COMPARISON OF TWO OUTCOME MEASURES TO DETECT CHANGES IN PHYSICAL FUNCTION FOR PATIENTS AFTER OPEN ABDOMINAL SURGERY.

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A dissertation report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in fulfilment of the requirements for the degree of Master of Science in Physiotherapy.

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DECLARATION

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

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2nd day of November 2020 in Randburg, Johannesburg.

ABSTRACT

Background: There is limited evidence regarding responsive physiotherapy-related outcome measures to assess patients' physical function recovery after open abdominal surgery in intensive care unit (ICU) settings. The Physical Function in Intensive Care Test-scored (PFIT-s) assesses physical function (strength, endurance, exercise capacity). The Chelsea Critical Care Physical Assessment (CPAx) assesses respiratory function and physical function.

Objectives: To measure and compare the responsiveness to changes in physical function scores; minimal clinically important difference (MCID) in physical function scores; floor and ceiling effects of scores; and, the level of convergent validity for CPAx and PFIT-s scores for patients after open abdominal surgery.

Design: A prospective observational longitudinal cohort study.

Methods: Participants were recruited from the Wits Donald Gordon Medical Centre surgical- and transplant ICUs. Participants' physical function was assessed on days one, three and five postoperatively and ICU discharge using the CPAx and PFIT-s (in random order) from August 2019-November 2019. Descriptive and inferential statistics were used for data analysis.

Results: Sixty-nine participants (mean age 54 (±15.5)) underwent open abdominal surgery. Majority were female (n=43, 62.3%). Effect size index (ESI) for CPAx=0.910 indicating large responsiveness to change. The ESI for PFIT-s=0.712 indicating moderate responsiveness to change. The MCID for CPAx=4.4 and PFIT-s=0.8. The CPAx tool had a limited floor and ceiling effect on ICU admission (floor effect: 0.00%, ceiling effect: 0.00%) and discharge (floor effect: 0.01%, ceiling effect: 7.25%). The PFIT-s had a significant ceiling effect (46.38%) on ICU discharge. CPAX and PFIT-s ICU admission scores and ICU discharge scores showed moderate convergent validity (r=0.60 n=69 p=0.00, and r=0.51 n=68 p=0.00 respectively).

Conclusion: Both the CPAx and PFIT-s are valid for assessing physical function in postoperative patients. The CPAx is more responsive to detect an improvement in physical function in this cohort recovering from open abdominal surgery. It has a clinically significant MCID with limited floor and ceiling effects.

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LIST OF ABBREVIATIONS

6MWT	- Six-Minute Walk Test
CPAx	- Chelsea Critical Care Physical Assessment
GICU	- General Intensive Care Unit
ICU	- Intensive Care Unit
ICU-AW	- Intensive care unit-acquired weakness
LOS	- Length of Stay
MCID	- Minimal Clinically Important Difference
MOS	- Marching on the Spot
MRC	- Medical Research Council
OM	- Outcome Measure
PFIT-s	- Physical Function in Intensive Care Test-scored
PPC	- Postoperative pulmonary complications
SF-36	- Short Form 36
SICU	- Surgical Intensive Care Unit
THC	- Transplant High Care
TICU	- Transplant Intensive Care Unit
TUG	- Timed Up-and-Go
WDGMC	- WITS Donald Gordon Medical Centre

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1. CHAPTER 1 INTRODUCTION

1.1 BACKGROUND

Every year 250 million surgeries are performed worldwide, and 18,895 operations are carried out per 100,000 inhabitants in Sub-Saharan Africa (Rose et al., 2017; Spence et al., 2016). Open abdominal surgery is done every day in the world, and since the 1940s physiotherapists have been involved postoperatively in the treatment of these patients (Browning, Denehy & Scholes, 2007). Postoperative pulmonary complications (PPC) like partial or complete atelectasis of lung segments or pneumonia has a 75% risk factor for occurring in patients that have abdominal surgery (Pasquina et al., 2006; Thomas & McIntosh, 1994). Risk factors such as sepsis 48 hours postoperatively, congestive heart failure within 30 days postoperatively, being older than 60, acute renal failure and a score of three, four or five on the American Society of Anesthesiologists physical status classification are associated with developing postoperative complications and thus admission into the intensive care unit (ICU) post-surgery (Siletz et al., 2017).

Since the 20th century, postoperative chest physiotherapy has been executed and, one recommended way of combating the PPC as mentioned above is through early mobilisation in the ICU environment (Browning, Denehy & Scholes, 2007; Pasquina et al., 2006). A growing evidence base is available concerning the value of early mobilisation in ICU (Adler & Malone, 2012). It has been shown that early mobilisation in critically ill patients is safe to perform (Hodgson et al., 2013). Seeing that mobilisation is the technique identified to combat PPC, it would make sense to assess and monitor the progression of physical function in patients after open abdominal surgery. The clinical practice of physiotherapy is relying more on the use of outcome measures (OM). Currently, only 11 reliable OMs, that assess physical function are available to clinicians to utilise in the ICU setting (Parry et al., 2015). These OMs help clinicians to objectively evaluate their patients, to identify areas requiring rehabilitation and to ensure adequate intervention for the identified areas.

Responsiveness of an OM can be described as the OM's ability to detect the degree of change in a patient's health care status when administered in a specific environment. The responsiveness of a tool indicates the tool's ability to detect a difference in the patient's functional condition every time that the tool is re-administered (Corner et al., 2015; Coster, 2013; Revicki et al., 2006). A tool's responsiveness to change also

involves its ability to detect a minimal clinically important difference (MCID) of change of a patient's condition. The MCID of an OM shows that when a patient's score improves when the tool is re-administered, that improvement indicates a clinically meaningful enhancement in the patient's function (Corner et al., 2015).

The Physical Function in Intensive Care Test-scored (PFIT-s) was explicitly intended for use in ICU as it examines both functional and body system impairments (Nordon-Craft et al., 2014)**.** Parry et al. reported in 2015 that **"**The PFIT-s can be used as a reference standard against which other functional measures can be compared (Parry et al., 2015:2)." Certain studies done on critically ill patients from mixed ICU's have measured the floor and ceiling effect of the PFIT-s. The OM has demonstrated a limited effect (ranging from 5% – 23%). The PFIT-s has moderate to high correlation when compared to other OMs such as handgrip strength, Medical Research Council (MRC) sum score, the six-minute walk test (6MWT) and timed up-and-go (TUG) test that are often used to measure strength or endurance in ICU patients (Denehy et al., 2013; Kayambu, Boots & Paratz, 2011; Nordon-Craft et al., 2014).

Corner et al. developed the Chelsea Critical Care Physical Assessment (CPAx) tool in 2012 and this tool not only assesses the physical function of the patient but also considers the respiratory impairments with which the patient might present. In this study, the CPAx tool presented a limited floor and ceiling effect (between 0.8% and 3.2%) for patients in a general ICU (GICU) setting. The CPAx tool has shown validity comparable to the MRC sum score as well as the SF-36 physical function domain (Corner et al., 2014, 2012).

Both these OMs have construct validity; both are valid, reliable and responsive to change in ICU patients (Corner et al., 2014; Denehy et al., 2013). There is, however, a difference in the construct validity of the PFIT-s in comparison to the CPAx tool. The question remains whether the CPAx - or PFIT-s tool is more responsive to detect a change in physical function in patients recovering from open abdominal surgery?

1.2 WORKING DEFINITIONS

CPAx: The CPAx OM consists of ten scored domains. The minimum score is zero, and the maximum score is five per domain. A score of zero indicates low physical function, and a score of five indicates normal physical function. The maximal score for the CPAx tool is 50/50, which reflects independent function.

PFIT-s: The PFIT-s OM consists of four scored domains. The minimum score is zero, and the maximum score is three per domain. When the patient obtains a score of zero in total for the PFIT-s, it indicates that the patient has low physical function or might be sedated and are unable to perform any of the assessment areas of the PFIT-s. A score of zero can also be indicative that the PFIT-s is too difficult for the patient's functional ability at the time of evaluation. When a patient obtains a score of 12 for the PFIT-s, it demonstrates good independent physical function and that the patient was able to perform each assessment component in the PFIT-s and receive the maximal score for every section. The maximal score for the PFIT-s is 12/12, which reflects independent function or that the OM is too easy for the patient being tested.

Clinimetric properties: This is the quantitative measurement of clinical phenomena of patient care through collection and analysis of comparative clinical data (Gabel et al., 2012). Others have described clinimetric properties of the CPAx and PFIT-s tools as these tools' responsiveness to detect the change in physical function; the MCID measured in specific patient populations using one of these tools; the floor and ceiling effects measured with these tools, and convergent validity (Corner et al., 2015; Denehy et al., 2013).

Responsiveness: The capacity of an OM to detect change (improvement or regression) in a patient's condition. For this study, the responsiveness of the CPAx and PFIT-s tools to detect a difference in a patient's functional ability after abdominal surgery will be evaluated (Denehy et al., 2013).

MCID: The minimal clinically important difference is the smallest amount of change that needs to occur to reflect a clinically meaningful change in a patient's function (Denehy et al., 2013). For this study, the MCID will be determined and reported for both the CPAx and PFIT-s tools in this adult surgical population (Denehy et al., 2013; Corner et al., 2015).

Floor effect: A floor effect occurs when patients obtain a score of zero on the OM administered. An OM tool is deemed less sensitive to detect a change in the health status of a cohort of patients when a high floor effect is measured (Corner et al., 2015).

Ceiling effect: A ceiling effect occurs when patients obtain maximal scores for the OM administered. An OM tool is deemed less sensitive to detect a change in the health

status of a cohort of patients when a high ceiling effect is measured (Corner et al., 2015).

Convergent validity: This is determined by investigating the overlap between two tests that presumably measure the same construct (Denehy et al., 2013).

1.3 Statement of Problem and Justification for research

The CPAx tool is utilised daily at Wits Donald Gordon Medical Centre (WDGMC) in the Transplantation Intensive Care Unit (TICU), Transplantation High Care (THC) and Surgical Intensive Care Unit (SICU) settings, and forms part of the comprehensive physiotherapy assessment performed for all patients in these units. The CPAx tool assesses limitations in body function, inclusive of respiratory function and activity limitations, and is responsive to detect a change in patient outcomes in ICU. However, most of the patient population in TICU, THC and SICU at WDGMC are not intubated for an extended period. Therefore, the responsiveness of the CPAx tool to detect a change in the patient population at WDGMC is questioned.

The PFIT-s OM is responsive to change even though it seems to focus more on the physical functional change in patients in the ICU. The PFIT-s OM does not have a respiratory component like the CPAx OM. The CPAx and PFIT-s OMs have been utilised in most clinical ICU settings from burns-, adult liver transplant-, MICU, SICU and trauma ICU's. Most studies using the CPAx and PFIT-s OM have been conducted over a mixed sample of patients with varying conditions but have not been utilised to study patients after open abdominal surgery exclusively (Corner et al., 2012, 2014; Parry et al., 2015; Mehrholz et al., 2016; Tadyanemhandu & Manie, 2016; Whelan, van Aswegen & Corner, 2018).

It is therefore pertinent to determine which of these two OM tools (CPAx or PFIT-s) would be most sensitive to detect a change in physical function in patients recovering from open abdominal surgery as seen in the WDGMC TICU, THC and SICU settings.

1.4 Research Question

What are the clinimetric properties of the CPAx and PFIT-s tools to detect changes in physical function in a cohort of adult patients who had open abdominal surgery?

1.5 Research Aims

To test the clinimetric properties of the CPAx and PFIT-s tools to assess physical function in a cohort of adult patients who had open abdominal surgery.

1.6 RESEARCH OBJECTIVES

1.6.1 To describe the demographic- and clinical profiles of patients who had open abdominal surgery at the WDGMC.

1.6.2 To measure and compare the CPAx and PFIT-s tools' responsiveness to detect changes in physical function scores for patients who had open abdominal surgery.

1.6.3 To measure the MCID in physical function scores obtained with the CPAx and PFIT-s tools for patients who had open abdominal surgery.

1.6.4 To determine and compare the floor and ceiling effects of scores obtained with the CPAx and PFIT-s for patients who had open abdominal surgery.

1.6.5 To determine the level of convergent validity for scores obtained with the CPAx and PFIT-s tools for patients who had open abdominal surgery.

1.7 TYPE OF STUDY

A prospective observational longitudinal cohort study was conducted and reported on according to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines (Vandenbroucke et al., 2007).

1.8 SIGNIFICANCE OF RESEARCH

Early mobilisation of patients and the utilisation of OMs to evaluate the effect of rehabilitation interventions used on patients are crucial components of evidence-based practice for physiotherapists who work in acute care settings. Patient assessment with the CPAx is part of the daily clinical practice at WDGMC TICU, THC and SICU. However, the responsiveness and appropriateness of this tool that we utilise in patients who underwent open abdominal surgery are unknown. Identifying an OM that is responsive and demonstrates MCID for this patient population will assist with goal-directed progressive therapy sessions, improved functional outcomes and ensure time and cost-effective service provision.

Results of the study will be made available to the patients on request, the research office at WDGMC, the physiotherapists, the intensivists and the surgeons working with patients in the TICU, THC and SICU daily. The results will also be disseminated through a presentation at local- and international conferences and publication in a peer-reviewed journal.

2. CHAPTER 2 LITERATURE REVIEW

The information discussed in this literature review was found by searches performed on the following search engines: EBSCO Host, Google Scholar, PubMed, Research Gate, Science Direct and Scopus. The following search terms were used: "postoperative pulmonary complications", "postoperative pulmonary complications + pain", "functional complications after abdominal surgery", "pain + postoperative", "early mobilisation in ICU", "benefits of early mobilisation in ICU", "intensive care unit acquired weakness", "Frailty", "Chelsea Critical Care Physical Assessment tool", "CPAx", "physiotherapy + outcome measures + ICU", "rehabilitation outcome measures in ICU", "PFIT", "PFIT-s", "The Physical function in intensive care test scored" "physiotherapy + outcome measures + abdominal surgery", "outcome measures + abdominal surgery", "rehabilitation + abdominal surgery" and "function + abdominal surgery". English language articles were collected and analysed.

1.1 POSTOPERATIVE PULMONARY COMPLICATIONS AFTER ABDOMINAL SURGERY

Postoperative pulmonary complications (PPC) have no universally accepted definition, and multiple variations are available. Postoperative pulmonary complications are described as the presence of acute respiratory distress syndrome (ARDS), aspiration pneumonitis, atelectasis, bronchospasm, pleural effusion, pneumonia, pneumothorax, pulmonary embolus, respiratory infection and respiratory failure after undergoing surgery (Canet et al., 2010; Jammer et al., 2015; Miskovic & Lumb, 2017). Another broad definition of PPC by Rudra and Sudipta (2006) are: "an identifiable disease or dysfunction that is clinically relevant and adversely affects the clinical course" (Rudra & Sudipta, 2006:89). Depending on the inclusiveness of the definitions, PPC occur in 2% to 23% of all patients that have undergone abdominal surgery and these complications are even more prevalent than postoperative cardiac complications (Fisher, Majumdar & McAlister, 2002; Miskovic & Lumb, 2017; Moran et al., 2016).

Postoperative pulmonary complications are related to an enhanced probability of early postoperative mortality, increased morbidity, ICU admission, increased hospital LOS and multiple hospital readmissions (Fernandez-Bustamante et al., 2017; Knihs et al., 2020; Shander et al., 2011). Miskovic & Lumb demonstrated in 2017 that PPC result in an increased LOS in hospital by 13-17 days, that the 90-day postoperative mortality rate was 24,4% and that one in five patients passed away within 30 days following major surgery.

Three commonly described predisposing factors to developing PPC are age, incision location, as well as surgical procedure duration. Age has been listed as patients 60 years and older often present with increased frailty. Xue (2011) termed frailty as: "a clinically recognisable state of increased vulnerability, resulting from an ageing-associated decline in reserve and function across multiple physiologic systems such that the ability to cope with every day or acute stressors is compromised" (Xue, 2011:1). Physiological- and anatomical muscle changes starting at midlife are referred to as sarcopenia. Sarcopenia is the result of the loss of muscle strength due to the loss of muscle quality and muscle mass (Xue, 2011). Frailty and sarcopenia have been described as a predictor of complications, increased risk of poor health outcomes, -mortality and -length of hospital stay due to muscles' adaptive capacity gradually decreasing with age (Hoogeboom et al., 2014; Tahiri et al., 2016; Xue, 2011). Thus, being sarcopenic or frail predisposes the patient to the development of PPC (Dhaliwal et al., 2020; Hoogeboom et al., 2014; Knihs et al., 2020; Tahiri et al., 2016).

Incision sites can predispose the patient to PPC up to 15 times more as upper abdominal incisions and laparotomies have a higher PPC complication rate compared to lower abdominal incisions and laparoscopic procedures. When surgical procedures are performed close to the diaphragm, it leads to a secondary reflex inhibition of the chest wall and peritoneum resulting in pain and diaphragmatic splinting, atelectasis, impaired gas exchange, reduced cough effort, reduced mucociliary riddance, potential micro-aspiration and potentially pneumonia (Rudra & Sudipta, 2006; Shea et al., 2002). Upper abdominal surgeries and open abdominal surgeries thus have a higher risk for the development of PPC postoperatively.

General anaesthesia is utilised in most surgical procedures; however, it has been correlated with the development of atelectasis and decreased lung volumes postoperatively. The residual effects of anaesthesia are due to uncoordinated, shallow breathing and diaphragmatic dysfunction that the patient presents with postoperatively. Shallow breathing and inspiratory muscle dysfunction enhance the atelectatic effect by decreasing surfactant production in the lungs resulting in more collapse of alveoli (Colucci et al., 2015; Denu et al., 2015; Lawrence et al., 2004; Miskovic & Lumb, 2017; Shea et al., 2002; Vassilakopoulos et al., 2000). Surgical procedures with a duration longer than two hours have shown a higher PPC association because of artificial ventilation and paralysis, resulting in a modification of the neural drive of the diaphragm due to reflex inhibition of phrenic nerve output and the central regulation of breathing.

Lengthy surgical procedures result in a 30% reduced functional residual capacity, and a 50% reduced vital capacity in the patient (Fisher, Majumdar & McAlister, 2002; Miskovic & Lumb, 2017). Lockstone et al. have shown in 2020 that 85% of patients experience PPC after upper abdominal surgery since lung volumes are at their lowest for the first three days postoperatively. Diaphragmatic dysfunction, weakness and atrophy can have an onset within 48h after intubation and could potentially lead to difficulty to wean off ventilation, this inherently predisposes the patient to the development of PPC (Hermans & Van den Berghe, 2015; Shea et al., 2002).

It thus shows that being exposed to general anaesthesia and having abdominal surgery is enough of a reason to have PPC excluding factors such as other postoperative complications, being older than 60 and having any other premorbid conditions. It is therefore imperative to assess whether using an OM that evaluates the patient's respiratory function in addition to physical function provides a more comprehensive picture of the patient's recovery postoperatively.

1.2 FUNCTIONAL COMPLICATIONS AFTER ABDOMINAL SURGERY

Functional complications after abdominal surgery are poorly described as very little is understood about the predictors of poor recovery, and few articles explore and monitor the course to a total restoration of preoperative independence. Most studies addressing functional complications are small, focus on short follow-up periods and utilise patient self-reported OMs instead of therapist administered performance-based OMs (Lawrence et al., 2004). However, Kamarajah et al. demonstrated in 2020 that postoperative physical function, as well as quality of life, deteriorates between 20-40% as a result of having major surgery.

Patients who had abdominal surgery often get admitted into ICU after having their procedures due to the known risk of postoperative complications and longer respiratory function impairments as discussed under the PPC section. Factors such as sepsis 48 hours postoperatively, congestive heart failure within 30 days postoperatively, being older than 60, acute renal failure and a score of 3, 4 or 5 on the American Society of Anaesthesiologist physical status classification are related with developing postoperative complications and thus necessitates ICU admission post-surgery (Siletz et al., 2017).

Farhan et al. described in 2016 that surgical patients have more extended postoperative bed rest periods related to pain, surgical muscle trauma, posttraumatic

inflammation and the resultant anaesthetic- and neuromuscular blocking agent effects. Surgical procedures, surgical stress on the body, long term bed rest and opioid usage for pain control result in muscle catabolism and acquired muscle weakness in 56% to 74% of all SICU patients (Van Aswegen et al., 2011; Farhan et al., 2016; Hoogeboom et al., 2014).

Intensive care unit-acquired weakness (ICU-AW) was defined by Corner (2012) as: "a syndrome encompassing myopathic, neuropathic and atrophic changes, which clinically presents as profound weakness" (Corner, 2012:216). Muscle weakness, thus the loss of limb strength, power and aerobic capacity, is a common phenomenon in the SICU and predicts adverse outcomes of critically ill patients (Hoogeboom et al., 2014; Schaller et al., 2016). Muscle mass can atrophy by 2% per day in ICU, and adverse outcomes such as decreased functional ability, thromboembolic disease, orthostatic hypotension, microvascular dysfunction, pressure sores, insulin resistance, delirium, joint contractures and respiratory complications have been described (Farhan et al., 2016; Tahiri et al., 2016).

Disuse atrophy, as well as reduced neural activation, results in the reduction of cross-sectional muscle mass and -fibres. Among humans, mostly type I muscle fibres are lost impeding independent functionality post ICU discharge (Farhan et al., 2016).

Addressing ICU-AW and recovery to preoperative functional ability is essential as it takes the longest to recover. One year after surgery 20-30% of patients having localised surgical procedures and 80% of patients having renal- and liver transplants still presented with lasting weakness (Farhan et al., 2016; Lawrence et al., 2004; Tahiri et al., 2016). Patients who have cancer or liver disease have shown to present with preoperative sarcopenia and frailty (Boer et al., 2016; Dhaliwal et al., 2020; Handforth et al., 2015; Kurniawan, 2019). Preoperative sarcopenia is linked with increased ICU- and hospital LOS and increased time on mechanical ventilation postoperatively (Boer et al., 2016; Dhaliwal et al., 2020; Handforth et al., 2015; Kurniawan, 2019).

Early and goal-directed mobilisation postoperatively can combat the effects of ICU-AW, decreasing the duration of delirium, shorten mechanical ventilation time, reduce ICU- and hospital LOS and increase hospital discharge functional independence (Dhaliwal et al., 2020; Farhan et al., 2016; Schaller et al., 2016). Lawrence et al. reported in 2004 that performance-based assessments captured impairment and

functional restrictions more accurately to reflect the health- and physical functional abilities of the patient.

A preoperative and postoperative therapeutic exercise training program comprising of inspiratory muscle training, aerobic exercise and low-intensity anaerobic exercise training has shown to advance the physical fitness of patients, to enhance oxygen transportation and to improve their functional recovery after abdominal surgery (Hoogeboom et al., 2014; Lawrence et al., 2004; Moran et al., 2016; Zafiropoulos, Alison & McCarren, 2004). Thus, reducing the risk of PPC and preventing lowered health-related quality of life due to functional impairments and disability (Dhaliwal et al., 2020; Kamarajah et al., 2020; Moran et al., 2016; Strik et al., 2018; Whelan, van Aswegen & Corner, 2018). Identifying an OM that accurately reassesses the progression of patients after abdominal surgery will assist in identifying areas of physical function that is reduced due to the surgical insult or preoperative frailty. Regular reassessment with a responsive OM will help guide the clinician to choose the most appropriate rehabilitation interventions.

1.3 THE ROLE OF POSTOPERATIVE PAIN IN PULMONARY AND FUNCTIONAL COMPLICATIONS AFTER ABDOMINAL SURGERY

Pain is very subjective, it is defined by the person and experienced at individualised intensities, but any surgical intervention will have associated pain postoperatively. Postoperative pain can influence patients in three ways, namely 1. neuroendocrine and metabolic stress responses, 2. affected lung function and 3. affected mobility (Shea et al., 2002).

The stress response postoperatively results in more cortisol, catecholamines, aldosterone, angiotensin II, antidiuretic hormone, prostaglandins production, glucose and protein catabolism affecting the cardiovascular stability, coagulation- and immune function of the patient (Van Aswegen et al., 2011; Shea et al., 2002). This stress response itself influences the patient's surgical outcomes, as protein and glucose catabolism would result in more rapid ICU-AW and poor healing of the surgical incision site. Cardiovascular instability of the patient would delay mobilisation, which would result in weakness as well as increase the risk for PPC development (Mackay, Ellis & Johnston, 2005; Shea et al., 2002).

The effects of general anaesthesia in combination with postoperative pain, the presence of abdominal distention and diminished cough reflexes after upper abdominal

surgery cause atelectasis and reduced lung volumes (Colucci et al., 2015; Lawrence et al., 2004; Miskovic & Lumb, 2017; Shea et al., 2002; Vassilakopoulos et al., 2000). Forced vital capacity and peak expiratory flow are mostly affected when measuring postoperative lung volumes as deep breathing is inhibited by pain and increased in abdominal wall tone (Lawrence, Cornell & Smetana, 2006; Miskovic & Lumb, 2017; Rudra & Sudipta, 2006). Reduced lung volumes and inadequate cough efforts due to pain increase the risk for secretion accumulation and -retention (Shea et al., 2002). By adequately addressing pain, especially for patients with incisions close to the diaphragm, the possibility for PPC decrease (Rudra & Sudipta, 2006). Better pain control will encourage deep breathing, enhancing lung volumes and combating further atelectasis (Rudra & Sudipta, 2006; Shea et al., 2002). It will also improve cough effort, which would reduce secretion retention (Miskovic & Lumb, 2017; Shea et al., 2002). Thus by providing adequate pain control, avoiding oversedation or respiratory depression, the risk for PPC decrease dramatically. In turn, pain control would also improve mobility.

Shea et al. established a negative association between mobilisation and pain intensity in 2002. Pain and anxiety encourage immobility and prolonged periods of lying in bed which have been linked with ICU-AW (Boden et al., 2018; Corner, 2012; Li et al., 2013; Do Nascimento et al., 2014; Shea et al., 2002). Pain has also been linked with slower walking pace and intensity (Zafiropoulos, Alison & McCarren, 2004). However, early mobilisation has revealed to enhance functional independence at hospital discharge and decreased ICU- and hospital LOS (Schaller et al., 2016). Adequate pain control without oversedation can enhance mobilisation abilities, thus preventing functional complications such as ICU-AW, joint contractures, pressure sores, deep vein thrombosis and loss of independent functional status (Lawrence et al., 2004).

Various types of pain control are available postoperatively. Each has benefits and disadvantages to the patients and different abilities to control postoperative pain. Epidural anaesthesia blocks the stress responses to surgery and has significantly fewer pulmonary complications as it reduces respiratory muscle dysfunction and pain-related hypoventilation. The combination of epidural analgesia and opioids are recommended for patients undergoing abdominal surgery. Epidural usage has demonstrated statistically significant pain reduction and reduced respiratory failure (Lawrence, Cornell & Smetana, 2006; Miskovic & Lumb, 2017; Rudra & Sudipta, 2006). Epidural usage can, however, result in hypotension, respiratory muscle weakness,

urinary retention and neurological injury and the risk should be considered for every individual patient (Kendall et al., 2017).

Neuromuscular blocking agents are associated with myopathy and prolonged muscle weakness and can result in delirium in 67% - 73% of patients (Farhan et al., 2016). These agents are more commonly used during surgery but can be utilised postoperatively if the patient requires paralysis. It is not widely utilised as the best option for postoperative pain management.

Opioids are effective in pain management but have shown to promote atelectasis, depress the respiratory drive by reducing phrenic nerve- and diaphragmatic activity, cause hypotension and can increase the risk of aspiration due to slower gastrointestinal motility (Farhan et al., 2016; Rudra & Sudipta, 2006). Patient-controlled epidural analgesia or oral analgesia has shown to be more effective compare to opioid usage (Mackay, Ellis & Johnston, 2005).

Adequate management of postoperative pain is thus essential in promoting early mobilisation to avoid weakness and functional dependence and prevent PPC from developing.

1.4 THE CHELSEA CRITICAL CARE PHYSICAL ASSESSMENT TOOL AS AN OUTCOME MEASURE

The CPAx was developed by Corner et al. in 2012 to cover all stages of ICU recovery thus from full dependence to independence and has shown to have strong clinimetric properties (Corner et al., 2012; Parry et al., 2015). The CPAx OM has ten domains that assess a patient's functional ability and respiratory function (Corner et al., 2014).

According to Corner et al. in 2012, the assessment components are as follows:

- "Respiratory function: Amount of respiratory support required, in terms of both ventilation and oxygenation.
- Cough: Cough effectiveness, in terms of consistency and secretion clearance.
- Bed mobility: The ability and level of assistance required to move around the bed.
- Supine to sitting on the edge of the bed: The ability and level of assistance required to sit on the edge of the bed from supine.
- Dynamic sitting: The level of support required to maintain sitting balance, progressing to the ability to reach out of the base of support.
- Sit to stand: The ability and level of assistance needed to stand from a sitting position with less than 90 degrees of knee flexion.

- Standing balance: The amount of support required to maintain standing, ranging from a tilt table to independent.
- Transferring from bed to chair: Mode of transfer from bed to chair (e.g. cradle hoist transfers, standing hoist, independent, etc.).
- Stepping: Assesses the physical ability to walk, and support required (e.g. frame, physical assistance, etc.).
- Grip strength: Grip strength measured by a grip dynamometer as a percentage of expected, when age and gender corrected" (Corner et al., 2012:3).

The CPAx is a simple OM to use and is scored out of 50. The maximum score (50) indicates the normal respiratory and physical function, and the higher the score, the higher the patient's abilities. A score of zero indicates total dependence from the patient, from respiratory needs to all physical activities and activities of daily living. A score of zero is the floor of physical function and not the floor effect as the CPAx was designed to detect a change in low functioning patients (Corner et al., 2015). The CPAx has demonstrated to have a limited floor and ceiling effect when utilised in the ICU, but the ceiling effect might be more apparent when the tool is used for outpatient rehabilitation assessments (Corner et al., 2014, 2015; Parry et al., 2015).

The CPAx is a validated OM to assess physical morbidity and function, muscle mass and strength. It has demonstrated strong reliability, internal consistency, responsiveness to change and good construct validity with the MRC sum score, Glasgow Coma Scale score, Bloomsbury sedation scale and Australian Therapy OMs (Corner et al., 2014, 2015; Parry et al., 2015). Corner et al. demonstrated in 2015 in patients that sustained burns injuries, that a change in score of six points represented a clinically meaningful change in the patient's condition or ability. Thus, when a difference in the patient's physical function is noted, for it to be considered a significant change, their CPAx score must change with six points.

The CPAx has been utilised in most clinical ICU settings from burns-, adult liver transplant-, GICU, neurological-, SICU and trauma ICU's. Most studies using the CPAx OM have been conducted over a mixed sample of patients with varying conditions but have not been utilised to study patients after open abdominal surgery exclusively (Corner et al., 2012, 2014; Parry et al., 2015; Mehrholz et al., 2016; Tadyanemhandu & Manie, 2016; Whelan, van Aswegen & Corner, 2018).

The tool was developed in London in the United Kingdom. An online training module, for the use of CPAx tool in clinical settings, was designed by Evelyn Corner and is available free of charge. Physiotherapists from England, Ireland, Scotland, Wales, United States of America, Switzerland, Australia, South Africa, Canada, Sweden, Denmark, Belgium, Brazil and Japan have reportedly completed the training. They are actively using CPAx in their respective clinical settings (Corner, Handy & Brett, 2016). To date, researchers in the United Kingdom, Australia and South Africa have used the CPAx tool for clinical studies.

Utilising the CPAx enables the clinician to create problem-orientated rehabilitation plans in the ICU and motivate the patient using the CPAx score as it is a performance-based OM (Corner, Handy & Brett, 2016; Whelan, van Aswegen & Corner, 2018). The CPAx can lastly assist the clinician with follow-up, and long term rehabilitation planning as the CPAx has demonstrated strong associations with hospital-discharge locations (Corner et al., 2014; Corrigan, 2015). Patients with lower scores need more long term rehabilitation and have reduced functional abilities upon discharge from the hospital.

1.5 THE PHYSICAL FUNCTION IN INTENSIVE CARE TEST SCORED AS AN OUTCOME MEASURE

The PFIT-s assesses the physical capacity of critically ill patients and provides the clinician with information about muscle strength and function. The PFIT-s is a simple and inexpensive tool that has been tested for its clinimetric properties and has proven to be valid, reliable, responsive and sensitive to detect a functional change when used in ICU patients (Skinner et al., 2009; Denehy et al., 2013; Parry et al., 2015; Tadyanemhandu & Manie, 2016; Parry, Huang & Needham, 2017). The PFIT-s can be utilised as long as the patient is alert, able to follow instructions and stable enough to mobilise and participate even if the patient is still on mechanical ventilation (Nordon-Craft et al., 2014). Ideally, the patient must sit out of bed for the assessment but sitting over the edge of the bed is also accepted should the patient not be able to mobilise out of bed (Denehy et al., 2013; Nordon-Craft et al., 2014).

The four test components are:

- Sit to Stand: The amount of support needed by the patient is assessed by the physiotherapist, to come from sitting over the edge of the bed or from sitting in a chair, into a standing position.
- Marching on the Spot (MOS): The number of steps a patient can take over a measured period. The maximum time frame that the patient must perform the MOS

is three minutes. The MOS recording is stopped if the patient doesn't take a step for longer than one second or if the patient doesn't clear their foot off the floor when stepping.

- Upper limb muscle strength grading: Muscle strength is assessed on the left- and right upper limb individually while the patient sits over the edge of the bed or in a chair. The muscle strength assessment is performed with an outstretched arm at 90 degrees of shoulder flexion, and resistance is applied distal to the elbow joint by the therapist. The highest score obtained between the left or right upper limb is utilised in the PFIT-s score calculation.
- Lower limb muscle strength grading: Muscle strength is assessed on the left- and right lower limb individually while the patient sits over the edge of the bed or in a chair. The muscle strength assessment is performed with a knee at 90 degrees of flexion, and resistance is applied over the ankle joint by the therapist. The highest score obtained between the left or right lower limb is utilised in the PFIT-s score calculation.

Each element is scored from zero to three, and a maximum score of 12 can be attained on the PFIT-s ordinal scoring scale (Denehy et al., 2013). A converted ordinal to interval scale is available as part of the assessment to determine the clinically meaningful change in score for patients (Denehy et al., 2013; Parry et al., 2015).

The higher the PFIT-s score, the more functionally able the patient is. Additionally the rating of perceived exertion via the modified Borg Scale (scored between zero and ten), peripheral oxygen saturation ($Sp0_2$), heart rate (HR) and mean arterial blood pressure are monitored during testing and training (Denehy et al., 2013). Due to the cardiovascular assessments (rate of perceived exertion, HR, SpO_2) that are recorded during the PFIT-s evaluation, this test can be utilised for objectively prescribing exercise to the patient at an appropriate level to attain the desired training effect and to use as a reassessment for progression (Denehy et al., 2013; Skinner et al., 2009).

Multiple validity tests have been performed on the PFIT-s. It has demonstrated moderate convergent validity with the 6MWT, TUG, MRC sum score and grip strength, according to Denehy et al. (2013) and Nordon-Craft et al. (2014). Parry et al. (2015) showed that the PFIT-s has excellent construct validity with muscle strength measurements and moderate construct validity with the Functional Status Score for the ICU OM and ICU mobility scale. The PFIT-s also has predictive validity, in that

higher baseline and discharge PFIT-s score were linked with more successful discharge to home, reduced hospital LOS and identifying patients that will require ongoing rehabilitation (Denehy et al., 2013; Nordon-Craft et al., 2014; Parry et al., 2014, 2015; Tadyanemhandu & Manie, 2016; Parry, Huang & Needham, 2017). The PFIT-s score can assist clinicians with a better assessment of functional impairments and cardiovascular responses to endurance testing to aid their planning with regards to their patient's rehabilitation needs upon discharge from the ICU (Denehy et al., 2013; Nordon-Craft et al., 2014).

The PFIT-s has demonstrated varying floor effects of between 9% – 32% and ceiling effects of between 5% – 22% throughout the literature (Denehy et al., 2013; Nordon-Craft et al., 2014; Parry et al., 2015; Parry, Huang & Needham, 2017). The biggest reason for significant floor effects was varying sedation protocols at different institutions with ICU admission and that the PFIT-s doesn't cover test items for low functioning patients in the ICU. The ceiling effects were present upon discharge from the ICU, indicating that a combination of OM should be utilised to assess higher functional activities after ICU discharge (Nordon-Craft et al., 2014; Parry et al., 2015).

Denehy et al. (2013) showed that the PFIT-s is very responsive to change in physical function with an effect size index (ESI) of 0.82. The MCID was determined by Parry et al. (2015) as a score of 1.5 out of 10 on the interval scoring scale. The MCID indicates that when a patient's score changes by 1.5 points that there is a meaningful change in their physical function (Parry, Huang & Needham, 2017).

The PFIT-s tool was developed in Melbourne, Australia and researchers from Australia, Germany, South Africa, Turkey, the United States of America and Zimbabwe have used it in most clinical ICU settings from medical-, surgical- and trauma ICU's (Denehy et al., 2013; Nordon-Craft et al., 2014; Skinner et al., 2009). Most studies using the PFIT-s OM have been conducted over a mixed sample of patients with varying conditions (Parry et al., 2015; Mehrholz et al., 2016; Tadyanemhandu & Manie, 2016; van Aartsen & van Aswegen, 2018).

1.6 Outcome Measures used for assessing physical function in patients with open abdominal surgery

In 2017, Parry et al. described 11 physical function assessment instruments that have been tested in the ICU. Most of the OM described have been utilised in mixed ICU's or the study population wasn't well defined. The World Health Organization (WHO)

established the International Classification of Functioning, Disability and Health (ICF) framework in 1980 looking at health from three perspectives, namely body function and structure, activities and participation (World Health Organisation, 2002). Outcome measures are objective tools that assist in exploring the effect of critical illness on body functions and structures and how the impairments affect activities and participation of the individual.

Denehy et al. (2013) tested the clinimetric properties of the PFIT-s against the MRC sum score, the 6MWT and the TUG in a mixed ICU population of 116 patients. The PFIT-s showed moderate correlation with all three other OMs in terms of convergent validity. In this study, it was demonstrated that the PFIT-s has a large responsiveness to change and that a MCID of 1.5 points on the interval scale was considered a significant change in physical function for the patients. Denehy et al. have shown that higher PFIT-s scores can predict higher MRC sum scores, discharge-locations and length of hospital stay (Denehy et al., 2013).

Corner et al. (2014) utilised the CPAx to assess 499 ICU patients. One hundred and twenty-six patients had abdominal surgery out of the 499. The CPAx was compared to the PFIT-s and the Functional Status Score for Intensive Care. The CPAx OM demonstrated the link between CPAx ICU discharge score and hospital-discharge locations. Comparing the Functional Status Score for Intensive Care to the CPAx, a similar hospital-discharge connection was observed indicating a similarity of content in the two OMs. The PFIT-s showed a floor effect of 21.5% and ceiling effect of 22.2% in ICU in a previous study and was compared to the CPAx which had a limited floor and ceiling effect in this study (Corner et al., 2014).

Corner et al. (2015) also utilised the CPAx to assess 30 patients that were admitted to the burns ICU. The CPAx was tested for its clinimetric properties in burns patients and demonstrated a true change in CPAx score of three and a MCID of six in the burns ICU. In burns patients, the CPAx showed a limited floor and ceiling effect again (Corner et al., 2015).

Parry et al. (2015) utilised the PFIT-s, Functional Status Score for Intensive Care, ICU Mobility Scale, Short Physical Performance Battery and MRC sum score in a mixed ICU to assess 66 patients at awakening in ICU and ICU discharge. The PFIT-s demonstrated correlations with the MRC sum score and is valid for evaluating muscle strength. It had a small floor and ceiling effect, and the MCID was calculated as 1.0 to

1.4 points for the PFIT-s. All the OMs utilised in this study showed the ability to detect a change in the patient's functional status. Still, the PFIT-s and ICU Mobility Scale were only moderately responsive to change. In this study, higher PFIT-s scores predicted discharge to home (Parry et al., 2015).

Betteridge, Bradley & Reilly (2015) utilised the Rehabilitation Complexity Scale, the ICU Mobility Scale and the CPAx in 105 adult patients with liver dysfunction who were managed in the ICU. All three of these OMs showed the ability to measure physical improvements from admission to discharge from the ICU. A correlation between LOS for the Rehabilitation Complexity Scale as well as the CPAx was found (Betteridge, Bradley & Reilly, 2015).

Tadyanemhandu & Manie (2016) utilised the PFIT-s for 32 patients admitted into ICU after laparotomy. The PFIT-s indicated an improvement in physical function before discharge from the ICU (Tadyanemhandu & Manie, 2016).

Avci et al. (2017) utilised the PFIT-s in 64 patients that underwent abdominal surgery and compared the PFIT-s to the 6MWT and the TUG. They found that patients presented with lower PFIT scores, more functional limitations after upper abdominal surgery and that the PFIT-s successfully identified patients requiring more rehabilitation postoperatively. The PFIT-s and the 6MWT were moderately correlated for criterion and concurrent validity (Avci et al., 2017).

Whelan, van Aswegen & Corner (2018) reported on using the CPAx OM in 26 patients in the ICU. Ten out of 26 patients had abdominal surgery. The CPAx improved patient care with regards to the accurate initial evaluation and for monitoring progression of therapy as well as to motivate patients for rehabilitation sessions. The CPAx detected an improvement of physical function in all patients during ICU admission and at discharge (Whelan, van Aswegen & Corner, 2018).

1.7 CONCLUSION

Based on the review of the OMs utilised in patients that underwent abdominal surgery, the CPAx has been used four times and PFIT-s five times in mixed ICU populations. Both OMs have demonstrated their ability to report on the modification in physical function in the ICU. However, the CPAx focuses on respiratory and physical function and the PFIT-s more on aspects of physical function, namely strength, endurance, and exercise capacity (Corner et al., 2014). There is little literature available regarding

suitable OMs to use for assessing the patients that underwent abdominal surgery and that are managed in ICU postoperatively, especially in the South African context. It, therefore, justifies further investigation to compare the CPAx- to the PFIT-s OM and to identify their clinimetric properties for the assessment of patients that underwent abdominal surgery. Identifying a responsive OM that is sensitive to change in physical function for patients that underwent abdominal surgery would better guide postoperative rehabilitation and assist in objective progress monitoring in ICU.

3. CHAPTER 3 METHODOLOGY

2.1 STUDY SETTING

The WDGMC situated in Parktown, Johannesburg is the first and only private academic teaching hospital in South Africa and forms part of the Wits Academic teaching hospital complex. This 190-bed facility not only offers patients access to specialists who are experts in their field, but it is also a sub-specialist training hospital in South Africa. Patients managed at WDGMC are adult- and paediatric patients with orthopaedic conditions, oncology, ear nose and throat surgery, gynaecology, plastic surgery, organ transplantations, general surgery, colorectal surgery and rheumatology. Most cases attended to at the hospital are done on an elective basis as the hospital does not have any trauma-related admissions. The WDGMC ICU and high care units comprise of a ten-bed TICU, four-bed THC, a fifteen-bed SICU and a fourteen-bed medical ICU.

The TICU, THC, SICU and medical ICU units are serviced by one physiotherapy practice, namely Carr and Associates Physiotherapy. Carr and Associates Physiotherapy have five physiotherapists (four full-day physiotherapists and one half-day physiotherapist) who work in the respective TICU, THC, SICU and medical ICU. At WDGMC, the mobilisation protocol post abdominal surgery is aimed at early, active mobilisation if the patient is stable enough and if no contraindications are present for mobilisation. Most patients will sit in a chair day one postoperatively, progressing to walking on the spot, walking in the ICU and then mobilising out of the ICU. All patients are treated to promote physical function and to prevent PPCs. The time spent on treating either mobility or assisting with the prevention of chest complications is patient-guided, and patients receive individualised rehabilitation programs. All five physiotherapists have an additional workload outside of the TICU, THC, SICU and medical ICU units in the paediatric transplant ward, the orthopaedic ward and the outpatients department.

2.2 SUBJECTS

2.2.1 Source of Subjects

Potential adult participants were recruited from WDGMC's TICU, THC and SICU.

2.2.2 Sample Selection

A consecutive sampling method was used to recruit participants into this study from 12 August 2019 until 4 November 2019.

2.2.2.1 Inclusion Criteria

Participants were eligible to participate in the study if they were admitted to ICU for longer than 24 hours, older than 18 years of age and underwent open abdominal surgery (including general-, colorectal- or transplantation surgery). Participants were included if they could follow instructions, score at least three out of five on the Standardised Five Questions test (assessment of the level of cooperation), and were ready to mobilise out of bed on postoperative day one.

2.2.2.2 Exclusion Criteria

Participants were excluded from this study if they presented with unstable cardiac function such as myocardial ischaemia or pulmonary emboli, underwent continuous dialysis therapy, presented with an amputation affecting functional performance, any current encephalopathy, and those that presented with any ongoing or history of neurological disease.

2.2.3 Sample size estimation

The total number of patients who received open abdominal surgery at WDGMC from January 2017 – December 2017, was 176 (eighty-one patients that underwent general open abdominal surgery, 40 patients that underwent kidney transplantation surgery and 55 patients that underwent liver transplantation surgery).

The sample size was calculated using the Raosoft sample size calculator, with the margin of error set at 10%, the confidence interval set at 95% and the response distribution set at 50% for a population of 176.

The estimated sample size was, therefore, 63 participants. Sample sizes of more than 50 participants are recommended for studies assessing clinimetric properties of measurements to enhance the generalisability of findings (Parry et al., 2015).

Previous studies that used either of these OMs had sample sizes varying between 26 and 499 participants (Denehy et al., 2013; Corner et al., 2014, 2015; Betteridge, Bradley & Reilly, 2015; Parry et al., 2015; Tadyanemhandu & Manie, 2016; Avci et al., 2017; Whelan, van Aswegen & Corner, 2018).

2.2.4 Variables

2.2.4.1 Dependent variables:

- Maximum physical function score as measured with the CPAx and the PFIT-s tools.

2.2.4.2 Independent variables:

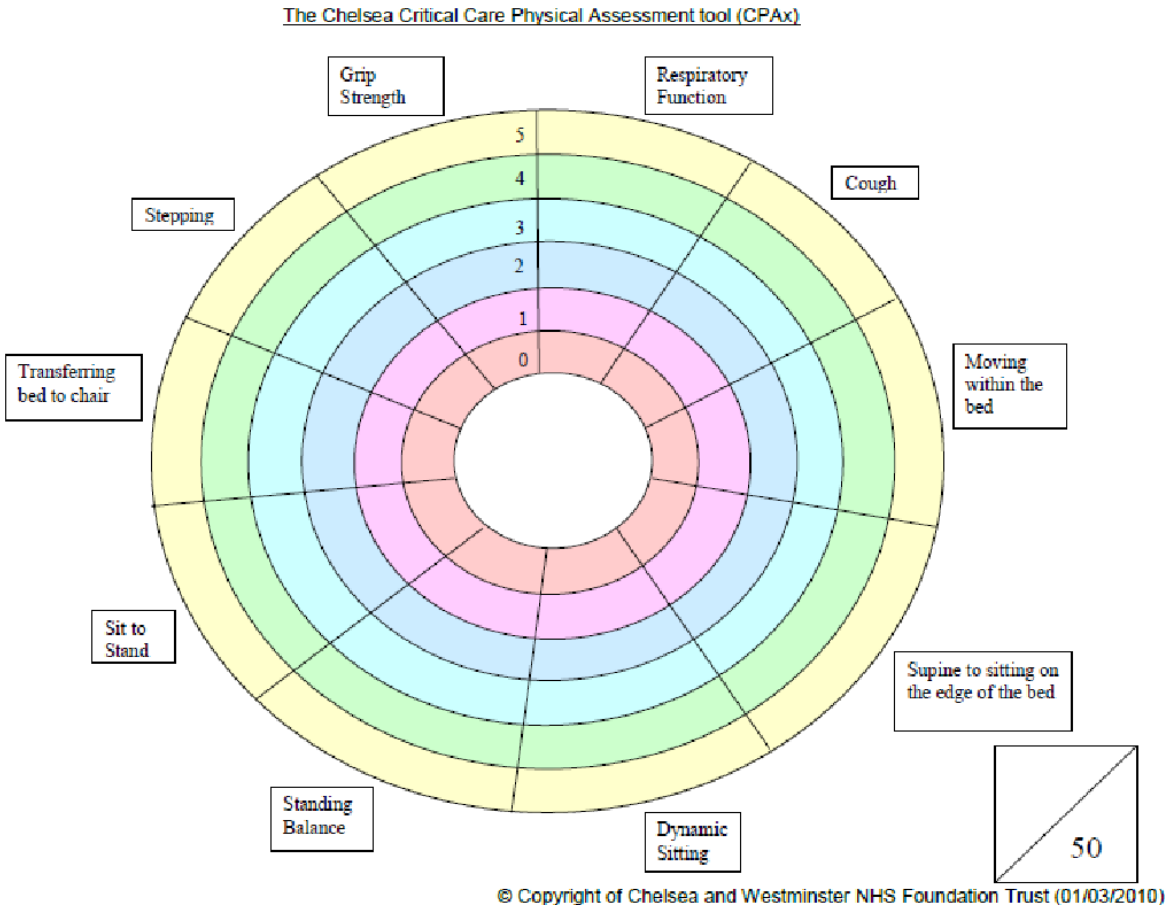
- Number of days on mechanical ventilation
- Age
- ICU LOS
- Participants with an epidural in situ
- Haemodynamic stability of the participant
- Duration of surgery
- Number and type of postoperative complications developed
- Each participant's number of physiotherapy treatment sessions received during the study
- Indication for surgery
- Number of theatre interventions
- Pain management techniques

2.3 STUDY PROCEDURES

2.3.1 Outcome Measures

2.3.1.1 CPAx Outcome Measure (See Appendix 2a, 2b and 2c)

Please see Chapter 2, section 2.4, for a thorough outline and discussion on the CPAx OM.



(Corner et al., 2012)

(Corner et al., 2012)

2.3.1.2 PFIT-s Outcome Measure (See Appendix 3a and 3b)

Please see Chapter 2, section 2.5, for a thorough outline and discussion on the PFIT-s OM.

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	Stand and step transfer with mobility aid OR physical	Independent transfer without equipment.

PFIT Score	0	1	2	3	Total
Assistance	Unable	Assist x2	Assist x1	No assist	
Cadence (steps/min)	Unable	>0 - 49	50 -<80	80+	
Shoulder (grade)	0,1 or 2	3	4	5	
Knee (grade)	0,1 or 2	3	4	5	

(Denehy et al., 2011)

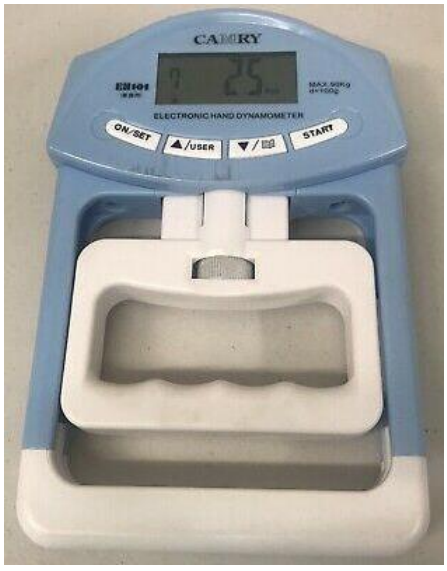
Ordinal score /12	0	1	2	3	4	5	6	7	8	9	10	11	12
Interval PFIT score /10	0	2.0	3.2	3.9	4.4	4.9	5.4	5.9	6.4	7.1	7.9	8.8	10

(Denehy et al., 2011)

2.3.2 Instrumentation

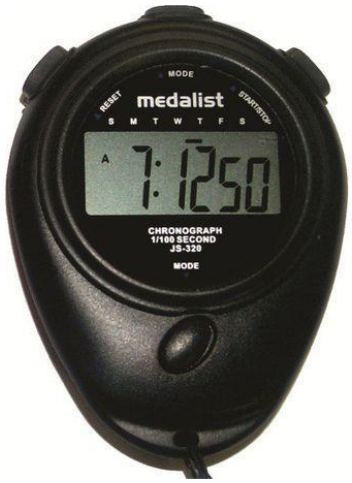
2.3.2.1 Handheld Dynamometer

A Camry Model EH101 electronic hand dynamometer was used to obtain the grip strength of the participant during the CPAx's grip strength assessment. The grip strength dynamometers were supplied by Carr and Associates Physiotherapy as this tool is utilised daily in all the ICUs at WDGMC.



2.3.2.2 Stopwatch

The black Medalist JS3212 stopwatch was used for the PFIT-s tool's administration. The PFIT-s has a MOS component where time must be assessed up until three minutes.



2.3.2.3 Individual Participant Record Sheets (Appendix 7 – 10)

These were used to collect participants' demographic information, ICU admission dates, ICU discharge dates, diagnosis, length of intubation, ICU LOS, pain management techniques, postoperative complications, number of theatre trips, and other relevant information.

Participants were assessed on day one-, day three-, day five postoperatively and on day of discharge from the TICU, THC or SICU. Four different participant record sheets were used on the four intervals of assessment.

2.4 DATA COLLECTION PROCEDURE

Both the researcher and the research assistant were trained in the use of the respective OM tools. For the CPAx they were obligated to do the online CPAx training module (http://cpax.ocbmedia.com/) developed by E. Corner. The primary researcher and the research assistant had to provide their certificate of completion for the CPAx OM, and the researcher kept copies of these certificates.

For the PFIT-s tool, training was provided by another physiotherapist, Hannes van Aartsen, who is experienced in using the PFIT-s tool. The PFIT-s training was given to the researcher, and the researcher then trained the research assistant working for Carr and Associates Physiotherapy.

2.4.1 Main Study

For information regarding the pilot study that was conducted before the main study, please refer to Appendix 1 (page 65) that describes the pilot study and its results.

Participants were screened daily at WDGMC's TICU, THC and SICU for possible participation in this research using the stated inclusion and exclusion criteria on the handover round in the morning, which occurred between the intensivist and researcher. Once suitable participants were identified, the researcher approached willing potential participants to explain the aims of the study, to provide further explanations about the study and to obtain informed written consent for participation in the presence of the ICU nurse responsible for the participant's care.

Once informed consent was obtained, the researcher informed the research assistant of such. The participants were assigned and assessed by the researcher (where time constraints allowed) or by the trained research assistant physiotherapist working in the unit according to their workload capacity and logistics in the various ICUs at the time of the study.

The sequence with which the PFIT-s and CPAx tools were administered to each participant was randomised using a computer-generated randomisation list (for example for participant A on Day one the CPAx was administered first and then the PFIT-s, Day three the PFIT-s was administered first and then the CPAx, etc.). This randomisation was done to prevent any learning effect by participants. The researcher kept sealed envelopes that contained the randomisation sequence for the CPAx and PFIT-s assessment for each participant's interval day of assessment. These envelopes were assigned to participants after written consent was obtained.

All participants had both the CPAx and PFIT-s OM assessments done on an interval basis on postoperative days one, three, and five and on the day of discharge from the TICU, THC and SICU. The assessments consisted of administering the CPAx and PFIT-s tools two hours apart (as per randomisation list allocation) to allow the participants to rest between test sessions.

During the participant's hospital stay, standard physiotherapy care was performed as per each participant's individual need by the trained physiotherapists working in the unit. The researcher's role during the study was to approach participants to notify them

about the study, to obtain informed consent from them, to assign the sealed envelopes to participants and administer the OM and to collect data for each participant.

When the interval assessment days (day three, day five or ICU discharge) occurred over a weekend, the assessment was done on the following Monday due to non-specialist weekend staff's (locums) inability to complete the assessments. All participants' data was captured on individual participant record sheets as per the interval assessment days. Following discharge from the TICU, THC and SICU, all participants continued to receive physiotherapy in the ward as required but not from the same physiotherapy practice, and all OM usage was terminated.

During the OM assessments in this study, participants were monitored for adverse events such as pulling out of drip lines, drop in blood pressure, decrease in saturation, falling, opening of the wound or excessive drainage from the wound site. Any adverse events experienced by participants were recorded on the record sheets. Any complications that the participants presented with, and that was diagnosed by a medical doctor in the patient records, were recorded on the record sheets.

All information obtained during the study was captured by the researcher, in consultation with her supervisor, on Excel spreadsheets in preparation for data analysis.

2.5 ETHICAL CONSIDERATIONS

Approval to perform this study was obtained from the University of the Witwatersrand Human Research Ethics (Medical) Committee (M181167 – Ethical clearance certificate available in Appendix 11). Permission to conduct the study was obtained from the WDGMC's Chief Executive Officer, Head of the research office, Head of the ICU, Head of the transplant unit, Head of the surgical unit and the owner of the Physiotherapy practice (Please see permission letters under Appendix 12-16). Informed and written consent was obtained from each participant after a comprehensive information sheet was given and explained to them. 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 participant information obtained during this study was coded to preserve the participants' identity. A separate coding list was kept on which each participant's name and allocated study code was documented. All material containing any data or

information regarding this study was password protected and stored on a cloud database. Any information obtained was used for statistical purposes only, and no personal information was disclosed about any participants. This study was registered with the Pan African Clinical Trial Registry (trial registration number: PACTR201908553378781). During the study, strict adherence to the principles of the Declaration of Helsinki while conducting research on humans was applied.

2.6 STATISTICAL ANALYSIS

Data were captured on an Excel spreadsheet and coded for analysis. The statistical analysis was performed using the IBM® Statistical Package for Social Sciences Statistics version 26.0 for Windows and Excel (Windows version 365, Microsoft Corporation, Seattle).

The demographic data and the CPAx and PFIT-s scores (admission and discharge from ICU) were assessed for normality of distribution using the Shapiro-Wilk test. All ratio data (age, duration of surgery, hours ventilated and ICU LOS) and all ordinal data (CPAx and PFIT-s scores) demonstrated a non-normally distributed data set. For these variables, the median and interquartile ranges were used to summarise the data (Corner et al., 2015).

Categorical variables (gender, hand dominance, indications for surgery, epidural usage for pain management) were summarised as numbers and percentages. Floor and ceiling effects of the CPAx and PFIT-s tools were summarised as number and percentages. Data were compared using tables, pie charts and line graphs. For this study, the floor effect will reflect the percentage of participants that scored 0/50 on the CPAx or 0/12 on the PFIT-s and the ceiling effect will reflect the percentage of participants that scored 50/50 on the CPAx or 12/12 on the PFIT-s.

The CPAx and PFIT-s scores were compared at admission and discharge from ICU to determine their responsiveness to change in participants' physical function. The Mann-Whitney U test was used to determine the Z score for each tool. The responsiveness of each tool was assessed by determining each tool's ESI (Denehy et al., 2013). The ESI was calculated for each tool using r = Z and divided by the square root of the sample size (Corner et al., 2015; Denehy et al., 2013). A positive ESI reflects an improvement in health status. Effect size indexes of 0.2, 0.5 and 0.8 reflect small, moderate and large responsiveness to change respectively (Denehy et al., 2013).

The MCID was calculated by using half of the largest standard deviation (SD), and the standard error of measurement (SEM) for the scores obtained with the CPAx and PFIT-s tools as this method is reported to give a good approximation of MCID of an OM tool (Denehy et al., 2013; Corner et al., 2015). The SEM is calculated using the SD multiplied by the square root of one minus Cronbach alpha (r) (Corner et al., 2015; Denehy et al., 2013).

For this study, the construct is physical function scores. Convergent validity was assessed using the Spearman's rank correlation (rho) to evaluate whether the CPAx and PFIT-s have similar underlying constructs (Denehy et al., 2013).

4. CHAPTER 4 RESULTS

Results of the study are reported in narrative form in this chapter.

3.1 STUDY POPULATION

The number of participants admitted into TICU, THC and SICU during the period August 2019 until November 2019 and the recruitment of participants to the study is summarised in the flow diagram in Figure 4.1. Twenty-eight participants were excluded from this study. Ninety-eight participants had open laparotomy procedures done, and one participant had a planned laparotomy which changed to a laparoscopic procedure.

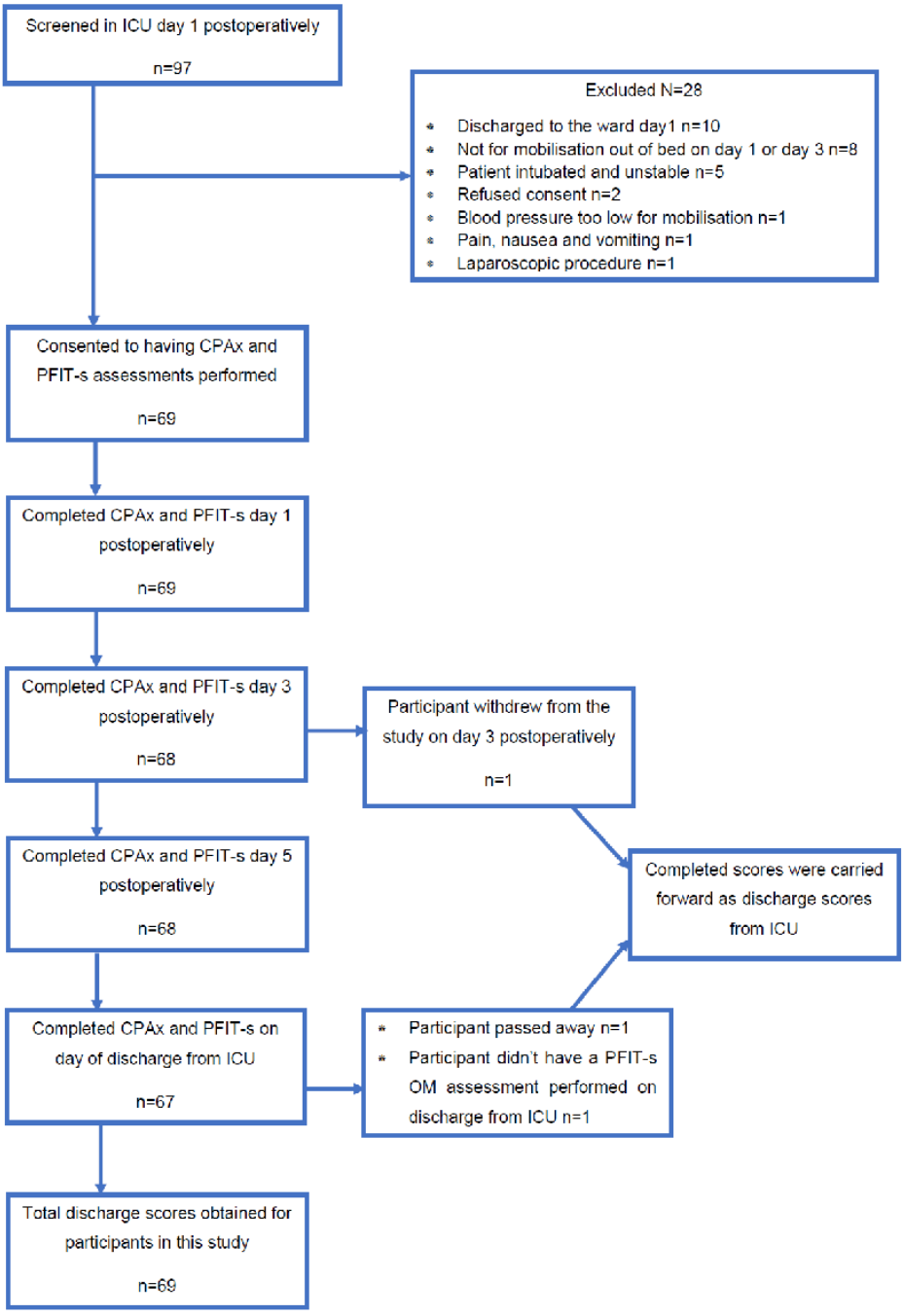


Figure 4.1: Participant flow through the CPAx and PFIT-s open abdominal surgery study at WDGMC.

If any participants passed away, withdrew from the study or didn't complete their assessment in ICU, during the duration of this study in the TICU, THC and SICU, the last recorded CPAx and PFIT-s assessment scores obtained were carried forward and utilised as that participants' discharge score. One participant withdrew on day three postoperatively, one participant passed away after day five's assessment, and one participant didn't complete his PFIT-s assessment on discharge from the ICU.

3.2 Baseline Characteristics of the Study Population

3.2.1 Age

The mean age for the participants was 54 (±15.5) years with the minimum age being 18 years, and the maximum age being 81 years (Figure 4.2).

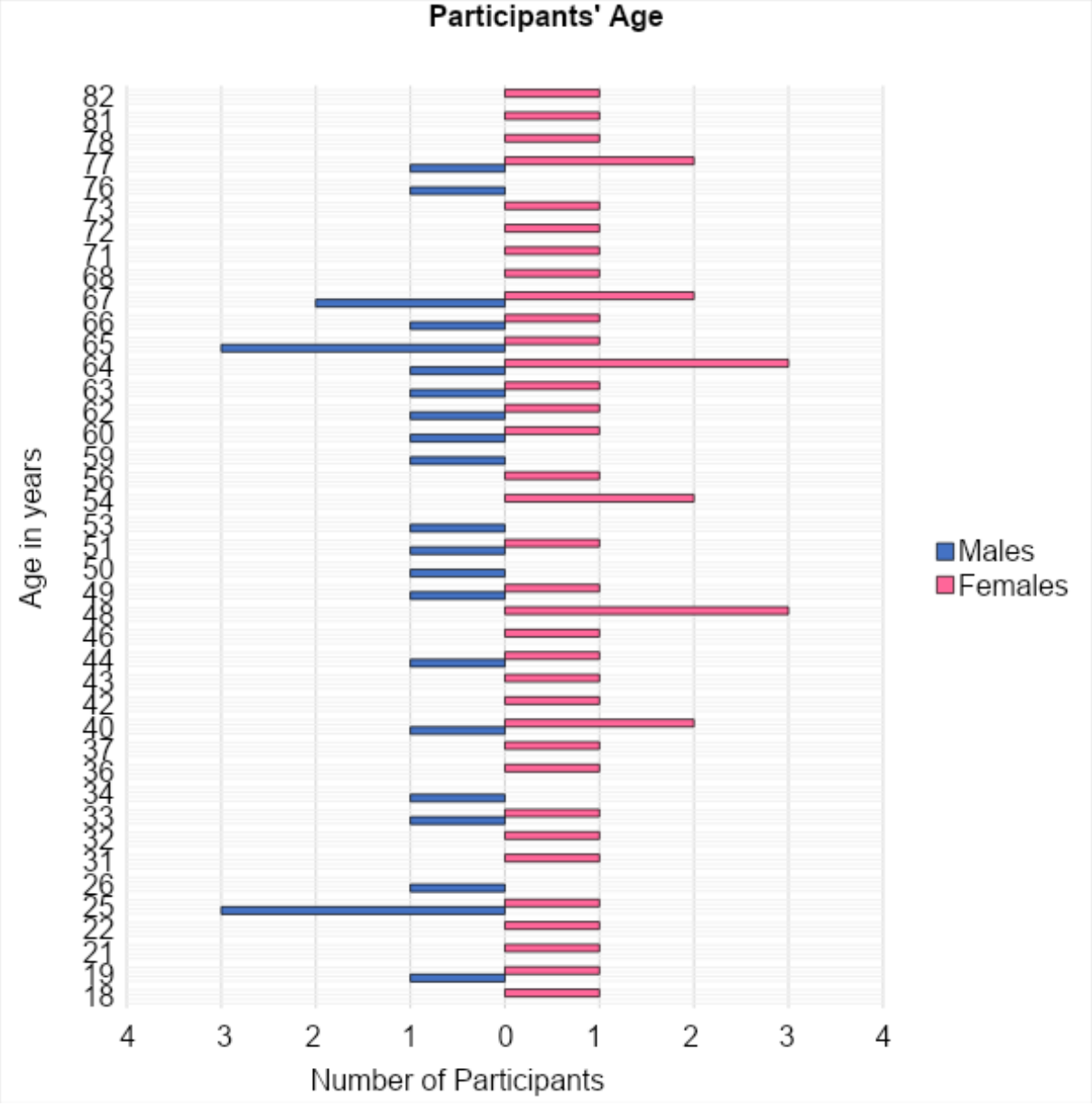


Figure 4.2: Age Distribution of Participants

3.2.2 Gender

The participant population consisted of 37.7% (n=26) male and 62.3% (n=43) female participants (Figure 4.3).

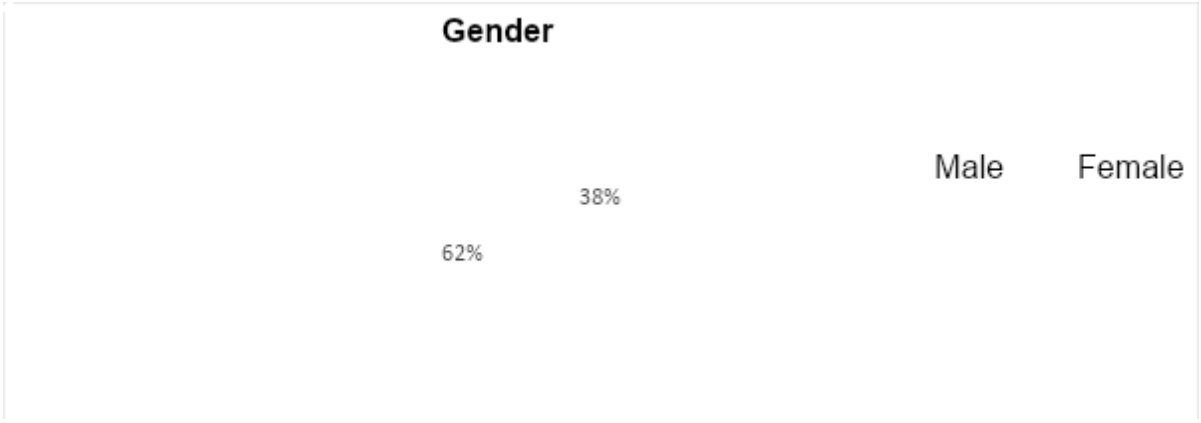


Figure 4.3: Gender Distribution of Participants

3.2.3 Diagnosis

The participant population consisted of 46 (66.7%) participants who underwent open abdominal surgery and were managed in the SICU and 23 (33.3%) participants who underwent open abdominal surgery and were managed in the TICU. The most common diagnosis and reason for surgery was cancer (n=29, 42.1%), followed by bowel obstruction (n=8, 11.6%), explorative laparotomy (n=5, 7.3%), liver transplant (n=5, 7.3%), kidney transplant (n=5, 7.3%) and hepatectomy (n=5, 7.3%). Table 4.4, Figure 4.5 and Figure 4.6 summarise the conditions requiring open abdominal surgery.

Table 4.4: Diagnoses of participants

CONDITIONS PREVALENCE IN STUDY POPULATION N=69	
DIAGNOSIS/PROCEDURE	*N (%)*
BOWEL OBSTRUCTION	8 (11.59%)
CANCER	29 (42.03%)
FISTULA REPAIR	2 (2.90%)
RECTAL PROLAPSE	1 (1.45%)
EXPLORATIVE LAPAROTOMY	5 (7.25%)
NISSAN FUNDOPLICATION	1 (1.45%)
LIVER TRANSPLANT	5 (7.25%)
KIDNEY TRANSPLANT	5 (7.25%)
LIVER TRANSPLANT DONOR	3 (4.35%)
MESO-CAVA SHUNT	2 (2.90%)
HEPATECTOMY	5 (7.25%)
NEPHRECTOMY	3 (4.35%)

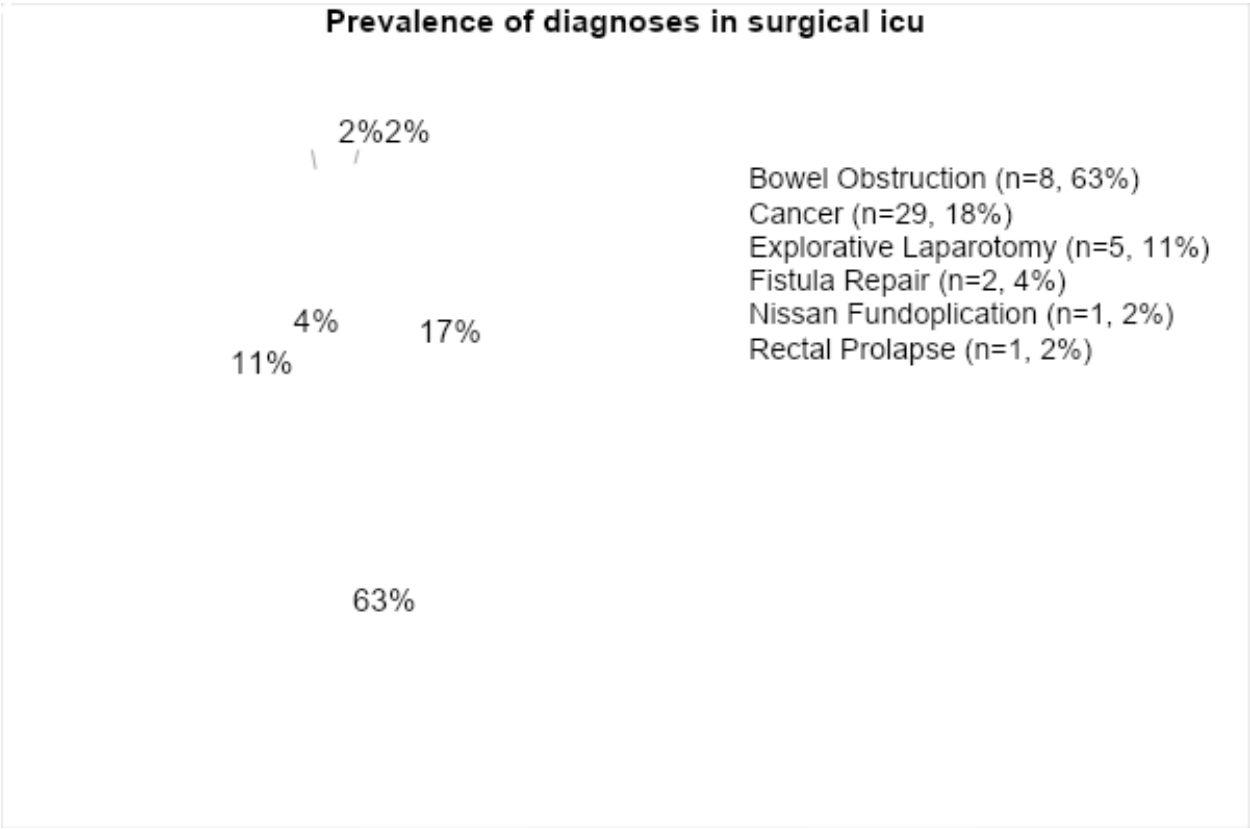


Figure 4.5: Prevalence of SICU diagnoses

The most prevalent condition, which open abdominal surgery was performed for and managed postoperatively in the SICU, was cancer followed by bowel obstruction.

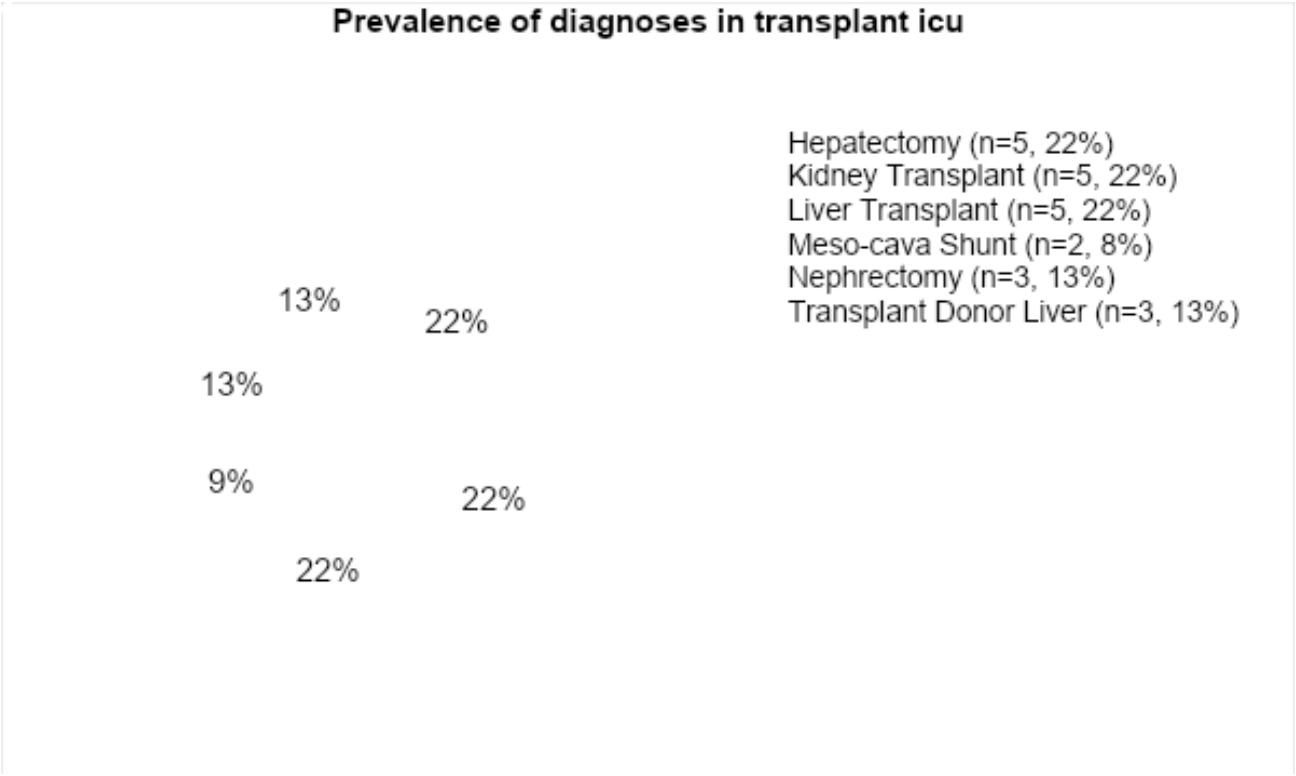


Figure 4.6: Prevalence of TICU diagnoses

The most prevalent condition, which open abdominal surgery was performed for and managed postoperatively in the TICU, were liver- and kidney transplantations as well as cancer-related hepatectomies.

3.2.4 Hand dominance

Ninety-six percent of participants demonstrated right-hand dominance, and 4% left-hand dominance (Figure 4.7).

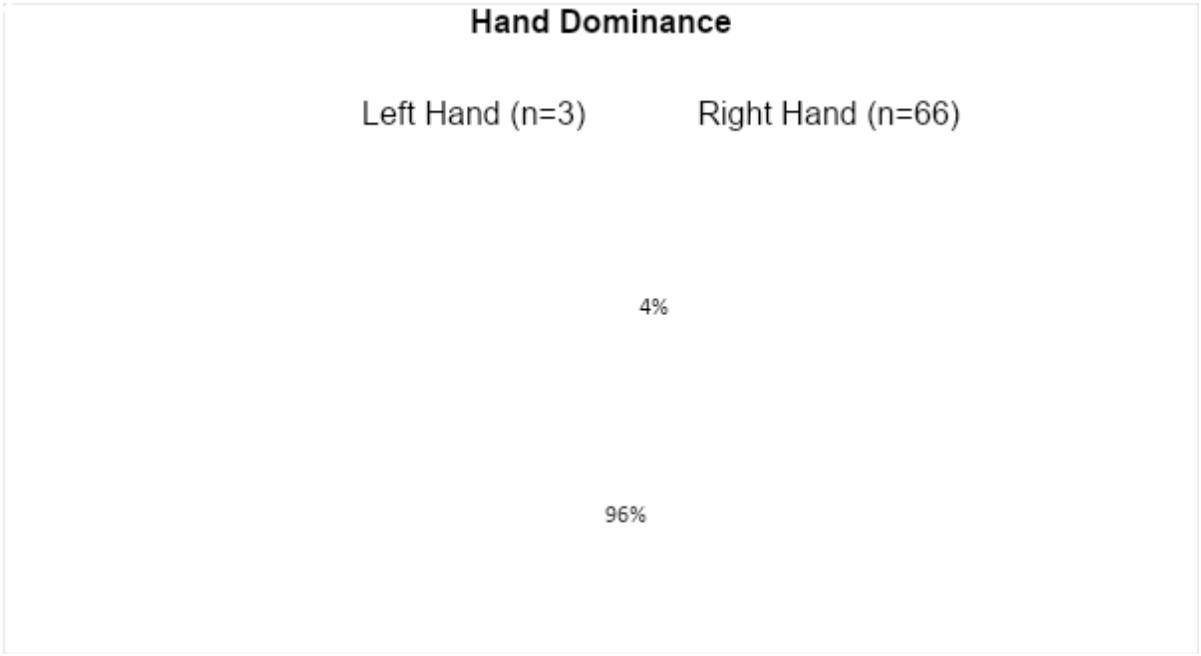


Figure 4.7: Hand dominance of Participants

3.2.5 Clinical Outcomes

3.2.5.1 ICU LOS

The median ICU LOS for participants was three days (IQR = 2-6, range = 1-22) with a minimum one day, and a maximum of 22 days (Figure 4.8).

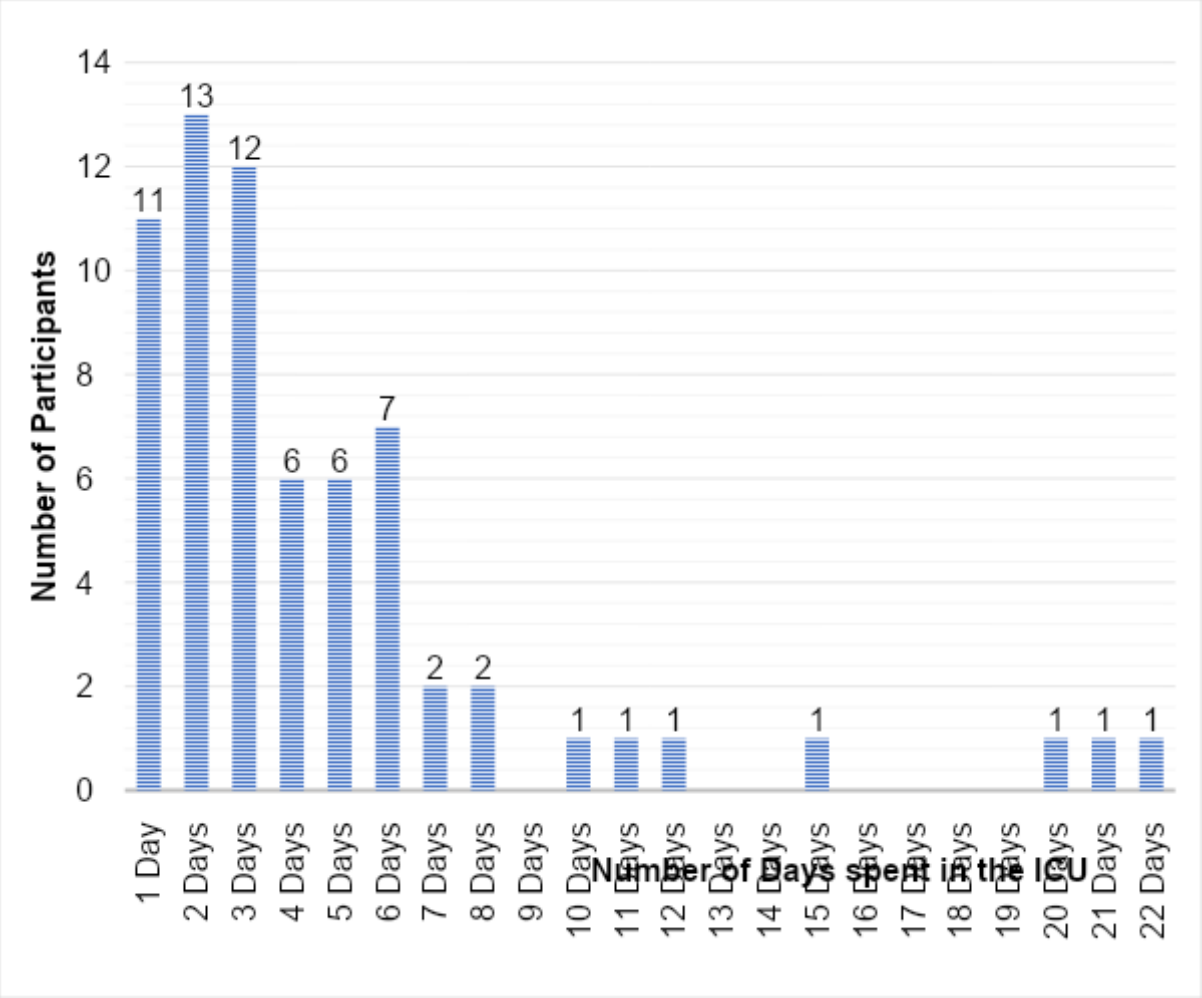


Figure 4.8: ICU length of stay for participants

3.2.5.2 Number of hours on mechanical ventilation

The median number of hours spent on a mechanical ventilator for participants was 5 hours (IQR = 3-6, range = 1-41) with a minimum of 1 hour and a maximum of 41 hours (1 day and 17 hours). The mechanical ventilation time recorded included mechanical ventilation during surgery.

3.2.5.3 Pain management techniques

On day one postoperatively, most participants were managed with intravenous (n=65, 94%) pain medication in conjunction with rectal sheath catheters (n=27, 39%) or oral (n=24, 35%) pain medication. Day five demonstrated the lowest incidences of pain medication interventions and on the day of discharge from the ICU a sharp rise in oral medication (10% to 55%) as well as intravenous (10% to 58%) pain control preferences to manage participants' pain was observed (Figure 4.9).

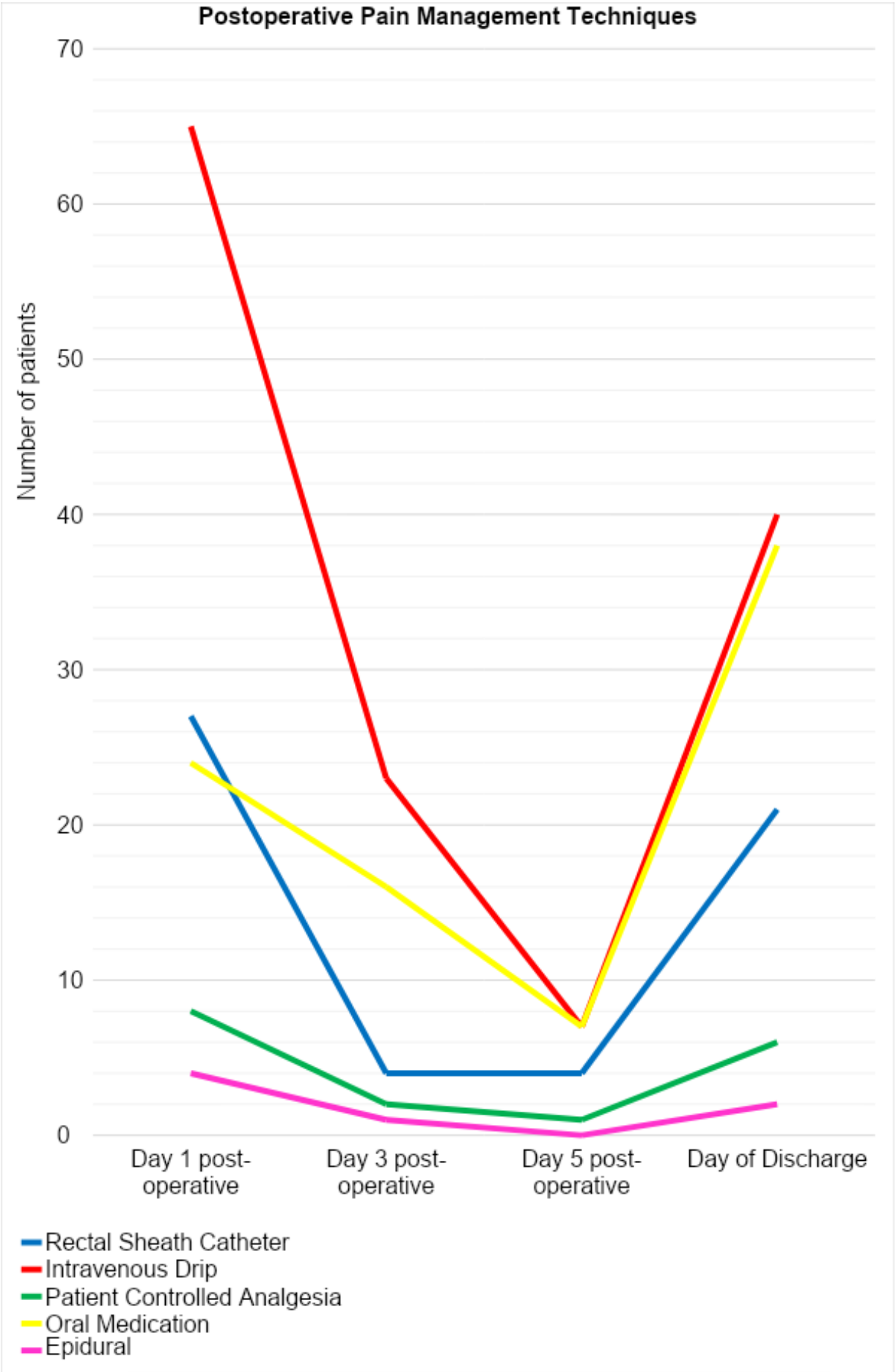


Figure 4.9: Pain management techniques on interval assessment days.

3.2.5.4 Duration of surgery

The median number of hours spent in surgery for participants were five hours (IQR = 3-6, range = 1-10) with a minimum of one hour and a maximum of ten hours as per figure 4.10. All participants were mechanically ventilated from the start to end of the surgery, and duration of surgery can thus also be interpreted as anaesthetic time.

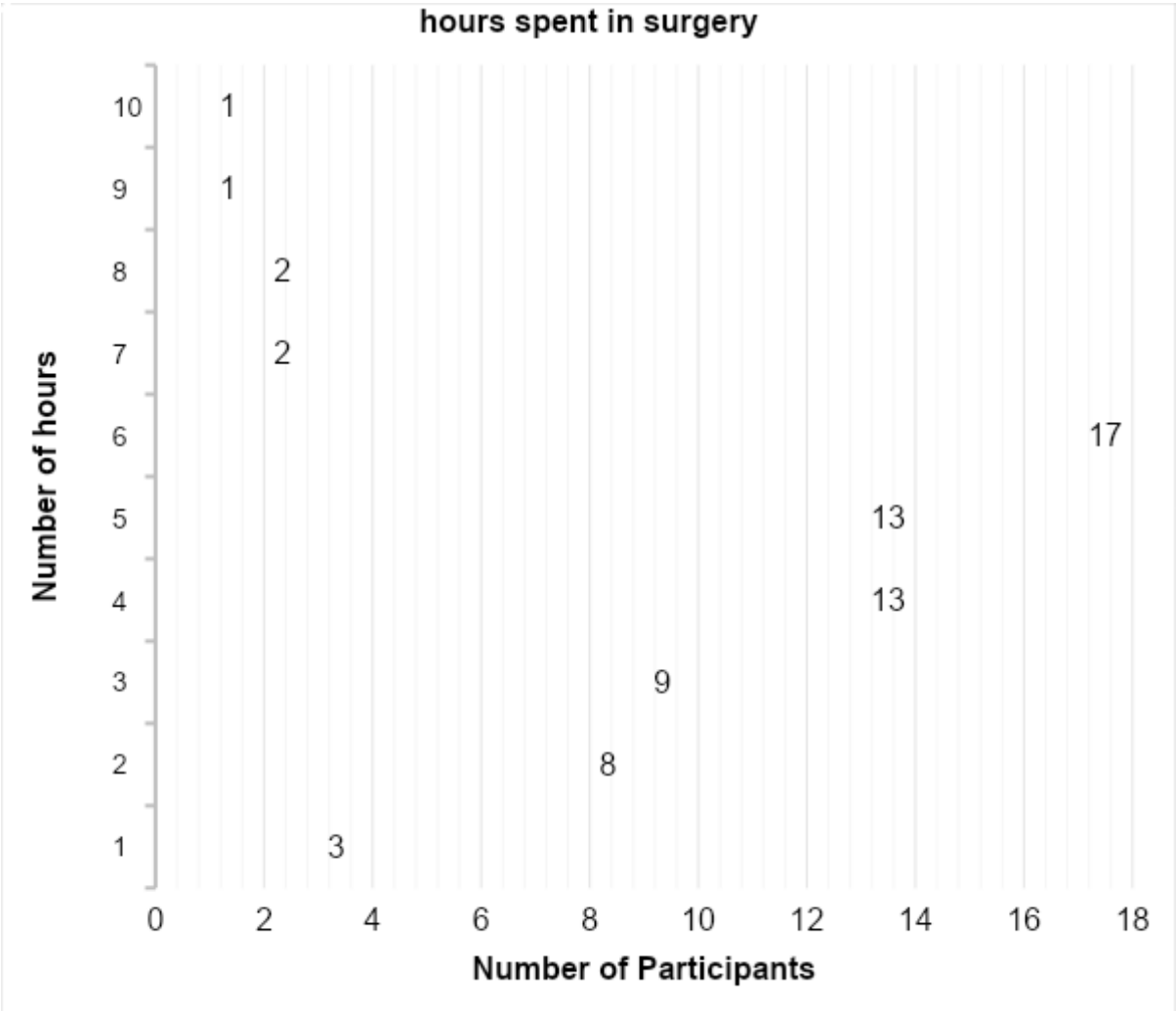


Figure 4.10: Number of hours spent in surgery by participants.

3.2.5.5 Number and type of postoperative complications developed

Hypotension (n=15, 18%) was the most common postoperative complication, followed by pain (n=13, 16%) and low haemoglobin levels (n=10, 12%) as per figure 4.11.

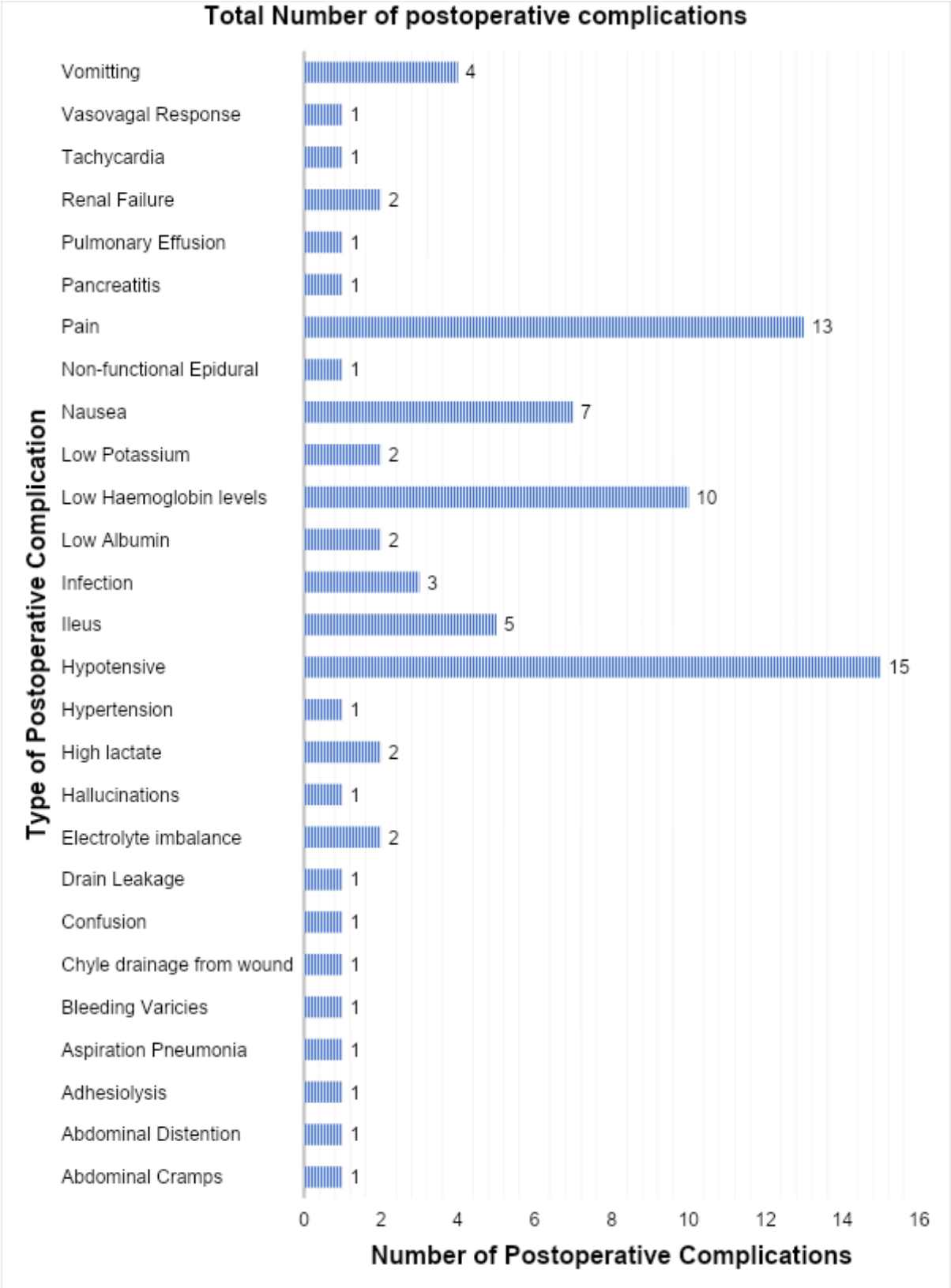


Figure 4.11: Total number of postoperative complications as assessed over the interval assessment days.

On day one, the most common postoperative complications were hypotension (n=5, 6%) followed by pain (n=4, 5%). On day three, the postoperative complications remained unchanged in prevalence. On day five, the most common postoperative

complications were low haemoglobin levels (n=3, 4%) followed by hypotension (n=2, 2%) and ileus (n=2, 2%). On the day of discharge from the ICU, the most common postoperative complications were pain (n=5, 6%) followed by low haemoglobin levels (n=4, 5%) and hypotension (n=4, 5%). The day of discharge also had the highest prevalence of postoperative complications, with 29 recorded complications.

3.2.5.6 Number of theatre interventions

Sixty-seven participants had one theatre intervention, and two participants had two theatre interventions during this study (Figure 4.12).

Figure 4.12: Total number of theatre interventions per participant.

3.2.5.7 Each participants' number of physiotherapy treatment sessions received during the study

The median number of physiotherapy treatment sessions received by participants was four (IQR = 3-7, range = 1-26) with a minimum of one treatment session and a maximum of 26 treatment sessions. Two participants' treatment sessions were not accounted for as they withdrew from the study.

3.3 THE CPAX AND PFIT-S TOOLS' RESPONSIVENESS TO DETECT CHANGES IN PHYSICAL FUNCTION SCORES FOR PARTICIPANTS WHO HAD OPEN ABDOMINAL SURGERY

Scores obtained at admission to ICU and discharge from ICU for the CPAx and PFIT-s OMs were compared to determine the responsiveness of these tools to changes in participants' physical function abilities. The CPAx and the PFIT-s scores demonstrate functional abilities by the participants. Table 4.13 demonstrates the median scores,

interquartile ranges, minimum- and maximum scores as recorded on ICU admission, day three postoperatively, day five postoperatively and on ICU discharge by the OMs, respectively.

Table 4.13: CPAx and PFIT-s's median score, interquartile ranges, minimum- and maximum scores.

	CPAx Admission Score	CPAx Day3 Score	CPAx Day 5 Score	CPAx Discharge Score
Median	38	40	40	47
Interquartile ranges	35 – 41	37 - 45	37.5 - 45	43.5 - 48
Minimum score	10	7	4	4
Maximum score	49	49	50	50
	PFIT-s Admission Score	**PFIT-s Day 3 Score**	**PFIT-s Day 5 Score**	**PFIT-s Discharge Score**
Median	9	10	10	11
Interquartile ranges	7 - 11	8 - 11	8 - 11	10 -12
Minimum score	2	1	0	0
Maximum score	12	12	12	12

All scores were assessed with the Shapiro-Wilk test for normality of distribution. The CPAx admission to ICU score was compared for each participant and demonstrated a p=0.00. The CPAx discharge from ICU score was compared for each participant and demonstrated a p=0.00. The PFIT-s admission to ICU score was compared for each participant and demonstrated a p=0.00, PFIT-s discharge from ICU score was compared for each participant and demonstrated a p=0.00. None of the scores were therefore normally distributed.

Z-scores were calculated to determine whether there was a meaningful change in physical function from ICU admission to ICU discharge as measured by the CPAx and PFIT-s, respectively. CPAx Z-score -7.560 (Mann Whitney U test, p=0.00) and PFIT-s Z-score -5.916 (Mann Whitney U test, p=0.00). These scores indicate that the CPAx and PFIT-s both measured significant changes in physical function for all participants from ICU admission to ICU discharge.

The responsiveness of each tool was assessed by determining each tool's ESI. The ESI was calculated for each tool using r = Z and divided by the square root of the

sample size. The ESI for the CPAx = 0.9101 indicating a large responsiveness to change, and the ESI of the PFIT-s = 0.7122 indicating a moderate responsiveness to change.

3.4 THE MCID IN PHYSICAL FUNCTION SCORES OBTAINED WITH THE CPAX AND PFIT-S TOOLS FOR PARTICIPANTS WHO HAD OPEN ABDOMINAL SURGERY

The CPAx and PFIT-s admission to ICU scores had the largest standard deviation (SD) and was used to give an estimate of the MCID. The mean CPAx score was 36.1 (±8.82), and the mean PFIT-s score was 7.23 (±1.58) on admission to ICU. The standard error of measurement (SEM) is calculated using the SD multiplied by the square root of one minus Cronbach alpha (r). The CPAx showed r=0.816 (Cronbach alpha) and SEM = 3.8 and the PFIT-s demonstrated r=0.825 (Cronbach alpha) and SEM = 0.7. The SEM is representative of the true change in scores for the cohort recovering from open abdominal surgery. The CPAx and the PFIT-s OM scores are calculated in integers, and thus the SEM and MCID were rounded up.

The MCID was calculated by using half of the largest SD and the SEM for the scores obtained with the CPAx and PFIT-s tools. The MCID for CPAx = 4.4 and PFIT-s = 0.8. Table 4.14 provides all the data used to estimate the MCID.

Table 4.14: MCID results for the CPAx OM and PFIT-s OM

	CPAX	PFIT-s
SD	8.82	1.58
r	0.82	0.83
SEM	3.8 ≈ 4	0.7 ≈ 1
MCID	4.4 ≈ 4	0.8 ≈ 1

3.5 THE FLOOR AND CEILING EFFECTS OF SCORES OBTAINED WITH THE CPAX AND PFIT-S FOR PARTICIPANTS WHO HAD OPEN ABDOMINAL SURGERY

The CPAx had a limited floor and ceiling effect on admission and discharge from ICU. The PFIT-s demonstrated a limited floor effect on admission and discharge from ICU, as well as a limited ceiling effect on admission to ICU but a significant ceiling effect (46.38%) on discharge from ICU. Table 4.15 summarises the floor and ceiling effects for each OM on admission and discharge from ICU.

The median CPAx admission score was 38 (IQR = 35-41, range = 10-49), and the median PFIT-s admission score was 9 (IQR = 7-11, range = 2-12). No adverse events were recorded in this study with the assessments of the OMs on participants. No

participants scored 0 on either the CPAx or PFIT-s on ICU admission, thus indicating 0.00% floor effect on ICU admission for both OMs. No participants scored 50/50 for the CPAx on admission, but the PFIT-s demonstrated a ceiling effect on ICU admission of 5.8% (n=6).

The median CPAx discharge score was 47 (IQR = 44-48.25, range = 4-50), and the median PFIT-s discharge score was 11 (IQR = 10-12, range = 0-12). Two participants withdrew from the study on day three postoperative, on discharge from ICU, one participant passed away, and one participant got discharged before administering their PFIT-s OM. For these participants their last recorded scores were utilised as their discharge scores, demonstrating an ICU discharge floor effect for the CPAx of 0.01% (n=1) and the PFIT-s of 5.8% (n=2). On ICU discharge, the CPAx showed a ceiling effect of 7.25% (n=6), and the PFIT-s demonstrated a ceiling effect of 46.38% (n=32).

Table 4.15: OM Floor- and Ceiling Effects in Percentages

CPAX AND PFIT-S FLOOR AND CEILING EFFECTS		
Floor effect on Admission to ICU	CPAx	0.00%
	PFIT-s	0.00%
Floor effect on Discharge from ICU	CPAx	0.01%
	PFIT-s	5.80%
Ceiling effect Admission to ICU	CPAx	0.00%
	PFIT-s	2.90%
Ceiling effect on Discharge from ICU	CPAx	7.25%
	PFIT-s	46.38%

p

3.6 THE LEVEL OF CONVERGENT VALIDITY FOR SCORES OBTAINED WITH THE CPAX AND PFIT-S TOOLS FOR PARTICIPANTS WHO HAD OPEN ABDOMINAL SURGERY

For this study, the construct is physical function scores. Convergent validity was assessed using the Spearman's rank correlation (rho) to evaluate whether the CPAx and PFIT-s have similar underlying constructs. The CPAx and PFIT-s admission scores demonstrated a r=0.60 (n=69 p=0.00) and CPAx and PFIT-s discharge scores demonstrated a r=0.51 (n=68 p=0.00) indicating moderate to good convergent validity. The correlations are demonstrated in figures 4.16 and 4.17.

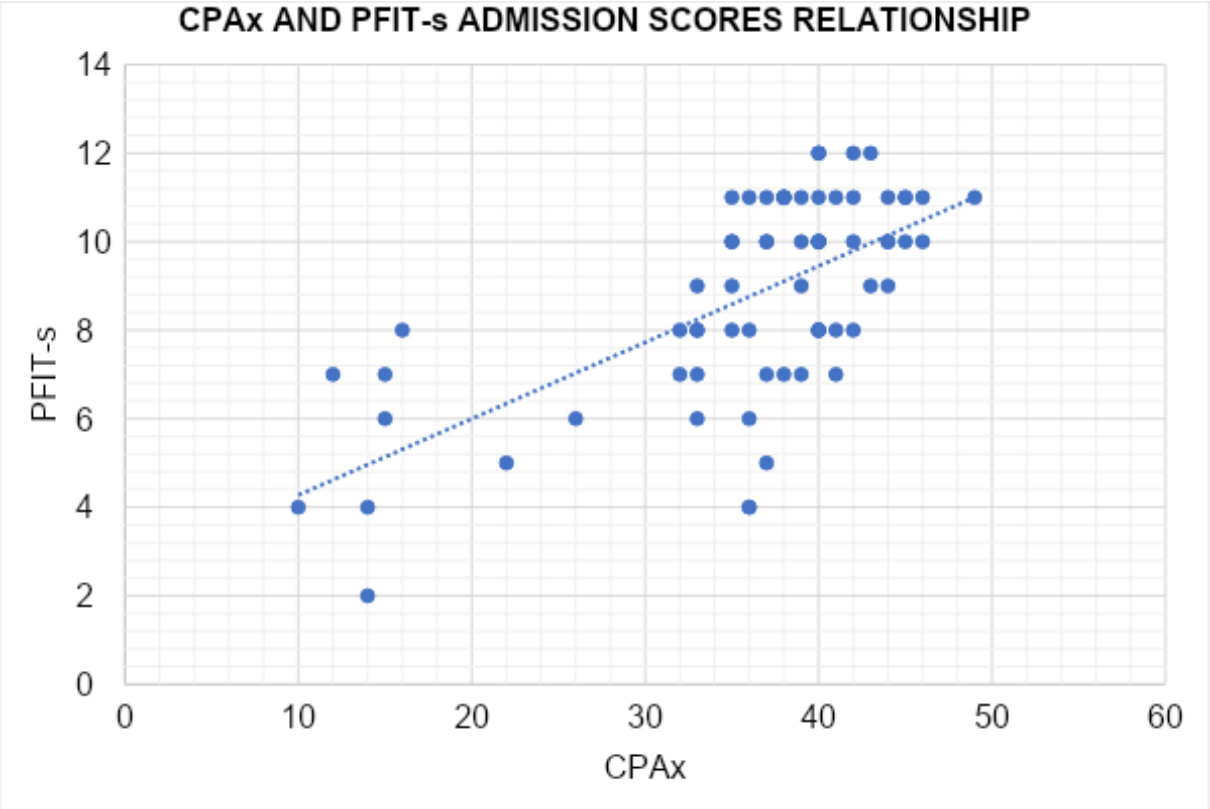


Figure 4.16: Relationship between the CPAx and PFIT-s scores at ICU admission.

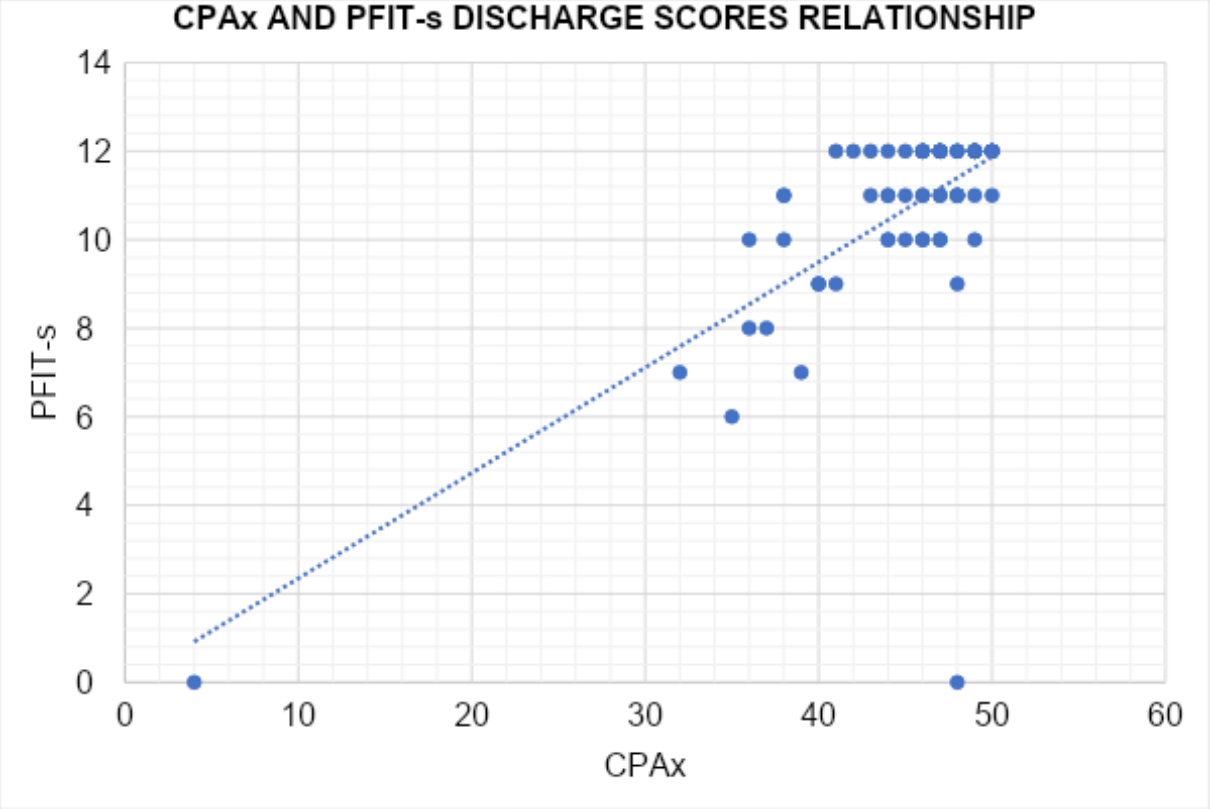


Figure 4.17: Relationship between the CPAx and PFIT-s scores at ICU discharge.

5. CHAPTER 5 DISCUSSION

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

This study exclusively assessed the clinimetric properties of the CPAx and PFIT-s OMs on patients that underwent open abdominal surgery as identifying the most appropriate OM will assist with detecting improved functional outcomes and rehabilitation for the specific surgical population.

4.1 CHARACTERISTICS OF THE STUDY COHORT

This study explored the clinimetric properties of the CPAx and PFIT-s OMs in patients that had undergone open abdominal surgery. To understand and compare the clinimetric properties found in this study, we need to discuss the characteristics of our study population in comparison to previously studied cohorts. The participants in the current study were predominantly female (n=43, 62%) and had a mean age of 54 years. The study cohort reported on by Denehy et al. (2013) was predominantly male (n=70, 60%) with a mean age of 59.3 years. The cohort in the study by Nordon-Craft et al. (2014) was also mostly male (n=32, 63%) with a mean age of 50 years and those in the Parry et al. (2015) study was also mostly male (n=40, 61%) with a mean age of 58 years. In the one study performed on the CPAx tool, Corner et al. (2015) recruited predominantly male participants (n=19, 63%) with a mean age of 47.1 years. The participants in the current study are thus comparable to these other cohorts with regards to age but not gender.

In the current study, the median ICU LOS for the participant cohort was three days with a median mechanical ventilation duration of five hours. Denehy et al. (2013) demonstrated a median ICU LOS of seven days and a median mechanical ventilation duration of 92 hours for their cohort; Nordon-Craft et al. (2014) showed a median ICU LOS of 20 days and median mechanical ventilation duration of 12 days; and, Parry et al. (2015) demonstrated a median ICU LOS of eight days and median mechanical ventilation duration of five days for their cohort. All three studies investigated the use of the PFIT-s on physical function. Corner et al. (2015) assessed the use of the CPAx tool on physical function in their cohort and showed a median ICU LOS of 17 days and a median mechanical ventilation duration of 14 days. In comparison, the cohort in the current study spent a much shorter time in ICU and on mechanical ventilation.

Participants in the current study underwent open abdominal surgery predominantly for cancer, bowel obstruction, cancer-related hepatectomy, and liver- and kidney transplantation. The cohorts reported on by Denehy et al. (2013), and Parry et al. (2015) predominantly had chest complications, cardiac issues, sepsis and some received surgery. The participants in the study done by Denehy et al. (2013) had some liver disease or renal failure or received transplantation surgery. Nordon-Craft et al. (2014) recruited medical ICU patients with conditions related to chest complications and sepsis. Corner et al. (2015) recruited all participants from the burns ICU, and all participants had at least one surgical intervention performed on them during their ICU LOS. Based on this analysis, the patient population from the current study is different when compared to previously recruited cohorts. Not only is the current study's entire cohort surgical but also had diagnoses associated with preoperative frailty and sarcopenia (Dhaliwal et al., 2020; Handforth et al., 2015; Kurniawan, 2019).

This current study is the only study known of that reports on postoperative complications for the participants recovering from open abdominal surgery that were assessed with the PFIT-s and CPAx. In this study, the most common postoperative complications were hypotension (n=15, 18%), pain (n=13, 16%) and low haemoglobin levels (n=10, 12%). These postoperative complications affected the participants as they limited physical ability or mobilisation for some but did not affect the OM scores obtained. Each OM indicated a change in the patient's physical function as their postoperative complications changed, and no adverse events were recorded in this study.

However, postoperative complications after elective open abdominal surgery are not uncommon. Tevis and Kennedy (2016) demonstrated that one-third of patients having colorectal surgery presented with postoperative complications such as infections and gastrointestinal complications. These complications are correlated to prolonged hospital LOS, worse postoperative- and long-term outcomes and often affect the quality of life of the patient (Tevis & Kennedy, 2016). Knihs et al. (2020) demonstrated that 87.4% of their liver transplantations patients presented with postoperative complications such as PPC (26.7%), graft-related rejection complications (21.1%) and viral infections (14.4%). None of these complications was identified as the most prevalent in this current study, partially because our study focused on complications affecting the participant's ability to mobilise. Medical complications such as infections,

PPC's and gastrointestinal complications wouldn't stop the participants from mobilising but could affect their performance on the OM assessments.

Of interest is that Boer et al. (2016) identified that skeletal muscle quality and -muscle mass could be a predictor of postoperative complications for patients that undergo open abdominal surgery. Cancer- and transplantation patients have a predisposition to postoperative complications due to their recognized preoperative sarcopenia (Dhaliwal et al., 2020; Handforth et al., 2015; Kurniawan, 2019). Kirchhoff, Clavien and Hahnloser (2010) acknowledged that the duration of surgery longer than 120 minutes for patients having open abdominal surgery is associated with higher complications. In the current study, the median intraoperative time was five hours. Jakobson et al. (2014) also substantiated the duration of surgery longer than 130 minutes in patients having open abdominal surgery as a risk factor for the development of postoperative complications. Based on these outcomes from Boer et al. (2016), Jakobson et al. (2014) and Kirchhoff, Clavien and Hahnloser (2010) this current study population presents with a higher risk for postoperative complications.

Postoperative pain was the second most common complication identified in this study, and Kirchhoff, Clavien and Hahnloser (2010) demonstrated that adequate pain management decreases the incidences of postoperative complications such as PPCs and gastrointestinal complications. Lawrence et al. (2004) described the same effect regarding pain control as pain management enhances mobilisation and prevents further postoperative complications.

The hypotension and low haemoglobin levels identified as postoperative complications in this study can be associated with the high risk of intraoperative bleeding that occurs during open abdominal surgery or the side effects related to the type of pain medication administered postoperatively (Jakobson et al., 2014; Kirchhoff, Clavien & Hahnloser, 2010; Lawrence et al., 2004; Mueller, Platz & Kremer, 2004; Schaller et al., 2016; Veličković et al., 2020; Yang et al., 2015).

It is evident that this current study looked at a unique population when compared to other OM based studies and presented information regarding postoperative complications that might influence the participant's ability to mobilise. None of the postoperative complications identified in this study could be prevented by early mobilisation. However involving these patients in a preoperative optimisation of their independent functional capacity, improving their muscle strength, their respiratory- and

cardiovascular capacity, might lower their risk for postoperative complications medically and physically (De Almeida et al., 2017; Van Egmond et al., 2020; Jakobson et al., 2014; Knihs et al., 2020; Strik et al., 2018).

4.2 THE CPAX AND PFIT-S TOOLS' RESPONSIVENESS TO DETECT CHANGES IN PHYSICAL FUNCTION SCORES

This study investigated whether the CPAx and PFIT-s scores can detect a meaningful change in physical function in a surgical cohort after open abdominal surgery. Responsiveness, as defined under section 1.2, is one way to assess the clinimetric properties of a chosen OM. The data from this study shows that both the CPAx and the PFIT-s demonstrated its ability to detect changes (regression or progression) in physical function, in terms of responsiveness, in the population that underwent open abdominal surgery. For the current study, the CPAx demonstrated large responsiveness (CPAx = 0.9101) and the PFIT-s moderate responsiveness (PFIT-s = 0.7122) to change in physical function in the surgical study population.

Supporting these findings, the study by Parry et al. (2015) reported the PFIT-s demonstrated moderate responsiveness to change in 66 GICU and SICU patients. This correlation might have been evident in both cohorts those in the current study had somewhat similar ICU LOS as well as mean age compared to those of the Parry et al. (2015) study. In contrast, Denehy et al. (2013) and Nordon-Craft et al. (2014) demonstrated large responsiveness of the PFIT-s to change in physical function in their surgical and medical cohorts, respectively. In these two studies, the duration on mechanical ventilation was longer in comparison to that of the current study, indicating that length on mechanical ventilation as well as ICU LOS might influence the responsiveness to change of the PFIT-s OM.

The CPAx, on the other hand, has only had one study that looked at the responsiveness of the OM in 30 patients with burn injuries in ICU (Corner et al., 2015). Due to the severity of disability of the patients in the Corner et al. (2015) study, they were unable to comment about the responsiveness of the CPAx to changes in physical function for their patients. It is thus not possible to support or negate the outcome regarding the large responsiveness of the CPAx in this current study's surgical population.

Both the CPAx and PFIT-s OM has shown its ability in this study to report on the changes in physical function in a cohort of adult patients who had open abdominal surgery. From the results, it is apparent that the CPAx would be a more appropriate OM tool to use in patients similar to the cohort studied in terms of responsiveness to detect changes in physical function.

4.3 THE MCID IN PHYSICAL FUNCTION SCORES OBTAINED WITH THE CPAX AND PFIT-S TOOLS

Another way to test the clinimetric properties of an OM tool is by assessing the MCID, as defined in section 1.2. In this study, the CPAx and the PFIT-s OM scores are calculated in integers, and thus the MCIDs were rounded up. Both the CPAx and PFIT-s produced reliable MCID figures which can be utilised to evaluate the change in physical function for the participants and whether that change is meaningful to either themselves or the clinician. The MCID for the PFIT-s was previously determined by Parry et al. (2015) in GICU and SICU participants as a score of 1.5 out of 10 on the interval scoring scale. Denehy et al. (2013) reported the MCID in their study as between 1.0 and 1.4 points in a GICU and SICU cohort.

In comparison, in the current surgical cohort, the PFIT-s MCID was similar and equated to 0.8, which was rounded up to 1. The cohorts in the studies by Denehy et al. (2013) and Parry et al. (2015) had similar ICU LOS and mean age groups as the current study's population. The MCID score of 1 identified in this study adds further validity to the previously identified integer scores to identify meaningful physical changes in patients that had open abdominal surgery.

When assessing the CPAx's MCID, the only reported study by Corner et al. (2015) was conducted in a population that sustained burns, and they described their MCID as 6. However, in this study, the MCID for the CPAx was identified as 4.4 and rounded to 4. The differences in CPAx MCID scores might be due to the different groups of patients assessed, as the patients with burn injuries had lower functional scores at baseline when compared to the current study's surgical patients. The Corner et al. (2015) study population also had a much longer ICU LOS as well duration of mechanical ventilation when compared to this surgical study population. In Corner et al. (2015) study the patients had a median of 30% total body surface area of burns and a CPAx ICU admission median score of zero, whereas, in this study, the median for the CPAx admission score was 38. The admission scores indicate that this study's cohort had a much higher baseline of function on admission to the ICU. A lower functional baseline

score, increased ICU LOS and increased time on mechanical ventilation might need a more significant MCID score for the patient or clinician to perceive the physical change as meaningful thus explaining why the current study's MCID score was slightly smaller in comparison to the Corner et al. (2015) study.

Even though the CPAx MCID for the current cohort doesn't correlate with the Corner et al. (2015) score, identifying these MCID cut off points will assist future researchers in determining MCID scores more accurately for their particular patients; thus making the CPAx cut off marks easily identifiable for rehabilitation interventions.

The current study shows that the MCID scores obtained might be influenced by ICU LOS, duration on mechanical ventilation and admission to ICU baseline OM scores. Both the PFIT-s and CPAx OM showed specific MCID scores which can be used to assess patients that underwent open abdominal surgery continuously to monitor their progress and confidently determine meaningful individual physical changes.

4.4 THE FLOOR AND CEILING EFFECTS OF SCORES OBTAINED WITH THE CPAX AND PFIT-S

The clinimetric properties of an OM can further be described by determining floor- and ceiling effects for each tool, as high floor- and ceiling effects identify less sensitivity to change in physical function (Corner et al., 2015). The study investigated the floor- and ceiling effects of the CPAx and PFIT-s respectively at the time of ICU admission and ICU discharge. If either of these OMs presents with high floor- and ceiling effects, it would indicate that the OM is too easy or too difficult for the cohort of patients to perform (Corner et al., 2015; Parry et al., 2015).

In this study, the CPAx demonstrated a limited floor- and ceiling effect on admission and discharge from ICU. This data correlates well with the floor- and ceiling effects that Corner et al. (2014, 2015) identified during their assessments of the CPAx in a GICU and SICU cohort and burns ICU population.

From the current study's data, the PFIT-s confirmed a limited floor effect on admission and discharge from ICU, as well as a limited ceiling effect on admission to ICU and this, corresponds to results identified in studies done by Denehy et al. (2013) in a GICU and SICU cohort, Nordon-craft et al. (2014) in a medical ICU cohort and Parry et al. (2015) in a GICU and SICU cohort. However, in this study, a significant ceiling effect of 46.38% was identified on discharge from ICU. Nordon-craft et al. (2014) demonstrated a ceiling effect of 5% on discharge from the ICU, Parry et al. (2015) a

ceiling effect of 10.6% and Denehy et al. (2013) a ceiling effect of 22.2%, none of them being quite as high as in the current study. It is worthy to note that factors such as patient characteristics can influence the floor- and ceiling effects of an OM (Denehy et al., 2013). Denehy et al. (2013) and Parry et al. (2015) looked at patients from GICU and SICU's and Nordon-craft et al. (2014) at medical ICU patients. The current study's cohort was specifically from SICU with a specific procedure, namely elective open abdominal surgery, mostly female, with a shorter ICU LOS and shorter duration of mechanical ventilation. All of these factors could explain the high ceiling effect this study generated for the PFIT-s at ICU discharge.

This study's median PFIT-s ICU admission score was 9, whereas Nordon-craft et al. (2014) had a baseline median of 3.2 and Parry et al. (2015) a baseline median of 4.7 indicating that their patient populations had lower functional baseline scores which could explain why they didn't see such a substantial ceiling effect on discharge from ICU. Denehy et al. (2013) had more similar findings to the current study; however, they didn't report on the ICU PFIT-s score means or medians for their study cohort. Therefore, a comparison of results between the two studies is not possible. It was noted in their research, that higher-order activities like walking away from the bed might have an influence on the ceiling effect of the PFIT-s in ICU, which could have also been the case for this study's surgical patient cohort.

Therefore, it is reasonable to recommend that the CPAx is a more appropriate OM to utilise in patients that underwent elective open abdominal surgery, as it covers low- to high functioning tasks within the ICU LOS and is sensitive to detect a change in physical function irrespective of gender, ICU LOS, duration of mechanical ventilation and baseline functional scores.

4.5 THE LEVEL OF CONVERGENT VALIDITY FOR SCORES OBTAINED WITH THE CPAX AND PFIT-S TOOLS

Lastly, the convergent validity of the two OMs were assessed to determine their clinimetric properties. Confirming convergent validity would validate that the OM can identify a meaningful change in physical function for the current study's cohort of patients evaluated (Denehy et al., 2013; Corner et al., 2015).

The current study's results indicated that both the CPAx and the PFIT-s demonstrated moderate to good convergent validity, thus identifying that they both measure physical function in patients that underwent open abdominal surgery. This validity confirms that when these OMs are compared, there is a moderate relationship between them in terms of assessment of physical function. This validity was questioned at the start of this study as the CPAx OM contains a respiratory component which the PFIT-s OM does not. As identified in the literature review section, patients that have had open abdominal surgery often present with PPC, and when an OM takes this component into account, it could potentially reflect the change in physical function more accurately for surgical patients postoperatively in comparison with an OM that does not take respiratory function into account. Thus a lower score or lower physical function as assessed by the CPAx OM tool would easily identify and explain why a patient's physical function is deteriorating as it might be due to PPC.

The convergent validity of the PFIT-s was reported to have a moderate correlation to the MRC sum score in a GICU and SICU cohort (Denehy et al. 2013) and high correlation to the MRC sum score and grip strength in medical ICU patients (Nordon-Craft et al. 2014). No convergent validity studies have been performed on the CPAx. However, the CPAx was reported to have moderate to strong construct validity with the MRC sum score in a GICU and trauma ICU cohort (Corner et al., 2012). The CPAx and the PFIT-s both assess muscle strength directly or indirectly as muscle strength is essential to be able to accomplish functional activities. This study's convergent validity can thus be explained due to the proven relationship each of these OMs are reported to have with the MRC sum score.

The CPAx scored slightly better when compared to the PFIT-s, but the current study's results confirm that both these OMs can determine a meaningful change in physical function in surgical patients postoperatively.

4.6 LIMITATIONS TO THE STUDY AND RECOMMENDATIONS

During this study, even though the researcher managed to collect data and reach the estimated sample size fairly quickly a lot of the patients admitted into the ICU at WDGMC were discharged from the ICU on day one following surgery. The early discharges prevented the study from potentially looking at a larger representative sample of patients with open abdominal surgery during their ICU stay.

Parry et al. (2015) described that a sample size of 50 is sufficient for the assessment of the clinimetric properties of OM tools. We acknowledge that this study reached its required sample size (n=69), but the participants were recruited from a single-centre. Utilising a surgical cohort from a single-centre might have affected the outcomes we generated and limited the extent of generalisation with regards to the clinimetric properties of the OMs assessed on patients that had open abdominal surgery.

During the data collection period for this study, the CPAx or PFIT-s OMs were not administered to patients over the weekends, as the primary researcher and research assistant don't work every weekend and a large number of rotating non-specialist therapists provide physiotherapy cover in the units over the weekends, and this may have influenced the study findings.

During this study, no blinding of the two assessors or the five treating physiotherapists were performed. The sequence of testing for the PFIT-s and CPAx tools was randomised using a computer-generated randomisation list to prevent any learning effect by the study participants. Still, the treating physiotherapists knew which participants were part of the study, and participants knew which OM they were being tested with. It is unlikely that this might have changed the clinical decision making regarding rehabilitation provided as all participants in the WDGMC unit have the CPAx administered as part of their routine assessment. Different therapists treated all participants throughout their ICU stay, which would have ruled out any bias.

Another limitation is that the surgical patients weren't followed to the ward and until discharge from the hospital. Further research is needed to see whether the CPAx OM has any correlation with regards to the hospital LOS for patients that underwent open abdominal surgery. Also, whether it is applicable to utilise the CPAx for this surgical patient cohort until discharge from the hospital with regards to determining discharge destination.

Lastly, we utilised the distribution-based method to determine the MCID in this study (Norman, Sloan & Wyrwich, 2003; Denehy et al., 2013). This method might be criticized as anchor-based methods, or a combination of methods are preferred (Norman, Sloan & Wyrwich, 2003; Revicki et al., 2006). However, for the sake of comparison of the MCID scores to other studies looking at these OMs, we followed the same MCID method as reported by Denehy et al. (2013) and Corner et al. (2015).

Based on this study's results, the CPAx tool should be considered as a postoperative OM for assessing patients that are going to have elective open abdominal surgery. The CPAx has shown its ability to identify meaningful physical changes in patients that have had elective surgery related to cancer, liver- and kidney transplantation and bowel obstruction.

It is recommended that further research of a similar nature is performed from more clinical sites on patients recovering from elective abdominal surgery to establish comparative results for the clinimetric properties of the CPAx. The CPAx has shown its ability to predict post-discharge destination in previous studies, which wasn't assessed in this current study (Corner et al., 2014; Corrigan, 2015). Thus, measuring the effect of CPAx after elective open abdominal surgery on patients' hospital LOS, as well as its predictive ability for patients' post-discharge destination, might yield compelling results in the South African context.

6. CHAPTER 6 CONCLUSION

This prospective observational longitudinal cohort study aimed to measure and compare the CPAx and PFIT-s tools' responsiveness to detect changes in physical function scores; to measure the MCID in physical function scores obtained with the CPAx and PFIT-s tools; to determine and compare the floor and ceiling effects of scores obtained with the CPAx and PFIT-s and to determine the level of convergent validity for scores obtained with the CPAx and PFIT-s tools for patients who had open abdominal surgery.

Sixty-nine participants were assessed in this study. The majority were female (n=43, 62.3%) and had a mean age of 54 (±15.50) years. The most common diagnosis and reason for surgery was cancer (42,1%), followed by bowel obstruction (11,6%), explorative laparotomy (7,3%), liver transplant (7,3%), kidney transplant (7,3%) and hepatectomy (7,3%).

The median ICU LOS for participants was three days, the median number of hours on mechanical ventilation was five hours and the median number of hours spent in surgery was five hours indicating that this study population spent a much shorter time in ICU and on mechanical ventilation when compared to studies of the same nature. Postoperative complications identified in this study were hypotension, pain and low haemoglobin levels, which were unique when compared to previous clinimetric assessment studies on the CPAx and PFIT-s OMs.

The CPAx showed large responsiveness to change (ESI=0.9101) and the PFIT-s moderate responsiveness to change (ESI=0.7122) in this study cohort post elective open abdominal surgery. The MCID identified for patients that had open abdominal surgery is CPAx=4 and PFIT-s=1. The CPAx had a limited floor and ceiling effect on ICU admission and discharge. The PFIT-s demonstrated a significant ceiling effect (46.38%) on ICU discharge which was the highest identified ceiling effect compared to previous clinimetric assessment studies done on the PFIT-s. Convergent validity regarding the CPAx and PFIT-s admission and discharge scores demonstrated moderate convergent validity. No previous convergent validity assessments have been done on the CPAx or to compare validity between the CPAx OM and the PFIT-s OM.

The current study is the first comparative clinimetric assessment study done on the PFIT-s and CPAx OMs in a cohort of South African patients who had elective open abdominal surgery. The CPAx tool has historically been used as part of routine physiotherapy management of patients undergoing elective open abdominal surgery at WDGMC in Johannesburg. The findings of this study confirm that the CPAx tool should be used in future physiotherapy rehabilitation of patients similar to the study cohort at the study site as it is superior to the PFIT-s in relation to its responsiveness to detect changes in physical function, its higher MCID, its limited ceiling and floor effects and its convergent validity. Use of the CPAx OM in the management of such patients will assist physiotherapy clinicians to provide goal-directed progressive therapy to their patients to optimise their recovery from elective open abdominal surgery for cancer, bowel obstruction and liver- or kidney transplantation.

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8. APPENDICES

Appendix 1: The Pilot Study

Procedures Before the Pilot Study

Both the CPAx OM and PFIT-s OM training sessions had to be completed before the physiotherapists could administer the outcome measurements on participants for the pilot study. After the training, both the researcher and the research assistant met to discuss any questions or discrepancies they had regarding their understanding of the OM tools. The outcome measurement tools were practised twice on each other to ensure that all clinicians were comfortable with administering the tool and understood each component of each OM. These practice sessions were also performed to ensure uniform testing on participants. The researcher participated in practising the OM tool's administration but also provided advice and guidance when questions arose during the practice sessions from the research assistant.

Four individual participant record sheets were drafted by the researcher and her supervisor to record demographic information, ICU admission dates, ICU discharge dates, diagnosis, length of intubation, ICU LOS, pain management techniques, postoperative complications, number of theatre trips and the number of physiotherapy sessions the participants received during their hospital stay in ICU and HC. The CPAx and PFIT-s outcome measurement tools, as well as the type of oxygen support and amount of oxygen received by each participant, were added onto the record sheets to assess.

Participants were assessed on day one-, day three-, day five postoperatively and on day of discharge from the ICU or HC and a participant record sheet was created for each day of assessment.

Pilot Study

The pilot study was executed on eight participants which equated to slightly more than ten percent of the total study population. The pilot study aimed to assess the inter-rater reliability for PFIT-s assessments scores between the researcher and the research assistant and to record the time it took to administer the PFIT-s. The duration of performing the PFIT-s was essential to determine how long each testing session with individual participants was likely to take during the main study.

The eight participants were recruited from TICU and SICU. Eight participants were selected as this allowed the researcher and the research assistant to be the lead assessor and secondary assessor on at least four participants each and permitted for possible dropouts from the study without affecting the aim of the pilot study.

For each participant's assessment, the two physiotherapists assessed the participant together but decided on the participant's CPAx scores and PFIT-s scores separately. Each physiotherapist assessed four participants as the lead assessor doing the testing, mobilisation and transfers and evaluated four participants as the secondary assessor observing or assisting with the examination, transfer and mobilisation.

After completion of the pilot study, the results were discussed with the supervisor and analysed for good inter-rater reliability of the PFIT-s scores. Good inter-rater reliability was obtained from the analysis. For the CPAx scores, a strong positive correlation was found between tester one and tester two ($r=0.899$), which was statistically significant ($p=0.02$). For the PFIT-s scores, a strong positive correlation was found between tester one and tester two ($r=0.822$), which was statistically significant ($p=0.05$). Therefore, no changes were implemented for the data collection procedure of the main study. Data collected from the eight pilot study participants were excluded in the primary study data set.

Appendix 2: Chelsea Critical Care Physical Assessment - 2A

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 (>15 l)	Receiving standard oxygen therapy (<15 l)	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 Yankauer 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 of two or more people (maximal)	Initiates movement. Requires assistance of at least one person (moderate)	Initiates movement. Requires assistance of one person (minimal)	Independent in ≥3 seconds	Independent in <3 seconds
Supine to sitting on the edge of the bed	0.9920.899 to 1.000Dynamic Unable/unstable	Initiates movement. Requires assistance of two or more people (maximal)	Initiates movement. Requires assistance of at least one person (moderate)	Initiates movement. Requires assistance of one 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 of two or more people (maximal)	Requires assistance of at least one person (moderate)	Requires assistance of one 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 aids	Independent without aids and full dynamic standing balance (i.e. able to reach out of base of support)
Sit to stand (starting position: ≥90° hip flexion)	Unable/unstable	Sit to stand with maximal assistance (standing hoist or similar)	Sit to stand with moderate assistance (e.g. one or two people)	Sit to stand with minimal assistance (e.g. one 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 of at least one person (moderate)	Using mobility aid and assistance of one person (minimal)	Using mobility aid or assistance of one person (minimal)	Independent without aid
Grip strength (predicted mean for age and gender on the strongest hand)	Unable to assess	<20%	<40%	<60%	<80%	≥80%

(Corner et al., 2012)

Appendix 2: Chelsea Critical Care Physical Assessment - 2B

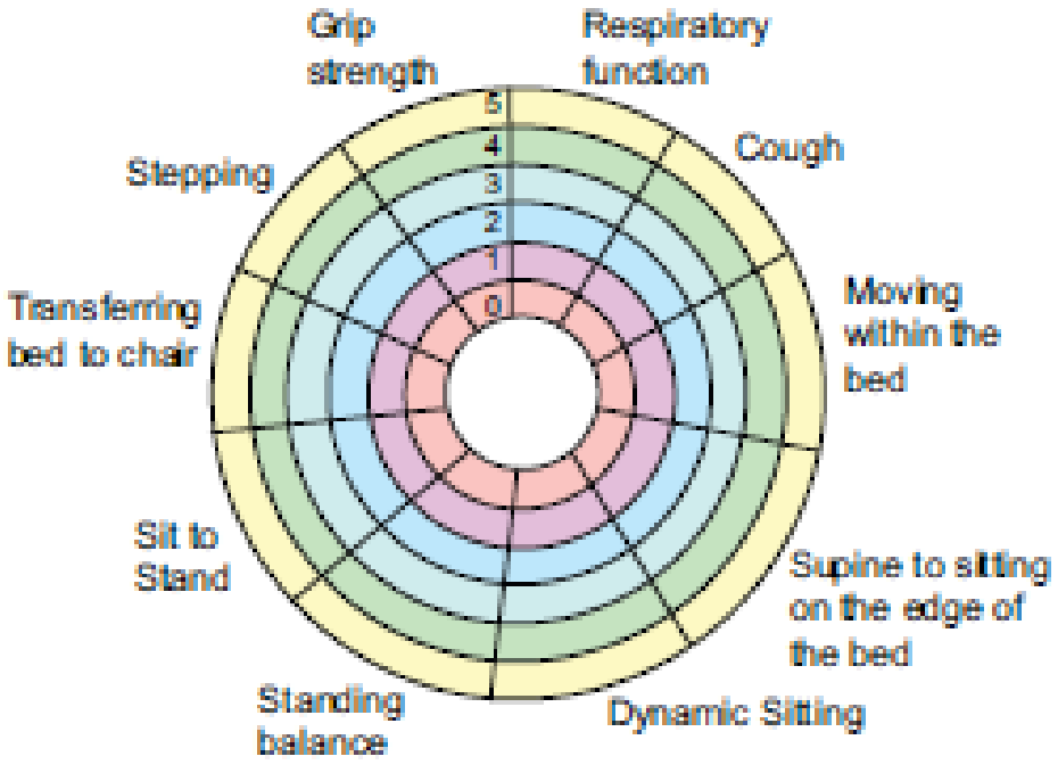
Age (years)	Men							Women						
	Hand	Mean	<20%	<40%	<60%	<80%	≥80%	Hand	Mean	<20%	<40%	<60%	<80%	≥80%
15 to 19	R	48.91	9.38	18.76	28.15	37.53	37.53	R	28.82	5.78	11.53	17.29	23.08	23.06
	L	42.13	8.43	16.85	25.28	33.70	33.70	L	24.98	5.00	9.99	14.99	19.98	19.98
20 to 24	R	48.15	9.63	19.26	28.89	38.52	38.52	R	28.33	5.67	11.33	17.00	22.66	22.66
	L	43.08	8.62	17.23	25.85	34.46	34.46	L	25.78	5.16	10.31	15.47	20.62	20.62
25 to 29	R	53.76	10.75	21.50	32.26	43.01	43.01	R	33.82	6.76	13.53	20.29	27.06	27.06
	L	48.60	9.72	19.44	29.16	38.88	38.88	L	30.31	6.06	12.12	18.19	24.25	24.25
30 to 34	R	52.63	10.53	21.05	31.58	42.10	42.10	R	33.97	6.79	13.59	20.38	27.18	27.18
	L	49.98	9.80	19.59	29.39	39.18	39.18	L	31.64	6.33	12.66	18.98	25.31	25.31
35 to 39	R	53.16	10.63	21.26	31.90	42.53	42.53	R	32.46	6.49	12.98	19.48	25.97	25.97
	L	51.75	10.35	20.70	31.05	41.40	41.40	L	29.77	5.95	11.91	17.86	23.82	23.82
40 to 44	R	55.49	11.10	22.20	33.29	44.39	44.39	R	30.34	6.07	12.14	18.20	24.27	24.27
	L	50.40	10.08	20.16	30.24	40.32	40.32	L	26.23	5.25	10.49	15.74	20.98	20.98
45 to 49	R	49.93	9.99	19.97	29.96	39.94	39.94	R	35.30	7.06	14.12	21.18	28.24	28.24
	L	48.94	9.79	19.58	29.36	39.15	39.15	L	32.06	6.41	12.82	19.24	25.65	25.65
50 to 54	R	49.40	9.88	19.36	29.04	38.72	38.72	R	28.37	5.67	11.35	17.02	22.70	22.70
	L	41.46	8.29	16.58	24.88	33.17	33.17	L	26.28	5.26	10.51	15.77	21.02	21.02
55 to 59	R	45.71	9.14	18.28	27.43	36.57	36.57	R	29.78	5.95	11.90	17.86	23.81	23.81
	L	42.16	8.43	16.86	25.30	33.73	33.73	L	27.81	5.56	11.12	16.69	22.25	22.25
60 to 64	R	40.59	8.12	16.24	24.35	32.47	32.47	R	26.35	5.27	10.54	15.81	21.08	21.08
	L	37.25	7.45	14.90	22.35	29.80	29.80	L	23.47	4.69	9.39	14.08	18.78	18.78
65 to 69	R	40.87	8.17	16.35	24.52	32.70	32.70	R	23.60	4.72	9.44	14.16	18.88	18.88
	L	36.57	7.31	14.63	21.94	29.26	29.26	L	23.38	4.68	9.35	14.03	18.70	18.70
70 to 74	R	37.48	7.50	14.99	22.49	29.98	29.98	R	25.84	5.17	10.34	15.50	20.67	20.67
	L	35.49	7.10	14.20	21.29	28.39	28.39	L	22.92	4.58	9.17	13.75	18.34	18.34
75+	R	32.76	6.55	13.10	19.66	26.21	26.21	R	19.40	3.88	7.76	11.64	15.52	15.52
	L	28.59	5.72	11.44	17.15	22.87	22.87	L	17.64	3.53	7.06	10.58	14.11	14.11

Table developed from normal UK hand grip strength values in Gilbertson L, Barber-Lomax S. Power and pinch grip strength recorded using the hand-held Jamar dynamometer and B+L hydraulic pinch gauge: British normative data for adults. Br J Occupat Ther 1994;57:483–8.

(Corner et al., 2012)

Appendix 2: Chelsea Critical Care Physical Assessment - 2C

Appendix 1b. The Chelsea Critical Care Physical Assessment Tool



(Corner et al., 2012)

CPAx RECORDING SHEET			
Respiratory Function		Standing Balance	
Cough		Sit to stand	
Moving within the bed		Transferring from bed to chair	
Supine to sitting on the edge of bed		Stepping	
Dynamic sitting balance		Grip Strength	
		TOTAL CPAx Score	

Dominant Hand: L / R

Grip L Hand: _____

Grip R Hand: _____

Type of Oxygen: _____

% or L/min: _____

Appendix 3: Physical Function in Intensive Care Test-scored - 3A

PFIT-s RECORDING SHEET					
1. Heart Rate (beats per minute) Immediately			Pre: _____	Post: _____	
2. SpO_2 (%) Immediately			Pre: _____	Post: _____	
PFIT Score	**0**	**1**	**2**	**3**	**Total**
Sit – stand assistance	Unable	Assist x2	Assist x1	No assist	
Chair/bed height (distance to floor, cm) Chair arms used?	_____ Yes No				
Marching on the spot Cadence (steps/min)	Unable	>0 - 49	50 -<80	80+	
Rating of perceived exertion	Pre-test: _____		Post-test: _____		
	Nr of steps: _____		Duration(sec): _____		
Shoulder (grade) Left	Gr0,1 or 2	Gr3	Gr4	Gr5	
Shoulder (grade) Right	Gr0,1 or 2	Gr3	Gr4	Gr5	
Knee (grade) Left	Gr0,1 or 2	Gr3	Gr4	Gr5	
Knee (grade) Right	Gr0,1 or 2	Gr3	Gr4	Gr5	
				TOTAL PFITs Score	

- An example of instructions to the patient:

"While you are exercising try to estimate how hard you are exerting yourself using this scale. It starts at number 0 where it feels easy or like nothing at all and progresses through to number 10 where you feel like you are working at your maximum. Think of the total amount of exertion and physical fatigue you are feeling. How much exertion are you feeling right now?"

	Modified BORG Rating Perceived Exertion Scale
0	Nothing at all
0.5	Very very weak (just noticeable)
1	Very weak
2	Weak (light)
3	Moderate
4	Somewhat strong
5	Strong (heavy)
6	-
7	Very Strong
8	-
9	-
10	Maximal

Type of Oxygen: _____ % or L/min: _____

Appendix 3: Physical Function in Intensive Care Test-scored - 3B

The PFITs (interval score) is then obtained from the Rasch analysis algorithm (see table 2). The conversion to an interval scoring scale is required for parametric statistics to be used in data analyses.

Ordinal score /12	0	1	2	3	4	5	6	7	8	9	10	11	12
Interval PFIT score /10	0	2.0	3.2	3.9	4.4	4.9	5.4	5.9	6.4	7.1	7.9	8.8	10

Table 2. PFIT ordinal and interval scale scoring (Denehy, 2013)

Appendix 4: Modified Borg Dyspnea Scale

	Modified BORG Rating Perceived Exertion Scale
0	Nothing at all
0.5	Very, very weak (just noticeable)
1	Very weak
2	Weak (light)
3	Moderate
4	Somewhat strong
5	Strong (heavy)
6	-
7	Very Strong
8	-
9	-
10	Maximal

Appendix 5: Research Consent Form

CONSENT FORM

I hereby confirm that I have been informed about the nature, conduct, benefits and risks of the study: ***Comparison of two outcome measures to changes in physical function for patients after open abdominal surgery.***

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: Participant Information Sheet

PARTICIPANT INFORMATION SHEET

Comparison of two outcome measures to detect changes in physical function for patients after open abdominal surgery.

Dear potential participant,

My name is Marelee Fourie. I am a physiotherapy clinician working at WITS Donald Gordon Medical Centre. I am performing a research study entitled '*Comparison of two outcome measures to detect changes in physical function for patients after open abdominal surgery*'. The purpose of my study is to determine the effect of using two assessment tools called CPAx and the PFIT-s on patients for the duration of their ICU admission after abdominal surgery. CPAx and PFIT-s are paper-based assessment tools that are used by physiotherapists in countries such as Australia and England to evaluate a person's ability to do everyday activities in a hospital setting. These tools are not invasive measures.

With the CPAx assessment 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. This assessment tool is already in use in the Wits DGMC general ICU and forms part of standard physiotherapy patient management.

For the new PFIT-s tool there are four different areas/activities that the tool assesses relating to patient function. These areas are sit to stand from the edge of the bed or from a chair, marching on the spot, upper limb muscle strength and lower limb muscle strength tests.

Both these tools assist physiotherapists to set specific rehabilitation goals for their patients for each treatment session to ensure progression of patient management.

<u>Why am I being asked to participate?</u>

- You had open abdominal surgery.
- In this ICU we (physiotherapists) use the CPAx tool as a routine tool to assess our patients' physical function. We want to test the tool's ability to detect change in physical function for patients such as you. We will compare the score you achieve on the CPAx to the score you achieve on the PFIT-s tool.
- Your participation in this study is completely voluntary. If you decide not to participate, you will not be penalised in any way and will continue to receive the usual medical, nursing and

physiotherapy care provided for any patients in our ICU and high care unit following open abdominal surgery.

What does the study involve?

In this study, you will receive physiotherapy assessment using both the PFIT-s and the CPAx tools. The assessments include measuring your ability to perform everyday tasks such as coughing, rolling, sitting up in bed, standing, stepping, moving into a chair, hand grip strength, upper limb and lower limb strength and marching on the spot. This will be measured on the first day, third day and fifth day after your surgery and on the day that you are discharged from the ICU. You will receive standard physiotherapy treatment, based on the assessment findings of the respective tools, which involves exercises and rehabilitation depending on what tasks you are struggling with. We will monitor how your heart rate and oxygen saturation levels respond to the tools while we administer them.

What are the benefits?

The benefits to participation in this study include that you will receive free physiotherapy assessment with the CPAx and PFIT-s tools on days 1, 3 and 5 of your ICU stay postoperatively as well as on the day of discharge from ICU.

What are the risks?

There are no known risks associated with use of the PFIT-s and the CPAx tools or to participating in this study.

What is the cost?

Your participation in this study will not lead to any additional cost of care to you or your family. We will not charge you for the assessments received on the days that we administer the two assessment tools (days 1, 3, 5 and day of discharge from ICU).

Confidentiality and anonymity

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

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 (Marelee Fourie) at 082 293 8271. Alternatively, you can contact the Human Research Ethics Committee: Prof Clement Penny at clement.penny@wits.ac.za or 011 717 1234.

Appendix 7: Individual Participant Recording Sheet – Day 1 Post Surgery

Assessment 1: Individual Participant Recording Sheet: Day 1 post-surgery

Participant Identity code: ____ Epidural in situ: Yes / No

1. Age: _____
2. Gender: _____
3. Date of ICU admission: _____
4. Time of ICU admission: _____
5. Diagnosis: _____
6. Date of intubation: _____
7. Time of intubation: _____
8. Date of extubation: _____
9. Time of extubation: _____
10. Indication for surgery: _____
11. Duration of surgery: _____
12. Number of theatre trips: _____
13. Number of post-operative complications: _____
14. Type of post-operative complications: _____
    _____
15. Pain management techniques: _____
16. Date of epidural removal: _____
17. Date of physiotherapy referral: _____

CPAx RECORDING SHEET			
Respiratory Function		Standing Balance	
Cough		Sit to stand	
Moving within the bed		Transferring from bed to chair	
Supine to sitting on the edge of bed		Stepping	
Dynamic sitting balance		Grip Strength	
		TOTAL CPAx Score	

Dominant Hand: L / R

Grip L Hand: _____

Grip R Hand: _____

Type of Oxygen: _____ % or L/min: _____

PFIT-s RECORDING SHEET					
1. Heart Rate (beats per minute) immediately			Pre: _____	Post: _____	
2. SpO_2 (%) immediately			Pre: _____	Post: _____	
PFIT Score	**0**	**1**	**2**	**3**	**Total**
Sit – stand assistance	Unable	Assist x2	Assist x1	No assist	
Chair/bed height (distance to floor, cm) Chair arms used?	_____ Yes No				
Marching on the spot Cadence (steps/min)	Unable	>0 - 49	50 -<80	80+	
Rating of perceived exertion	Pre-test: _____		Post-test: _____		
	Nr of steps: _____		Duration(sec): _____		
Shoulder (grade) Left	Gr0,1 or 2	Gr3	Gr4	Gr5	
Shoulder (grade) Right	Gr0,1 or 2	Gr3	Gr4	Gr5	
Knee (grade) Left	Gr0,1 or 2	Gr3	Gr4	Gr5	
Knee (grade) Right	Gr0,1 or 2	Gr3	Gr4	Gr5	
				TOTAL PFITs Score	

- An example of instructions to the patient:

"While you are exercising try to estimate how hard you are exerting yourself using this scale. It starts at number 0 where it feels easy or like nothing at all and progresses through to number 10 where you feel like you are working at your maximum. Think of the total amount of exertion and physical fatigue you are feeling. How much exertion are you feeling right now?"

	Modified BORG Rating Perceived Exertion Scale
0	Nothing at all
0.5	Very very weak (just noticeable)
1	Very weak
2	Weak (light)
3	Moderate
4	Somewhat strong
5	Strong (heavy)
6	-
7	Very Strong
8	-
9	-
10	Maximal

Type of Oxygen: _____ % or L/min: _____

Appendix 8: Individual Participant Recording Sheet – Day 3 Post Surgery

Assessment 2: Individual Participant Recording Sheet: Day 3 post-surgery

Participant identity code: ☐ Epidural in situ: Yes / No

1. Age: _____
2. Gender: _____
3. Diagnosis: _____
4. Date of intubation: _____
5. Time of intubation: _____
6. Date of extubation: _____
7. Time of extubation: _____
8. Indication for f/u surgery: _____
9. Duration of f/u surgery: _____
10. Number of theatre trips: _____
11. Number of post-operative complications: _____
12. Type of post-operative complications: _____
    _____
13. Pain management techniques: _____
14. Date of epidural removal: _____
15. Number of physiotherapy treatment sessions received to date: _____

CPAx RECORDING SHEET			
Respiratory Function		Standing Balance	
Cough		Sit to stand	
Moving within the bed		Transferring from bed to chair	
Supine to sitting on the edge of bed		Stepping	
Dynamic sitting balance		Grip Strength	
		TOTAL CPAx Score	

Dominant Hand: L / R

Grip L Hand: _____

Grip R Hand: _____

Type of Oxygen: _____ % or L/min: _____

PFIT-s RECORDING SHEET					
1. Heart Rate (beats per minute) immediately			Pre: _____	Post: _____	
2. SpO_2 (%) immediately			Pre: _____	Post: _____	
PFIT Score	**0**	**1**	**2**	**3**	**Total**
Sit – stand assistance	Unable	Assist x2	Assist x1	No assist	
Chair/bed height (distance to floor, cm) Chair arms used?	_____ Yes No				
Marching on the spot Cadence (steps/min)	Unable	>0 - 49	50 -<80	80+	
Rating of perceived exertion	Pre-test: _____		Post-test: _____		
	Nr of steps: _____		Duration(sec): _____		
Shoulder (grade) Left	Gr0,1 or 2	Gr3	Gr4	Gr5	
Shoulder (grade) Right	Gr0,1 or 2	Gr3	Gr4	Gr5	
Knee (grade) Left	Gr0,1 or 2	Gr3	Gr4	Gr5	
Knee (grade) Right	Gr0,1 or 2	Gr3	Gr4	Gr5	
				TOTAL PFITs Score	

- An example of instructions to the patient:

"While you are exercising try to estimate how hard you are exerting yourself using this scale. It starts at number 0 where it feels easy or like nothing at all and progresses through to number 10 where you feel like you are working at your maximum. Think of the total amount of exertion and physical fatigue you are feeling. How much exertion are you feeling right now?"

	Modified BORG Rating Perceived Exertion Scale
0	Nothing at all
0.5	Very very weak (just noticeable)
1	Very weak
2	Weak (light)
3	Moderate
4	Somewhat strong
5	Strong (heavy)
6	-
7	Very Strong
8	-
9	-
10	Maximal

Type of Oxygen: _____ % or L/min: _____

Appendix 9: Individual Participant Recording Sheet – Day 5 Post Surgery

Assessment 3: Individual Participant Recording Sheet: Day 5 post-surgery

Participant identity code: ____ Epidural in situ: Yes / No

1. Age: _____
2. Gender: _____
3. Diagnosis: _____
4. Date of intubation: _____
5. Time of intubation: _____
6. Date of extubation: _____
7. Time of extubation: _____
8. Indication for f/u surgery: _____
9. Duration of f/u surgery: _____
10. Number of theatre trips: _____
11. Number of post-operative complications: _____
12. Type of post-operative complications: _____
13. Pain management techniques: _____
14. Date of epidural removal: _____
15. Number of physiotherapy treatment sessions received to date: _____

CPAx RECORDING SHEET			
Respiratory Function		Standing Balance	
Cough		Sit to stand	
Moving within the bed		Transferring from bed to chair	
Supine to sitting on the edge of bed		Stepping	
Dynamic sitting balance		Grip Strength	
		TOTAL CPAx Score	

Dominant Hand: L / R

Grip L Hand: _____

Grip R Hand: _____

Type of Oxygen: _____ % or L/min: _____

PFIT-s RECORDING SHEET					
1. Heart Rate (beats per minute) immediately			Pre: _____	Post: _____	
2. SpO_2 (%) immediately			Pre: _____	Post: _____	
PFIT Score	**0**	**1**	**2**	**3**	**Total**
Sit – stand assistance	Unable	Assist x2	Assist x1	No assist	
Chair/bed height (distance to floor, cm) Chair arms used?	_____ Yes No				
Marching on the spot Cadence (steps/min)	Unable	>0 - 49	50 -<80	80+	
Rating of perceived exertion	Pre-test: _____		Post-test: _____		
	Nr of steps: _____		Duration(sec): _____		
Shoulder (grade) Left	Gr0,1 or 2	Gr3	Gr4	Gr5	
Shoulder (grade) Right	Gr0,1 or 2	Gr3	Gr4	Gr5	
Knee (grade) Left	Gr0,1 or 2	Gr3	Gr4	Gr5	
Knee (grade) Right	Gr0,1 or 2	Gr3	Gr4	Gr5	
				TOTAL PFITs Score	

- An example of instructions to the patient:

"While you are exercising try to estimate how hard you are exerting yourself using this scale. It starts at number 0 where it feels easy or like nothing at all and progresses through to number 10 where you feel like you are working at your maximum. Think of the total amount of exertion and physical fatigue you are feeling. How much exertion are you feeling right now?"

	Modified BORG Rating Perceived Exertion Scale
0	Nothing at all
0.5	Very very weak (just noticeable)
1	Very weak
2	Weak (light)
3	Moderate
4	Somewhat strong
5	Strong (heavy)
6	-
7	Very Strong
8	-
9	-
10	Maximal

Type of Oxygen: _____ % or L/min: _____

Appendix 10: Individual Participant Recording Sheet – Day of ICU DC

Assessment 4: Individual Participant Recording Sheet: ICU discharge

Participant identity code: ____ Epidural in situ: Yes / No

1. Age: _____
2. Gender: _____
3. Date of ICU admission: _____
4. Time of ICU admission: _____
5. Diagnoses: _____
6. Number of theatre trips: _____
7. Number of post-operative complications: _____
8. Type of post-operative complications: _____
   _____
9. Pain management techniques: _____
10. Date of epidural removal: _____
11. Number of physiotherapy treatment sessions received to date: _____
12. Total number of physiotherapy sessions by D/C: _____
13. Date of ICU discharge: _____
14. Time of ICU discharge: _____

CPAx RECORDING SHEET			
Respiratory Function		Standing Balance	
Cough		Sit to stand	
Moving within the bed		Transferring from bed to chair	
Supine to sitting on the edge of bed		Stepping	
Dynamic sitting balance		Grip Strength	
		TOTAL CPAx Score	

Dominant Hand: L / R

Grip L Hand: _____

Grip R Hand: _____

Type of Oxygen: _____ % or L/min: _____

PFIT-s RECORDING SHEET					
1. Heart Rate (beats per minute) Immediately			Pre: _____	Post: _____	
2. SpO_2 (%) Immediately			Pre: _____	Post: _____	
PFIT Score	**0**	**1**	**2**	**3**	**Total**
Sit – stand assistance	Unable	Assist x2	Assist x1	No assist	
Chair/bed height (distance to floor, cm) Chair arms used?	_____ Yes No				
Marching on the spot Cadence (steps/min)	Unable	>0 - 49	50 -<80	80+	
Rating of perceived exertion	Pre-test: _____		Post-test: _____		
	Nr of steps: _____		Duration(sec): _____		
Shoulder (grade) Left	Gr0,1 or 2	Gr3	Gr4	Gr5	
Shoulder (grade) Right	Gr0,1 or 2	Gr3	Gr4	Gr5	
Knee (grade) Left	Gr0,1 or 2	Gr3	Gr4	Gr5	
Knee (grade) Right	Gr0,1 or 2	Gr3	Gr4	Gr5	
				TOTAL PFITs Score	

- An example of instructions to the patient:

"While you are exercising try to estimate how hard you are exerting yourself using this scale. It starts at number 0 where it feels easy or like nothing at all and progresses through to number 10 where you feel like you are working at your maximum. Think of the total amount of exertion and physical fatigue you are feeling. How much exertion are you feeling right now?"

	Modified BORG Rating Perceived Exertion Scale
0	Nothing at all
0.5	Very very weak (just noticeable)
1	Very weak
2	Weak (light)
3	Moderate
4	Somewhat strong
5	Strong (heavy)
6	-
7	Very Strong
8	-
9	-
10	Maximal

Type of Oxygen: _____ % or L/min: _____

Appendix 11: Ethical Clearance Certificate

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Ms Marelee Fourie

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M181167

NAME: (Principal Investigator)	Ms Marelee Fourie
DEPARTMENT:	Therapeutic Sciences - Physiotherapy Wits Donald Gordon Medical Centre Intensive Care and High Care Unit
PROJECT TITLE:	Comparison of two outcome measures to detect changes in physical function for patients after open abdominal surgery
DATE CONSIDERED:	30/11/2018
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof Heleen van Aswegen
APPROVED BY:	Dr. CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	18/12/2018

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

DECLARATION OF INVESTIGATORS

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

Principal Investigator Signature

Date 01/07/2019

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 12: Permission Letter from the CEO of WDGMC

Donald Gordon
Medical Centre

MEDICLINIC

03 July 2018

To whom it may concern

Re: Permission to conduct research at Wits Donald Gordon Medical Centre

This letter serves to confirm that permission is granted from the CEO, Dr Susan Tager at WDGMC for Marelee Fourie, to conduct her MSc Physiotherapy study titled:

"Responsiveness of two outcome measures to detect changes in physical function for patients after open abdominal surgery", at the Wits Donald Gordon Medical Centre.

No data collection may start at WDGMC until a Clearance Certificate has been obtained to do the study from the Wits Human Research Ethics Committee (Medical).

Yours faithfully,

Dr Sue Tager
CEO
Wits Donald Gordon Medical Centre
Tel: (+27) 011 356 6302
Mobile: 082 457 7134
Email: sue.tager@mediclinic.co.za

Appendix 13: Permission Letter from the Intensivist

Dr Gunter K Schleicher

MBBCh(WITS), DTM&H, FCP(SA), FCCP, M.Med, Cert Pulmonology(SA)

Specialist Physician/Pulmonologist

Director, Wits DGMC ICU

Pr No 0180050156256

ROOMS: Wits University Donald Gordon Medical Centre, Eton Road, Parktown
Tel: (011) 726-7403/4

POSTAL ADDRESS: PO Box 98818, Sloane Park, 2152, SOUTH AFRICA

Email: schleicher@worldonline.co.za

FAX: (011) 726-7407

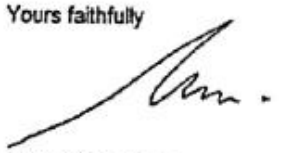
2 July 2018

To whom it may concern

Re: Marelee Fourie

I, Dr GK Schleicher, Director of the Wits Donald Gordon Medical Centre ICU, give Marelee Fourie permission to conduct her MSc research project entitled "Comparison of two outcome measures to detect changes in physical function for patients after open abdominal surgery" at the WDGMC ICU. The study will have no financial implications for the patients enrolled or to the Hospital. No interventions with potential harmful effects are performed, and there is no increased risk to the patients' standard level of medical care.

Yours faithfully



Gunter Schleicher

Appendix 14: Permission Letter from the Colorectal Surgical Team

Suite 2,
27 Eton Road,
Parktown.

To Whom It May Concern

Dear Sir or Madam

In order to assist Dr Marelee Fourie (mareleevw@gmail.com) in her MSc Study I formally agree to give her permission to access the Redcap Database set up for the evaluation of patients with colorectal cancer. I do this as the principle investigator of a colorectal research project supported by an MRC grant and which has been enabled and facilitated by the Wits Donald Gordon Research Group .

Yours sincerely,
Dr Brendan Bebington,
Head of Colorectal Surgery at Wits Donald Gordon Medical Centre.

Appendix 15: Permission Letter from the Transplant Surgical Team

Prof JF Botha and Associates
TRANSPLANT SURGEONS
Practice # 042 000 0372145

Wits University Donald Gordon Medical Centre
Patient-centred. Independent. Academic.
MEDICLINIC
+ 27 11 356 6488 / 6067 / 6000

2nd August 2018
18 Eton Rd
Parktown
2193

Dear Marelee,

RE: Responsiveness of two outcome measures to detect changes in physical function for patients after open abdominal surgery.

I agree to the enrollment of adult liver and kidney transplant recipients in your proposed study as mentioned above. Please do not hesitate to contact me with any queries regarding these patients.

Kind Regards

Jean Botha
Director of Transplantation
Wits Donald Gordon Medical Centre
Parktown

Appendix 16: Permission Letter from the Physiotherapy Practice

3 August 2018

Dear Marelee

PERMISSION TO PERFORM STUDY: COMPARISON OF TWO OUTCOME MEASURES TO DETECT CHANGES IN PHYSICAL FUNCTION FOR PATIENTS AFTER OPEN ABDOMINAL SURGERY.

I hereby give permission for you to perform the above study. This permission is given in my capacity as Allied Health Representative of the Medical Executive Committee of the Wits Donald Gordon Medical Centre as well as owner of Carr and Associates which is the Practice that will be treating these patients.

Yours sincerely

Michele Carr
082 378 8919

Appendix 17: Plagiarism Report

Faculty of Health Sciences, Postgraduate Office
Phillip V Tobias Building, 2nd Floor
Cnr York & Princess of Wales Terrace, Parktown 2193
Tel: (011) 717 2745 | Fax: (011) 717 2119
Email: Mathoto.senamela@wits.ac.za

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I Marelee Fourie (Student number: 445892) am a student registered for the degree of MSc Physiotherapy in the academic year 2020.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: _____ Date: 03/08/2020

Appendix 18: Randomisation List for Participants

The list below indicates the randomisation order utilised for the OM tool administration during the study. The OM identified on the list per participant, was the OM that the participant would start their assessment with on a particular day postoperatively. If an interval assessment day fell on the weekend, the participant was assessed the following Monday. All participants received standard physiotherapy during the week and weekend.

Pt Code	Day 1 Ax	Day 3 Ax	Day 5 Ax	Day DC Ax
1	PFIT-s	CPAx	PFIT-s	CPAx
2	PFIT-s	PFIT-s	CPAx	CPAx
3	CPAx	CPAx	CPAx	PFIT-s
4	CPAx	CPAx	CPAx	PFIT-s
5	PFIT-s	PFIT-s	PFIT-s	PFIT-s
6	CPAx	CPAx	PFIT-s	CPAx
7	CPAx	CPAx	PFIT-s	PFIT-s
8	CPAx	CPAx	CPAx	PFIT-s
9	CPAx	PFIT-s	CPAx	CPAx
10	CPAx	CPAx	PFIT-s	PFIT-s
11	PFIT-s	PFIT-s	PFIT-s	CPAx
12	PFIT-s	PFIT-s	CPAx	CPAx
13	CPAx	CPAx	PFIT-s	CPAx
14	PFIT-s	PFIT-s	CPAx	PFIT-s
15	CPAx	PFIT-s	CPAx	PFIT-s
16	PFIT-s	CPAx	PFIT-s	CPAx
17	CPAx	CPAx	PFIT-s	PFIT-s
18	CPAx	CPAx	PFIT-s	CPAx
19	CPAx	PFIT-s	PFIT-s	PFIT-s
20	CPAx	CPAx	CPAx	PFIT-s
21	PFIT-s	PFIT-s	PFIT-s	PFIT-s
22	PFIT-s	CPAx	CPAx	PFIT-s
23	PFIT-s	CPAx	PFIT-s	PFIT-s
24	CPAx	CPAx	CPAx	CPAx
25	CPAx	PFIT-s	CPAx	CPAx
26	CPAx	CPAx	CPAx	PFIT-s
27	CPAx	CPAx	PFIT-s	PFIT-s
28	PFIT-s	PFIT-s	CPAx	PFIT-s
29	PFIT-s	PFIT-s	CPAx	PFIT-s
30	CPAx	CPAx	PFIT-s	CPAx
31	CPAx	CPAx	PFIT-s	CPAx
32	CPAx	PFIT-s	PFIT-s	PFIT-s
33	PFIT-s	PFIT-s	PFIT-s	CPAx
34	PFIT-s	CPAx	PFIT-s	PFIT-s
35	CPAx	CPAx	CPAx	CPAx

Pt Code	Day 1 Ax	Day 3 Ax	Day 5 Ax	Day DC Ax
36	CPAx	CPAx	PFIT-s	CPAx
37	PFIT-s	PFIT-s	CPAx	PFIT-s
38	PFIT-s	CPAx	CPAx	CPAx
39	CPAx	PFIT-s	CPAx	CPAx
40	CPAx	PFIT-s	CPAx	CPAx
41	PFIT-s	CPAx	CPAx	PFIT-s
42	PFIT-s	CPAx	PFIT-s	PFIT-s
43	CPAx	CPAx	CPAx	PFIT-s
44	CPAx	CPAx	PFIT-s	CPAx
45	CPAx	CPAx	PFIT-s	CPAx
46	CPAx	CPAx	CPAx	CPAx
47	CPAx	CPAx	PFIT-s	CPAx
48	CPAx	PFIT-s	CPAx	PFIT-s
49	PFIT-s	CPAx	PFIT-s	PFIT-s
50	PFIT-s	PFIT-s	CPAx	PFIT-s
51	PFIT-s	PFIT-s	CPAx	PFIT-s
52	PFIT-s	CPAx	PFIT-s	PFIT-s
53	CPAx	PFIT-s	PFIT-s	CPAx
54	CPAx	PFIT-s	CPAx	CPAx
55	CPAx	CPAx	PFIT-s	PFIT-s
56	CPAx	CPAx	CPAx	CPAx
57	CPAx	CPAx	PFIT-s	PFIT-s
58	CPAx	CPAx	CPAx	CPAx
59	CPAx	PFIT-s	CPAx	PFIT-s
60	CPAx	CPAx	CPAx	PFIT-s
61	PFIT-s	PFIT-s	CPAx	PFIT-s
62	CPAx	CPAx	PFIT-s	PFIT-s
63	PFIT-s	PFIT-s	CPAx	PFIT-s
64	PFIT-s	CPAx	PFIT-s	CPAx
65	PFIT-s	CPAx	PFIT-s	CPAx
66	PFIT-s	PFIT-s	PFIT-s	PFIT-s
67	PFIT-s	CPAx	CPAx	PFIT-s
68	CPAx	PFIT-s	PFIT-s	CPAx
69	PFIT-s	CPAx	PFIT-s	CPAx

Appendix 19: Turn-It-In Report

445892:445892_M_Fourie.docx

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