharge. This can be explained by the relatively low number of CPAx scores available for data analysis at ICU discharge.

When comparing initial CPAx scores with SOFA scores at discharge from the ICU, a moderate positive relationship between the two variables was established. Similarly when CPAx scores at ICU discharge were compared with SOFA scores at ICU discharge, a statistically significant positive association was found. This finding was unexpected and a possible explanation could be the small sample size at ICU discharge (only 10 participants had CPAx scores and SOFA scores measured at ICU discharge). A larger cohort of patients may be necessary in order to further investigate the association between CPAx scores and SOFA scores.

5.5 PHYSIOTHERAPISTS' PERCEPTIONS AND VIEWS OF THE USEFULNESS OF THE CPAX TOOL

Corner et al. (2013) reported that CPAx was endorsed by physiotherapists that have reviewed and used the tool in a clinical setting. The current study also showed that clinicians supported the use of the tool. It is encouraging that both clinicians involved in this study had positive perceptions towards the use of the CPAx tool. This is important due to the fact that in the past, outcome measures in general have been described as time consuming and high in equipment requirements (Maher & Williams, 2005). Due to lack of funds in the South African public health care sector, outcome measures such as CPAx that require minimal equipment, may be useful in

the ICU setting. The tool also demonstrated good inter-rater reliability in spite of the small sample size used in the pilot study. This is in line with the good inter-rater reliability that was established by Corner et al. (2013) in their proof-of-concept pilot study.

It should be noted that both clinicians verbally reported to the researcher that the tool was quick and easy to administer. They also reported that the respiratory domain is a factor that makes the CPAx tool unique when comparing it to other functional outcome measures (Corner et al., 2013). The views from these two participants may however be biased as they could have influenced each other's ideas about the tool seeing that they worked together in the two ICUs in which the study was conducted. Therefore these findings should not be generalised but confirmed or refuted in future trials.

5.6 CHALLENGES ENCOUNTERED AND LIMITATIONS TO THE STUDY

5.6.1 Recruiting Participants into the CPAx Group

Although there were 299 admissions in total into the trauma and general ICUs during the period of 19 October 2015 to 29 February 2016, many participants did not meet the inclusion criteria. Secondly, some participants were admitted and discharged over weekends which meant they were not considered for recruitment into the study.

Due to long surgical waiting lists, many trauma patients were placed on bed rest while waiting for open reduction and internal fixation of their fractures. As these patients could not be mobilised due to unstable fractures, they could not be recruited into the study. Had these fractures been surgically stabilised immediately on admission to ICU, there would have been an opportunity to recruit these patients into the CPAx group.

5.6.2 Matching Participants in the Historical Control Group with Those Recruited into the CPAx Group

The researcher underestimated the difficulty required to appropriately match control participants with those in the CPAx group. The first problem encountered was matching according to diagnosis. Surgical patients were matched according to the surgical procedure that was performed. This was fairly straightforward in the case where the patients underwent a standard laparotomy or vascular procedure. However, unique or uncommon surgical procedures were a lot more difficult to match. Patients with traumatic injury were matched according to the injuries

sustained. This was challenging due to the wide variety of traumatic injuries that can be sustained in an assault situation or a motor vehicle accident.

The second problem encountered was matching according to APACHE II scores. It was very difficult to match these scores within three points and this was often as a result of the GCS score on admission. Participants who had a low GCS on admission had very high APACHE II scores when compared to participants of the same age and diagnosis with a higher GCS on admission. In a trial performed by Beattie et al. (2012) which described a population of people who acquired VAP bundles, APACHE II scores were also utilised to match the participants between the two groups. Beattie et al. (2012) accepted APACHE II scores within five points as an acceptable match whereas in the current study, cases were matched according to APACHE II scores within a range of three points. By matching the participants within a range of three points instead of five points, it can be suggested that participants in the two groups in the current study were more closely matched for mortality risk when compared with the groups in the study by Beattie et al. (2012).

Although participants in both groups were matched according to age, gender, diagnosis and APACHE II scores, the statistically significant difference in SOFA scores between the two groups indicated that participants in the two groups had different baseline characteristics with regards to the extent of organ dysfunction. This may have influenced the outcomes of the study. When performing future studies of a similar nature, it may be worth considering matching the patients according to initial SOFA scores as well as the other baseline variables mentioned above. The number of complications that participants developed during their ICU stay was not recorded or taken into account. This may have impacted on the matching process and may explain why the historical control group participants had higher degrees of organ dysfunction than the CPAx group participants.

5.6.3 **Sample Size**

Even though the proposed sample size for the study was achieved, it was a small sample size in total which gave the researcher limited power to detect differences in clinical outcomes between the two groups. A sample size calculation based on the effect of the CPAx tool on patient LOS of for example 24 hours instead of 12 hours (as used in this study), may yield a larger study sample at the same level of power (90%) to detect differences in clinical outcomes. This study might have produced more significant results if a lower power percentage (80%) was

used during the power calculation. This would have resulted in more subjects being recruited into the study.

5.6.4 Administration of CPAx Assessments

The CPAx tool was not administered to participants over weekends as a result of restrictions on staff availability, factors related to staff training (the two research assistants who performed CPAx assessments were not always on duty over weekends) and the logistics of data collection. There were some occasions where this resulted in participants only receiving one assessment using the CPAx tool before being discharged to the wards. Similar limitations were reported in an observational study performed in a cohort of 52 patients who had suffered from burn injuries (Corner, et al., 2015). In the aforementioned study, CPAx assessments were not administered over weekends and treating therapists were not blinded (Corner, et al., 2015). As described by Corner et al (2015) it is unlikely that CPAx scores would have altered clinical decision making; however, it cannot be ruled out.

There was no blinding of treating clinicians in this study. Those that performed the assessments using the CPAx tool were also closely involved in rehabilitation and clinical decision making throughout the participants' ICU LOS.

5.6.5 Content Validation of the Questionnaire

The questionnaire used in the second part of this study was drawn up by the researcher and her supervisor. Content validation of the questionnaire was not performed prior to the start of the study and the questionnaire was not piloted.

5.7 RECOMMENDATIONS FOR FUTURE TRIALS

A larger sample size could be used in future trials of a similar nature in order to verify the results obtained in this study. A randomised controlled multi-centre trial design could be used to determine more accurately the effect of CPAx on patient duration of stay in ICU and in hospital. Measuring the effect of the CPAx tool on participants' duration of mechanical ventilation could also be an interesting clinical outcome to consider. Such a study design could yield a wider perception of physiotherapists regarding the usefulness of the CPAx tool in daily clinical practice in South African ICUs.

CHAPTER 6

6. CONCLUSION

The data presented in this study show that the use of the CPAx tool does not have a significant influence on ICU and hospital LOS in a sample of surgical and trauma participants. The tool appears to be more useful when used in the care of patients who have undergone surgical procedures rather than those who have sustained complex traumatic injuries.

CPAx scores on ICU admission and discharge appeared to have an inconsistent association with APACHE II scores on ICU admission. Initial SOFA scores had an inverse association with CPAx scores on ICU admission as well as ICU discharge. SOFA scores at ICU discharge had an unexpected positive association with initial CPAx scores and CPAx scores on ICU discharge.

The small number of physiotherapy clinicians that participated in this single-centre study supported the use of the CPAx tool for assessment of physical function of patients in ICU and generally had positive perceptions towards the use of the tool.

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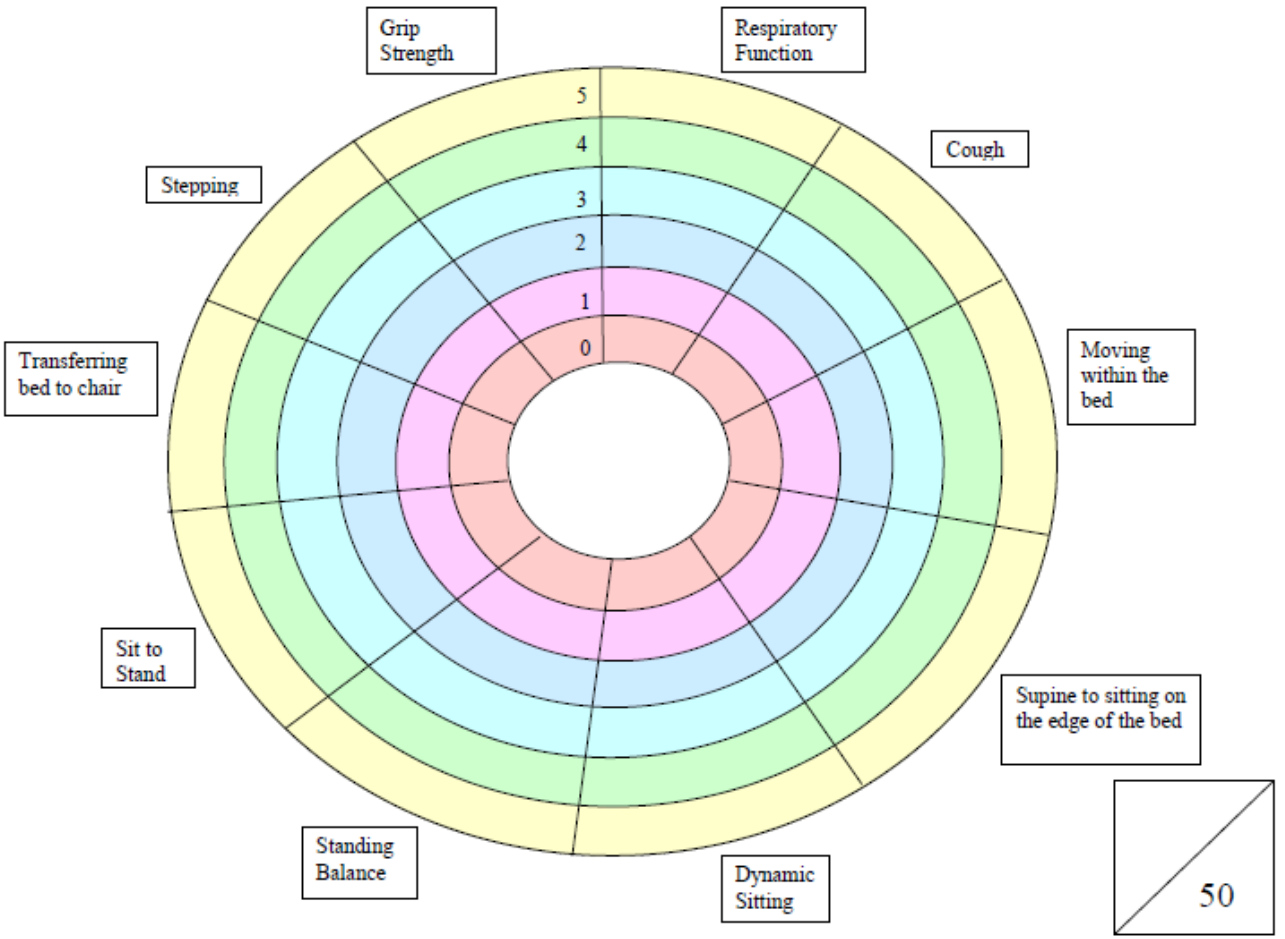
APPENDIX 1

The Chelsea Critical Care Physical Assessment tool (CPAx)

Aspect of Physicality	Level 0	Level 1	Level 2	Level 3	Level 4	Level 5
Respiratory Function	Complete ventilator dependence. Mandatory breaths only. May be fully sedated/ paralysed.	Ventilator dependence. Mandatory breaths with some spontaneous effort.	Spontaneously breathing with continuous invasive or non-invasive ventilatory support.	Spontaneously breathing with intermittent invasive or non-invasive ventilatory support **Or** continuous high flow oxygen (>15litres).	Receiving standard oxygen therapy (<15 litres).	Self-ventilating with no oxygen therapy.
Cough	Absent cough, may be fully sedated or paralysed.	Cough stimulated on deep suctioning only.	Weak ineffective voluntary cough, unable to clear independently e.g. requires deep suction.	Weak, partially effective voluntary cough, sometimes able to clear secretions e.g. requires yanker suctioning.	Effective cough, clearing secretions with airways clearance techniques.	Consistent effective voluntary cough, clearing secretions independently.
Moving Within the Bed e.g. rolling.	Unable, maybe fully sedated/ paralysed.	Initiates movement. Requires assistance ≥ 2 people (maximal).	Initiates movement. Requires assistance≥1 person (moderate).	Initiates movement. Requires assistance 1 person (minimal).	Independent in ≥3 seconds.	Independent in <3 seconds.
Supine to Sitting on the Edge of the Bed.	Unable/ Unstable.	Initiates movement. Requires assistance ≥ 2 people (maximal).	Initiates movement. Requires assistance≥1 person (moderate).	Initiates movement. Requires assistance 1 person (minimal).	Independent in ≥3 seconds.	Independent in <3 seconds.
Dynamic Sitting (i.e. when sitting on the edge of the bed/unsupported sitting)	Unable/ Unstable	Requires assistance ≥2 people (maximal).	Requires assistance≥1 person (moderate).	Requires assistance 1 person (minimal).	Independent with some dynamic sitting balance, i.e. able to alter trunk position within base of support.	Independent with full dynamic sitting balance, i.e. able to reach out of base of support.
Standing Balance	Unable/ unstable/ bedbound.	Tilt table or similar	Standing hoist or similar.	Dependant on frame, crutches or similar.	Independent without aides.	Independent without aids and full dynamic standing balance, i.e. able to reach out of base of support.
Sit to Stand (Starting position: ≤ 90 degrees hip flexion)	Unable/ Unstable.	Sit to stand with maximal assistance e.g. standing hoist or similar.	Sit to stand with moderate assistance e.g. 1-2 people.	Sit to stand with minimal assistance e.g. 1 person.	Sit to stand independently pushing through arms of the chair.	Sit to stand independently without upper limb involvement.
Transferring from Bed to Chair.	Unable/ Unstable.	Full hoist.	Standing hoist or similar.	Pivot transfer (no stepping) with mobility aid or physical assistance.	Stand and step transfer with mobility aid OR physical assistance.	Independent transfer without equipment.
Stepping	Unable/ Unstable.	Using a standing hoist, or similar.	Using mobility aids AND assistance > 1 person (moderate).	Using mobility aid AND assistance 1 person (minimal).	Using mobility aid OR assistance 1 (minimal).	Independent without aid.
Grip Strength (predicted mean for age and gender on the strongest hand.)	Unable to assess.	< 20%	< 40%	< 60%	< 80%	≥80%

The Chelsea Critical Care Physical Assessment tool (CPAx)



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APPENDIX 2

INDIVIDUAL PARTICIPANT RECORD SHEET

1. Participant identity code : _____
2. Age : _____
3. Gender : _____
4. Date of ICU admission : _____
5. Time of ICU admission : _____
6. Diagnosis:_____

   _____
7. APACHE score (within 24 hours of admission) according to online calculator: _____

Variable	**Unit**	**Value**
Fi02	%	
Pa02	mmHg	
Temperature (rectal)	˚C	
MAP	mmHg	
pH		
HR	Bpm	
RR	Bpm	
Na	mEq/L	
K	mEq/L	
Creatinine	mg/dL	
Hct	%	
WCC	$X10^9$/L	
GCS		
Presence of acute renal failure	Yes/No	
Immunocompromised or severe organ insufficiency	Yes/No	

8. SOFA score and CPAx score

SOFA variable	**Unit**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**
Fi02	%										
Pa02	mmHg										
Ventilation	Yes/No										
Platelets	X103mm3										
Bilirubin	Mg/dL										
GCS	-										
MAP	mmHg										
Vasopressors	Yes/No										
Creatinine	Mg/dL										
Urine output	ml/day										
CPAx score	-										

SOFA variable	**Unit**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**	**Date**
Fi02	%										
Pa02	mmHg										
Ventilation	Yes/No										
Platelets	X103mm3										
Bilirubin	Mg/dL										
GCS	-										
MAP	mmHg										
Vasopressors	Yes/No										
Creatinine	Mg/dL										
Urine output	ml/day										
CPAx score	-										

9. Date of discharge from ICU : _____

10. Date of discharge from hospital ward : _____

11. Other (re-admissions into ICU etc) : _____

APPENDIX 3

QUESTIONNAIRE

Please answer each question by placing a tick next to the appropriate answer (only one answer per question please)

Please give details on additional information when requested.

SECTION 1

1. What is your level of qualification?

BSc		MSc		PhD	

2. What is your preferred area of physiotherapy?

Cardiopulmonary/ICU		Sports/NMS		Neurology	
Orthopaedics		Paediatrics		Public health	

3. How many years of clinical experience do you have in physiotherapy?

<5 years		5-10 years		11-15 years		16-20 years		>20 years	

4. How many years of experience do you have working in the ICU setting?

<3 years		3-6 Years		7-9 years		10-12 years		>12 years	

5. How many hours a week do you work in an ICU setting?

< 5 hours		5-10 hours		11-15 hours		16-20 hours		> 20 hours	

6. What is your average daily patient load in ICU?

0-3 pts		4-6pts		7-9pts		>9pt	

7. What is your average daily patient load outside of ICU?

0-3 pts		4-6pts		7-9pts		>9pt	

8. Outside the ICU setting, do you use outcome measures to assess patients' response to treatment?

Never		Seldom		Sometimes		Often	

SECTION 2

1. Have you heard about the CPAx tool prior to your participation in this study?

Yes		No	

2. If yes, how did you learn about the CPAx tool?

Literature		Information evening, lecture, course		Word of mouth (colleagues, etc).	

3. A- Are you aware of a tool that can be used in the ICU setting that measures physical morbidity besides the CPAx tool?

Yes		No	

B – If yes, which one/s?

_____

C- How regularly do you use these other tools?

Never		Rarely		Sometimes		Often	

4. If you prefer not to use an outcome measure, please supply further information below:

_____

_____

_____

SECTION 3

Please tick either 'Yes' or 'No' for each of the statements about CPAx found in the table below:

The CPAx tool:	**Yes**	**No**
Enhances accuracy of assessment		
Is not appropriate/useful when used with patients with certain admission diagnoses		
Assists with patient care planning and goal setting		
Assists in evaluating patient progression		
Assists in motivating patients to partake in treatment		
Assists in motivating physiotherapists regarding patient treatment		
Enhances communication with the patients		
Is time consuming to administer		
Is difficult to interpret		
Has variables that are not relevant to patient care		
Requires too much effort than proved necessary		
Is comprehensive enough to be administered independently		

APPENDIX 4


This is to certify completion of;
'The Chelsea Critical Care Physical Assessment Tool (CPAx):
Assessing functional recovery from critical illness' e-learning module
Vanessa Bodkin
Date of completion October 2015
Eve Corner, CPAx developer


This is to certify completion of;
'The Chelsea Critical Care Physical Assessment Tool (CPAx):
Assessing functional recovery from critical illness' e-learning module
Raquel Mão-Cheia
Date of completion September 2015
Eve Corner, CPAx developer

This is to certify completion of;

'The Chelsea Critical Care Physical Assessment Tool (CPAx): Assessing functional recovery from critical illness' e-learning module

Megan Whelan

Date of completion September 2015

Eve Corner, CPAx developer

APPENDIX 5

CONSENT FORM

I hereby confirm that I have been informed about the nature, conduct, benefits and risks of the study: ***Use of the CPAx Tool in a South African Intensive Care Unit: Clinical Outcomes and Physiotherapists' Perceptions***

I hereby acknowledge that I have received, read and understood the information sheet pertaining to the study.

I am aware that the results of the study, including personal details such as gender, age and diagnosis will be anonymously processed into a research paper.

I hereby acknowledge that I have been given the opportunity to ask questions related to the study and acknowledge that the researchers have answered my questions adequately.
I understand that I, without prejudice, may withdraw my consent and participation from the study at any time.

Signed:

Participant's name : _____

Signature/thumbprint : _____

Date : _____

Researcher's name : _____

Signature : _____

Date : _____

APPENDIX 6

TEMPORARY CONSENT FORM FOR PATIENT SPOUSE/PARENTS

I hereby confirm that I have been informed about the nature, conduct, benefits and risks of the study: ***Use of the CPAx Tool in a South African Intensive Care Unit: Clinical Outcomes and Physiotherapists' Perceptions***

I hereby acknowledge that I have received, read and understood the information sheet pertaining to the study.

I am aware that the results of the study, including personal details regarding my relative's gender, age and diagnosis will be anonymously processed into a research paper.

I hereby acknowledge that I have been given the opportunity to ask questions related to the study and acknowledge that the researchers have answered my questions adequately.

I understand that participation of my son/daughter or spouse in the study may be withdrawn at any time without prejudice.

Proxy for participant:

Printed name : _____

Signature/thumbprint : _____

Date : _____

Researcher's name : _____

Signature : _____

Date : _____

APPENDIX 7

R14/49 Ms Megan Whelan

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150726

NAME: (Principal Investigator)	Ms Megan Whelan
DEPARTMENT:	Physiotherapy Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	The Use of the CPAx Tool in a South African Intesive Care Unit: Clinical Outcomes and Physiotherapists' Perceptions
DATE CONSIDERED:	31/07/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Heleen van Aswegen

APPROVED BY: Professor P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 26/08/2015

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 Secretary in Room 10004, 10th floor, Senate House, University.

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**.

Principal Investigator Signature

Date 08/10/2015

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 8

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 3 July 2015

TITLE OF PROJECT: The use of the CPAx Tool in a South African Intensive Care Unit: clinical outcomes and physiotherapists' responses

UNIVERSITY: Witwatersrand

Principal Investigator: M Whelan

Department: Physiotherapy

Supervisor (If relevant): H van Aswegen

Permission Head Department (where research conducted): Yes

Date of start of proposed study: July 2015
Date of completion of data collection: Dec 2016

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....
Recommended
(On behalf of the MAC)
Date: 03 July 2015

.....
Approved/Not Approved
Hospital Management
Date: 06/07/15

APPENDIX 9

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PA TO THE CEO
Enquiries: Ms. Thabile Ndlovu
Tel : (011) 933- 9145
Fax: (011) 938-1005
Email: Thabile.Ndlovu2@gauteng.gov.za

To : **Ms Megan Whelan**
M150726

From : **Dr. Sandile Mfenyana**
CEO: CHBA hospital

Date : **19 October 2015**

Re : **Application for Permission to conduct a study in the Use of CPAx Tool in a South African Care unit: Clinical Outcomes and Physiotherapists Perceptions**

Your application for permission to conduct study in the Use of CPAx Tool in a South African Care unit: clinical Outcomes and Physiotherapist Perceptions at Chris Hani Baragwanath Academic Hospital have been approved by the CEO: Dr. Sandile Mfenyana.

Hoping that the Institution (CHBAH) will meet the requirements of the study concerned.

Wishing you well in your future endeavors

Regards,

Dr. SCB Mfenyana
CEO : CHBAH

APPENDIX 10

Letter of permission to Chris Hani Baragwanath Academic Hospital

To the Director of Critical Care,

My name is Megan Whelan. I am a physiotherapy clinician working at Chris Hani Baragwanath Academic Hospital. I am requesting permission to perform a research study entitled *'Use of the CPAx Tool in a South African Intensive Care Unit: Clinical Outcomes and Physiotherapists' Perceptions'*.

The purpose of my study is to determine the effect of using an assessment tool called CPAx on length of time patients spend in the Intensive Care Unit (ICU) and in the hospital. CPAx is a paper-based assessment tool that is used by physiotherapists in the United Kingdom to evaluate a person's ability to do everyday activities. It is not an invasive measure. There are ten different areas/activities of patient function that the tool assesses namely: respiratory function, cough effort, moving in the bed, lie to sit, sitting balance, sit to stand, standing balance, stepping, transfer to a chair and grip strength.

In the first part of the study, participants in the Main ICU and Trauma ICU at Chris Hani Baragwanath Academic hospital will receive a physiotherapy assessment using the CPAx tool. This will be measured every second day during the week while participants are in the ICU. They will receive physiotherapy treatment, based on the assessment findings of the CPAx tool, which involves exercises and rehabilitation depending on what tasks they are struggling with. I will be monitoring how many days participants spend in the ICU as well as how many days they spend in the hospital.

For the second part of the study, all physiotherapy clinicians who administered the CPAx tool to the research participants will be issued with a questionnaire that they will be asked to complete. The questionnaire will be used to assess their views on the use of the CPAx tool in clinical practice.

I am in the process of applying for clearance to perform the study from the Human Research Ethics Committee of the University of the Witwatersrand.

I am requesting permission to access the clinical database in order to determine APACHE scores of patients previously admitted into the ICU.

For any further information pertaining to the study please feel free to contact me on 071 482 2036.

Yours sincerely,

Megan Whelan

Megan Whelan

I J. M. BROWN hereby give my permission for Megan Whelan to access the clinical database for her study (mentioned above).

Signed: _____ Date: 7/9/2015

APPENDIX 11

Use of the CPAx Tool in a South African Intensive Care Unit: Clinical Outcomes and Physiotherapists' Perceptions

PARTICIPANT INFORMATION SHEET

Dear potential participant,

My name is Megan Whelan. I am a physiotherapy clinician working at Chris Hani Baragwanath Academic Hospital. I am performing a research study entitled *'Use of the CPAx Tool in a South African Intensive Care Unit: Clinical Outcomes and Physiotherapists' Perceptions'*. The purpose of my study is to determine the effect of using an assessment tool called CPAx on the period of time spent in the ICU and in the hospital. CPAx is a paper-based assessment tool that is used by physiotherapists in countries such as England to evaluate a person's ability to do everyday activities. It is not an invasive measure. There are ten different areas/activities that the tool assesses relating to patient function. These areas include: respiratory function, cough effort, moving in the bed, lie to sit, sitting balance, sit to stand, standing balance, stepping, transfer to a chair and grip strength. The tool assists physiotherapists to set specific rehabilitation goals for treatment sessions.

What does the Study Involve?

In this study, you will receive physiotherapy assessment using the CPAx tool. This assessment includes measuring your ability to perform everyday tasks such as coughing, rolling, sitting up in bed, standing, stepping, moving into a chair and grip strength. This will be measured every second day of the week for the duration of time that while you are in the ICU. You will receive physiotherapy treatment, based on the assessment findings of the CPAx tool, which involves exercises and rehabilitation depending on what tasks you are struggling with. I will be monitoring how many days you spend in the ICU as well as how many days you spend in the hospital.

What are the Risks?

There are no known risks associated with use of the CPAx tool or to participating in this study.

What is the Cost?

Your participation in this study will not lead to any additional cost to you or your family.

Confidentiality and Anonymity

If you decide to participate in this study, I will give you a study identity code and this code will be used when we enter your information into the database of information for the study. Therefore your information will remain anonymous and information obtained from the study will be used for statistical purposes only.

What are Your Rights?

You may withdraw your consent for participating in the study at any stage. No questions will be asked regarding your decision and you will not be penalised for your decision to withdraw participation.

Contact Details:

If you have any further queries or questions about the study you can contact me on 0714822036. If you wish to report any complaints about or problems with the study you can contact the Human Research Ethics Committee of the University of the Witwatersrand by emailing:
peter.cleaton-jones1@wits.ac.za

APPENDIX 12

Use of the CPAx Tool in a South African Intensive Care Unit: Clinical Outcomes and Physiotherapists' Perceptions

PARTICIPANT INFORMATION SHEET FOR PHYSIOTHERAPISTS

Dear potential participant,

My name is Megan Whelan. I am a physiotherapy clinician working at Chris Hani Baragwanath Academic hospital. I am performing a research study entitled *'Use of the CPAx Tool in a South African Intensive Care Unit: Clinical Outcomes and Physiotherapists' Perceptions'*. The purpose of my study is to determine the effect of using an outcome measure called the Chelsea Critical Care Physical Assessment tool (CPAx) on length of time that patients spend in the Intensive Care Unit (ICU) and in the hospital. I also wish to investigate the perceptions of physiotherapists towards the use of the tool as well as facilitators and barriers to using the tool. CPAx is a paper-based assessment tool that is used by physiotherapists in the United Kingdom to evaluate a person's ability to do everyday activities. It is not an invasive measure. There are ten different areas/activities that the tool assesses namely: respiratory function, cough effort, moving in the bed, lie to sit, sitting balance, sit to stand, standing balance, stepping, transfer to a chair and grip strength.

What does the Study Involve?

In order to participate in this study, you will be required to complete the online CPAx training module. The online link will be emailed to you. Following completion of this module, you will be required to administer the CPAx tool to clinical participants in the trial. Once data collection has been completed, you will be required to complete a printed survey that will assess your experience of using the CPAx tool in your daily clinical practice.

What are the Risks?

There are no known risks associated with the CPAx tool or to participating in the study.

What is the Cost?

There are no costs involved.

Confidentiality and Anonymity:

All participants' documentation will remain anonymous and information obtained from the study will be used for statistical purposes only.

What are Your Rights?

You may withdraw your consent for participating in the study at any stage. No questions will be asked regarding your decision.

Contact Details

If you have any further queries or questions pertaining to the study you can contact me on 0714822036. If you wish to report any complaints or problems you can contact the Human Research Ethics Committee of the University of the Witwatersrand by emailing:
peter.cleaton-jones1@wits.ac.za

APPENDIX 13

TURN-IT-IN REPORT

Researchfinal2.docx

ORIGINALITY REPORT

15%	10%	11%	7%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

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11	Bissett, Bernie, Margot Green, Vince Marzano, Susannah Byrne, I. Anne Leditschke, Teresa Neeman, Robert Boots, and Jennifer Paratz. "Reliability and utility of the Acute Care Index of Function in intensive care patients: An observational study", Heart & Lung The Journal of Acute and Critical Care, 2016. Publication	<1%
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33	Corner, E.J., H. Wood, C. Englebretsen, A.	

	Thomas, R.L. Grant, D. Nikoletou, and N. Soni. "The Chelsea Critical Care Physical Assessment Tool (CPAx): validation of an innovative new tool to measure physical morbidity in the general adult critical care population; an observational proof-of-concept pilot study", Physiotherapy, 2012. Publication	<1%
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	model to predict mortality in patients with cancer admitted to the intensive care unit", Journal of Critical Care, 2012. Publication	
39	Nates, J. L., M. Cardenas-Turanzas, C. Wakefield, S. Kish Wallace, A. Shaw, J. A. Samuels, J. Ensor, and K. J. Price. "Automating and simplifying the SOFA score in critically ill patients with cancer", Health Informatics Journal, 2010. Publication	<1%
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58	Parment, K.. "Long-term immunosuppression in burned patients assessed by in vitro neutrophil oxidative burst (Phagoburst^(R))", Burns, 200711 Publication	<1%
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63	www.jove.com Internet Source	<1%
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124	R. Van Peppen. "Promoting the use of outcome measures by an educational programme for physiotherapists in stroke rehabilitation: a pilot randomized controlled trial", Clinical Rehabilitation, 11/01/2009 Publication	<1%
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128	Roland P.S. Van Peppen. "Outcome measures in physiotherapy management of patients with stroke: a survey into self-reported use, and barriers to and facilitators for use", Physiotherapy Research International, 12/2008 Publication	<1%
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assessment tool: an observational study of recovery from critical illness", Critical Care, 2014.
Publication

131	Maher, Carol, and Marie Williams. "Factors influencing the use of outcome measures in physiotherapy management of lung transplant patients in Australia and New Zealand", Physiotherapy Theory and Practice, 2005. Publication	<1%
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