



*Physical function performance and recovery of
patients undergoing abdominal surgery in
relation to post-operative complications – A
prospective real world study*

by

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of the award of Master of Science

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i. Declaration

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ii. Summary

Title: *Physical function performance and recovery of patients undergoing abdominal surgery in relation to post-operative complications – A prospective real world study.*

Objective: The primary aim of the study is to evaluate the physical function performance differences between those who develop complications and those who do not and determine their impact on recovery.

Background: Complication rates in abdominal (colorectal, hernia repair & cholecystectomies) surgery are variable and appear to be lower in minimally invasive, less complex surgery. Complications are associated with significant costs in terms of morbidity, finance, psychological and impact on recovery. Factors that have been identified as associated with complications include age, BMI, surgical approach, co-morbidities, American Society of Anaesthesiologists (ASA) status, physical function frailty and level of dependency. It is also clear that these factors individually are unlikely predictors but highlight the need for multifactorial assessment. Surgical procedures in their essence cause significant physiological stress which can often mimic similar physiological effects of exercise. Cardiopulmonary exercise testing (CPET) can be useful in predicting complications, however is generally unavailable and not always suitable. No one measure has been identified to predict complications in an abdominal surgery population, hence the need to evaluate physical function performance as a whole and analyse differences that may emerge between those who develop complications and those who do not.

Methods: Participants were recruited (n = 49) via the pre-operative assessment unit in the University Hospital Limerick. Pre-operative assessment included the following: demographics data, six-minute walk distance, VO₂Peak, spirometry, peak cough flow, self-reported activity using the International Physical Activity Questionnaire (IPAQ), ASA score, surgical

grade, Malnutrition Universal Scoring Tool (MUST) score, albumin and creatinine levels. Post-surgery data included surgery type, length, surgical approach, initial 24-hour pain relief, length of stay and complications. At 30 and 60 days, participants were contact via telephone and the telephone IPAQ repeated, questioned regarding their self-assessed physical recovery and post hospital discharge complications.

Results: Surgery types fell into the following 4 categories: colorectal (n = 21), colorectal reversals (n = 7), hernia repairs (n = 10) and cholecystectomies (n = 5). The complications rate was 41.9% (n=18) pre-discharge, 30.2% (n=13) at 30 day's post- surgery and 21% (n = 9) at 60 day's post-surgery. Obesity (P=0.005*), longer operating time (P=0.05*), >2 co-morbidities (P = 0.033*), low activity levels (P=0.020*), low VO₂Peak (P=0.017*) and lower 6-minute walk distance (P=0.019*) were statistically different between complications and non-complications groups with worse scores seen in the complications group. Length of stay was significantly increased in the complications groups at a median of 8.5 nights versus 2 nights in the non-complications group (P<0.001*). Both the complications and non-complications groups activity levels reduced significantly regardless of the presence of complications and did not return to baseline levels by 60-days post-surgery (P<0.001*). The complications groups also significantly increased their sedentary time from a median of 5 to 7.5 hours daily (P=0.007*). Self-reported physical recovery was almost 100% in the non-complications group at 60 days whilst the complications groups reported a median of feeling approximately 75% recovered.

Conclusion: This study highlighted significant differences between groups which are potentially modifiable such as BMI and physical activity and as such warrants further investigation. Regardless of complications, this cohort did not return to or near baseline activity levels and the complications group increased their sedentary activity significantly. If looked at in the larger context of physical activity in the prevention and management of various diseases, could be physically and financially detrimental in the future.

iii. **Acknowledgements**

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iv. **Abbreviations**

<u>Abbreviation</u>	<u>Full term</u>
ADL's	Activities of Daily Living
ASA	American Society of Anaesthesiologists
AT	Anaerobic Threshold
BMI	Body Mass Index
CCI	Comprehensive Classification Index
CHAMPS	Community Health Activities Model Programme for Seniors
COPD	Chronic Obstructive Pulmonary Disease
CPET	Cardiopulmonary Exercise Testing
CVA	Cerebrovascular Accident
ESC	European Society of Cardiology
FEV ₁	Forced expiratory volume in one second
FVC	Forced vital capacity
GI	Gastrointestinal
IADL's	Independent Activities of Daily Living
ICF	Institutional Care Facilities
ISWT	Incremental Shuttle Walk Test
IQR	Inter Quartile Ratio
LAPAQ	LASA Physical Activity Questionnaire
LOS	Length of Stay
LRTI	Lower Respiratory Tract Infection
METS	Metabolic Equivalent
Md	Median
MUST	Malnutrition Universal Scoring Tool
MI	Myocardial infarction
O ₂	Oxygen
OR	Odds Ratio
OT	Operating Theatre
PEFR	Peak Expiratory Flow Rate
PCF	Peak Cough Flow
PAD	Peripheral Arterial Disease

POMS	Postoperative morbidity survey
QoL	Quality of Life
SD	Standard Deviation
SDS	Symptom Distress Scale
SF36	Short Form 36
SPPB	Short Physical Performance Battery
SSI's	Surgical site infections
STS	Sit to Stand
TUGT	Timed Up and Go Test
USA	United States of America
VO _{2max}	Maximal Oxygen Uptake
VO ₂ Peak	Peak Oxygen Uptake
WHO	World Health Organisation
6MWT	Six-minute walk test

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Chapter 1

1. Introduction

1.1 Background

In 2012 the World Health Organisation reported that in Ireland alone, 299,335 various surgeries were performed, equating to 6,526 per 100,000 population with a significant proportion of these being abdominal surgery (Weiser *et al* 2012). A number of studies have highlighted the physiological stresses of surgery, the risks associated with surgery and the types of complications that patients may experience as a result of abdominal surgery (Finnerty *et al* 2013, Kirchoff *et al* 2010). These post-operative complications have significant costs associated with them, both financially and on quality of life (Fuller *et al* 2009, Derogar *et al* 2012). Due to the increasing age of the general population, there is a subsequent increase in the number of elderly patients undergoing elective surgery and the associated risk of post-operative complications. These increased complication rates will add to further costs and demands on health resources worldwide (Manton *et al* 1995, Weiser *et al* 2012). Thus, it would seem logical to research ways to identify and minimise these risks, where possible.

1.1.1 Abdominal Surgeries

The term abdominal surgeries encompasses a wide variety of surgeries which breach the abdominal wall, known as a laparotomy. However, they vary according to the anatomical system causing the initial issue e.g. aortic aneurysm is regarded as a vascular surgery, caesarean section as a uterine surgery and a cholecystectomy as an upper gastro-intestinal (GI) tract surgery (Lavelle-Jones, 2002). As the range of abdominal surgeries is quite broad, the following will mainly focus on colorectal surgeries as surgeries representing the lower GI tract, cholecystectomies as representing the upper GI tract and hernia repairs due to internal breaches of the abdominal wall.

Colorectal surgeries pertain to areas of the large intestine and rectum. Stoma's may also be formed where by part of the bowel that has been resected is brought to the surface of the abdominal wall. This can be reversible depending on the

initial reason for its formation (Williams *et al* 2008). See Figure 1.1. Hernia repairs are performed due to part of the bowel herniating through the part of the abdominal wall (Williams *et al* 2008). Cholecystectomies refer to removal of the gallbladder (Lavelle-Jones, 2002).

Abdominal surgeries are generally performed using three different incision types: open, laparoscopic and robotic laparoscopic (Williams *et al* 2008). See Figure 1.2. Open incisions are known to provoke a stronger physiological stress response versus a laparoscopic approach (Scott and Miller 2015). All surgeries are graded according to their complexity regardless of the problematic bodily system where the issue originates (NICE, 2016). For example a colonic resection would be regarded as a major complex surgery versus drainage of an abscess would be regarded as minor surgery. See Table 1.1 for further examples. The complexity of the surgery also affects the physiological stress responses that the individuals may suffer (Scott and Miller 2015).

Figure 1.1 Colostomy & Ileostomy -
<http://www.mdguidelines.com/colostomy-and-ileostomy>

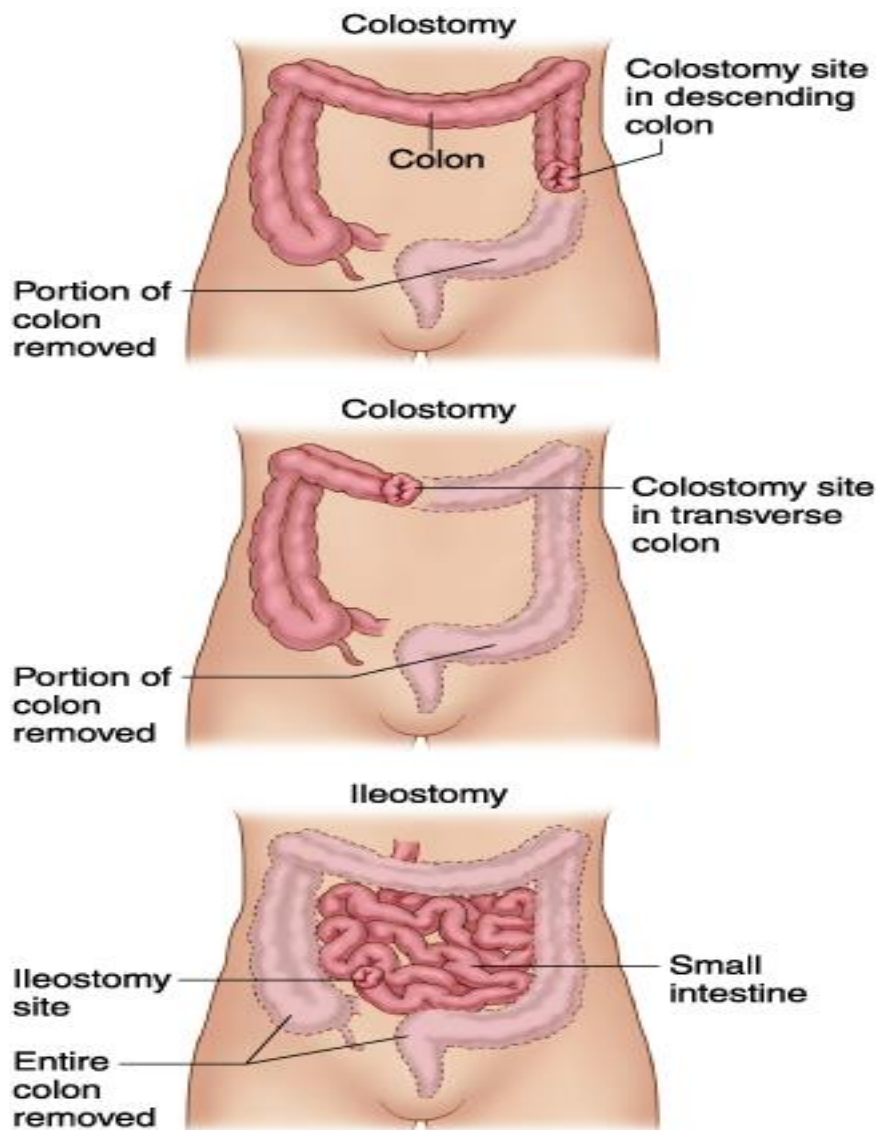
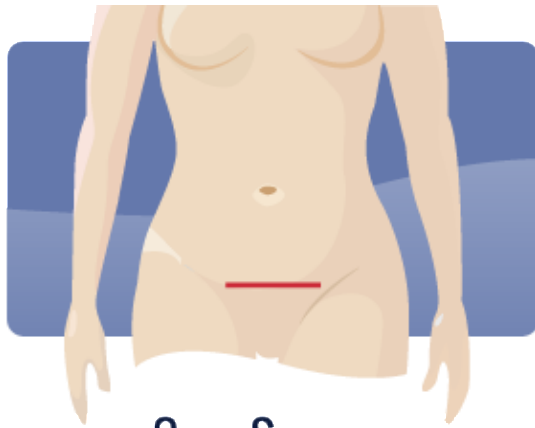
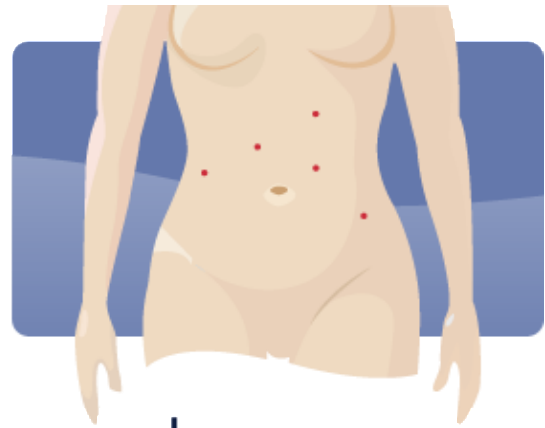


Figure 1.2 Various Surgical Incisions -
<http://laproscopicsurgerynj.com/minimally-invasive-surgery/>



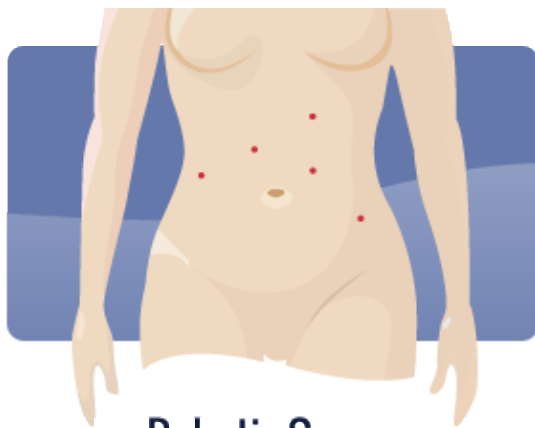
Open Surgery

The surgeon makes a large incision to reach your organs.



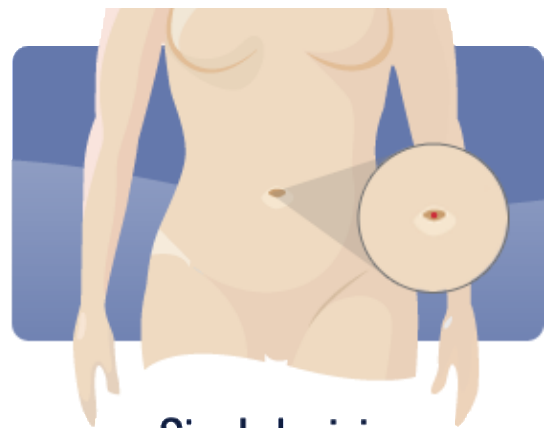
Laparoscopy

Surgery is done through a few small incisions, using long, thin instruments and a tiny camera.



Robotic Surgery

Similar to laparoscopy, but uses a 3D, high-definition vision system, and special instruments for enhanced precision & dexterity.



Single Incision Robotic Surgery

Robotic surgery performed through a single incision point for reduced scarring and faster recovery time.

Table 1.1 Surgical Grades & Examples NICE 2016

Numeric	Grade	Example
I	Minor	Excision of lesion, breast abscess drainage
II	Intermediate	Inguinal hernia repair, knee arthroscopy
III	Major	Abdominal hysterectomy, lumbar discectomy
IV	Major complex	Colon resection, radical neck dissection

1.1.2 Physiological Stress of Surgery

It is widely known that surgery produces significant stress response effects on the body. (Scott & Miller 2015, Finnerty *et al* 2013). The cause of this stress is twofold: initial injury from the incision(s) and mobilisation of tissues and secondly from the inflammatory responses that follow (Scott & Miller 2015). Metabolic rate increases in response to stresses placed on the body in an attempt to restore homeostasis. Initially these changes may be beneficial, however, prolonged changes in inflammatory, metabolic and catabolic responses lead to complications, delayed healing and increased mortality (Finnerty *et al* 2013). Prolonged reactions are also responsible for catabolism of muscle tissue which in turn leads to poorer muscle function and when teamed with poor immunity and delayed wound healing, can lead to detrimental complications. The ability of the gut to absorb nutrients may also be affected during a time when optimal nutrition is imperative to respond to the body's hypermetabolic and hyper catabolic state (Finnerty *et al* 2013).

Sharma *et al* 1996 identified the responses that occur to the body in response to the creation of a pneumoperitoneum¹, in order to visualise the abdomen in laparoscopic surgery. As a result of increased intra-abdominal pressure, there are significant increases in heart rate, systemic blood pressure, mean arterial pressure, venous return and systemic vascular resistance. Stroke volume decreases and cardiac output is maintained via tachycardia, thus significantly impacting on the body, particularly in patients who are cardiac compromised. These responses are also seen during exercise and so patients who are accustomed to these changes regularly, may have more reserve to cope with the stresses of surgery (Plowman & Smith 2013). The respiratory system can also be compromised due to the effects of ventilation and anaesthesia. This can lead to immediate postoperative complications such as hypoventilation, upper airway obstruction and hypoxaemia (Karcz & Papadacos 2013).

The European Society of Cardiology (Poldermans *et al* 2009) recommends preoperative assessment for patients undergoing laparoscopic surgery as the “procedures demonstrate a cardiac stress similar to open procedures and it is recommended that patients should be screened accordingly” despite the fact that laparoscopic surgeries tend to yield less complications and less of a stress response (Desborough 2000). It appears to be reasonable that a person’s preoperative physical function and fitness should be sufficient in order to withstand the stress placed on their body during surgery and to enable quicker return to normal function.

¹ Pneumoperitoneum: gas or air in the peritoneal cavity

1.2 Literature Review

1.2.1 Literature Review Aims

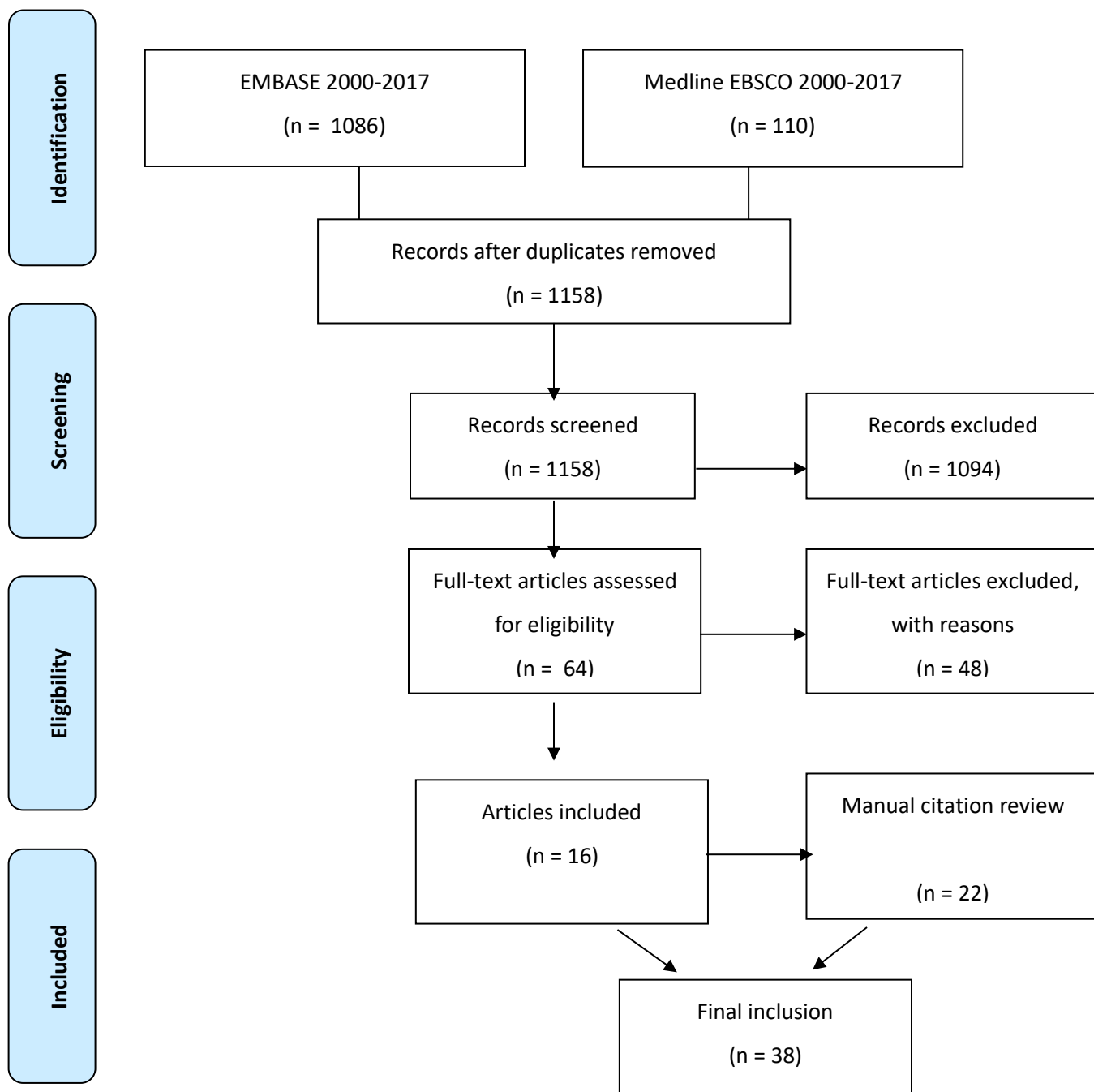
This literature review aims to:

- Identify the postoperative complications related to abdominal surgeries.
- Analyse the costs to the patients and health systems.
- Identify the risk factors associated with the development of postoperative complications.
- Investigate the evidence surrounding physical function assessments methods used to predict complications.
- Examine current guidance in preoperative assessment.

1.2.2 Literature Search Methods

A systematic search was conducted using the EMBASE and Medline EBSCO search engines in March 2016 and July 2017. Terms that were used were related to functional and physical activity screening, complications, abdominal surgeries and recovery. See Appendix I for full search terms used. The search criteria was English articles, including only humans and between the years 2000-2017. Literature was searched from the year 2000 onwards to reflect more recent laparoscopic surgical trends. A total of 1196 articles were yielded. After title and abstract screening, 64 were included and upon further full article reading 16 of these were suitable for inclusion. Inclusion criteria was terms related to the following: abdominal surgery, risk factors, complications, morbidity, physical fitness and recovery. Manual review of individual reference lists of studies yielded a further 22 relevant articles for inclusion. International guidance documents were also searched and included (n = 6). See Figure 1.3. Please see Appendix II for summary table of included articles.

Figure 1.3 Literature Search Prisma



1.2.3 Complications

Complications after abdominal surgery are defined as “any deviation from the normal post-operative course” (Dindo *et al* 2004).

1.2.3.1 Rates of complications

Rates of overall morbidity post colorectal surgery range from 11-69% (mean 33%), as identified in a systematic review by Schiphorst *et al* 2015 analysing data from 18 studies, including 6153 patients. The variability is largely due to many of the studies not using pre-defined determinants of postoperative surgical and nonsurgical morbidity. Pulmonary complications were reported between 0-11% of cases of the 6152 patients. Cardiac complications were identified as ranging from 0-7% in the analysis of 10 studies (n=3773) but have been reported as up to 28% in general abdominal surgery patients and vary according to co-morbidities (Atalay *et al* 2011, Wiklund *et al* 2001). The variability in reporting classification of postoperative complications throughout the evidence will be further discussed.

1.2.3.2 Types of complications

Complications can be broadly categorised into surgical and medical. Surgical complications that have been identified post abdominal surgery include wound inflammation, wound discharge, ileus, incisional hernia, necrotising intestine, intra-abdominal abscess, bleeding and anastomotic leakage (Kirchoff *et al* 2010, McGillicuddy *et al* 2009, Wolters *et al* 1996, Bosma *et al* 2016).

Medical complications can include pulmonary, cardiovascular and other systems. Pulmonary complications that have been identified include atelectasis, pulmonary infection, pneumonia, respiratory failure, refractory hypoxaemia and pleural effusion (McGillicuddy *et al* 2009, Wolters *et al* 1996, Atalay *et al* 2011, Artinyan *et al* 2008, Longo *et al* 2000, Schiphorst *et al* 2015). Cardiovascular complications include myocardial ischaemia, cardiac arrest, deep venous thrombosis, pulmonary thrombosis, arrhythmias, supraventricular tachycardia, cerebrovascular accident (CVA) and congestive heart failure (McGillicuddy *et al*

2009, Wolters *et al* 1996, Atalay *et al* 2011, Schiphorst *et al* 2015). Other reported complications include urinary tract infections, renal failure/insufficiency, sepsis, gastroenteritis and delirium have also been documented as complications (Wolters *et al* 1996, McGillicuddy *et al* 2009, Artinyan *et al* 2008, Longo *et al* 2000, Bosma *et al* 2016). The diversity of complications on the various bodily systems that can occur post abdominal surgery is evident.

1.2.3.3 Classification of Complications

A limitation of the literature is the non-uniform classification of complications. The most commonly used surgical complication classification tool is the Clavien-Dindo classification. Dindo *et al* 2004 introduced an updated classification tool based on the previous tool developed by Clavien *et al* 1992 in order to address this problem. Previously, complications were named, however this scoring tool grades complications according to what management they require. This allowed for a more robust way of capturing data which has been found to be a reliable and comprehensive tool (Dindo *et al* 2004). Complications range from grade I – V and vary from small deviations in the postoperative course such as localised surface wound infection to patient death. See Table 1.2.

Lesser known classification tools include the Comprehensive Classification Index (CCI) or Complications Index Tool and the postoperative morbidity survey (POMS). The CCI is relatively new and uses the Clavien-Dindo classification but also takes the number of complications into account and scores them between 0-100. This was developed due to a limitation of the Clavien-Dindo classification as it only takes into account the worst complication and does not account for any complications deemed as less severe (Slankemanac *et al* 2013). The POMS, an older and not widely used tool, categorises morbidity in terms of the following: pulmonary, infections, renal, cardiovascular, GI, neurological, haematological, wound and pain (Grocott *et al* 2007).

Table 1.2 – Clavien-Dindo Surgical Complications Classification 2004

Grade	Description of Complications
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as anti-emetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic or radiological intervention
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications) * requiring IC/ICU management
Grade IVa	Single organ dysfunction (including dialysis
Grade IVb	Multiorgan dysfunction
Grade V	Death of a patient
*	Brain hemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks. CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.

1.2.4 Costs associated with post-operative complications

Complications are widely accepted to be associated with costs be they life limiting, physical, financial or psychological (Zoucas and Lydrup 2014, Vonlanthen *et al* 2011, Fuller *et al* 2009, Walburn *et al* 2009, Ebrecht *et al* 2004, Herbert *et al* 1993, Kiecolt- Glaser *et al* 2002, Kiecolt- Glaser *et al* 1998, Pinto *et al* 2016 , Bosma *et al* 2016, Lawrence *et al* 2004, Tahiri *et al* 2016 and Tran *et al* 2014) .

1.2.4.1 Mortality

Mortality appears to be as low as 1% in elective colorectal surgeries but has been reported up to 5.8% (Schiphorst *et al* 2015, Tevis & Kennedy 2013). It has been reported to be as high as 15% for emergency colorectal surgeries (McGillicuddy *et al* 2009). Factors associated with an increase mortality risk in elderly patients undergoing emergency colorectal procedures include older age, high estimated blood loss, sepsis at initial presentation, delayed surgery and the development of complications (McGillicuddy *et al* 2009). The link between postoperative complications and mortality in this group and general surgical patients, has been proven to be significant with the relative risk of mortality increasing from 2.1 in the presence of one complication to 7.2 when multiple complications are present (Tevis & Kennedy 2013).

1.2.4.2 Recovery and Functional Ability

The loss of a person's ability to be functionally independent has been linked to depression, poor quality of life (QoL), shorter survival and huge economic impact on all associated with a person's care, particularly in the elderly (>65 years) (Luciani *et al* 2008). More importantly, elderly patients often regard their recovery, after surgery, to their previous baseline functional status as being as important as survival itself (Chee 2010, Fried *et al* 2002). Few studies have analysed the impact that post-operative complications have on a patients recovery in returning to preoperative functional levels.

Lawrence *et al* 2004 studied the return to functional independence in 372 patients over 60 years who underwent major abdominal surgery. They used a multi-

factorial assessment approach using self-reported and performance based tools. At six months post-surgery, they found the following percentages of study participants had not returned to baseline: Activities of Daily Living (ADL's), 9%, Instrumental Activities of Daily Living (IADL) 19%, Physical component of the Short Form 36 (SF36) 16%, the mental component scale of the SF36, 17%, timed walk 37%, functional reach, 58%, and grip strength , 52%. These results are limited in that they do not account for complications and so cannot be assumed to be directly related to the presence of complications. Nevertheless, the results show a large percentage who failed to reach full recovery by 6 months, in many domains of functional ability, many of which can be addressed with appropriate interventions such as exercise or individualised rehabilitation.

Tahiri *et al* 2016 assessed the impact of post-operative complications on the recovery of 149 elderly patients (>70 years) who underwent elective abdominal surgery in a Canadian hospital. Surgeries included colorectal, hernia repairs, hepatobiliary, gastric and splenectomy surgeries. A complication rate of 34.9% and a mortality rate of 2.68% was reported in this study. Assessment was once again multi-factorial in relation to functional ability, co-morbidities and frailty. Functional ability was measured using the short physical performance battery (SPBB) which assesses standing balance, gait speed and ability to rise from a chair. Complications were reported using the Complications Index Tool. The SPBB was repeated at 1 week, and at 1,3 and 6 months postoperatively. Results are shown in Table 1.3. It was shown that the more severe the complication, the longer the recovery. Results indicated that even at 6 months, only 58.3% returned to baseline function, concluding that the number and severity of complications impact negatively on recovery. This study also highlighted a significant number of patients with an uncomplicated post-operative course who did not fully return to their baseline function. This mirrors the Lawrence *et al*/2004 study findings that a large proportion of patients do not return to baseline function by six months, as both populations were of similar age and underwent similar surgeries. The authors hypothesised that those without complications had higher baseline SPBB and therefore possibly found it harder to achieve their baseline SPPB scores postoperatively versus those who were less active or had lower SPBB scores to

begin. This theory does not explain why those who had a better baseline and an uncomplicated post-operative period should experience delayed recovery even at 6 months.

Table 1.3 Percentage of patients returning to baseline function following abdominal surgery – adapted from Tahiri et al 2016

Recovery time line	1 Week	1 Month	3 Months	6 Months
No complications	30.4%	58.3%	69%	73.7%
Complications	10.9%	34.2%	53.7%	58.3%

Tran *et al* 2014 reviewed functional recovery outcomes in 137 abdominal surgery patients who were discharged on the day of surgery. Seventeen various surgeries were performed and the most prevalent included open inguinal herniorrhaphy (40%) and laparoscopic cholecystectomy (28%). Eleven percent reported complications categorised as per the Clavien-Dindo classification. They found that 33% (n = 44) of participants, at 2 months, had not returned to their preoperative functional activity levels. On the contrary, there were a significant number (n = 88) who were better than baseline at 2 months postoperatively (P <0.01). The most significant determinants of recovery at 3 weeks were presence of a complication, older age, low baseline health related quality of life or greater baseline energy expenditure as measured by the community health activities model programme for seniors (CHAMPS). The CHAMPS is a questionnaire relating to physical activities which are converted to metabolic equivalents (MET's) from which total weekly energy expenditure is calculated. At 2 months post-surgery, only baseline energy expenditure was significant in relating recovery to baseline measures. The authors reported that those with higher baseline CHAMPS scores were less likely to have recovered to these levels at 2 months. This may support the previous study's theory regarding those having higher functional baselines taking longer to recover to these levels. The mean

age however was 53 with a range from 18-84 and so the CHAMPS may not be suitable for all participants as it is aimed at senior citizens and so may not account for those with higher baseline status.

A similar study by Onerup *et al* 2015 analysed how preoperative physical activity levels were associated with recovery after elective cholecystectomy, which would be regarded as a non-complex surgery (n=150). Physical activity was measured using a self-reported questionnaire, The Saltin-Grimby Physical Activity Scale. Objective measures showed that those who were more physically active prior to the operation were more likely to be discharged after one day and back to work within three days. This may be in contrast to the previous two studies findings, however they did not analyse return to work. Participants were also asked to rate how physically recovered they felt given the options of 0%, up to 25%, up to 50%, up to 75% and fully recovered. They found no significant relationship between baseline activity and postoperative subjective physical recovery. However they did find that those who underwent laparoscopic surgery versus open had a 2.7 times higher chance of feeling recovered ($P = .01$) with 77% feeling highly physically recovered after three weeks. The mean age of participants was 51.9 years and so may reflect a younger population than the previously mentioned studies. Another factor may be the minimally invasive, low complexity of the surgery in comparison to the previous studies. There is a lack of high quality evidence in relation to self-recovery reports in patients undergoing abdominal surgery but this shows some promise in using even simple tools.

Van. Cleave *et al* 2011 studied the factors that influenced recovery in 316 patients over the age of 65 who underwent surgery for various cancers including colorectal. The findings are similar to the work of Tran *et al* 2014 as they found that those with an uncomplicated postoperative course had better than baseline functional ability at 6 months. Conversely, those who had complications were more likely to have three or more co-morbidities. Co-morbidities will be discussed further. Poorer functional recovery was also associated with those who reported three or more symptoms on the Symptom Distress Scale (SDS) which assesses frequency of nausea, severity of nausea, appetite, insomnia, frequency of pain,

severity of pain, bowel pattern, concentration, appearance, breathing, outlook and cough. A limitation of this study was that it was retrospectively conducted using data from previous studies and had a variety of cancer types where recovery and treatment may vary. It does however highlight some possibly modifiable risk factors that may help predict complications and recovery trajectory.

Tevis and Kennedy 2013 reviewed 18 studies relating to how surgical complications impact on patient centred outcomes, in a general surgical population. Surgeries included general abdominal, colectomies, colorectal, abdominopelvic and pancreatectomy. Patient centred outcomes were seen as mortality, morbidity, discharge disposition, QoL and LOS. They highlighted that having one or more complications increased the likelihood of needing care in an institutional care facility (ICF) two fold. Presence of any complication(s) increased mortality rates at thirty days, ninety days and one year post surgery. In agreement with Van. Cleave *et al* 2011 mortality levels at all time points were lowest in those who were able to be discharged to their own home independently followed by those who required home assistance upon discharge and the highest rates were seen in those who were discharged to ICF's. These findings may not necessarily be as a result of complications alone and may be associated with poorer initial functional capacity, age and frailty. The review is limited in that few of studies included used a standardised complication classification system and arbitrary grading from minor to severe was used, thus complication rates may have been under or over estimated.

It is evident from the literature that recovery to baseline functional ability appears to be influenced by the complexity of the surgery, severity of the complications, baseline physical activity levels and co-morbidities (Tahiri *et al* 2016, Tran *et al* 2014, Van. Cleave *et al* 2011, Onerup *et al* 2015) . There is conflicting evidence that some patients recover to better than baseline functional activity levels whilst some, even without complication, appear not to return to baseline functional activity (Van. Cleave *et al* 2011, Tran *et al* 2014, Onerup *et al* 2015, Tahiri *et al*

2016, Lawrence *et al* 2004). It raises the question of why do some people physically recover very well and why some don't seem to.

1.2.4.3 Financial

Zoucas and Lydrup 2014 performed a retrospective study to determine the costs of elective colorectal surgical morbidity in a hospital in Sweden. They found in a group of 530 patients that 35% of them developed complications but only 14% of them required intervention. The highest costs were associated with complications graded as >II as per the previously mentioned Clavien-Dindo classification. Table 1.2. These complications were associated with a 78% increase in length of stay (LOS), thus increasing financial costs. Patients who had a normal post-operative course, average LOS was 9 days and mean(SD) costs were €12,410 ± 384. Their study showed a significant rise in costs when patients develop complications costing a mean(SD) of €25,680 ± 2289 when any complication was present to the most expensive being suture/staple line dehiscence costing a mean(SD) of €47,306 ± 17194). This is particularly important when SSI's are largely preventable (Odom-Forren 2006). A potential limitation is that costs may have been under or over estimated as costs were estimated based on LOS, time under anaesthesia and time spent in postoperative care unit or the intensive care unit. These parameters however did incorporate the costs of salaries, medical supplies and medications which would improve the accuracy of costs.

Vonlanthen *et al* 2011 performed a cost analysis of complications associated with major surgical procedures in the Switzerland and reported their health care costs as being comparable to the United States of America (USA). On a cohort of 1200 patients, 389 of these had abdominal surgery in the form of colon resections, with a mean LOS of 11 days. Morbidity levels were higher than previously mentioned studies at 54.8%, compared with Schiphorst *et al* 2015 (mean 33%) and Zoucas and Lydrup 2014 (35%). Of those who developed complications, 28.3% of these had more than one complication. Vonlanthen *et al* 2011 measured morbidity using the Clavien-Dindo classification and reported a proportional relationship with increasing severity of complications and total hospital costs, which is comparable to the previous study. Those without complications had an mean(SD) cost of \$26,420 ± 21.913 and costs increased exponentially when complications

were apparent: Grade I (\$29,166 ± 19,106), Grade II (\$43,370 ± 29,399), Grade IIIa (\$59,822 ± 37,330) and Grade IIIb (\$95,550 ± 70,362). They also determined the cost of some organ specific complications e.g. cardiopulmonary, as per the grade that they were i.e. Grade I \$33,046, Grade II \$ 36,107, Grade III \$44,049, Grade IV/IVb \$138,971 and Grade V \$87,039. Grade V costs were likely lower as this grade correlates with patient death. The financial analysis methods used in this study were more robust than Zoucas and Lydrup 2014 as costs were directly attributed to each individual case, giving more reporting accuracy.

Fuller *et al* 2009, USA, investigated the costs of 64 potentially preventable hospital acquired complications and were able to report costs for specific complications. Although the data was from a variety of surgeries, not exclusively abdominal, the information is still useful as they calculated the costs of the complications on top of standard care costs depending on their reason for admission. They extrapolated data from claims made at 278 hospitals in Maryland and California and found similar costs. Post-operative respiratory failure was the most expensive at \$118,841 and obstetric haemorrhage with transfusion the least expensive at \$3,081. See Table 1.4 for some of the complications associated with abdominal surgery.

Table 1.4 - Ranking of Potentially Preventable Complication's – adapted from Fuller et al 2009

Rank	Description	Cost \$
1	Post-operative respiratory failure with tracheostomy	118, 841
2	Renal failure with dialysis	47,888
3	Post-operative wound infection & deep wound disruption with procedure	27,814
4	Acute pulmonary oedema and respiratory failure with ventilation	27,134
5	Gastrointestinal ostomy complications	25,882
6	Septicaemia and severe infection	23,451

7	Re-opening surgical site	19,442
8	Pneumonia and other lung infections	16,901
9	Pulmonary embolism	16,331
10	Moderate infection	16,063
11	Venous thrombosis	15,976
12	Ventricular fibrillation/ Cardiac arrest	15,241
13	Post-operative infection and deep wound disruption without procedure	14,347
14	Stroke and intracranial haemorrhage	14,013
15	Other pulmonary complications	11,566
16	Renal failure without dialysis	9,934
17	Urinary tract infection	9,637
18	Acute myocardial infarction	8,147
19	Acute pulmonary oedema and respiratory failure without ventilation	7,109
20	Congestive heart failure	5,801
21	Other cardiac complications	4,642
22	Cardiac arrhythmias and conduction disturbances	4,431
23	Obstetric haemorrhage with transfusion	3,081

This information may be very helpful for hospitals in budget planning once they can classify their average complication rates and highlight the substantial cost increases associated with complications. It is difficult to deduce if the costs that have been reported are useful or comparable locally due to a lack of available data in Ireland and the United Kingdom, but a common trend shows that the financial costs increase significantly with rate and severity of complications (Fuller *et al* 2009, Zoucas & Lydrup 2014, Vonlanthen *et al* 2011).

1.2.4.4 Psychosocial, Anxiety and Depression

Evidence analysing the impact of complications on psychological factors including anxiety and depression is quite sparse. This is despite the fact that

distress caused by surgical complications can delay wound healing and reduce immunity (Walburn *et al* 2009, Ebrecht *et al* 2004, Herbert *et al* 1993, Kiecolt-Glaser *et al* 2002, Kiecolt- Glaser *et al* 1998).

Bosma *et al* 2016 investigated the impact of colorectal surgery on health status, anxiety and depressive symptoms, regardless of complications. The study was prospective and conducted in the Netherlands on 218 patients. Patients were asked to fill in 3 different questionnaires relating to depression, anxiety and health status preoperatively and at 3 time points post-operatively – 3 days, 6 weeks and 1 year. Similarly to Vonlanthen *et al* 2011, they reported a complication rate of 59.6%. They found that levels of anxiety and depressive symptoms in all patients who underwent colorectal surgery increased post-operatively but tended to return to normal levels at 6 weeks post-surgery, regardless of the presence of complications or not. However, they did find that those who had complications greater than grade III on the Clavien-Dindo classification had poorer overall health status. Of note, the domains that they suffered most were in limitations in physical activities, social activities, general mental health, vitality and general health perception. They also found that these had usually returned to normal by one year post complication.

Pinto *et al* 2016 conducted a systematic review and meta-analysis analysing the effect of surgical complications on psychosocial well-being. The 51 studies used included cardiothoracic (n=17), vascular (n=4) and GI (n=29) surgeries. The authors reported that those who had complications had significantly worse psychosocial outcomes over their counterparts who had none and that these effects can last up to and beyond one year post complication. QoL appears to suffer also for a lengthy period. These results found that the negative impact of the complications on the patients was not influenced by either the complexity of the surgery or the severity of the complications encountered. This is useful to note as there may be an assumption that the more severe the complication or surgery, the more of a negative impact it would have on the patient, but this appears not to be true in all cases. This also contradicts the findings of Bosma *et al* 2016, but can possibly be explained by the fact that only colorectal surgeries

were analysed whereas the GI surgeries in this study varied from surgeries on the stomach, the bowel, rectum and gallbladder or indeed the variety of QoL assessment tools used. The authors also highlighted that more attention may be needed to patients psychological needs in the early postoperative phase to ensure no psychological adverse outcomes in the long term. A strength of the review is that only studies were included that used patient self-reported measures.

These studies highlight a need for high quality studies investigating the effectiveness of post-operative psychological care in the short and long term. It has clear implications for patient's welfare up to and beyond a year post-operatively and could impact on other areas of their health with altered health perception (Pinto *et al* 2016, Bosma *et al* 2016).

1.2.5 Risk Factors Associated with the Development of Postoperative Complications

Physical parameters will be discussed in terms of physical activity, sedentary behaviour, strength and frailty to investigate its relationship with postoperative morbidity.

1.2.5.1 Physical Function and Activity

The World Health Organisation (WHO) has recognized physical inactivity as one of the biggest risk factors for premature mortality and morbidity, regardless of co-morbidities (WHO 2011). However, the influence of physical activity on outcome has not been effectively studied given the significant physiological stress of surgery and recovery on the body (Desborough 2000).

Wiklund *et al* 2001 investigated 5939 patients who underwent non cardiac surgeries in the USA to assess if preoperative activity levels were predictive of cardiac complications. Surgeries were varied and included abdominal, hepatic, neck, orthopaedic and pulmonary procedures. Metabolic equivalent (METS) were calculated by the assessors based on a description of the patient's ADL's using

the Duke Activity Status which was a limitation of the study with a high chance of bias introduced. Ninety-four participants (1.6%) suffered cardiac complications and 6 of those died as a direct result of the complications. Complications were determined retrospectively by analysing the hospital's medical records and codes relating to cardiac issues. These were then reviewed by an assessor to determine if the patients had new or old cardiac coding attached to their records. No formal complication classification system was used and no details were included as to inclusion/exclusion criteria of complications which is another potential limitation of this study. They found that baseline MET level did not predict cardiac complications ($P = 0.793$), however, the accuracy of how these were calculated has been called into question. There was a trend that < 4 MET's at baseline, coupled with an American Society of Anaesthesiologists (ASA) score of 3 or more influenced likelihood of cardiac complication. See Table 1.5 for ASA categories. The descriptors used of METS <4 included : self-care of oneself, eat, dress, use a toilet, walk indoors around the house and walk 1-2 blocks on the level at 2-3mph. However, they found a significant relationship between cardiac complications, age and ASA physical status ($P <0.001$). Whilst the study had large numbers and found some significant results, it would be more worthwhile had they used more robust measures of physical activity as this limits the study in some respects.

Feeney *et al* 2011 studied the correlation between pre-esophagectomy patients activity levels and postoperative pulmonary complication's (PPC's). Activity levels measured were more accurate than the previous study as physical activity was measured objectively using a triaxial accelerometer for at least 4 days. Feeney *et al* 2011 found activity levels to be low with participants spending 78.75% of a typical day inactive and 18.75% of the day in light activity. In relation to complications, there was a significant difference between the PPC and non PPC groups as they tended to be less active whereas those who did not develop complications, spent more time in moderate intensity activities ($P <0.01$). Despite low numbers ($n=37$), it appeared that physical activity levels proved to have a stronger relationship with PPC's ($p = .03$) than spirometry or body composition.

Dronkers *et al* 2013 found preoperative physical activity and function to be statistically significant in predicting recovery through the use of physical tests and self-reported activity scores. Participants (n=169) were scheduled for major oncological abdominal surgery. Activity levels were measured using a subjective tool, the LASA physical activity questionnaire (LAPAQ) and physically measured using the Timed Up and Go Test (TUG). The LAPAQ was found to be the most robust in predicting outcomes of recovery. A potential limitation of the study is that recovery was determined as being discharged home as it suggests that they are physically well enough to do so, but potentially differing levels of support mean this measure of recovery may be flawed. The study may have been strengthened had a measure of physical recovery been used. Other assessment methods used by this study will be further discussed in section 1.2.7.5 and 1.2.7.6.

Dependency in relation to functional health status, as determined by ability to perform basic ADL's, has been proven to have a linear relationship with risk of development of surgical infection, pulmonary, cardiovascular, neurological and renal complications ($p < 0.05$) (Isik 2014). These results were from a robust retrospective study of 25,591 colorectal cancer surgery patients whereby their functional status was ranked as either independent, partially dependent or totally dependent based on their ability to perform basic ADL's. Basic ADL's included bathing, dressing, toileting, feeding and mobility and are relatively simple to question patients on their ability to perform. The assessors determined participants' ability when self-assessed on whether they could perform the tasks independently, with some assistance or requiring total assistance regardless of aids or prostheses. The authors suggested that using this tool would lead to more realistic outcomes during the postoperative period.

It appears from the studies mentioned that physical activity and physical function play a role in determining patients chances of developing complications and indeed their recovery and discharge destinations (Wiklund *et al* 2001, Feeney *et al* 2011, Dronkers *et al* 2013, Isik 2014). However, more studies need to be conducted using a multifactorial approach to measuring physical activity and functional status to determine what the most suitable measure may be.

1.2.5.2 Sedentary Behaviour

To the best of the authors knowledge, no studies have specifically examined the relationship between preoperative sedentary behaviour or inactivity and if it presents an increased risk of complication development post abdominal surgery. Feeney *et al* 2011, in esophagectomy patients, as previously mentioned, did find a significant difference between PPC and non PPC groups in relation to their inactivity levels ($P < 0.05$).

1.2.5.3 Muscular Strength and Endurance

Muscular strength has been shown to have a strong association with all-cause mortality regardless of physical activity, muscle mass or fitness levels (Volaklis *et al* 2015, Newman *et al* 2006). Simple, quick measures such as hand dynamometry have been proven to be reliable as a measure of overall physical strength and as a predictor of mortality. It has also been shown to be useful in predicting post-operative complications (Volaklis 2015, Newman *et al* 2006).

Newman *et al* (2006) studied 2292 healthy adults between 70-79 years in the USA to determine if strength and/or muscle mass were predictive of mortality. To assess strength, knee extension was measured using an isokinetic dynamometer and hand grip strength measured using a isometric dynamometer. CT scans were used to determine muscle mass. Participants were contacted every six months for six years to determine mortality rates. Results showed a strong relationship between quadriceps and hand grip strength and mortality, whereas muscle mass did not. This study used a more objective measure of strength and was conducted on healthy adults so it is unclear if this data relates to a surgical population also.

Volaklis *et al* 2015 in a narrative review of 23 studies investigating the presence of an association between mortality risk and strength in healthy and non-healthy individuals. They found that mortality risk increased as strength levels decreased when all-cause mortality was examined. This was also the case for people >85 years and those with cancer. No studies examined the relationship in surgical

patients but did conclude that higher muscular strength is protective of mortality in people with cardiovascular disease (CVD), renal failure, cancer, peripheral arterial disease (PAD) and chronic obstructive pulmonary disease (COPD). This study is in agreement with the findings Newman *et al* 2006 suggesting that muscular strength play an important role in its relationship with mortality. More studies are required examining its relationship with morbidity and the most appropriate assessment tools to do so.

1.2.5.4 Frailty

Frailty has been shown to be a risk factor, however the definition of frailty is varied amongst the literature (Trevis and Kennedy 2013). Nevertheless, in colorectal and cardiac surgeries, frailty has been identified as a risk factor for post-operative complications, independent of age, which leads to increased length of stay and re-admission rates (Robinson *et al* 2013). In review by Partridge *et al* 2012, they highlighted that frailty has been reported as high as 41.8-50.3% in an older population requiring elective surgery of any type. This suggests that a large cohort of those who require surgery will inevitably be frail and therefore at a higher risk. The various definitions and assessment tools used to measure frailty make it difficult to reach consensus on what types of patients are deemed frail.

An older study from 1980, measured frailty using a hand dynamometer and found that those deemed as frail had a higher risk of developing complications and an increased length of stay (Klidjian *et al* 1980). Mackary *et al* 2010 sub categorised 594 surgical patients, >65 years, frailty levels through assessing their weight loss, grip strength, exhaustion, physical activity levels and walking speed and scoring them from 0-5. Classifications were: 0-1 non frail, 2-3 intermediately frail, 4-5 frail. Patients who were deemed as intermediately frail had an odd ratio (OR) of 2.06 while frail patients had an OR of 2.54 in developing complications. Frailty was shown to be independently associated with complications, LOS and discharge to an assisted care facility. It must also be noted that some of the markers used to determine frailty in this study are potentially reversible and perhaps minimising risk. It appears from the literature that frailty can be

measured and may be useful in preoperative assessment, particularly to take into account physiological versus chronological age.

1.2.6 General Identified Risk Factors

1.2.6.1 Age

There is conflicting evidence regarding age as a risk factor. In studies where age has been shown to be a risk factor, it has also been linked with co-morbidities and physical function and so may not be the only influencing factor Kirchoff *et al* 2010, Dronkers *et al* 2013, Bosma *et al* 2016, Zoucas *et al* 2014, Wiklund *et al* 2001). The idea that physiological age may be of more use than chronological age was suggested by Dronkers *et al* 2013. The author suggested that chronological age is not always an appropriate assessment of a person and that their ability to perform physical tasks or gravity of a disease may be more of a reflection of their physiological age. This theory may be useful in answering why there is conflicting evidence surrounding age as a predictor of complications and future studies may need to assess physical parameters and disease severity also. This highlights the links between physical functional ability and predicting postoperative outcomes.

1.2.6.2 Body Mass Index (BMI) and Nutritional Status

BMI >25 has been shown to be a risk factor in the development of intra-operative complications and has led to a need for the surgeon to convert from a laparoscopic to an open surgical approach (Dostalík *et al* 2005, Pikarsky *et al* 2002, Brooks-Brunn 1997). The main reason for conversion is that the increased intra-abdominal fat distribution hinders the surgeons visibility (Martin and Stochii, 2011). Patients with increased BMI are also more likely to develop surgical site infections (SSI's), ileus and incisional hernias (Pikarsky *et al* 2002). Obese patients tend to have higher complications rates, higher chance of reoperation and therefore length of stay (Pikarsky *et al* 2002, Amri *et al* 2014). Malnutrition and preoperative weight loss of >10% have also been shown to negatively influence outcomes (Kirchhoff *et al* 2010, Zoucas *et al* 2014).

1.2.6.3 Surgeon Experience

Surgeon experience and speciality has been shown to be a risk factor until the surgeon reaches a plateau in his or her learning curve (Kirchoff *et al* 2010). Unfortunately, there is no definite number of surgeries that constitutes mastery in their skill and so outcomes that are used to assess their skill include are length of surgery, conversion rates, complications, length of stay, overall morbidity and mortality (Kirchoff *et al* 2010).

1.2.6.4 Hospital Facilities

Tevis and Kennedy 2013 reported lower mortality rates, following complications, were associated with hospitals who had sufficient nursing staff, more than two hundred beds, high quality technology and were teaching hospitals in general surgical patients. Conversely, they reported on a study that analysed mortality rates in two similar hospitals and found that mortality rates differed between 4.1 – 7.6% and rose to 11.1 - 16.8% when mortality after complications were considered. More research should be conducted to assess if hospital resources play a key role in patient mortality due to surgical complications.

1.2.6.5 Laparoscopic versus Open Surgical Approach

The laparoscopic approach has been proven to be associated with a lesser risk of complications versus an open approach, hence a paradigm shift towards more minimally invasive approaches in recent years. Patients post laparoscopic colectomy have been shown to have better morbidity rates at 30 days than those who had an open approach (Tevis and Kennedy 2013). In elderly patients with colorectal cancer, the laparoscopic approach has proven significant in reducing the risk of cardiac complications versus an open approach and the trend remains the same in relation to pulmonary complications (Sciphorst *et al* 2015). In frail patients, the laparoscopic approach was associated with decreased mortality, complications and LOS (Isik *et al* 2015). In emergency colorectal procedures

where an open approach was necessary, it was associated with development of post-operative pneumonia (McGillicuddy *et al* 2009).

1.2.6.6 ASA Score

This is an internationally used score, by Anaesthetists, describing a patients physical status with grade I being a normal healthy patient and grade VI classifying someone as brain dead. Various factors are taken into consideration when determining the suitable grade such as BMI, smoking status, co-morbidities and the acuity of a patient's main complaint at the time. It is used for all patients undergoing anaesthesia. Those who are classified as grade III or IV preoperatively have a higher risk of complication development both intra and postoperatively (Wolters *et al* 1996). This is supported by the work of Bowles *et al*, 2008 who reported having an ASA score of III and at least two comorbidities were predictive of grade 3 complications and mortality.

Table 1.5 ASA Score Definitions

Score	Description
I.	Patient is completely fit healthy individual
II.	Patient has mild systemic disease
III.	Patient has severe systemic disease that is not incapacitating
IV.	Patient has an incapacitating disease that is a constant threat to life
V.	A moribund patient that is not expected to live 24 hours with or without surgery
VI.	Patient is brain dead

1.2.6.7 Comorbidities

The presence of co-morbidities increase the risk of developing complications, particularly when coupled with ASA scores ≥ 3 . Presence of comorbidities such as chronic obstructive pulmonary disease (COPD), neurological disorders, diabetes, smoking, hypertension, previous myocardial infarction (MI) and

smoking status have been strongly linked as risk factors in the development of complications (Wolters *et al* 1996, Bosma *et al* 2016, Atalay *et al* 2011, Robinson *et al* 2009).

1.2.6.8 Blood Results

Haematocrit <30%, albumin <3.5g/L, creatinine >1.4mmol/L levels, preoperative anaemia and hyponatraemia have all been linked with risk of complications. In many cases these are potentially reversible (Kirchoff *et al* 2010).

1.2.7 Physical Performance Assessment Review

The following will review some established and emerging evidence that supports the use of various assessments in order to assist with risk stratification and prediction of outcomes.

1.2.7.1 Cardiopulmonary Exercise Testing (CPET)

CPET is regarded as the gold standard in the measurement of aerobic capacity. In the determination of its predictive use for mortality, Lai *et al* 2013 established cut off values of anaerobic threshold (AT) and found that these were highly predictive of mortality post colorectal surgery. They also found that those who were fitter, had a reduced length of stay. CPET has also been found to be useful in predicting morbidity in both colorectal and rectal surgery (West *et al* 2014, West *et al* 2014). Moran *et al* 2016, in a systematic review analysed the role of CPET as a risk assessment method for patients undergoing intra-abdominal surgery, concluded that the evidence to support CPET testing as a predictor was strong but added that cut off values for protective levels of fitness need to be established in this population. This echoed the results of a previous systematic review by Smith *et al* 2009. Predictive cut off values of maximal oxygen uptake (VO_{2max}) have been well established in lung resection surgery (Beckles *et al* 2003) – see Table 1.6. However, in 2016, West *et al*, provided evidence to support the following cut off points in 703 patients post major colorectal surgery: oxygen uptake at estimated lactate threshold as 11.1ml/min/kg (P <0.001) and

peak oxygen uptake (VO_{2Peak}) as 18.2ml/min/kg ($P < 0.001$) indicating their ability to detect patients at risk of colorectal surgical morbidity. A difficulty with CPET is due to the fact that equipment is expensive, not widely available, time consuming, requires a skilled practitioner to perform and evaluate, and is not suitable for patients with disabilities or musculoskeletal impairments.

Table 1.6 VO_{2max} Cut off Values in Complication Prediction in Lung Resection Surgery (Beckles et al 2003)

>20mL.kg.min	No increased risk of death or complications.
<15mL.kg.min	Increased risk of perioperative complications.
<10mL.kg.min	Very high risk of postoperative complications.

1.2.7.2 Six Minute Walk Test (6MWT)

The 6MWT is a widely used measure in research, of a person's ability to walk for six minutes, over and back a thirty metre distance, where breaks are allowed and in doing so measures functional capacity (American Thoracic Society 2002).

In 2016, Moran *et al* published a systematic review concluding that the 6MWT needed further validation in its ability to predict post-operative outcome but highlighted that it has not yet been linked with mortality or LOS predictions. It is important to note that Lee *et al* 2013, found that the distance walked significantly correlated with VO_{2peak} and complications. Both of these were found to be associated with post-operative medical morbidity only versus surgical morbidity. Paisani *et al* 2012 found that 6MWT results were not predictive of pulmonary complications in upper abdominal surgery. The study was limited in that they did not collect data on any other complications that may have occurred, only used upper abdominal surgery patients and no laparoscopic patients were included. Conversely, Awdah *et al* 2015 found that a result of <300 metres was associated with higher rates of complications and an increased LOS. This study however included major upper abdominal patients as well as patients who underwent

surgeries requiring thoracotomy and sternotomy. Similarly, Keeratichananont *et al* 2016, reported that a cut off of <325m was predictive of PPC's showing 100% specificity and 77% sensitivity. However, the study was mixed and included abdominal and thoracic surgery. Moriello *et al* 2008 did show that 6MWT was a valid marker of recovery in patients post elective colon resection. This was supported by the work of Pecorelli *et al* 2015 who proved its construct validity as a predictor of recovery post colorectal surgery. Results are poor due to limited studies and its predictive measure should be evaluated in predicting complications, morbidity and LOS in all abdominal surgeries. It remains useful in research however as it is self-regulated meaning that most patient types, provided they can walk, can perform the test, regardless of aerobic capacity. It is also reflective of an everyday task, for the majority of people (Shi *et al* 2016).

1.2.7.3 Incremental Shuttle Walking Test (ISWT)

The ISWT is an incremental and externally paced walking test where patients either self-cease the test due to symptoms or fail to reach a set distance within a certain time frame (Singh *et al* 1992). The ISWT has been used by Nutt and Russell 2012 to predict morbidity and mortality after elective major colorectal surgery. The authors found that there was significant differences in the distances achieved by those who did have complications (276.6m) versus those who did not (138.9m). They also found that a distance of 250 metres had good specificity to predict post-operative morbidity. This test may be useful in risk prediction in some populations but may not be as suitable for more frail patients who may tolerate an endurance type test more than an incremental one as the test may need to be ceased much sooner.

1.2.7.4 Stair Climbing

Few studies have investigated the link between stair climbing and prediction of morbidity and mortality. Girish *et al* 2001 found that the inability to climb two flights of stairs (36 steps) was highly predictive, 82%, of post-operative complications in patients who underwent cardiothoracic and abdominal surgery. Reddy *et al* 2015 tasked abdominal surgery patients with going up and down seven steps and

found average times taken as related to complications. Significant findings were that those who had no complications took an average of fifteen seconds where those who did took 22.9 seconds to complete the task. Both studies showed a trend towards decreased LOS associated with better stair climbing ability and vice versa. These studies suggest that both timed and symptom led stair climbing can help predict outcomes. A potential limitation of this type of test is that some patients may not have the physical ability to perform the test due to musculoskeletal disease or injury.

1.2.7.5 Thirty Second Sit to Stand Test

This test assesses the number of times a person can go from sitting to a full stand without using their hands. It has yet to be used as a predictor of outcome in abdominal surgery patients. However, when tested on community dwelling older adults, >60 years, it was shown to be a reliable and valid predictor of lower body strength (Jones *et al* 1999). This may be a quick and useful test in a preoperative assessment setting and needs further investigation.

Dronkers *et al* 2013, in an abdominal surgical population, used a similar test, the ten times sit to stand (STS) test as a quick and simple measure of determining leg power and endurance. Their results showed a trend toward > 27 seconds as being predictive of mortality, >26seconds being predictive of discharge destination and 25 seconds as predictive of average length of stay. Unfortunately these trends did not prove to be significant which may be due to a possible ceiling effect but do however give an indication of physical function when included in a multi-factorial assessment. It may be useful in research as it mimics a simple everyday task for the majority mobile people and is easily converted into an endurance type measure of lower limb strength.

1.2.7.6 Hand Dynamometry

Dronkers *et al* 2013, in an abdominal surgical population, found that grip strength using a dynamometer is significantly correlated with discharge destination and mortality (P = 0.05). In a systematic review by Sultan *et al* 2012, investigating

preoperative muscle strength on postoperative outcomes, they found the following: association between poor preoperative strength and increased morbidity, mortality and LOS as measured by hand dynamometry. The authors stressed that more research is needed in the area but reported it as a useful, quick and easy bedside measure of strength, which may reflect the patient's overall body strength.

1.2.7.7 Pulmonary Function Tests (PFT's)

A key determinant of good lung function in the postoperative period is a patient's forced vital capacity (FVC) as this allows them to generate enough volume to cough effectively (Smith *et al* 2000). There is inconclusive data in relation to the predictive value of PFT's in relation to postoperative morbidity. Kanat *et al* 2007 used PFT's in determining risk factors for the development of PPC's in patients who underwent upper abdominal surgery. Their findings highlighted significant differences in forced expiratory volume in one second over FVC (FEV_1/FVC) when the groups with and without complications were compared. This may be useful as PPC's occurred in 10 (45.5%) of 22 patients with normal PFTs and 25 (68.8%) of 38 patients with abnormal preoperative PFT's. Girish *et al* 2001 found that patients who developed PPC's post abdominal surgery had a mean FEV_1 of 1.6L whereas those that didn't develop PPC's had a mean FEV_1 in 2.35L. Older studies have used percentage of predicted score and found an FEV_1 of < 70% predicted and an FVC of <70% as indicative of increased risk in developing PPC's (Barisone *et al* 1997, Gass & Olsen, 1986). On the contrary, Silva *et al* 2010, reported no significant differences in pulmonary function and the development of PPC's in 521 surgical patients.

1.2.7.8 Peak Cough Flow (PCF)

Cough strength along with their FVC are considered important in relating to a patient's ability to clear secretions post-operatively to reduce the risk of pulmonary complications (Smith *et al* 2000). Colucci *et al* 2015 provided the first into the ability of PCF to predict pulmonary complications in 101 patients who underwent open upper abdominal surgery. They found a significant relationship in PCF

reduction compared to preoperative measures on days one (54%) three and five (72%) post-operatively. This was also strongly correlated with FVC on each day but not with pain scores. Limitations of this study however were that the information cannot be extrapolated for use in patients who under-go lower abdominal or laparoscopic surgeries. They also had a very low rate of pulmonary complications at 6%. Assessment of PCF may be useful in other surgical populations.

1.2.7.9 Self-Reported Activity

The author found no direct studies investigating self-reported physical inactivity as a predictor of post abdominal surgery outcome. As previously mentioned, the LAPAQ was used by Dronkers *et al* 2013 and proved to be a robust predictor of recovery in patients post major abdominal surgery. Onerup *et al* 2015 used the Saltin Grimsby physical activity questionnaires and found good correlation between self-reported activity, complications and recovery. In a multi-factorial assessment of physical function, self-reports may be useful in the determination of risk.

1.2.7.10 Objective Activity Measures

Accelerometry has been used in an abdominal surgical population to measure both preoperative and postoperative activity levels (Feeney *et al* 2011, Inoue *et al* 2003). It has the ability to measure tri-planar motion and so can determine activity levels, but not all devices can measure intensity as heart rate monitoring would be required. It would be of further interest had both the studies also used a self-reported activity tool in comparing subjective versus objective data. Accelerometry appears accurate but requires the patient to wear the device for at least 4 days and so compliance may be a potential issue.

1.2.8 Current Guidance in Preoperative assessment

Preoperative assessment of patients by anaesthetists is a key component of the Helsinki Declaration on Improving Patient Safety (Mellin-Olsen *et al* 2010).

Preoperative assessment, to assess risk, is now well established globally under the guidance of international documents such as those developed by the National Institute of Clinical Excellence (NICE, 2016) and the ESC. The Health Service Executive (HSE) in Ireland produced guidance in relation to a model of care for pre-admission units (HSE National Clinical Programme for Anaesthesia). It includes the main goals of the units as identified by Hepner (2009).

These are:

- Evaluation of patient readiness for anaesthesia and surgery
- Optimise patient health before surgery
- Enhance quality of peri-operative care
- Reduce the morbidity of surgery and length of stay
- Return to normal functioning

Patients are assessed for fitness for surgery based on their demographics, past medical/ surgical history which is used to determine their ASA score, graded from I – V. This ranges from a healthy person to someone who is moribund. It is used globally and was found to be able to predict postoperative outcome accurately (Wolters *et al* 1996).

Guidance from NICE and the ESC recommend various preoperative tests, based on ASA severity, surgical grade/complexity and types of comorbidities (NICE 2003, ECS 2009). These may include chest x-ray, electrocardiogram (ECG), haemostasis, renal function, blood glucose, pregnancy, arterial blood gases (ABG's), sickle cell disease trait, cardiac evaluation and pulmonary function tests (PFT's).

The author only found one guidance document (AAGBI 2010) that recommended the testing of health status in the view of physical function despite a growing body of evidence that proves that cardiopulmonary exercise testing (CPET) can help predict outcomes, assist with risk stratification of patients and guide prehabilitation programmes (Stringer *et al* 2012, Levett *et al* 2015, Myers *et al* 2015, AAGBI 2010).

1.3 Research Gap

1.3.1 Summary of Available Evidence

From the literature we know that complication rates are variable and appear to be lower in minimally invasive, less complex surgery. Complications bring significant costs in terms of morbidity, finance, psychological and slow recovery. Factors that have been identified as being associated with complications include age, BMI >25, open surgical approach, multiple co-morbidities, high ASA status score, poorer physical function, frailty and level of dependency. It is also clear that these factors individually are unlikely predictors but highlight the need for multifactorial assessment. CPET can be useful in risk assessment in terms of developing complications and suitability for surgery, however is generally not available as an assessment tool in most centres due to its cost including machinery, training and staffing. Not all patients are suitable from a cardiovascular perspective to perform CPET as it is a maximal test and suitable submaximal testing is yet to be identified (Thompson *et al* 2013). It is also clear that surgical procedures in their essence cause significant physiological stress which can impact on the patient in both the short and long term.

What is unclear currently, is if simple, low cost, submaximal tests that mimic common daily functions (walking, standing, gripping etc.) are useful to detect significant differences between patients who suffer complications and those who do not in abdominal surgical patients. The physical recovery of this population and the impact that complications have on recovery also needs clarity. It is also unclear what impact, if any, sedentary behaviour has on outcomes considering emerging evidence that sedentary behaviour is detrimental to health even in those who meet current physical activity guidelines (ACSM (Garber *et al*) 2011). The evidence surrounding physical recovery suggests disparities between uncomplicated post-operative courses and poor return to physical function which must also be addressed.

1.4 Purpose of the study

This study purpose is to prospectively analyse physical functional performance in relation to post-operative complications in patients undergoing abdominal surgery.

1.5 Aims and Objectives

The primary aim of the study is to evaluate the physical function performance differences between those who develop complications and those who do not and determine their impact on recovery.

Secondary outcomes are:

- Profile all cause morbidity and mortality in the study population up to 60 days postoperatively.
- Evaluate the differences between those who develop post-operative complications and those who do not, in the pre-operative setting as measured by the following variables: pre-operative demographics, six minute walk test, sit to stand test, hand dynamometry, the International Physical Activity Questionnaire (IPAQ), peak cough flow and PFT's.
- Analyse self-reported post op activity levels at 30 and 60 days post operatively to establish return to baseline functional levels and the impact the presence of complications may have on these.
- Determine self-reported physical recovery levels at 30 and 60 days post-surgery and assess the impact that complications may have on recovery.

Chapter 2

2. Methodology

The following methods are in accordance with the STROBE (strengthening the reporting of observational studies in epidemiology) guidelines for cohort studies (Vandenbroucke et al 2007).

2.1 Design

This was a prospective cohort study of patients who underwent elective abdominal surgeries which evaluated the differences between individuals who develop complications and those who do not and many physical function variables. Abdominal surgeries were defined in this study as any surgery that breaches the abdominal wall to include laparoscopic, laparoscopic assisted and open surgeries. A range of quantitative data was collected. Outcomes measures used were chosen to reflect common every day functional activities. A real world research approach was used basing the study around routine care pathways for the patients, aiming to enhance adherence and get participants who are truly representative of an abdominal surgery population (Bartlett *et al* 2013). Real world research is a new concept in research which aims to move away from stringent inclusion/exclusion criteria and uses a more patient centred approach to study design to improve patient engagement and leading to more meaningful results (Bartlett *et al* 2013).

2.2 Ethics

Ethical approval was sought and granted by the University of Limerick Hospitals Ethics committee prior to commencement of the trial. REC reference 43/16. Appendix III. Participants were given a unique code during data collection to ensure no breaches in confidentiality. The researcher was the sole individual with access to the key code. All data was kept on the researcher's password protected laptop. Excel sheets with data were encrypted and only accessible to the researcher. Hard copies of information containing participant's details were kept in a locked filing cabinet, with the researcher holding the key.

2.3 Setting

The study took place at the pre-operative assessment unit and surgical wards in the University Hospital Limerick. Data was collected from September 2016 until

July 2017. Of note, this study took place in a Level 4 University hospital which is a centre of excellence for colorectal cancer amongst others. The standard clinical pathway continues from preoperative assessment, to admission on day of surgery, enhanced recovery after surgery (ERAS) protocol if suitable including 1-2 nights in the postoperative care unit (POCU), transfer to ward or home with clinic follow up approximately 6 weeks post-surgery.

2.4 Study Procedure

For the purposes of clarity, the study procedure is segregated into the following sections: pre-inclusion stage, preoperative data collection and postoperative data collection including pre-discharge, 30 and 60 day follow up.

2.4.1 Pre-inclusion Stage

Patients who were routinely contacted by nursing staff from the preoperative assessment unit and met the eligibility criteria were then contacted by the primary researcher by telephone. They were given a brief overview of the study and asked if they would like further information. Those who agreed to receiving further information about the study were sent a patient information letter (Appendix IV). Contact occurred between 7-21 days before their appointment date.

These patients, who had received prior study information, were subsequently approached by the primary researcher during their preoperative assessment and asked if they wished to participate by the researcher. Patients were given the opportunity at this point to ask any questions about the study. Those who agreed were then screened for the inclusion and exclusion criteria. See Table 2.1 for eligibility criteria. They were informed that the researcher would extract data from their medical charts pre and post operatively and would be contacting them twice, at one and two month time points to assess their recovery over the phone.

Consent to participate was sought and a consent form was signed by the patient and researcher. (Appendix V). Copies of the consent form were given to the

participant and one was placed in the medical chart with the original stored securely by the researcher. Those who were eligible were then assessed by the primary researcher. Assessments were performed on the same day that consent was obtained while they attended their assessment with the nursing staff and Anaesthetic doctors in the preoperative assessment clinic.

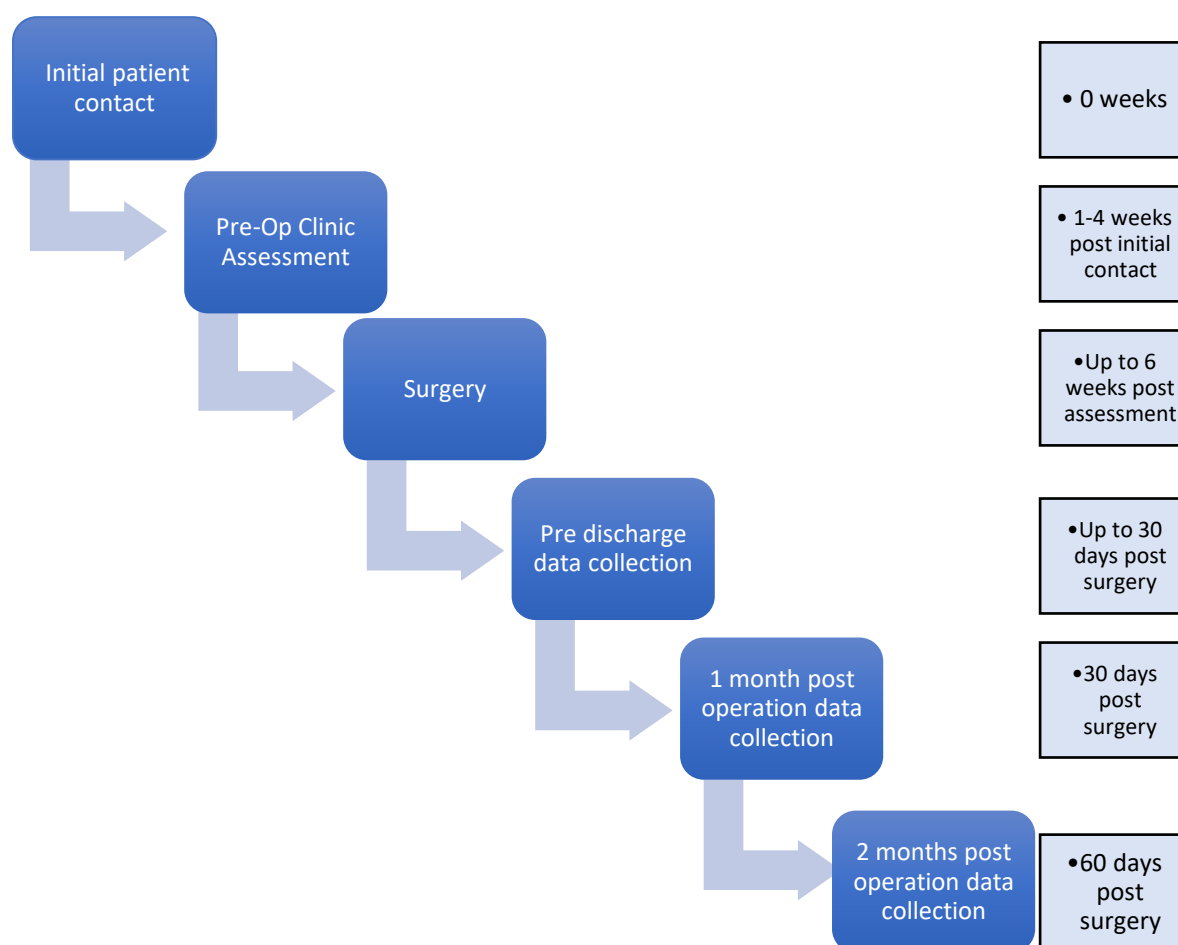
See Figure 2.2 for full timeline of data collection.

Figure 2.1 Study Eligibility Criteria

Inclusion Criteria	<ul style="list-style-type: none"> • Consent to participate in the study. • Eighteen years or above. • Planned for elective abdominal surgery as previously stated. • ASA score <4. See Appendix XV
Exclusion Criteria	<ul style="list-style-type: none"> • Abdominal surgery within one year prior to study entry. • Unable or unwilling to give informed consent. • Inability (cognitive) to perform the pre-operative tests, as characterised by inability to understand the information in the patient information leaflet. • Current systemic acute illness e.g. lower respiratory tract infection as diagnosed by the Consultant Anaesthetist in the pre-operative assessment clinic. • Scheduled for non-abdominal surgery such as thoracic, head and neck, gynaecological, perianal. • Unstable angina or myocardial infarction in the previous month. • Physical limitation precluding inability to participate in pre-operative test(s) • Resting heart rate >120bpm, systolic blood pressure > 180 mm Hg, diastolic blood pressure >100 mm Hg.

2.4.2 Data Collection

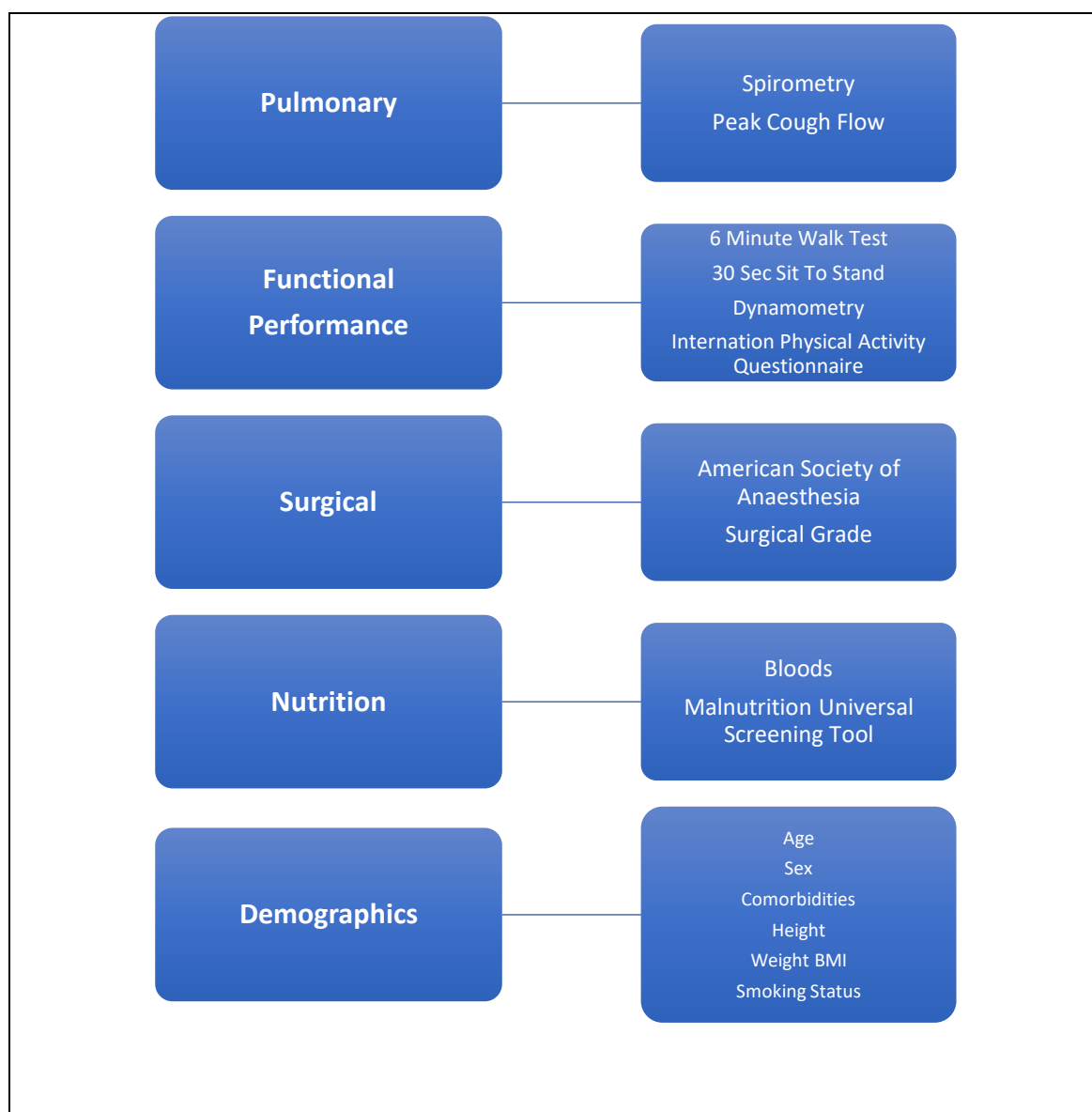
Figure 2.2 Timeline of Data Collection



2.4.3 Preoperative Data Collection

The following section outlines the data and methods of data collection used throughout the study. See Figure 2.3 for overview of data collected using various outcomes measures. See Appendix VI for data collection sheet

Figure 2.3 Pre-Operative Data Collection



2.4.3.1 Demographics

Demographics collected included the following; age, sex, co-morbidities, smoking status, weight and height. Height was measured in centimetres (cm) using a SECA 213 – portable height measure and weight was taken in kilograms (KG), using the SECA 876 digital scales. BMI (Kg/m²) was calculated from weight and height measures into a numerical score using the following formula [Weight (kg) ÷ height²(m²)]. Co-morbidities were scored using the Charlson Co-morbidity Index (Charlson *et al* 1994). See Appendix VII. Patients were asked to self-report if they were independent in all activities of daily living (ADL's), required assistance or were fully dependent on others.

2.4.3.2 Pulmonary Measures

2.4.3.2.1 Spirometry

PFT's were performed to obtain the participant's vital capacity (VC), forced vital capacity (FVC), forced expiratory pressure in one second (FEV1), FEV1/FVC ratio and peak expiratory flow rate (PEFR).

The instructions and methods used were as per the American Thoracic Society (ATS) and European Respiratory Society (ERS) Guidelines 2005 to ensure reliability (Miller *et al* 2005). See Appendix VIII. Participants were given a unique code on the spirometer with data pertaining to their age, sex, height and race entered also. Testing required participants to perform two different tests, three times each. In the initial test, participants were seated and instructed to inhale as deeply as possible before blowing into the spirometer until they felt they needed to inhale again. The second test required them to be seated and after a maximal inhalation, to exhale as forcefully as they could until they felt the need to inhale again. Local infection control policies were implemented in relation to the mouth filters that were used. Results were recorded numerically and as a percentage compared to norms of the same sex, race, age, and height. This data was generated by the spirometer post testing.

The spirometer (Vitalograph Model 2120 Hand Held REF 79XXX) was serviced prior to initiation of the study and was calibrated daily using a 3 litre syringe to ensure reliable results. Figure 2.4. the authors found no reliability or validity studies relating spirometry to abdominal surgery patients. Data is sparse and generally related to respiratory patients. It is a widely used assessment tool both research and in clinical practice, particularly assessment and monitoring of lung function with established reliability and validity across a range of clinical populations (Finkelstein *et al* 1992, Janssens *et al* 1999, Cheng *et al* 2003).

Figure 2.4 Vitalograph Spirometer

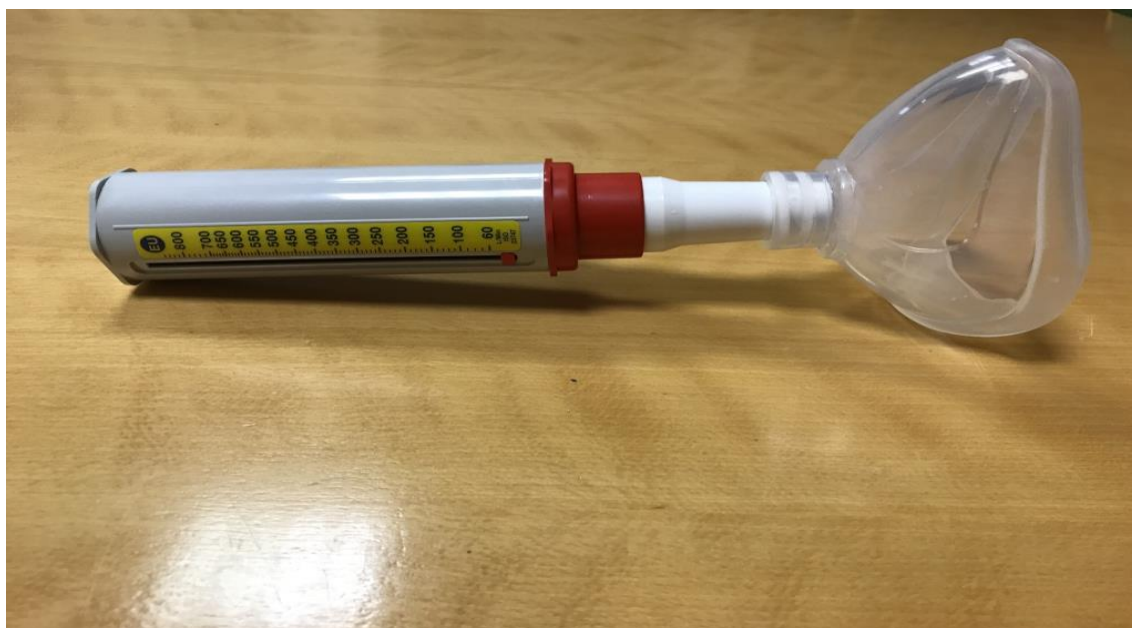


2.4.3.2.2 Peak Cough Flow

This was performed by attaching a naso-oral mask to a peak flow meter (*Mini-Wright Peak Flow Meter*, Clement Clarke International). Figure 2.5. Participants were requested to inhale maximally, in a seated position, prior to placing the mask over their nose and mouth, and coughing forcefully. This was repeated three times to give numerical scores (Appendix IX). The highest score was recorded. New face masks and flow meters were used for each patient. Results were recorded in litres per minute (L/min). The researcher attempted to limit any reliability bias by using standardised instructions and corrections as required.

The authors found no published data with regards to its validity and reliability in an abdominal surgery population, however normative data has been published for adults between 18 and 40 years (Cardoso et al 2012). Dohna-Schwake *et al* 2005 found it to be a reliable measure in predicting lower respiratory tract infections (LRTI) in a neuromuscular diseases population (n=46). They found that a cut off <160 L/min was sensitive and specific in segregating patients at risk of developing an LRTI.

Figure 2.5 Peak Cough Flow



2.4.3.3 Physical Performance Measures

2.4.3.3.1 Six Minute Walk Test

This was performed as per the ATS guidelines 2002, as recommended by Biccard 2005. Appendix X. Participants were instructed to walk up and down a thirty-metre distance, over a six-minute period, and each length was recorded. The thirty-metre distance was measured with each metre marked, and the same area used for each test. If they were not at a start or endpoint at the six-minute mark, the distance that they had covered was recorded. Predicted distance was calculated against normative data based on age, sex, weight and height. Figure 2.6. Participants peak oxygen uptake (VO_2 Peak) was also calculated Figure 2.7.

Figure 2.6 Predicted Walk Distance Calculation (Enright et al 1998)

Men : $6MWD = (7.57 \times \text{height cm}) - (5.02 \times \text{age}) - (1.76 \times \text{weight kg}) - 309$

Women : $6MWD = (2.11 \times \text{height cm}) - (2.29 \times \text{weight kg}) - (5.78 \times \text{age}) + 667m$

Figure 2.7 VO_2 Peak calculation (Ross et al 2010)

$VO_2 \text{ Peak m/min/kg} = 4.942 + (.023 \times 6MWD)$

Construct validity has been established for patients after colon surgery by Moriello et al 2008. Reliability of the six minute walk test has yet to be established in the abdominal surgery population. It has been proven to have excellent test-retest reliability in the geriatric population (Harada et al 1999, Steffen et al 2002, Kervio et al 2003), Alzheimers disease (Ries et al 2009) and osteoarthritis (Kennedy et al 2005). Normative data has also been published for both healthy adults and community dwelling elderly between the ages of 60-89 years (Enright et al 1998, Steffen et al 2002).

2.4.3.3.2 Thirty Second Sit to Stand Test

This was performed as per instructions in Appendix XI. Participants were asked to go from a seated to standing position and vice versa, as many times as possible in thirty seconds, without the use of their hands to assist. The same standard height chair (17 inches) was used throughout which was placed against a wall for safety. Participants were instructed by the researcher when to start and stop, using a standard stopwatch. When the clock reached thirty seconds, if they were more than half way to a full stand, this was regarded as a stand.

Reliability or validity of the test has yet to be established in the abdominal surgery population. Excellent test-retest reliability, interrater reliability and criterion validity has been established in community dwelling elderly by Jones *et al* 1999. Many studies have published normative data between the ages of sixty to ninety four in both males and females (Jones *et al* 1999, MacFarlane *et al* 2006, Rickli & Jones 1999).

2.4.3.3.3 Hand Dynamometry

Grip strength was recorded, using a Baseline hydraulic hand held dynamometer, as a measure of overall physical function, independent of lower limb strength. Figure 2.8. Participants were asked to squeeze the dynamometer maximally for a period of 3 seconds, the result was recorded and the test repeated twice more. An average of the scores was recorded in pounds (lbs). See Appendix XII for full instructions. The dynamometer was cleaned pre and post each test using alcohol wipes.

Test – retest reliability has been proven in healthy older adults and community dwelling older adults by Abizanda *et al* 2012 and Bohannon *et al* 2005. Validity has also been established in healthy adults by Bellace *et al* 2000. It's validity and reliability has also been proven in a clinical setting when compared to isokinetic testing, which is considered the gold standard in muscle power testing (Stark *et al* 2011). Normative data is available for healthy adults and community dwelling

older adults (Desrosiers et al 2011, Jansen et al 2008 and Massy-Westropp et al 2011).

Figure 2.8 Hand Dynamometer



2.4.3.3.4 Self-Reported Physical Activity

This data was collected by the researcher using the short form International Physical Activity Questionnaire (IPAQ) which is a self-reported measure of activity levels in the previous seven days (IPAQ Research Committee 2005) Appendix XIII. The IPAQ incorporates questions relating to vigorous and moderate activities, as-well as walking and sitting time. It uses patient subjective reports to quantify the time spent, if any, doing the previously mentioned activities in the previous week. The patients weekly METS were then calculated using the formula and descriptors provided in the scoring protocol (Appendix XIV) See

Figure 2.9 for numerical scoring. Sedentary time was calculated in weekly minutes by multiplying their daily minutes answers by seven.

It has been shown to have good reliability but fair to weak validity in an abdominal surgery population (Tran et al 2013). Craig *et al* 2003 found it to be as reliable and valid as other self-reported activity tools in twelve different countries when they assessed it for reliability, criterion validity and construct validity. This is similar to the results of Helmerhorst *et al* 2012 who found acceptable reliability and moderate validity of self-reported activity questionnaires across a broad spectrum of clinical populations.

Figure 2.9 IPAQ Scoring Protocol – MET level

Walking 3.3METS

Moderate 4 METS

Vigorous 8 METS

MET level x minutes x number of days = MET minutes weekly

*if participants performed more than one level of exercise, calculate separately and add calculations for overall weekly METS.

2.4.3.4 Other

2.4.3.4.1 Blood Tests

Albumin and creatinine levels were taken in the pre-operative assessment clinic by a nurse or doctor as part of routine testing. Results were obtained through the hospitals iLAB system.

2.4.3.4.2 ASA Score

ASA score (NICE 2016) was determined by the assessing Anaesthetist and the score was retrieved from the medical chart (Appendix XV). The same anaesthetist assessed all patients in the study to ensure consistency.

This has been proven to have moderate inter-rater reliability and is a valid marker of patients pre-operative status in a cohort of 10,864 patients (Sankar et al 2014). Further evidence of its validity and reliability is limited, despite its common usage in preoperative assessment.

2.4.3.4.3 Surgical Grade

Surgical grade was also determined by the assessing Anaesthetist and the information taken from the medical chart. See Table 1.1 (Literature Review Section)

2.4.3.4.4 Nutritional Status

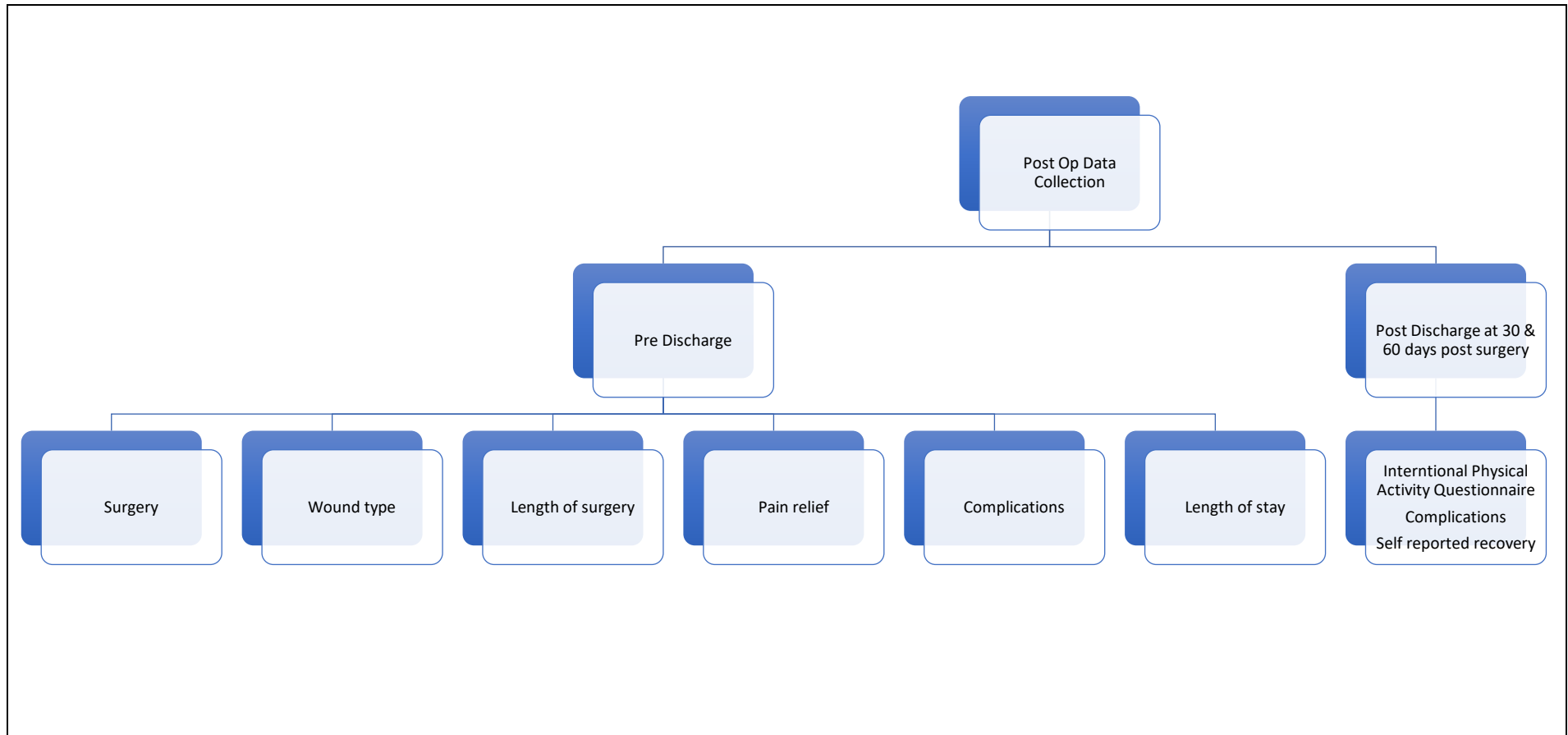
This was assessed using the Malnutrition Universal Screening Tool (MUST) which is recommended by the HSE to use in all pre admission units to determine if patients are malnourished or are at risk of malnourishment (www.hse.ie/anaesthesia). The tool uses information based on the patient's BMI, percentage weight loss in the previous three to six months and lastly their acute disease effect or likelihood of no nutritional intake for more than 5 days. This is then used to categorise patient's into low, moderate or high risk and they are managed according to their needs. See Appendix XVI for online score calculator which was used by the researcher. Scores were categorised into low, medium or high risk.

The concurrent validity of the MUST has been shown to be fair-good-excellent when compared with other malnutrition tool in both inpatients and outpatients (Stratton *et al* 2004). It has also been shown to have predictive validity in relation to mortality (Rasheed & Woods 2013).

2.4.4 Postoperative Data Collection

These sections were divided into pre-discharge and 30 and 60 days postoperatively for data collection purposes. See Figure 2.10 for outline of data collected.

Figure 2.10 Postoperative Data Collection



2.4.4.1 Pre-Discharge Data Collection

The researcher collected the following data from the medical charts, on the day of hospital discharge: type of surgery and incision type, date of surgery, length of stay, initial twenty four hour post-operative analgesia, morbidity and mortality (Figure 2.10). If participants were discharged over a weekend, information was extracted on the following Monday. In the instance where charts had been removed from the ward, they were retrieved from medical records and the information extracted. The Clavien-Dindo Classification was used to categorise the various surgical complications into grades, based on severity, which has been proven to be reliable (Dindo et al 2004). (Appendix XVII)

Patients who developed perioperative or postoperative complications, re-excisions, a repeat surgery, readmissions within the time frame of the study were recorded from the medical chart on the day of discharge. Re-excisions and re-operations were regarded as within 6 weeks from the initial surgery, including re-admission as a result of the initial surgery (Onerup et al 2015). No data was unobtainable.

2.4.4.2 Post Discharge Data Collection

Participants were contacted by phone 30 and 60 days postoperatively and questioned in relation to the following:

- i. Complications that may have occurred since discharge (Appendix XVIII).
- ii. The telephone IPAQ. The telephone IPAQ (Appendix XIX) was re-administered to determine if preoperative activity levels had been re-established.
- iii. Physical recovery. They were asked to self-assess their own physical recovery using the same questions and classification as used in the previously discussed study by Onerup et al 2015. They were given the options of 0, 25, 50, 75 and 100% with the descriptors in Appendix XX. If

patients felt < 50% recovered, they were asked if they would like community physiotherapy to be arranged for them, or other appropriate follow up if this was not already in place

2.5 Study Size

A formal sample size calculation was difficult to perform given the lack of published information on correlations between putative prognostic factors and outcome after abdominal surgery. A non-probability sample of convenience was therefore chosen of at least 40 patients. Due to this, a power calculation was not possible and post-hoc power analysis is not deemed as useful.

2.6 Bias

There is a possibility of some investigator bias but this was limited by the use of standardised outcome measures with consistent instructions given. The same anaesthetist reviewed all patients therefore reducing bias in terms of ASA and surgical grades. All complications were factual from the medical records and were categorised accordingly. As previously stated, attempts to limit bias were made where possible.

2.7 Statistical Evaluation

Data was imported into IBM SPSS© version 24 from Microsoft Excel© version 15.32. Descriptive data was reported using percentages and numbers. Data was analysed for normality using the one sample Kolmogorov-Smirnov test and the following tests used as appropriate. Mann Whitney U tests were used to evaluate non-parametric data and Independent T tests were used as the parametric alternative. These were used when variables were split into groups based on the presence or not of complications. Relationships over time were analysed using the Wilcoxon Signed Ranks Test when analysing activity, inactivity and recovery. Results were deemed significant if $P \leq 0.05$ in all cases.

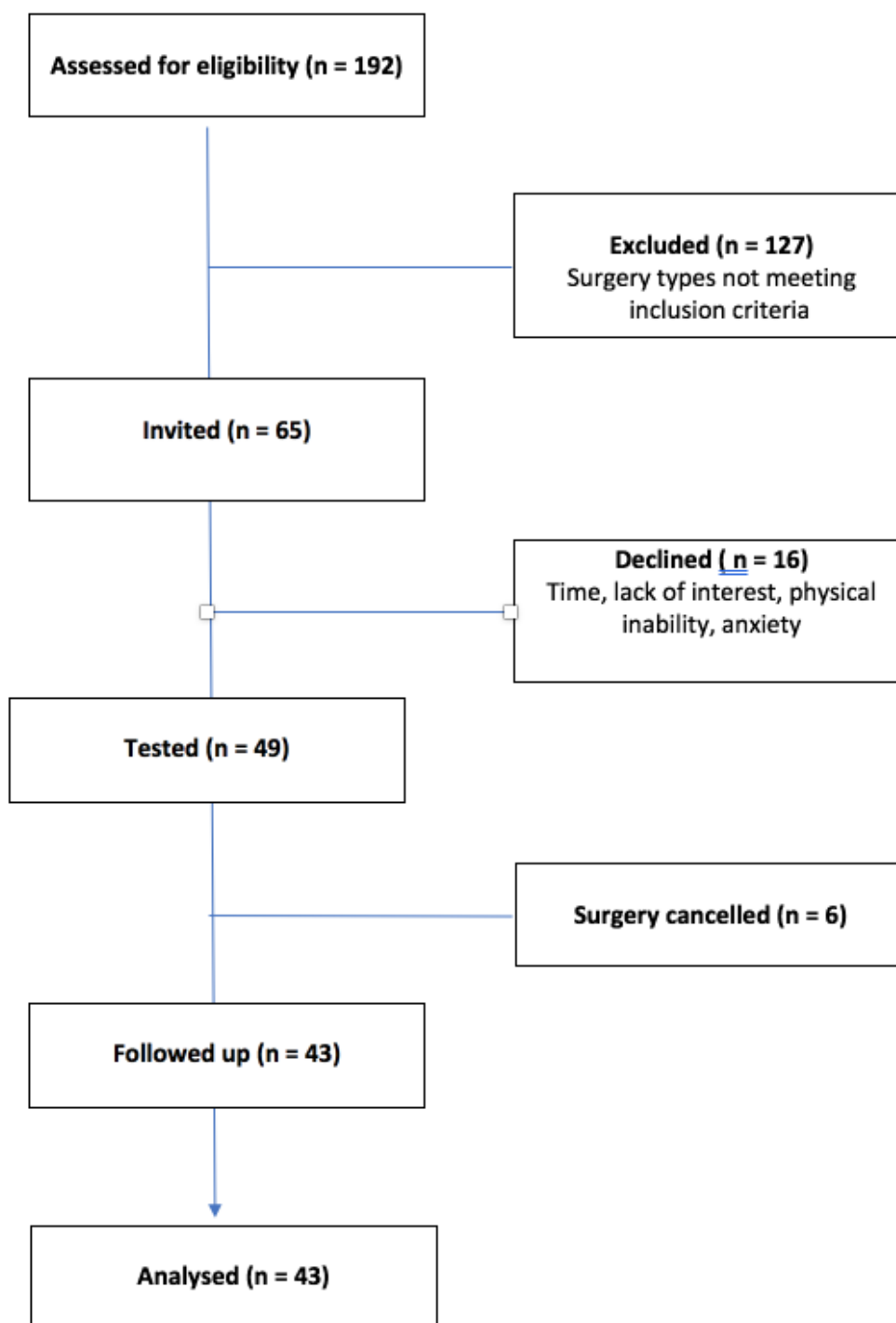
Chapter 3

3. Results

3.1 Participation

One hundred and ninety-two people were screened for study participation between September 2016 and June 2017. Of these, sixty-five people met the eligibility criteria and were agreeable to study participation. Reasons given for non-participation included lack of time (n=3), lack of interest (n=6), feeling unable to perform the assessment tests (n=4) and anxiety relating to the surgery (n=3). Forty-nine participants were assessed and 43 underwent related surgical procedures. In the six that were tested but did not undergo surgical procedures, reasons that excluded them were risks associated with performing the surgery (n=5) and biopsy results negating the need for surgery (n=1). From study entry, no participants were lost to follow up. See Figure 3.1.

Figure 3.1 Participation



3.2 Demographics of Participants

Eighteen females (41.9%) and twenty-five males (58.1%) participated in this study. Smokers accounted for 11.6% (n=5) and the majority of participants, 95.3% (n=41), self-reported as being fully independent in their ADL's. Thirty-three (76.75%) participants had at least one or more comorbidities according to the Charleston Comorbidity Index with a median (IQR 25-75) score of 3 (1,5). The majority of participants were deemed to be ASA grade II (n=29). The age of participants ranged from 29-79 years. Mean (SD) BMI kg/m² was 29 (5) and nutritional status was generally very good with only five participants (11.7%) entering into the medium-high risk category as per the MUST score.

Mean recorded weekly MET minutes were 2618 (3209) which equates to a mean of 6.23 MET hours in activity, on a daily basis. Mean weekly sitting was 2045 (1116.14) minutes which equated to 4.87 hours sitting daily. Participants mean rating of activity, based on their weekly METS expenditure was categorised as moderate. In relation to how these were categorised, 27.9% (n=12) were low, 51.2% (n=22) were moderately active and 20.9% (n=9) were highly active. See Tables 3.1 & 3.2 for full demographic information.

Table 3.1 General Participant Demographics

	N	Percentage
<u>Sex</u>		
Male	25	58.1
Female	18	41.9
<u>Smoker</u>		
Yes	5	11.6
No	38	88.4
<u>BMI*</u>		
<18 Underweight	1	2.3
18.5-24.9 Normal	5	11.6
25-29.9 Overweight	20	46.5
>30 Obese	17	39.83
<u>Self-reported Dependence</u>		
Independent	41	95.3
Assisted	2	4.7
Dependent	0	0
<u>Charleston Comorbidity Index</u>		
0	10	23.25
1	3	6.97
2	8	18.6
3	4	9.3
>4	18	41.79
<u>ASA Score*</u>		
I	8	18.6
II	29	67.44
III	6	13.95
IV	0	0
<u>Surgeries</u>		
<u>Colorectal</u>		
Robotic anterior resection, colonic anastomosis & ileostomy	1	2.3
Colostomy	1	2.3
Right hemicolectomy	5	11.6
Anterior resection with colostomy formation	1	2.3

Colectomy & Ileostomy closure	2	4.7
Low anterior resection & ileostomy	1	2.3
Low anterior resection	10	23.3
Robotic Proctectomy	1	2.3
Anterior resection, cholecystectomy, proctectomy & ileostomy	1	2.3
<u>Hernia Repairs</u>		
Right inguinal & incision hernia repairs	1	2.3
Incisional hernia repair	2	4.7
Inguinal hernia repair	3	7
Right inguinal & umbilical hernia repair	1	2.3
Anterior wall hernia repair	1	2.3
Parastomal Hernia repair	2	4.7
<u>Reversals</u>		
Reversal of Ileostomy	3	7
Reversal of Hartmann's Procedure	1	2.3
Reversal of colostomy	1	2.3
<u>Cholecystectomy</u>		
<u>Incisions</u>		
Open	5	11.6
Robotic	3	6.97
Laparoscopic	32	74.41
Laparoscopic Assisted	3	6.97
<u>Surgical Grade (NICE)</u>		
1	0	0
2	13	30.23
3	11	25.58
4	19	44.18

*BMI – Body Mass Index, ASA – American College of Anaesthesiology

Table 3.2 Demographics details of study participant's variables (Min/Max/Mean/SD)

N = 43	Minimum	Maximum	Mean	Standard Deviation
<u>Demographics</u>				
Age (years)	29	79	59.51	14.65
Weight (KG*)	55.5	141.8	86.52	19.26
Height (cm*)	116	197	170.39	14.18
BMI*(kg/m ²)	16	41.5	29.32	5.06
ASA*	1	3	1.95	.56
Albumin g/L	34	45	38.42	2.59
Creatinine micromol/L	56	110	78.26	12.87
Surgical Grade	2	4	3.14	0.86
<u>Pulmonary Function</u>				
VC*	1.58	8.02	3.83	1.32
VC% predicted*	67	178	105.21	22.92
FVC*	1.74	7.01	3.62	1.16
FVC% predicted*	72	193	101.81	21.55
FEV ₁ /FVC	0.49	0.92	0.76	0.08
FEV ₁ /FVC% predicted*	49	111	78.74	213
FEV ₁ *	1.45	5.49	2.75	0.87
FEV ₁ % predicted*	51	143	95	19.34
PEFR*	7.06	773	389.6	162.3
PEFR % predicted*	25	144	90.81	27.18
PCF*	200	850	369.3	127
<u>Physical Function</u>				
6MWT (metres)*	60	690	513.53	133.3
6MWT % Predicted*	10	133	96	21.8
6MWT Predicted (metres)	289.76	781.6	537.41	111.93
VO ₂ Peak* mL.kg.min ⁻¹	6.32	21.12	16.71	3.14
Sit to Stand (repetitions)	2	30	15.95	6.32

Dynamometry (lbs)	18	130	75.81	27.4
Weekly MET minutes*	0	10000	2618.5	3209.1
Weekly sitting minutes	420	6720	2045.05	1116.14
<u>Pre-Discharge Data</u>				
OT* (minutes)	50	350	146.16	84.34
Number of complications	0	4	.74	1.13
Grade of complications	0	4	.73	1.04
Length of stay	0	29	6.07	5.91
<u>30 day measures</u>				
Weekly MET minutes*	0	5544	585.35	894.47
Weekly sitting minutes	420	6720	2661.63	1235.36
Number of complications	0	3	0.4	0.69
Grade of complication	0	3a	0.65	1.11
% Recovery*	0	100	64.3	27.14
<u>60 Day Measures</u>				
Weekly MET minutes*	0	10000	1434.78	2595.59
Weekly sitting minutes	420	6720	2510.93	1237.63
Number of complications	0	1	0.21	0.41
Grade of complications	0	2	0.33	0.68
% Recovery*	1.00	100	82.7	24.74

* KG = kilogram, cm = centimetre, BMI = body mass index, ASA = American college of anaesthesiologists, VC = vital capacity, FVC = forced vital capacity, FEV₁ = forced expiratory volume in 1 second, PEF_R = peak expiratory flow rate, PCF = peak cough flow, 6MWT = 6 minute walk test, VO₂Peak = peak oxygen uptake, MET = metabolic equivalent, OT = operating theatre.

3.3 Complications

A detailed list of variables relating to the presence or absence of complications, including statistical analysis is available in Table 3.3. These results will be further explained and discussed.

Table 3.3 Pre and Post Surgery Patient Variables. Patients were separated by presence of postoperative complications.

Variable	Complications (n = 18)	Non- Complications (n = 25)	P <0.05
Age (years) Md (IQR)	71(51.5, 73.5)	60 (45.5, 69)	0.118
BMI # (kg/m²)	31.811 (5.24)	27.528 (4.16)	0.005*
Charleston Comorbidity Index Md(IQR)	5 (1,5.25)	2 (0,4)	0.033*
Height (cm) Md(IQR)	169 (163.7, 178)	170 (162,184)	0.588
VC# (L) Md(IQR)	3.33 (2.79,4.61)	3.6 (3.03,4.8)	0.35
VC #% Md(IQR)	105.5 (82.75, 119.25)	102 (93,114.5)	0.544
FEV₁/FVC # (L) Md(IQR)	0.785 (.7,.85)	0.74 (.7,.79)	0.223
FEV₁/FVC#% Md(IQR)	78.75 (70.75,92)	74 (70.5,82.5)	0.268
FVC # (L)	3.27 (0.93)	3.87 (1.25)	0.091
FVC%#	96.5 (16.13)	105.64 (24.33)	0.173
FEV₁ # (L)	2.52 (0.75)	2.91 (0.93)	0.149
FEV₁#%	96 (23.88)	94.32 (15.75)	0.782
PEFR# (L)	404.22 (168.30)	407.04 (153.70)	0.955
PEFR#%	95.5 (30.97)	87.44 (24.19)	0.344
PCF# (L/min)	346.11 (155.22)	386 (102.33)	0.315
6MWD# (m)	490 (420,561.25)	570 (502.5, 630)	0.019*
VO₂Peak #ml/min/kg	16.218 (14.26, 17.85)	18.050 (16.5, 19.43)	0.017*

Dynamometry (lbs)Md(IQR)	60 (50, 102)	80 (35, 100)	0.804
Pre-surgery weekly MET mins Md(IQR)#	777.5 (165, 1481)	1386 (866.25, 4749)	0.020*
30 Day weekly MET mins Md(IQR)#	132 (0, 408.37)	693 (107.25, 1014.75)	0.006*
60 Day weekly MET mins Md(IQR)#	247.5 (0, 618)	805 (495, 1308)	0.009*
Pre-surgery weekly sitting mins Md(IQR)#	2055 (897.65)	2037 (1268.5)	0.961
30 Day weekly sitting mins Md(IQR)#	3360 (2100, 4200)	2100 (1470, 2520)	0.265
60 Day weekly sitting mins Md(IQR)#	3150 (1702, 4200)	2100 (1260, 2520)	0.03*
STS#	14.94 (6.16)	16.68 (6.46)	0.381
Creatinine (micromol/L)	80.78 (12.35)	76.44 (13.17)	0.281
Albumin g/L Md(IQR)	38 (37, 38.25)	39 (36.5, 40.4)	0.117
OT minutes Md(IQR)#	142.5 (105, 245)	90 (60, 180)	0.05*
Length of stay (nights) Md(IQR)#	8.5 (7, 14.25)	2 (1, 4.5)	<0.001*
Recovery 30 days (%) Md(IQR)#	50 (25, 75)	75 (62.5, 82.5)	0.008*
Recovery 60 days (%) Md(IQR)#	82.5 (68.75, 100)	100 (75, 100)	0.147

*P ≤ 0.05 was deemed significant in Mann Whitney U and Independent T tests.

All data is presented as Mean and SD unless otherwise stated.

Median & interquartile ratios 25-75 are reported for non-parametric data.

#IQR – interquartile ratio. SD – standard deviation. Md = median, N/A = not applicable dependent on parametric or non-parametric data types. BMI = body mass index, VC = vital capacity, FVC = forced vital capacity, FEV₁ = forced expiratory volume in 1 second, PEFR = peak expiratory flow rate, PCF = peak cough flow, 6MWT = 6 minute walk test, VO₂Peak = peak oxygen uptake, MET = metabolic equivalent, OT = operating time.

3.3.1 Complication Rate

The overall complication rate pre-discharge, as graded using the Clavien-Dindo classification, was 41.9% (n=18). This corresponded to 30.2% (n=13) at 1 month and 21% (n=9) at 2 month's post-surgery. Figure 3.2. Of the 13 participants where complications were recorded at 30 days, 3 of these were patients who had been discharged and subsequently developed complications. This resulted in an overall complications prevalence of 48.83% (n=21). The number of complications were higher pre-discharge and decreased from 34 recorded complications to 17 within 30 days and further reduced to 9 by 60 days post-surgery. The severity of the complications encountered also seemed to decrease over time, the highest being grade 4 pre-discharge to no participants having > grade 3a at 30 days and no participants having >grade 2 by 60 days. There were no reported cases of mortality within the data collection timelines. See Table 3.4 for further information on postoperative complications.

Figure 3.2 Complication rates at all time points

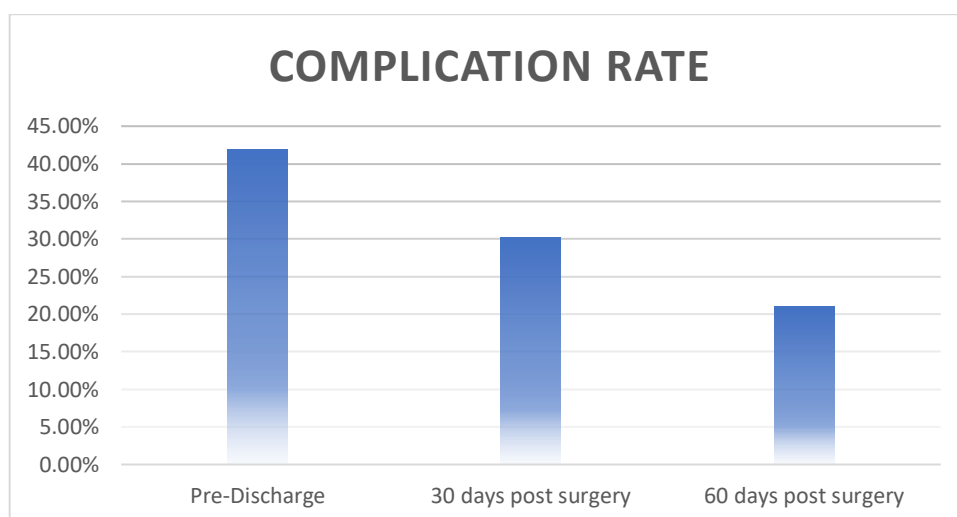


Table 3.4 Complications, Severity and Occurrence at all time points

	Pre-discharge	30 days post surgery	60 days post surgery
Percentage with complications	41.9	30.2	21
Number of complications overall	34	17	9
Range in severity of complications as per Clavien- Dindo	0 - 4	0 - 3a	0 – 2

3.3.2 Complication Type

A total of 34 various complications were recorded with a breakdown of 21 (64.8%) medical complications and 13 (35.2%) surgical complications. These ranged from relatively minor such as cellulitis to respiratory failure requiring intensive care admission. See Table 3.5 for full list of complications including grade of complications at all time points.

Table 3.5 Complication Types, Grades and Timeline

Time Point	Complication (n=1)	Grade
Pre-Discharge (n= 18)	CCF, sepsis, PE, confusion	4a
	Ileus/ hernia repair	3b
	A Fib, Lung consolidation, requiring non-invasive ventilation in High Dependency Unit	4
	Atelectasis, Vacuum dressing, influenza A, Wound infection	3
	Atrial-Fibrillation, Exacerbation Heart Failure	2
	Drain required	2
	Ileus	2
	Small bowel obstruction, septic, Urinary tract infection	2
	Ileus	2
	Pulmonary oedema, Wound infection, pneumonia	2
	Anastamotic leak	2
	Haemorrhage	2
	Nausea, atelectasis, rash	2
	increased stoma output	1
	Atelectasis	1
	Cellulitis	1
Atelectasis	1	
Bradycardia	1	
30 days (n=13)	Wound re-opened	3a
	Subheaptic collection, BL effusions, drain and thoracocentesis	3a
	Wound debridement and vacuum dressing	3a
	Readmission-ileus, drainage	3a

	Readmission 10/7 viral illness, Acute kidney injury, Ultrasound guided drainage	3a
	Abdominal collection, drain insertion	3a
	Gastroenteritis, cellulitis requiring re-admission	2
	Delayed wound healing	2
	Readmission 1/52 wound breakdown/infection	2
	Diarrhoea	1
	Delayed healing, daily dressing	1
	Low blood pressure	1
	Wound infection	1
60 Days (n=9)	Heart Failure	2
	Vacuum dressing	2
	Effusions remain	2
	Vacuum dressing due to poor wound healing	2
	Drain in situ	2
	Low blood pressure	1
	Daily dressings	1
	Daily dressings	1
	Wound dressings	1

3.4 Age

Age was not significantly different between the groups ($P = 0.118$). However, the median(IQR) age in the complications group was 71 (51.5, 73.5) versus 60 (45.5, 69) in the non-complications group. Table 3.3.

3.5 Sex

No statistically significant differences were found between the complications and non-complications groups in relation to sex ($P = 1.00$).

3.6 Smoking Status

There were no statistically significant differences between the complications and non-complications groups in relation to smoking status ($P = 1.00$). Participant's were classified as either current smokers or non-smokers

3.7 Dependence

No statistically significant differences were found between the complications and non-complications groups in relation to self-reported independence ($P = 1.00$).

3.8 BMI

Mean total group BMI was 29.3 (5) kg/m^2 and ranged from 16 kg/m^2 to 41.5 kg/m^2 . BMI was found to be significantly different between the groups ($P=0.005$). Complications group had a mean BMI of 31.811 kg/m^2 (5.246) whereas the non-complications had a mean BMI of 27.528 kg/m^2 , (6.46). Table 3.3.

3.9 Co-Morbidities

Co-morbidities were scored using the Charleston Co-morbidity Index which gives a score based on participants age and various co-morbidities that may or may not be present. See Appendix VI. Co-morbidity data was extracted from the medical charts. Median scores in the complications and non-complications

groups were 5 (1, 5.25) and 2 (0, 4). This was found to be statistically significantly different ($P = 0.033$) between the groups. Table 3.3.

3.10 Surgery

3.10.1 Surgery Types

See Table 3.1 for full details of surgeries performed. A total of nineteen different surgeries were performed in the study participants. These consisted of the following abdominal surgery types: colostomy/ileostomy reversals ($n=7$, 16.3%), hernia repairs ($n=10$, 23.3%), colorectal surgery ($n=21$, 48.4%) and cholecystectomies ($n=5$, 11.6%). The highest percentage of complications were observed in participants who had colorectal surgeries, however these also represented the most common type of surgery. See Table 3.6.

Table 3.6 Surgical Categories and Complications

Surgical Category	N	Percentage of total sample	Complication Incidence (N)	Percentage complications within surgical category
Colorectal reversals	7	16.3	3	42.85
Colorectal	21	48.8	11	52.38
Hernia repairs	10	23.3	4	40
Cholecystectomies	5	11.6	0	0
Total	43	100	18	N/A

3.10.2 Surgical Incision

Laparoscopic surgery was the most prevalent ($n=32$, 74.4%). See Table 3.7 for breakdown of results relating incisions to complications. This information was obtained from the operative notes. No statistical analysis was performed due to

lack of numbers in each type as laparoscopic surgeries far outweighed the other incision types.

Table 3.7 Incision Types & Complications

	Complications	Non-Complications	Total
Open (n)	3	2	5
Robotic (n)	1	2	3
Laparoscopic (n)	12	20	32
Laparoscopic Assisted (n)	2	1	3

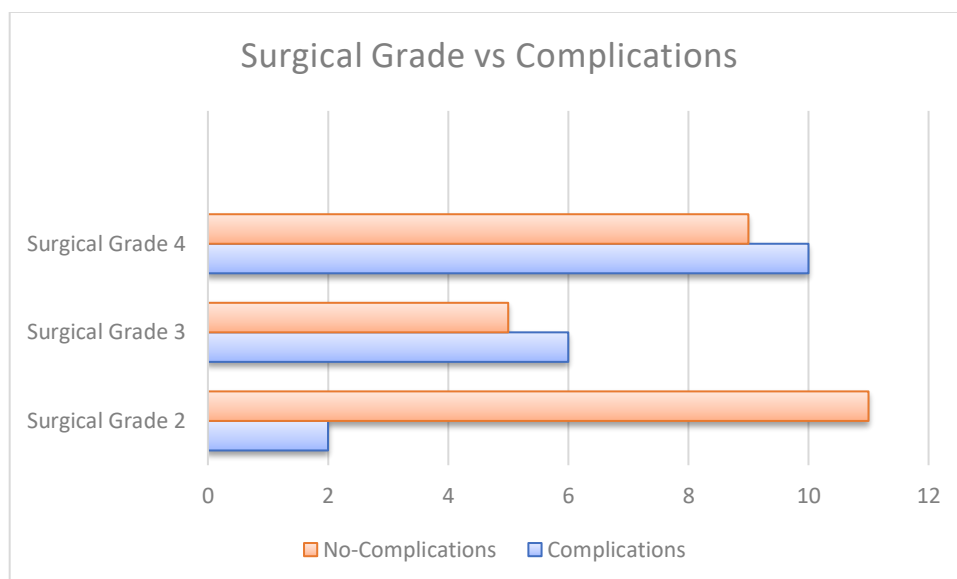
3.10.3 Surgical Grade

Table 3.8 outlines the surgical grade breakdown according to surgery type. The majority of complex surgeries, ≥ 3 were of a colorectal nature whilst the majority of the hernia and cholecystectomy surgeries trended towards lower complexity ≤ 2 . Figure 3.3 outlines the differences between the groups according to surgical grade.

Table 3.8 Surgical Grade & Surgery Type

	Surgical Grade 2	Surgical Grade 3	Surgical Grade 4
Colorectal (n)	0	5	18
Reversal (n)	0	4	1
Hernia repair (n)	8	2	0
Cholecystectomy (n)	5	0	0

Figure 3.3 Complications & Surgical Grade



3.10.4 Operating Time

Median operating time for the whole group was 146.16 minutes (75, 225). There was a significant difference between the groups in relation to longer operating times ($P = 0.05$). Operating time for the complications group was a median of 142.5(105, 245) minutes versus a median of 90 (60, 180) minutes in the non-complication group. This information was gathered from the anaesthetic records in which total operating time was accounted. Table 3.3

3.10.5 Post-Surgery Analgesia

Initial 24-hour analgesia management showed that 60.5% ($n=26$) commenced patient controlled intravenous analgesia and the others received oral pain relief. No statistically significant differences were found between the complications and non-complications groups in relation to the mode of analgesia administered in the initial 24 hours post-surgery ($P = 0.307$).

3.11 Length of Stay

LOS was calculated as bed nights and did not account for total hours admitted. A significant difference was found between the groups in relation to longer LOS and complications ($P < 0.0001$). Table 3.3. LOS increased for those who had complications from a median of 2 (1, 4.5) nights in those without complications to a median of 8.5 (7, 14.2) nights. Complications also caused 6 readmissions which resulted in an extra 38 night's hospital care. These were reported by participants during telephone interview and confirmed through review of their medical records.

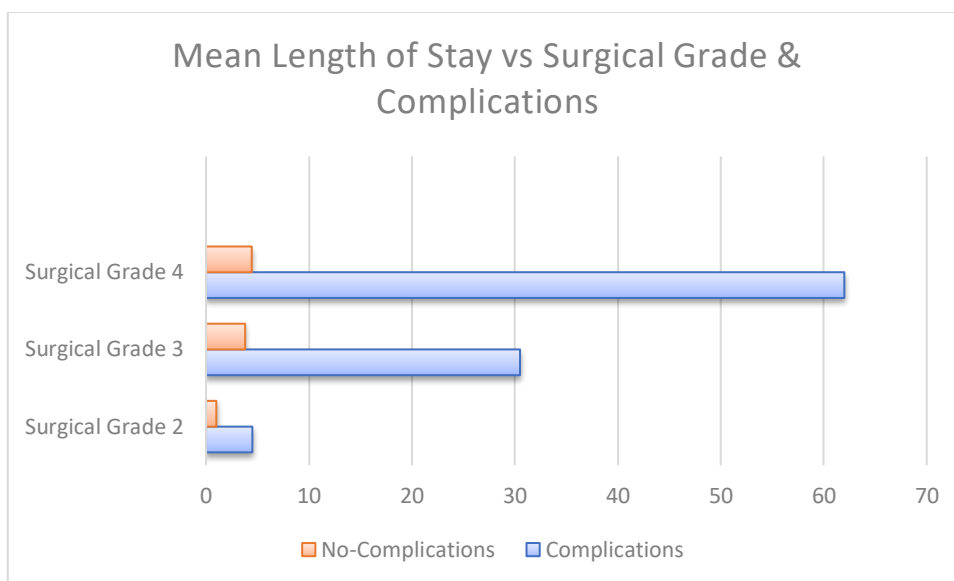
When LOS was reviewed according to grade of complication, a trend was seen showing higher LOS as the grade of complication increased in severity. E.g. participants who suffered a grade 4 complications had a mean LOS of 21.5 nights versus grade 1 who had a mean LOS of 7.2 nights. See Table 3.9.

Table 3.9 Mean LOS & Complication Grade

	Complication Grade 1	Complication Grade 2	Complication Grade 3	Complication Grade 4
Mean LOS	7.2	9.8	12	21.5

This same trend was apparent when mean LOS and surgical grade were compared between groups. For example, participants who underwent a grade 4 surgery and suffered a complication(s), had a mean LOS of 62 nights versus those without who had a mean LOS of 4.44. See Figure 3.4. It was not possible to perform statistical testing on this data due to a small sample size.

Figure 3.4 Mean Length of Stay, Surgical Grade & Complications



3.12 Physical Status Measurement

3.12.1 IPAQ

The IPAQ was divided into weekly MET minutes and weekly minutes sitting for the purposes of analysis. Patients were asked to answer 4 questions regarding time spent in various intensities of exercise and sedentary time which was converted to weekly MET minutes and weekly time spent sitting. Analysis was performed in 3 ways: total group trend changes between time points, differences between complications and non-complications groups at all time points and finally analysis of the split groups between mentioned time points.

3.12.1.1 Total group weekly MET minutes analysis between time points

When the total groups weekly MET minutes were analysed for changes over time, significant results were found when the weekly MET minutes were analysed for differences between following timelines: pre-surgery – 30 days post-surgery ($P < 0.001$), (Pre - Md 1188 [577.5, 3759]), (30 days - Md 528 [0, 766.5]), demonstrating a significant decline in activity levels. Pre-surgery – 60days (P

<0.001, Md 594 [132, 1089]) once again demonstrating a significant decline from baseline activity levels. Thirty – 60 days post-surgery (P <.001) showed a significant improvement in activity levels, however these remained significantly lower (P =<.001) than baseline figures. See table 3.10 and Figure 3.5 for trend analysis. When baseline weekly METS were compared with reported weekly METS at 60 days post-surgery, 13.95% (n = 6) had increased activity, 16.27% (n = 7) were the same as baseline and 69.78% (n = 30) reported worse than baseline results.

Figure 3.5 Weekly METS at all time points – total, complications & non-complications groups

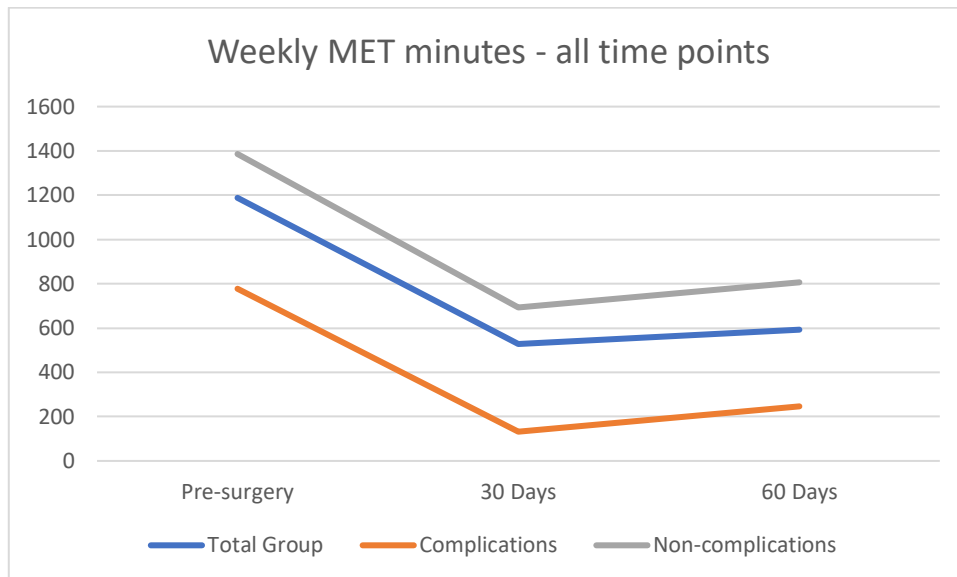


Table 3.10 IPAQ analysis of changes between time points

	Time points analysed	Full group (n=43)	Complications (n = 18)	Non-complications (n=25)
Weekly MET minutes	T1 – T3	T1 - 1188 (577.5, 3759) T3 – 528 (0, 766.5) P<0.001*	T1 –777.5 (165, 2481) T3 – 132 (0, 408) P = 0.003*	T1 - 1386 (866.5, 4749) T3 - 693 (107.25, 1014.75) P <0.001*
	T1 – T4	T1 - 528 (0, 766.5) T4 – 594 (132, 1039) P <0.001*	T1 – 777.5 (165, 2481) T4 – 247 (0, 618) P = 0.009*	T1 - 1386 (866.5, 4749) T4 - 805 (495, 1308) P = 0.002*
	T3 – T4	T3 - 528 (0, 766.5) T4 - 594 (132, 1039) P <0.001*	T3 – 132 (0, 408) T4 - 247(0, 618) P = 0.028*	T3 - 693 (107.25, 1014.75) T4 - 805 (495, 1308) P = 0.004*
Weekly minutes sitting	T1 – T3	T1 -1807 (1260, 2520) T3 – 2520 (1680, 3360) P <0.001*	T1 – 2100 (1260, 2520) T3 – 3360 (2100, 4200) P = 0.004*	T1 – 1680 (1260, 2520) T3 – 2100 (1470, 2520) P = 0.016*
	T1 – T4	T1 - 1807 (1260, 2520) T4 – 2520 (1680, 3360) P <0.001*	T1 - 2100 (1260, 2520) T4 – 3150 (1323, 4200) P = 0.007*	T1 – 1680 (1260, 2520) T4 – 2100 (1260, 2520) P = 0.079
	T3 – T4	T3 - 2520 (1680, 3360) T4 - 2520 (1680, 3360) P = 0.104	T3 – 3360 (2100, 4200) T4 – 3150 (1323, 4200) P = 0.389	T3 – 2100 (1470, 2520) T4 – 2100 (1260, 2520) P = 0.131

Data was reported as median and interquartile ratios 25-75

*P<0.05 using Wilcoxon Signed Ranks test to analyse differences between stated time points.

T1 – initial assessment, T3 – 30 days post-surgery, T4 – 60 days post-surgery.

3.12.1.2 Weekly MET minutes between group analysis at all time points

When data was analysed for differences between groups at pre-surgery, 30 days and 60 days the following results were found. There was a significant difference between the groups reported pre-surgery weekly MET minutes when the development of pre-discharge complications was taken into consideration ($P = 0.02$). The same analysis was repeated at 30 days where no differences were seen between groups ($P = 0.31$) and at 60 days where significant differences were apparent between groups ($P = 0.02$). It must be noted that the number of participants who reported complications reduced from $n=18$ pre-discharge to $n=13$ at 30 days and $n=9$ at 60 days. See Table 3.11 and Figure 3.5.

Table 3.11 IPAQ (Weekly MET minutes) Statistical Analysis between groups at all time points

Weekly MET minutes	Pre-surgery	30 days post surgery	60 days post surgery
Complications	777.5 (n = 18)	231 (n = 13)	132 (n = 9)
Non-Complications	1386 (n = 25)	610 (n = 30)	729.75 (n = 34)
Significance	0.02*	0.31	0.02*

* $P \leq 0.05$ was deemed significant in Mann Whitney U tests. All data was reported as median figures. Significance relates to differences between the groups at the stated time points.

3.12.1.3 Split group weekly MET minute analysis

The groups were split and analysis performed between the stated time points to assess for significant trends in activity levels. See Table 3.10. Participants with complications weekly MET minutes reduced significantly by 83% overall ($P = 0.003$) at 30 day's post-surgery and rose significantly by 14% ($P = 0.02$) at 60 days to 31.83% overall. Despite the significant improvement in activity levels from 30 – 60 day's post-surgery, a significant reduction remained from preoperative recorded weekly MET minutes to 60 days ($P = 0.009$).

Those without complications also reduced their weekly MET minutes significantly by 50% at 30 days ($P < 0.001$) and were seen to increase it significantly by 8% ($P = 0.004$) at 60 days bringing them to 58% of baseline figures. A significant reduction remained between initial weekly MET and at 60 day's post-surgery ($P = 0.002$). Thus, neither group had returned to baseline levels by 60 day's post-surgery. Figure 3.5

3.12.1.4 IPAQ activity level categorical analysis

In relation to weekly MET minutes, the following is how they are categorised into low <600 MET minutes weekly, moderate 600-1500 MET minutes weekly and high >1500. The complications group dropped from the moderate (Md 777.5) to low (Md 132) activity category at 30 days and remained there at 60 (Md 247.5) days which was statistically significant as discussed in the previous section. The non-complications group remained in the moderate activity group but dropped from the higher end (Md 1386) to the lower end at 30 days (Md 693) and at 60 days (Md 805) which proved statistically significant as previously discussed.

3.12.1.5 Total group weekly sitting minutes analysis

When the whole groups weekly sitting minutes were analysed for changes over time, significant results were found when the weekly sitting minutes were assessed at the following timelines: a significant increase from pre-surgery (Md 1807[1260-2520]) – 30 days post-surgery ($P < 0.001$, Md 2520[1680-3360]) and a significant increase from pre-surgery – 60days ($P < 0.001$, Md 2520 [1680-3360]). Significant changes were not apparent between 30 – 60 day's post-surgery ($P = 1.1$). This data shows a significant increase in sedentary time from pre-surgery to remaining at 60 day's post-surgery. See Table 3.10.

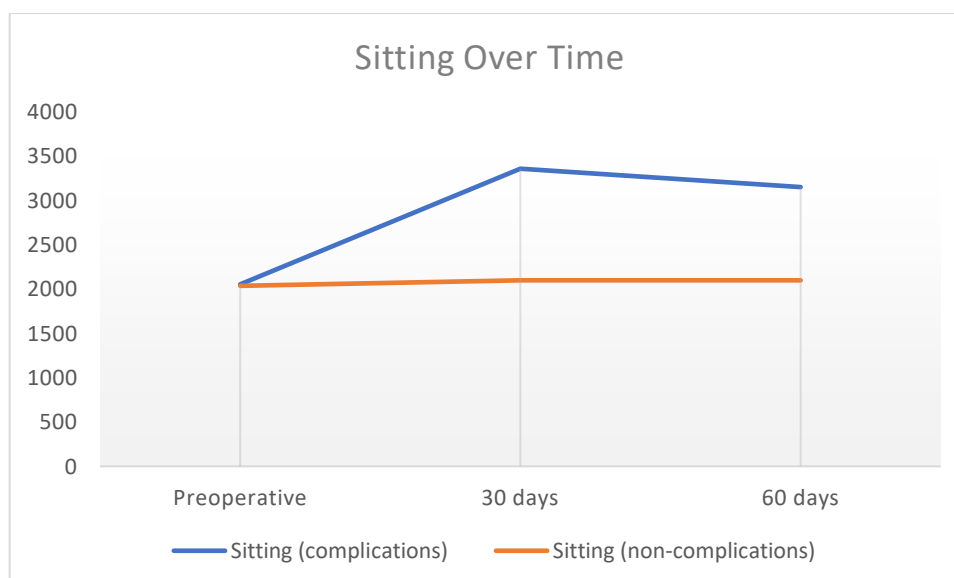
3.12.1.6 Weekly sitting minutes analysis between groups

There were no differences between the groups in relation to initial weekly sitting minutes ($P = 0.961$) or at 30 days ($P = 0.26$). A significant difference between the groups was apparent at 60 days however ($P = 0.03$). Table 3.3. Again, it must be noted that the number of participants who reported complications reduced from $n=18$ pre-discharge to $n=13$ at 30 days and $n=9$ at 60 days.

3.12.1.7 Split group analysis of weekly minutes sitting

Weekly minutes sitting increased minimally by 2.19% ($P = 0.84$) in the non-complications group and remained the same between 30 ($P = 0.313$) and 60 ($P = 0.005$) days. However, the complications group showed a significant increase in sitting by 64.87% ($P = 0.004$) at 30 days, which reduced by 10.3% ($P = 0.389$) at 60 days. Overall it remained significantly higher, 54.57% ($P = 0.007$), at 60 days than baseline figures. Figure 3.6 Table 3.10

Figure 3.6 Sitting (mins) – All time points (Complications (n=18) vs Non-complications (n= 25))



3.12.2 Pulmonary Function

This data was captured using a spirometer to assess pulmonary function using standardised equipment and instructions. Predicted pulmonary function values were calculated based on age, height, sex and race. Results are outlined in Table 3.3. No significant relationships were found between the groups in relation to spirometry values.

3.12.3 Peak Cough Flow

Using a face mask and peak flow meter, participants were asked to cough as strongly as possible with the mask sealed against their faces. They were given 3 opportunities to perform the test and the highest score was recorded. The mean peak cough flow of those who experienced complications was 346.11 L/min (155.22 with no significant differences ($P = 0.31$) to the non-complications group whose mean was 386L/min (102.33). Table 3.3.

3.12.4 Six Minute Walk Test

This test indirectly assessed cardiorespiratory fitness by measuring the distance covered in 6 minutes over and back over a 30-metre distance. This information was then used to calculate VO_2 Peak as previously explained in the methodology section (Figure 2.7). Data was analysed in 2 ways: actual distance measured and VO_2 Peak.

There was a significant difference between the complications and non-complications groups in relation to actual distance covered ($P = 0.019$). The complications groups covered a median distance of 490m (420, 561.25) whereas patients with no complications covered a median of 570m (502.5, 630). Table 3.3.

The median preoperative VO_2 Peak was 16.218 mL.kg.min⁻¹ (14.26, 17.85) in the complications group and slightly higher in the non-complications group at 18.050 mL.kg.min⁻¹ (16.5, 19.43). This proved to be a statistically significant difference ($P = 0.017$) in those with higher VO_{2peak} . Table 3.3.

3.12.5 Thirty Seconds Sit to Stand Test

Participants were asked to stand up from a seated position, on a standardised chair height, as many times as possible in 30 seconds, without the use of their hands. There was no significant difference in this variable between the complications and non-complications groups ($P = 0.381$). Table 3.3. Those with complications completed a mean of 14.94 (6.169) sit to stands compared with the other participants who managed to achieve a mean of 16.68 (6.46) stands.

3.12.6 Dynamometry

Participants were asked to grip the dynamometer as tightly as they could, in a standardised arm position, for 3 seconds. The average score was recorded from 3 attempts. There were no significant differences found between the groups in relation to complications ($P = 0.804$). Table 3.3. Median dynamometry scores were similar between groups with the complications groups achieving 60 (53) lbs versus 80 (45) lbs. Of note, median female scores were 55 lbs whilst males were 100 lbs.

3.12.7 ASA Score

This was determined by the assessing Anaesthetist who reviewed each patient at the pre-operative assessment clinic, and the information extracted from the medical chart. The breakdown of participants in each ASA category was as follows: I = 8, II = 29 and III = 6. No one who was categorised as ASA I reported a complication(s). There were similar number in both the complications and non-complications groups who were categorised at either ASA II (15 vs 14) or III (3 vs 3) however.

3.12.8 Bloods

Information was obtained from the hospitals iLab system from bloods extracted at the preoperative assessment. No significant relationships were found between groups in relation to complications and creatinine ($P = 0.281$) or albumin ($P =$

0.117). Albumin levels were very similar between groups (complications, median 38 (37, 38.25), non-complications median 39 (36.5, 40.5) with an overall group mean of 38.43 (2.593). This was similar for creatinine levels (Complications, mean = 80.78 (12.351) and non-complications, mean = 76.44 (13.179). Mean group creatinine levels were 78.26 (12.87). Table 3.3.

3.13 Recovery

Recovery was measured by asking participants “how physically recovered do you feel?” (Onerup *et al* 2015) leaving participants free to interpret what physical recovery meant to them. Recovery was analysed for the group as a whole, between the groups for differences and the trends over time analysed for both the complications and non-complications group.

3.13.1 Total group recovery analysis

Mean total group recovery was 64.3% (27.13%) at 30 days and 82.69% (24.73%) at 60 days which was a statistically significant improvement ($P < 0.001$) Md 75 (25,75). When it was assumed that all patients baseline was 100% physically, significant reductions were found from baseline to 30 days ($P < 0.001$) and from baseline to 60 days ($P < 0.001$).

3.13.2 Recovery analysis between groups

A significant difference was found between not having complications and recovery at one-month ($P = 0.008$) Md 75(62.5, 82.5) but this was not apparent at 2 months ($P = 0.147$) between groups. See Table 3.12

Table 3.12 Median postoperative self-reported recovery levels

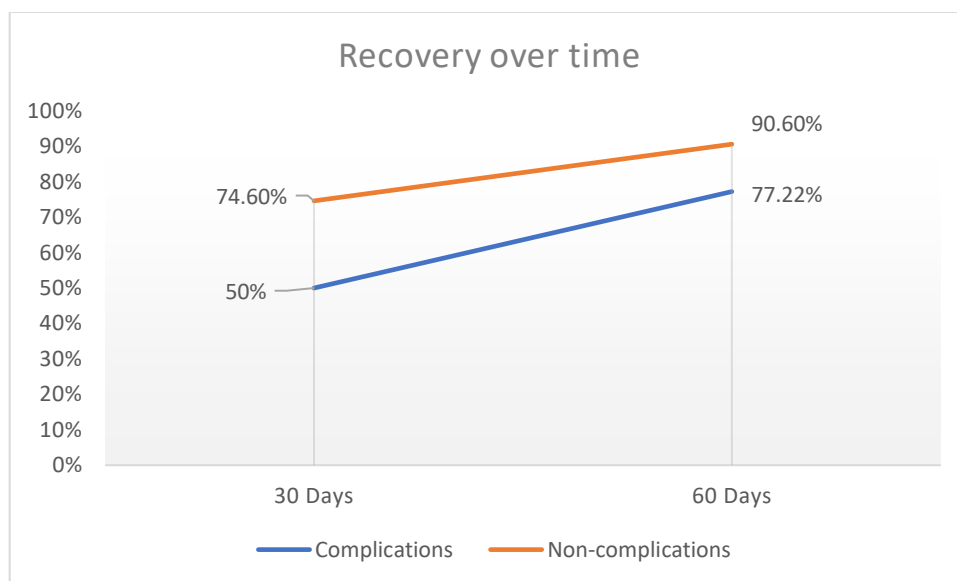
Complications	30 Days	60 Days
Yes	50%	77.22%
<i>Median(IQR)</i>	50(25,75)	82.5 (68.75,100)
No	74.6%	90.6%
<i>Median(IQR)</i>	75 (62.5, 82.5)	100 (75, 100)
Significance	0.008*	0.147

*P ≤ 0.05 was deemed significant in Mann Whitney U tests performed

3.13.3 Split group recovery analysis

Participants who experienced complications took longer to recover according to self-reports. Whilst the recovery levels of both groups increased from the one – two - month time points, those without complications reported higher self-recovery levels. When it was assumed that all patients baseline was 100% physically, statistically significant reduction in recovery were seen from baseline to 30 days and baseline to 60 days in the complications (P < 0.001, P = 0.004) and non-complications (P < 0.001, P = 0.004) groups. However, significant improvements in recovery were seen between 30-60 days in the complications (P = 0.002) and non-complications (P <0.001) groups. See Figure 3.7 and Table 3.13 for further information.

Figure 3.7 Recovery over time – Complications & Non-complications



Data presented as Median figures

Table 3.13 Recovery analysis over time points

	Time Points analysed	Full Group (n=43)	Complications (n=18)	Non-Complications (n=25)
Recovery	T1 – T3	T1 – 100(100, 100) T3 – 75 (50,75) P <0.001*	T1 – 100(100, 100) T3 – 50 (25,75) P <0.001*	T1 – 100 (100,100) T3 – 75 (62.5, 82.5) P <0.001*
	T1 – T4	T1 – 100 (100,100) T4 – 100 (75,100) P < 0.001*	T1 – 100 (100,100) T4 – 82.5 (68.75, 100) P = 0.004*	T1 – 100 (100, 100) T4 – 100 (75, 100) P = 0.004*
	T3-T4	T3 – 75 (50,75) T4 – 100 (75,100) P < 0.001*	T3 – 50 (25,75) T4 – 82.5 (68.75, 100) P = 0.002*	T3 - 75 (62.5, 82.5) T4 – 100 (75, 100) P <0.001*

Data was reported as median and interquartile ratios 25-75

*P<0.05 using Wilcoxon Signed Ranks test to analyse differences between stated time points.

T1 – initial assessment, T3 – 30 days post-surgery, T4 – 60 days post-surgery.

3.14 Summary of main findings

3.14.1 Preoperative Significant Findings

- Significant differences between groups in relation to BMI – complications group obese ($P = 0.005$).
- Co-morbidities significantly different between groups ($P = 0.033$).
- Significant difference in weekly MET minutes between groups pre-surgery ($P = 0.02$)
- Significant differences between the groups in terms of 6MWT ($P = 0.019$) and VO_2 Peak ($P = 0.017$).

3.14.2 Pre-Discharge Significant Findings

- Complication rate of 41.9% pre-discharge.
- Operating time significantly different between groups ($P = 0.05$).
- Increased LOS with presence and severity of complication(s).

3.14.3 30 Days Postoperative Significant Findings

- Significant differences were found between groups in relation to recovery at 30 days ($P = 0.008$).

3.14.4 60 Days Postoperative Significant Findings

- Significant difference in weekly MET minutes between groups at 60 days post-surgery ($P = 0.02$).
- Significant differences were apparent between groups in relation to weekly sitting minutes at 60 days post-surgery ($P=0.03$).

3.14.5 Significant Changes from Preoperative Assessment to 60 Days Postoperative

- Significantly reduced activity for total group from pre-surgery to 60 days post-surgery ($P < 0.001$). 69.78% of people not at baseline activity levels by 60 days.
- Significant reduction in weekly MET minutes in complications group from pre-surgery to 60 days post-surgery ($P = 0.009$) demonstrating a reduction to 31.8% of baseline reported activity. The same was apparent in the non-complications group showing a statistically significant decrease from pre-surgery to 60 days post-surgery ($P = 0.002$) achieving 58% of baseline activity.
- The complications groups showed a significant increase in weekly sitting minutes from pre-surgery to 60 days post-surgery ($P = 0.007$) remaining 54.57% higher than baseline reports.
- Both groups showed a significant reduction in recovery from baseline to 60 days post-surgery.

Chapter 4

4. Discussion

In this study, we found a complication rate of 41.9% in a cohort of 43 participants. When we divided variables into groups based on “complications” versus “no complications” the following significant differences between the groups were found. These were: preoperative obesity, increased presence of preoperative co-morbidities, preoperative shorter walking distances, reduced preoperative VO₂Peak, preoperative self-reported reduced physical activity and sedentary time and longer surgical procedures. Post-operative complication(s) were associated with longer LOS, reduced self-recovery reports at 30 and 60 days, reduced self-reported activity levels and increased self-reported sedentary time.

Whilst the non-complications groups also reported significant reduction in activity and recovery from initial assessment to 60 days post-surgery, these were also significantly different between the groups. Of note, the non-complications group reported near full self-reported physical recovery by 60 days’ post-surgery, but their activity levels remained significantly lower than baseline, with very minimal changes in their sedentary time. It is important to note that although significant differences were found, this does not assume causality as the development of complications is multifactorial.

A unique aspect of this study was the incorporation of simple, quick, functional outcome measures in the preoperative assessment setting, some of which may assist with complication risk prediction which may be transferable to other cohorts. It is the first study to analyse physical self-recovery in colorectal and hernia repairs patients using a quick and simple measure. It adds to the minimal evidence surrounding the impact of complications on physical activity and particularly sedentary time in the postoperative period, in this cohort. It also highlights a number of significant variables that are potentially modifiable pre-operatively which may lead to risk reduction.

4.1 Demographics

In relation to gender, the groups were similar with a 42:58 female to male ratio. Most participants (88.4%) were non-smokers which is considerably lower than the national average of 23% (Department of Health 2015). Participants for the most part (95.3%) reported being independent in their daily lives suggesting they were able bodied enough to be physically active. More than 75% of participants had at least 1 co-morbidity suggesting that this proportion of the group were not in full health compared to the national average of 28% defined as having a long term illness or health problem (Department of Health, Health Ireland, 2015). In relation to BMI, 86% were overweight or obese which is above the national average of 60% (Department of Health, Health Ireland, 2015). The mean BMI of the whole group was also bordering on obese (29 kg/m²) and so may not be representative of national norms (<https://www.bmicalculator.ie/bmi-information/>). In relation to activity levels as measured by the IPAQ, comparing the participants to national norms the following was found: Low 27.9% vs 31%, Moderate 51% vs 37%, High 20.9% vs 32%, Sitting (weekly minutes) 2045 vs 2226 (Department of Health, Health Ireland, 2015). This shows that in relation to low activity and sitting time, the group was broadly representative of a normal population. Overall this was a predominantly overweight/obese group with a high proportion of co-morbidities. In addition, the majority were independent, smoking levels were low and physical activity levels were comparable to normal population levels.

4.2 Complications

4.2.1 Complications Rate

The complication rate was high at 41.9%. This rate was somewhat higher than comparable reviews by Schiphorst *et al* 2015, Zoucas and Lydrup 2014 and Tahiri *et al* 2016 who found a mean complications rate of 33% and 35% in colorectal surgery and general abdominal surgery patients. It is lower than a report by Vonlanthen *et al* 2011 who found 30 day morbidity rates as high as 54.8%, however this was in a colorectal population only. Rates have been reported

between 11-69% but as previously mentioned, comparisons are difficult as many studies did not report this measure using defined complications indexes.

The rate and severity of complications reduced over time from n=18 pre-discharge, n=13 at 30 days and n=9 at 60 days, which would be expected. However of the 13 participants at 30 days who reported complications, 3 of these participants suffered complications post discharge which required re-admission in all cases. Reasons for readmission in these 3 participants were varied including cellulitis, wound breakdown and abdominal collections requiring drainage. This appears to be lower than readmission rates reported by Kassin *et al*, 2012 at 11.3%, but these were general surgical patients. It was not within the remit of this study to decipher why this may have happened. Of note however, all complications had occurred within 30 days, with some participants still receiving treatment for their complications beyond 60 days. A crude cost analysis relating to the 38 nights unplanned care required revealed an extra cost to the hospital of approximately 30,934 euros. This is based on an approximate cost of 813 euros charged to health insurance companies per night in a public room (<https://www.hse.ie/eng/services/list/3/acutehospitals/hospitals/hospitalcharges.html>). Further research with cost analysis is required locally to decipher the true financial cost of complications and analysis of delayed complications.

4.2.2 Complication Types

Many of the participants developed complications such as ileus, hernia repair, delayed wound healing, exacerbation of CCF, emboli and pulmonary infections which reflects research in this area (Kirchoff *et al* 2010, McGillicuddy *et al* 2009, Wolters *et al* 1996, Bosma *et al* 2016, Atalay *et al* 2011, Artinyan *et al* 2008, Longo *et al* 2000, Schiphorst *et al* 2015). Notably, medical complications were much higher than surgical complications in this cohort which may relate to the metabolic, catabolic and inflammatory changes caused by latent surgical stresses, versus initial direct stresses caused by incisions (Finnerty *et al* 2013). This may be in keeping with the work of Sharma *et al* 1996 who reported on the stresses on the circulatory system caused by the creation of a

pneumoperitoneum, especially considering the majority of participants had laparoscopic surgery.

Mortality was expected to be low as it is generally higher in emergency cases (Schiphorst *et al* 2015, Tevis & Kennedy 2013, McGillicuddy *et al* 2009) rather than elective surgeries which were included in the present study. It remains interesting that there were no cases of mortality within the study period of 60 days as the presence of a single complication is known to increase the relative risk by 2.1, which further increases to 7.2 with multiple complications (Tevis & Kennedy 2013).

4.3 Age

Age was not significantly different between groups which may support the theory of Dronkers *et al* 2013, that physiological age, not chronological age may be more important in determining risk association. This adds to the conflicting evidence relating to age as a risk factor (Kirchoff *et al* 2010, Bosma *et al* 2016, Zoucas & Lydrup 2014).

4.4 Gender

Gender was not significantly different between the groups. This is unsurprising as to the best of the authors knowledge, it has not been found to be a risk factor amongst the literature (Kirchoff *et al* 2010, Bosma *et al* 2016, Zoucas & Lydrup 2014).

4.5 Smoking Status

Smoking was not significantly different between groups in this cohort. It must be noted however, that the participants in this study reported lower smoking rates than the national average and so numbers may be limited in order to prove or disprove any relationships with complications.

4.6 Dependence

The participants were generally functionally able to perform ADL's according to their own self reports and no significant relationships were found. A possible reason for this may be that patients were given detailed explanations of the tests that they would be required to participate in and some opted out as they felt unable to do them. Therefore these results can only be extrapolated in people who are independent in their ADL's.

4.7 Body Mass Index

The complications groups mean preoperative BMI classification was obese (31.8 kg/m²) and the non-complications group were classified as overweight (27.5 kg/m²). This was statistically significant between the groups (P = 0.005). These findings echo the results from Dostalík *et al* 2005, Pikarsky *et al* 2002 and Brooks-Brunn 1997 reported that a BMI of >25 kg/m² increased the risk of complications. Brooks-Brunn 1997 found that a BMI >27 kg/m² was associated with PPC's. However, participants in this study had a higher cut off BMI than the previous studies mentioned in relation to the development of complications. Pikarsky *et al* 2002 found similar results to this study, as they also found that the complications group in that study were also in the obese category. This has significant clinical implications as BMI is potentially modifiable using weight loss and exercise programmes and therefore risks may be reduced.

Of note however, nutritional status as measured by the MUST did not appear to be associated with complications. However, it must be noted that the majority of participants were not at risk from an underweight or history of recent major weight loss perspective. This study lacks sufficient numbers to determine if it is associated with complications as per Kirchhoff *et al* 2010 and Zoucas & Lydrup 2014.

4.8 Co-Morbidities

The presence of >2 co-morbidities in this population was found to be significant between the groups ($P = 0.003$). This is in line with previous research in this area (Wolters *et al* 1996, Bosma *et al* 2016, Atalay *et al* 2011, Robinson *et al* 2009) who also reported co-morbidities increased the risk of complication development.

4.9 Surgery

4.9.1 Surgical Type

Complication rates for colorectal, colorectal reversals and hernia repairs were approximately 50% in each of the surgical categories. Colorectal surgeries rates were slightly higher at >50%. Of particular note, participants who underwent cholecystectomies, representing upper GI surgery, did not suffer any complications. A possible solution for these results may lie in the complexity related to each surgery which will be discussed further.

4.9.2 Incision Type

The laparoscopic approach, including assisted and robotic accounted for the majority of incision types used ($n = 38$). More than half ($n = 3$) of the participants who had an open approach suffered complications. Groups were not comparable as numbers were imbalanced between approaches. Despite the laparoscopic approach being proven to reduce morbidity risk, a high rate of complications of 39.47% was still apparent in the laparoscopic approach groups. This is in contrast to the work of Isik *et al* 2015, Tevis and Kennedy 2013 and Sciphorst *et al* 2015. It also contrasts the work of Tahiri *et al* 2016 who found a lower complications rate of 13.5% using a laparoscopic approach. As the rate of complications appears higher in this population, it is possible that other confounding factors may have been associated rather than the surgical approach alone such as surgeon

experience, operating time, surgical complexity and previously mentioned variables influencing complications.

4.9.3 Surgical Grade

There appeared to be a possible trend that surgical grade ≥ 3 may be associated with a higher risk of complications which is reflective of results from similar research in this area (Zoucas & Lydrup 2014). Lower surgical grades showed minimal complications whilst the higher grades showed an approximate 50:50 ratio of complications to no complications in relation to surgeries defined as grade 3 or 4. This data is important as it shows that approximately 50% of those who undergo complex surgeries, are likely to suffer a complication and therefore other variables are likely to impact on the risk of complication development also. It was not possible to perform statistical analysis on this data due to lack of numbers in each category. It must be noted that 30 of the surgeries were graded as ≥ 3 so it is difficult to determine the strength of these results.

4.9.4 Operating Time

Length of surgery was found to be significantly different between groups as related to complications in this cohort ($P = 0.05$). The complexity of the surgery did not appear to be a factor influencing this because as previously discussed, groups were comparable when the surgical grade was ≥ 3 . A possible reason for this may be that surgical grading is quite crude and doesn't account for possible finer complexities such as tumour removal or sheer amount of diseased bowel and therefore the length of time required to perform the surgery. Another possible influencing factor may be the extended physiological stress caused by increased time under general anaesthetic or longer time forming a pneumoperitoneum. Few studies have reported on the length of surgery as an influencing factor but these results mirror those of Atalay *et al* 2011 who found a surgical duration of >60 minutes as a risk in COPD patients.

4.10 Length of Stay

LOS was significantly different between groups ($P < 0.001$) and was substantially higher in the complications group (mean 10 vs mean 2 nights). As previously mentioned, the implication of this would have been increased the financial costs and likely further hospital waiting list delays as projected LOS targets were assumingly not met. This is similar to findings by Zoucas and Lydrup 2014 who reported an almost 80% increase in LOS caused by complications. Vonlanthen *et al* 2011 reported a mean LOS of 11 nights for colorectal patients but this was regardless of complications or not, however this is still higher than this cohort. A potential reason for this is local policy whereby elective patients are pre-assessed for suitability for surgery at an initial outpatient appointment. Historically patients were admitted on the night prior to surgery, whereas now they are admitted on the morning of surgery, thus saving 1 bed night. The pre-assessment session also allows planning for discharge destination and a mobility review in order to minimise other confounding factors which may delay discharge. A review by Kirchoff *et al* 2010 supports our findings in the lack of complications minimising LOS.

4.11 Physical Status Measurements

4.11.1 IPAQ

Total group activity levels reduced significantly from pre-surgery assessment to 30 days ($P < 0.001$) and from pre-surgery to 60 days post-surgery ($P < 0.001$). This equated to 69.77% of the total group reporting worse activity levels at 60 days post-surgery. these figures are much higher than Tran *et al* 2014 who reported 33% of participants had not returned to baseline by 60 days. The difference between these studies is that this study used self-reported activity whilst the Tran *et al* 2014 study used objective measures of activity and function.

A significant difference was found between the groups in relation to the preoperative weekly MET minutes ($P = 0.02$). The complications group had

significantly lower reported weekly METS than the non-complications group. This difference remained when analysing weekly MET minutes at 60 days only ($P = 0.02$).

Both groups reported significantly lower weekly METS minutes at 30 days with significant improvements at 60 days. However, neither of the groups had returned to or were close to baseline weekly MET minutes at 60 days which was significantly worse in the complications group. This equated to the complications group reporting activity levels reaching only 31.83% of baseline and the non-complications group only 58% of baseline figures. This may be related to recovery which will be discussed later.

These results add to the findings of Dronkers *et al* 2013 and Onerup *et al* 2015 who used the LAPAQ and Saltin Grimsby physical activity questionnaire and found them to be useful in correlating complications in abdominal surgery with self-reported physical activity and recovery. To the best of the authors knowledge, this is the first study that has used the short form IPAQ as a measure of physical activity in this study population. The IPAQ may be a more suitable option as the LAPAQ has 31 questions, all of which may not be applicable as they are specific to particular activities which patients may not ever do, whereas the IPAQ has only 4 main questions all relating to exercise intensity regardless of exercise type. The Saltin Grimsby physical activity questionnaire contains only 4 questions also but does not account for sedentary time.

The negative long term implications of these results are potentially immeasurable given the role that exercise plays in relation to prevention and management of various common diseases, mental health disorders and cancers (Pedersen and Saltin 2015, Swedish National Institute of Public Health 2010). This is particularly pertinent if patients never return to appropriate activity levels and therefore increase their risk of disease development, progression or indeed death (Pedersen and Saltin 2015, Swedish National Institute of Public Health 2010). Many of the patients in this study required surgery due to the presence of colorectal cancer where exercise has been proven to reduce the chances of

developing colon cancer, amongst others (cancer.gov). It also has a role in reducing colon cancer specific and all-cause mortality, hence the importance of returning to exercise as a priority in their management (Schmitz *et al* 2010). Physical activity may also positively influence biomarkers in cancer development and inflammatory markers which are associated with cardiovascular disease (Ballard-Barbash *et al* 2012, Gleeson *et al* 2011). Therefore, encouraging return to physical activity may reduce the risk of developing disease or cancer recurrence in the future.

Total group weekly sitting time increased significantly from assessment to 30 and 60 days post-surgery, however this is likely to the complications group skewing data as the non-complications group did not vary their sitting habits significantly. The weekly amount of time spent sitting at 60 days was significantly different between groups as they were similar at baseline and at 30 days with no significant differences found ($P = 0.03$).

The complications group showed a significant upward trend in amount of time spent sitting which did reduce slightly at 60 days, but similar to the METS, had not reached baseline levels and remained significantly increased ($P = 0.007$). This equated to a significant increase in sedentary time from a median of 4.98 hours to 7.5 hours daily in the complications group. In the non-complications group, their median time sitting increased slightly but generally remained stable over the assessment period with no significant changes observed. This is of interest particularly when they reported less activity (METS) but did not appear to change their sitting time, whereas in the complications groups as METS decreased, sitting time increased and vice versa which would be anticipated.

The results mirror similar findings of Feeney *et al* 2011 using an objective measure, an accelerometer, in an oesophageal resection cohort investigating PPC's. Feeney *et al* 2011 also found that patients with PPC's also were less active and spent more time sedentary pre-operatively than those who did not develop PPC's. No follow up activity was recorded and so post-operative results from this study cannot be compared.

The negative effects of sedentary behaviour are becoming more evident which has been linked with the development of type 2 diabetes, cardiovascular disease, some cancers and all cause death (British Heart Foundation 2012, Pate *et al* 2008). As previously mentioned, sedentary behaviour is recognised as one of the biggest risk factors for mortality and morbidity (WHO 2011). Whilst an acceptable amount of sedentary time is yet to be established, prolonged sitting is more damaging than shorter bouts and has been regarded as detrimental even in those who meet the recommended levels of physical activity (Pate *et al* 2008, Garber *et al* 2011). It also has huge financial implication as the estimated cost of inactivity related illnesses stood at approximately £0.9 billion in the UK between 2006-2007 (British Heart Foundation 2012). It is worth noting that these decreases in activity levels and increases in sedentary time are potentially preventable and modifiable possible by education alone.

4.11.2 Pulmonary Function

Spirometry measures for the group as a whole were broadly normal based on their percentage predicted values which is based on their sex, ethnicity, height and age. Spirometry measures were not significantly different between groups.. This may have been due to low number of pulmonary complications (n=5) experienced as both groups were quite similar in terms of predicted spirometry values. This adds to the conflicting data regarding its predictive ability in this population but supports the findings of Silva *et al* 2010 who reported no relationship also. Barisone *et al* 1997 and Gass & Olsen, 1986 reported that having FEV₁ of < 70% predicted and an FVC of <70% related to developing PPC's. These results however are not comparable as both groups mean/median scores were higher than these. Further research may be warranted to investigate the use of spirometry in a larger cohort reviewing pulmonary complications specifically, taking pulmonary co-morbidities into consideration.

4.11.3 Peak Cough Flow

The data for PCF was broadly normal both in the general group and when analysed in relation to the complications and non-complications group. Normal data is regarded as between 240-500L/min in healthy Brazilian adults (Cardoso *et al* 2012). No European data is available currently, to the best of the authors knowledge. There was no significant relationship found relating PCF to complications. Studies are limited for comparison. Whilst Colucci *et al* 2015 found significance in PCF reduction postoperatively in open upper GI patients, this was not measured in this study and so cannot be compared. Further research is required to determine the usefulness of this quick and simple measure.

4.11.4 Six Minute Walk Test

Actual distance covered ($P = 0.019$) and VO_2 Peak ($P = 0.017$), which was extrapolated from this data, were found to be significantly different between groups. These findings are similar to those of Lee *et al* 2013, however they were related to medical morbidity only, whereas these results relate to both medical and surgical morbidity. Previous studies have given a cut of points of <300m as associated with morbidity (Awdah *et al* 2015) and <325m as associated with PPC's (Keeratichananont *et al* 2016). However, the findings of this study show a median of 490m in the complications group which is higher than the previously mentioned studies. It must be noted however, that both of the studies contained a mixed abdominal and thoracic surgery populations. These findings prove that using a quick, simple, standardised measure replicating a functional task is useful in predicting complications in this cohort.

4.11.5 Thirty Second Sit to Stand Test

There was no statistically significant difference between groups for this test. This is similar to the results of Dronkers *et al* 2013 who used the 10 times sit to stand test, a variation of the above. Results of both these studies show that using a sit

to stand as a test, measured by time and repetitions, does not appear useful in predicting complications in this population. A ceiling effect may have been evident and so a modification of the test, repeating the task until fatigue, may be a more useful measure of lower limb strength and endurance.

4.11.6 Dynamometry

It is difficult to determine if data from this study represents normal values as these tend to vary with age and sex. However, based on the mean age of the group being 59 years, they were broadly normal. Normal grip strength for a woman of this age has been found to be 61.7lbs and 99.2lbs for males of the same age (Massy-Westropp et al 2011). Despite the non-complications group having higher median scores, results were not statistically significant between groups. This is in contrast to a review by Sultan *et al* 2012 who found lower measures as associated with increased morbidity, mortality and LOS.

4.11.7 ASA Score

Statistical evaluation was not performed on ASA scores due to lack of numbers for appropriate testing. Numbers were very similar in grades II and III and it is unlikely that differences would be seen. Nobody who was graded as ASA I suffered a complication which could be expected as they would be regarded as healthy individuals but this did only account for 8 participants. This contradicts the work of Wolters *et al* 1996 and Bowles *et al*, 2008 slightly who reported ASA >III as associated with a higher risk of complications. Whilst numbers in this study support that, it must be noted that approximately 50% of those >III did not develop complications.

4.11.8 Bloods

There were no significant differences seen between groups in relation to both albumin and creatinine levels. This contradicts Kirchoff *et al* 2010 but is likely due to the fact that this was an elective cohort and whilst they required surgery, they were not acutely unwell and so deranged bloods would be unusual.

4.12 Recovery

As previously mentioned, the definition of recovery is poorly defined and so participants were simply asked “how physically recovered do you feel?” (Onerup *et al* 2015) Section 1.2.4.2. As expected, those with complications reported significantly lower self-recovery than those without at one month. Both groups showed a significant improvement at 60 days, however, neither group reported feeling 100% recovered. The complications groups’ self-recovery percentage was again lower than the non-complications group. It is worth noting that whilst the non-complications groups neared full recovery at 60 days, their weekly METS had not returned to baseline levels. This finding is supported by Onerup *et al* 2015 also found no relationship between preoperative physical activity and subjective self-recovery measurements. It would be assumed that physical recovery would also include return to baseline activities/function but there appears to be a discrepancy between researchers assumptions and patients perceptions. It is apparent that feeling physically recovered does not necessarily include return to physical activity. The potential issues surrounding poor return to physical activity have been discussed and it is clear that studies need to determine what “physical recovery” actually means to patients and what criteria they must meet themselves to be able to report being physically recovered.

Our results for what appear higher than those of Tahiri *et al* 2016 and Lawrence *et al* 2004 in both groups, however they used physical tests to measure recovery and not self-reports. This may be more pertinent in relating to why weekly MET levels had not reached baseline results by 60 days. These results support

several authors who found significant numbers who did not return to baseline activity regardless of complications such as Tran *et al* 2014.

There are limited studies analysing recovery in this population and a huge limitation is both the subjective and physical definitions of recovery. There appears to be an apparent discrepancy between subjective and objective measures of recovery as what researchers may define as recovered may not match the patients perceptions of recovery.

4.13 Strengths

This is an important study in adding to “real world research” as it was clinically focussed and clinically applicable whereas many trials are often skewed due to strict inclusion and exclusion criteria (Price *et al* 2015). This study’s exclusion criteria only pertained to age <18 years, surgical type and safety factors that limited their ability to participate rather than the use of stringent criteria in some studies. Therefore, it is likely that this cohort is representative of a typical surgical population undergoing the previously mentioned surgeries.

Participation was excellent. Reasons for this may be the fact that testing was done while participants waited to be seen by members of the surgical teams to ensure time efficiency in line with their clinical pathway. It is also worth noting that they were not requested to take any more time from their schedules, as they were due to attend the preoperative assessment clinic anyway. No participants were lost to follow up. The use of subjective reports over the phone, taking approximately 3-4 minutes of their time for each call, meant participants were more likely to answer the phone and continue to adhere and comply. This information is useful for researchers planning studies as many studies are limited due to participant fall out and making study design suitable to work around them in a non-intrusive way may yield better studies and results.

The nature of the study was prospective and designed around a normal clinical pathway which led to better inclusion and patient engagement. Otherwise, the variability in the nature of the patients was taken into account. Although the study

size was small, significant results were still obtained relating to physical function and complications. The study was conducted in a level 4 University hospital, a known centre of excellence, encompassing patients from the large Mid-West area of Ireland, and therefore participants likely represent national prevalence rates. The surgeries performed also reflect common general abdominal surgeries.

The outcome measures used were not time consuming or arduous for the participants as they replicated everyday functional tasks and therefore are clinically applicable in a busy hospital setting. The measures proven to be useful in detecting physical function differences between the groups were time efficient to perform, require minimal training, minimal equipment and low cost to administer. Every effort was made when administering the outcome measures used to standardised instructions and methods. Any complications reported were confirmed from the medical charts. In determining the grade of complication, a doctor was also asked to grade the complications independently, which were consistent throughout. These steps were taken to minimise bias.

As far as the authors are aware, it is the first study to show disparity between self-reports of physical recovery and physical activity in patients who have an uneventful postoperative period.

4.14 Limitations

As previously discussed in the demographics section, the study sample varied from the normal population in relation to smoking status, BMI, presence of co-morbidities. Due to these factors it is difficult to ascertain whether this cohort is representative of an abdominal surgical group as a whole. However, this represented a group who required surgery and so would be expected to deviate from the “normal population”.

Abdominal surgeries consist of a diverse range of surgeries. These results can only be extrapolated in relation to elective colorectal, cholecystectomy and hernia repair surgeries and do not represent all abdominal surgeries. Results are not

transferable to other abdominal surgeries such as vascular, urological, gynaecological, hepatic and gastric.

As the participants self-elected to participate in the study, the study sample may be representative of a more functionally independent population. The six-minute walk test and 30 second sit to stand test were self-motivated as standard cues were given. Therefore participants effort was not measurable and was likely to have varied amongst participants. As self-reported activity measures were used (IPAQ), it was not possible to determine if these were correct, over or under estimated. However, it is likely that any exaggerations were comparable amongst the groups.

The ACSM (Garber *et al* 2011) recommend 150 minutes of moderate or 75 minutes of vigorous intensity exercise weekly which equates to 600 MET minutes weekly. This cohort reported much higher levels than the minimum requirements, however the IPAQ differentiates walking from moderate activity and hence may not be comparable to ACSM recommendations. The IPAQ looks at all daily activity of >10 minutes in a day regardless of intensity and the ACSM does not clarify acceptable sedentary time but does recommend being active versus sedentary where possible.

Convenience non-random sampling was employed in this study which means that the data cannot rely on the probability theory and are therefore prone to bias. Therefore, findings of this study need to be verified by a larger scale observational study. The advantage of using a convenience sample helped generate results to direct future studies. Whilst numbers may seem small in this study, significant results were obtained. It does however mean that there may have been significant differences between groups for some of the insignificant variables, but the numbers were not adequate to detect this.

Participants who underwent colorectal surgeries were involved in the enhanced recovery after surgery protocol (ERAS), however this information was not obtained during data collection and would have been interesting to analyse also.

The study also didn't contain any estimation of the patients experience throughout the study. Future studies should include a qualitative component examining the patient and health care professionals experiences throughout the journey from pre-surgery to recovery and differentiating between those who do experience complications and those who do not.

4.15 Current Trends in Risk Reduction

Recent trends aimed at optimisation of patient care, risk reduction and expediting recovery will be discussed in the following.

4.15.1 Exercise Prehabilitation

The term exercise prehabilitation is used in research to express aerobic and resistance programmes designed at optimising a person's aerobic capacity, with the aim of reducing their risk of complications. It has been found to be effective at reducing complications in intra-abdominal surgeries, but few studies have proven this via randomised controlled trials, hence the data is in its infancy (Moran *et al* 2016, Pouwels *et al* 2014). Boereboom *et al* 2016, in a systematic review deemed there to be a lack of strong evidence to support exercise prehabilitation in patients who undergo surgery for colorectal cancer specifically. The idea of exercise prehabilitation supports the findings of this study as those who were more active, appeared not to suffer complications and so it seems reasonable that programmes that enhance activity pre-operatively would reduce the risk. What remains unclear is what exact type or exercise, intensity and duration is required to be protective. Therefore, whilst this appears to be emerging evidence, more research is needed to prove its effectiveness and the therapeutic doses required.

Exercise prehabilitation may be useful in exposing participants to similar cardiovascular stresses associated with surgery and therefore increase their readiness for the surgery (Plowman & Smith 2013). Exercise also has been proven to have ant-inflammatory effects (Gleeson *et al* 2011, Guinan *et al* 2017) and again may be useful in reducing overall bodily inflammation pre-surgery as

surgical stress will invoke an inflammatory response, as previously discussed in section 1.1.2 (Scott & Miller 2015, Fnnerty *et al* 2015). What may be helpful in relation to this study in linking it with exercise prehabilitation, would be to use the IPAQ as a measurement tool and determine if advice regarding increasing activity preoperatively has an effect and if so to what extent. This would help in determining other factors that affect complications.

4.15.2 Enhanced Recovery After Surgery

Enhanced recovery after surgery (ERAS) protocols use multimodal approaches designed to maximise recovery time after surgical procedures by optimising preoperative organ function and reducing the stress response caused by surgery. Key components of ERAS protocols include preoperative counselling, nutritional optimisation, analgesia standardisation, consistent anaesthetic regimens and early mobilisation (Melynk *et al* 2011). They have been proven to reduce morbidity and LOS in colorectal surgery patients, however do not appear to reduce mortality risk or readmissions (Rawlinson *et al* 2011). In non-colorectal major abdominal surgery, ERAS protocols were found to reduce LOS and financial costs that would be associated with complications (Visioni *et al* 2017). It stands to reason that these protocols are being proven to be successful given that of their aims are to reduce risk by targeting some of the modifiable factors associated with complications and increased LOS.

Whilst these protocols focus on the pre-operative and immediate postoperative period, it may be beneficial to roll this out for longer periods to ensure patients are indeed recovered. As this study shows, many have not physically recovered by 60 days post-surgery, are spending more time sedentary and are less active. Whilst they save bed days and aim to reduce risk of complications, longer term recovery may need to be addressed within these protocols based on these results. This is particularly important given the protective effects of exercise and the longer-term sequelae in preventing and treating many diseases (Pedersen and Saltin 2015, Swedish National Institute of Public Health 2010).

4.16 Anticipated Changes Based on Findings

Based on these findings I would anticipate a change in the scope of practice for Physiotherapist's who are well accustomed to exercise testing and exercise programmes in line with best practice recommendations. They are skilled in both assessment from a musculoskeletal, performance and cardiorespiratory perspective. Their role could be early on in the assessment process for patients in identifying those who are at potential risk of complications and encouraging change of modifiable factors – namely BMI and activity behaviours. This would only be suitable in non-urgent cases but could potentially lead to significant financial, physical and psychological savings in relation to complications. As previously mentioned, patients appear not to return to baseline activity levels and increase sedentary behaviours and so the role could be extended postoperatively with either advice or return to exercise sessions. For their success, it would be important to include these interactions within the normal clinical pathway of the patient.

4.17 Future Research Recommendations

Future studies are required investigating recovery in more detail. This would need to include qualitative and objective measures as there is no clear definition of recovery and patients and clinicians perceptions may be different. It would also be interesting to note if patients deem return to physical activity levels as part of their physical recovery or not. It would also be beneficial to note how long full recovery takes with or without complications, and indeed if full recovery is possible as evidence can be conflicting. In a long term study, it would be of interest to note any disease development or progression based on changes in activity levels due to postoperative complications.

It would be useful to investigate further the length of time it takes patients to recover to baseline activity levels or indeed if this can be achieved. In relation to sedentary behaviour, research would be beneficial to ascertain if patients who

have a complication ever return to baseline sitting time as in this cohort it increased significantly. In line with this, it would be of interest to ascertain if simply giving verbal or written advice post-operatively, at a follow up clinic, would impact on return to physical activity and reduce sedentary behaviours in the longer term.

In terms of measurements, it would be beneficial to test the ability of shorter walking tests, such as the 2 and 3 minute walk test, in replicating the results of this study, as they are less time consuming. It may also be useful to use an externally paced measure such as the incremental shuttle walk test, which would have less of a ceiling effect than the 6MWT.

As previously mentioned regarding the 30 second STS test, a ceiling effect may have been evident and is self-motivated meaning patients can pace their physical exertion. A future study could incorporate the previously mentioned modified STS test to examine its usefulness in determining lower limb strength and endurance. Other possible measures would be to use isokinetics or dynamometry, however global functional movements may be more reflective of an individual's overall abilities.

As far as the authors are aware, no study has been performed examining the ability to influence potentially modifiable risk factors such as activity and BMI, the effectiveness of this and to what extent the risk may be reduced.

Full financial analysis on the cost of complications versus uncomplicated postoperative courses would be worthwhile to study. It would also be helpful to determine the financial savings that may be possible by implementing programmes to influence reversible risk factors such as exercise classes, dietetic advice and education if they were deemed to be effective in risk reduction.

4.18 Conclusion

This study has shown the usefulness of practical, quick and easy outcome measures to measure physical function both subjectively (IPAQ) and objectively (6MWT). Self-reported activity questionnaire (IPAQ) may be beneficial in the pre-

operative setting. A number of factors highlighted as being worse in the complications group may indeed be reversible, such as BMI and physical activity, with the aim of complication risk reduction. Non-modifiable factors that were significantly different between the groups were presence of co-morbidities and surgery length. However, this needs further investigation. LOS is significantly longer when complications are present, thus leading to increased financial costs.

We also showed that physical recovery cannot be assumed and does take significantly longer to improve in people who experience complications. A useful way to measure this was use of a simple question relating to physical recovery, as used in this study. Recovery also appears not to be related to return to baseline activity levels. Worryingly, this study found that regardless of the presence of complications, activity levels reduced significantly and remained reduced at 60 days post-surgery. The presence of complications also significantly increased sedentary time. Whilst this may seem a minor issue at that time point, the “bigger picture” must be looked at. If patients do not return to or achieve at least the minimum activity requirements after a minor or major procedure, we do not know from this study, but it may have longer term effects on health and financially on the health system. It is worth noting that these effects may not become apparent for a number of years, and may not present as surgical problems, and so brief interventions encouraging physical activity during clinic reviews may potentially reverse these potential adverse longer term outcomes.

This study has highlighted numerous modifiable and non-modifiable factors which influence the development of complications and the possible long-term implications of post-surgery reduced physical activity. Returning to the HSE aims for their National Clinical Programme for Anaesthesia in pre-operative assessment (Hepner 2009), section 1.2.8, it appears from these results that we may be able to do more to “optimise patient health before surgery”. This is in conjunction with using these findings in aiming to “reduce morbidity of surgery and length of stay”. Whilst pre-admission units are mainly involved in assessment, they are not usually involved in patient follow up and it appears evident from these results that patients “return to normal function” is perhaps

being overlooked and needs to be addressed in line patients future health prevention and management. A multi-disciplinary approach in both the pre-operative and post-operative settings may be beneficial in increasing activity and maintain function even in patients who do not suffer complications as physical recovery may be slower than anticipated.

Appendices

Appendix I

Literature Search Terms

EMBASE

1. (('Pre-operative' OR 'preoperative' OR presurg* OR 'pre-surg*') NEAR/3 (screen* OR fitness OR 'physical activity' OR 'functional activity' OR 'functional status' OR 'exercise test*' OR exercis*)):ti,ab
2. 'abdominal surgery'/exp OR 'cancer surgery'/exp OR 'elective surgery'/exp OR 'general surgery'/exp OR 'geriatric surgery'/exp OR 'major surgery'/exp OR 'minimally invasive surgery'/exp OR 'esophagus surgery'/exp OR 'colon surgery'/exp OR 'colorectal surgery'/exp OR 'rectum surgery'/exp OR 'thorax surgery'/exp
3. ('colonic resection' OR 'colon resection' OR cystectomy* OR oesophagectom* OR esophagectom* OR 'hernia repair*' OR cholecystectom*):ab,ti
4. (surgery NEAR/4 (abdominal OR abdomen OR 'intra abdominal' OR intraabdominal OR oesophageal OR esophageal OR gastrointestinal OR colorectal OR colon* OR rect*)):ab,ti
5. #2 OR #3 OR #4
6. #1 AND #5
7. 'exercise test'/exp OR 'dynamometry'/exp OR 'pedometry'/exp OR 'spirometry'/exp
8. ('functional performance' NEAR/3 (test* OR evaluation* OR assessment*)):ti,ab
9. (Exercis* OR 'physical activit*' OR endurance OR physiotherap* OR prehab* OR 'physical functioning' OR 'physical fitness' OR 'aerobic capacity' OR 'anaerobic threshold' OR 'resistance training' OR 'muscle strengthening' OR 'oxygen consumption' OR 'aerobic fitness' OR 'cardiorespiratory fitness' OR 'cardiopulmonary fitness' OR 'inspiratory muscle' OR 'Peak cough flow' OR spirometr* OR 'pulmonary function test*' OR 'hand dynamometry' OR 'shuttle walk test' OR 'six minute walk test' OR 'Ten Meter Walk Test' OR 'stair climbing' OR 'Thirty-Second Sit to Stand'):ti,ab

10.#7 OR #8 OR #9

11.#6 AND #10

((('Pre-operative' OR 'preoperative' OR presurg* OR 'pre-surg*' OR 'before surgery') NEAR/3 (screen* OR fitness OR 'physical activity' OR 'functional activity' OR 'functional status' OR 'exercise test*' OR exercis*)):ti,ab OR 'preoperative period'/exp) AND (('abdominal surgery'/exp OR 'cancer surgery'/exp OR 'elective surgery'/exp OR 'general surgery'/exp OR 'geriatric surgery'/exp OR 'major surgery'/exp OR 'minimally invasive surgery'/exp OR 'esophagus surgery'/exp OR 'colon surgery'/exp OR 'colorectal surgery'/exp OR 'rectum surgery'/exp OR 'thorax surgery'/exp) OR ('colonic resection' OR 'colon resection' OR cystectomy OR oesophagectom* OR esophagectom* OR 'hernia repair*' OR cholecystectom*):ab,ti OR (surgery NEAR/4 (abdominal OR abdomen OR 'intra abdominal' OR intraabdominal OR oesophageal OR esophageal OR gastrointestinal OR colorectal OR colon* OR rect*)):ab,ti) AND ('exercise test'/exp OR 'dynamometry'/exp OR 'pedometry'/exp OR 'spirometry'/exp OR ('functional performance' NEAR/3 (test* OR evaluation* OR assessment*)):ti,ab OR (Exercis* OR 'physical activity' OR endurance OR physiotherap* OR prehab* OR 'physical functioning' OR 'physical fitness' OR 'aerobic capacity' OR 'anaerobic threshold' OR 'resistance training' OR 'muscle strengthening' OR 'oxygen consumption' OR 'aerobic fitness' OR 'cardiorespiratory fitness' OR 'cardiopulmonary fitness' OR 'inspiratory muscle' OR 'Peak cough flow' OR spiometr* OR 'pulmonary function test*' OR 'hand dynamometry' OR 'shuttle walk test' OR 'six minute walk test' OR 'Ten Meter Walk Test' OR 'stair climbing' OR 'Thirty-Second Sit to Stand'):ti,ab) AND ('postoperative complication'/exp OR complication*:ti,ab)

EBSCO Medline

(TI (('Pre-operative' OR 'preoperative' OR presurg* OR 'pre-surg*')) N3 (screen* OR fitness OR 'physical activity' OR 'functional activity' OR 'functional status' OR 'exercise test*' OR exercis*)) OR AB (('Pre-operative' OR 'preoperative' OR presurg* OR 'pre-surg*')) N3 (screen* OR fitness OR 'physical activity' OR

'functional activity' OR 'functional status' OR 'exercise test*' OR exercis*) OR (MH "Preoperative Care+") OR (MH "Preoperative Period")) AND ((MH "Surgery, Digestive System") OR (MH "Thoracic Surgery") OR TI ("colonic resection" OR "colon resection" OR cystectomy* OR oesophagectom* OR esophagectom* OR "hernia repair*" OR cholecystectom*) OR AB ("colonic resection" OR "colon resection" OR cystectomy* OR oesophagectom* OR esophagectom* OR "hernia repair*" OR cholecystectom*) OR TI (surgery N4 (abdominal OR abdomen OR 'intra abdominal' OR intraabdominal OR oesophageal OR esophageal OR gastrointestinal OR colorectal OR colon* OR rect*)) OR AB (surgery N4 (abdominal OR abdomen OR 'intra abdominal' OR intraabdominal OR oesophageal OR esophageal OR gastrointestinal OR colorectal OR colon* OR rect*))) AND ((MH "Exercise Test") OR (MH "Exercise Test, Cardiopulmonary") OR (MH "Aerobic Capacity") OR (MH "Anaerobic Threshold") OR (MH "Spirometry+") OR TI ("functional performance" N3 (test* OR evaluation* OR assessment*)) OR AB ("functional performance" N3 (test* OR evaluation* OR assessment*)) OR TI (Exercis* OR "physical activity" OR endurance OR physiotherap* OR prehab* OR "physical functioning" OR "physical fitness" OR "aerobic capacity" OR "anaerobic threshold" OR "resistance training" OR "muscle strengthening" OR "oxygen consumption" OR "aerobic fitness" OR "cardiorespiratory fitness" OR "cardiopulmonary fitness" OR "inspiratory muscle" OR "Peak cough flow" OR spiometr* OR "pulmonary function test*" OR "hand dynamometry" OR "shuttle walk test" OR "six minute walk test" OR "Ten Meter Walk Test" OR "stair climbing" OR "Thirty-Second Sit to Stand") OR AB (Exercis* OR "physical activity" OR endurance OR physiotherap* OR prehab* OR "physical functioning" OR "physical fitness" OR "aerobic capacity" OR "anaerobic threshold" OR "resistance training" OR "muscle strengthening" OR "oxygen consumption" OR "aerobic fitness" OR "cardiorespiratory fitness" OR "cardiopulmonary fitness" OR "inspiratory muscle" OR "Peak cough flow" OR spiometr* OR "pulmonary function test*" OR "hand dynamometry" OR "shuttle walk test" OR "six minute walk test" OR "Ten Meter Walk Test" OR "stair climbing" OR "Thirty-Second Sit to Stand")) AND (TI(complication*) OR AB(complication*) OR (MH "Postoperative Complications+"))

Appendix II

Summary of Articles Reviewed Aligned with Study Objectives

1. Identify postoperative complications related to abdominal surgeries

Author/Year	Aims & research question	Subjects/Setting	Methods	Classification Tool	Surgical approach	Results/ Analysis	Comments
Kirchoff <i>et al</i> 2010	A review to identify and minimise intra and postoperative complications	Elective & emergency colorectal patients	Literature search from 1980 – 2009	Nil commented on	Open and laparoscopic	Identified the following complications: Surgical site infection (SSI) Anastamotic leak, bleeding, ileus.	Summarises main complications and hi-lights influencable and non-influencable risk factors.
Sciphorst <i>et al</i> 2015	Examine the incidence of cardiac and pulmonary complications pre-discharge or within	Colorectal cancer patients	Systematic review of 18 RCT's, 6153 patients	No tool used, complications defined by authors	Open and laparoscopic	Incidence of cardiac complications of 0% for laparoscopic approach and 7% for open approach. Pulmonary	Significantly less cardiac complications with laparoscopic colectomies.

	30 days postoperatively.					complications between 0-11%. Overall morbidity identified between 11-60% and as general vascular, urogenital, neuropsychological, renal and other surgical complications.	
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2. Analyse the costs to the patients and health systems

Author/Year	Aims & research question	Subjects/Setting	Methods	Classification Tool	Surgical approach	Results/ Analysis	Comments
Lawrence <i>et al</i> 2004	Predictors of functional recovery after major abdominal surgery	Elective major abdominal surgery	Prospective study of 372 patients, assessed pre-surgery & 1,3,6 weeks, 3 & 6 months post-surgery.	Nil specific complications tool used. Instrumental activities of daily living (ADL), SF36, Geriatric depression scale. Mini mental state exam (MMSE), timed walk, functional reach & hand grip strength	Open and laparoscopic	At six months post-surgery, the following percentages of study participants had not returned to baseline: ADL's, 9%, Instrumental Activities of Daily Living (IADL) 19%, SF36 16%, the mental component scale of the SF36, 17%, timed walk 37%, functional reach, 58%, and grip strength , 52%.	Disability remains apparent at 6 months post-surgery and many of the potentially modifiable functional outcomes predicted recovery.

Tahiri <i>et al</i> 2016	Estimate the impact of complications on recovery	Elective abdominal surgery- colorectal, incisional hernia repair, hepatobiliary surgery, hernia repair, gastric surgery, splenectomy, small bowel resection & retroperitoneal sarcoma resection.	149 patients' recovery assessed at 1 week, 1, 3 & 6 months post-surgery.	Complications index tool (CIT), the short physical battery (SPPB)	Open and laparoscopic	34.9% complications rate. Higher CIT scores significantly associated with poorer recovery outcomes	The number and severity of complications impacts on physical recovery.
Tran <i>et al</i> 2014	Identification of recovery trajectory of physical activity and health related quality of life (HRQoL) after short stay abdominal surgery	17 elective various abdominal surgeries excluding any head/neck, gynaecological, or perianal surgeries.	132 patients' recovery was assessed preoperatively, at 3 weeks and 2 months post-surgery.	Community Health Activities Model Programme for Seniors (CHAMPS) & SF-36 comparing scores at all 3 timelines. Clavien Dindo Classifications for complications.	Open and laparoscopic	15 patients reported complications. Older age, presence of complication(s), poorer baseline HRQoL or very high baseline activity were less likely to be recovered to	33% of patients have suboptimal recovery even at 2 months post-surgery. The measures used appear useful in measuring recovery in

						baseline scores by 2 months.	this population.
Onerup et al 2015	Evaluate association between pre-operative self-reported activity with postoperative recovery and complications	Elective cholecystectomies.	200 patients assessed pre-surgery & 150 patients completed testing preoperatively and 3 weeks post-surgery.	Saltin-Grimby Physical Activity Level Scale, EQ5d visual analogue scale, return to work and self-reported percentage of physical and mental recovery. Complications not measured.	Open and laparoscopic	Higher chance of return to work within 3 weeks, hospital discharge within 1 day and better mental recovery in those who partook in regular physical activity.	Better preoperative activity levels associated with better outcomes in relation to length of stay (LOS) and recovery mentally and back to work.
Van Cleave et al 2011	Exploration of factors influencing functional status	Patients post cancer surgery – digestive system, genitourinary, thoracic, and gynaecological cancers requiring surgery.	Review of data subsets of 316 community dwelling older adults.	No formal complications measured. Enforced social dependency scale, SF36, symptom distress scale, measured	Open and laparoscopic	Better income and mental health associated with better functional status. Greater number of symptoms and co-morbidities	Factors influencing functional status in the older adult are multi factorial

				post-surgery, and again at 3 & 6 months post-surgery.		associated with poorer functional status. Reports of >3 comorbidities significantly related to poorer functional status.	
Tevis & Kennedy 2013.	Review to explore literature on complications in general surgery & examine their effects on patient centred outcomes,	General surgery	18 studies reviewed on patients who underwent general surgery	Clavien Dindo classification, surgeon defined morbidity, Accordion Severity Grading System	Open and laparoscopic	Complications incidence of 5.8-43.5% reported, mortality incidence of .79 – 5.7%. Frailty, hospital setting and operative approach (open) associated with complications. Complications lead to increased LOS, poorer return to home especially in older adults.	Complications appear to impact on patient centred outcomes but needs further evaluation.

Zoucas & Lydrup 2014	Assessment of financial implications of complications on healthcare resources.	Colorectal surgeries	Retrospective observational study of data from 530 colorectal surgeries.	Clavien Dindo classification	Open and laparoscopic	35% complication rate, median LOS of 9 days without complications and 16 with, increased costs 2.1fold when complication(s) present. BMI >25, obesity, surgery complexity and the surgeon significantly affected chances of complication development. Significant increased costs with complications, complex procedures, re-operation and	Reducing morbidity would significantly impact on financial costs
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						high comorbidity index.	
Vonlanthen et al 2011	Assess the impact of postoperative complications on full inpatient costs per case.	Major surgical procedures. 393 complex liver/bile duct surgeries, 110 pancreas, 289 colon resections, 308 roux-y- gastric bypasses.	1200 cohort study	Clavien Dindo classification	Open and laparoscopic	Dramatic increase in costs with the presence of complications, which increased exponentially with severity in complications grade.	Complications are the strongest indicator of financial costs.
Fuller et al 2009	Estimation of financial costs of potentially preventable hospital acquired complications.	Data from Maryland & California on all hospital acquired complications	278 hospitals data on their reporting systems	64 listed complications types on computer system	N/A as all complications accounted for	>9% increase in costs found when complications were presents.	Costs increase in the presence of complications which are potentially preventable.

Bosma et al 2016	Evaluation of the impact of complications on anxiety & depressive symptoms and health status.	Colorectal patients	218 elective patients assessed preoperatively and at 3 days, 6 weeks and at 1-year post surgery.	Clavien Dindo classification. Centre for epidemiological studies depression (CES-D), State-trait anxiety inventory (STAI) & SF36.	Open and laparoscopic	59.6% complication rate. Complications adversely affected anxiety, depression and health status	Severe complications most significantly affect health status.
Pinto et al 2016	Review to determine the impact of surgical complications on well-being and duration of the impact.	Cardiac, thoracic, abdominal and vascular	50 studies included in the review.	Variable and some undefined	Open and laparoscopic	2/3 of studies found complications were significantly associated with poorer psychosocial outcomes	Patients psychological needs should be better cared for post-surgery & complication.

3. Identify risk factors associated with the development of postoperative complications

Author/Year	Aims & research question	Subjects/Setting	Methods	Classification Tool	Surgical approach	Results/ Analysis	Comments
Wiklund et al 2001	Analysis of the predictive value of metabolic equivalents (METS) in perioperative cardiovascular morbidity and mortality	5939 non-cardiac surgeries including colorectal (n=322), Hernia repairs (n=97) & cholecystectomies (n=199)	METS calculated preoperatively and complications pre-discharge post-operatively	Cardiac complications only – no formal tool used. Duke activity status index. METS calculated using the ACC/AHA guidelines for perioperative cardiovascular evaluation in non-cardiac surgery.	Open and laparoscopic	METS are not a strong predictor of cardiac complications. Age and physical status are more predictive of complications	Cardiac outcomes are more apparent after vascular surgeries.
Feeney et al 2011	Investigate differences between activity levels, pulmonary	37 patients undergoing elective esophagectomy	Cross sectional study. Patients physically tested pre-operatively, and	Set criteria defining a PPC. Spirometry, accelerometry for 4 days.	Not stated	27% incidence of PPC's. significant differences seen between groups	Those who developed PPC's engaged in significantly

	function and body composition in those who do and do not develop postoperative pulmonary complications (PPC's) post-esophagectomy		data relating to PPC's captured post-operatively	Body composition analysis		in relation to sedentary behaviours and time in moderate activity.	less activity and spent more time sedentary and should be targeted preoperatively.
McGillycuddy et al 2009	Identify modifiable risk factors to improve surgical outcomes	Emergency colorectal patients	Retrospective review of 292 patient charts	Complications noted, no formal classification tool used.	Not specified	35% suffered a total of 195 complications, 15% mortality rate. Morbidity associated with shock, renal insufficiency, operating time, abdominal contamination or frank peritonitis.	Emergency surgeries only, so may not have same risk factors as elective patients.

Dronkers et al 2013	Association between physical activity, measurements of fitness and postoperative in hospital mortality, LOS and discharge destination.	Elective major oncological abdominal surgery.	Prospective study of 169 patients preoperatively and mortality information gathered post-surgery	LASA physical activity questionnaire (LAPAQ), hand dynamometry, timed up and go (TUG), sit to stand test (STS) & maximal inspiratory muscle strength. No formal complications classification used.	Open and laparoscopic	LAPAQ was a robust predictor of recovery outcomes.	Pre-operative questionnaire may be useful to help predict postoperative outcomes.
Isik et al 2015	Functional health status (FHS) ability to predict outcomes post colorectal surgery.	Elective colorectal surgeries for malignancy	Retrospective data audit of 25,591 patients charts.	Categorised using the FHS as either independent, partially dependent or totally dependent. Complications names, no formal tool used.	Open and laparoscopic	Significant linear relationships between declining FHS and surgical, infectious, pulmonary, cardiovascular, renal and	FHS significantly associated with complication development.

						neurological complications. Laparoscopic approach associated with reduced LOS, infections and mortality	
Newman et al 2006	Examine relationship between low muscle mass and strength in relation to mortality	Participants within the Health, aging and body composition study.	2292 tested and monitored over a 4.9 year follow up with an average age ranging from 70-79 years	Knee extension strength, grip strength, CT of body composition, DEXA scan and bloods	N/A	Strong relationship between mortality and quads and grip strength.	Strength, not muscle mass is associated with mortality.
Volkalis et al 2015	Investigate the role of muscular strength as a predictor of mortality	23 papers reviewed	Systematic review	N/A	N/A	Inverse and independent relationship found between muscular strength and all-cause mortality	May be useful in surgical population to predict mortality.
Robinson et al 2013	Determine relationship	Colorectal and cardiac surgeries	Prospective cohort study of	Seven baseline frailty traits tested.	Not specified	Positive association	Simple frailty measure

	between pre-operative frailty and postoperative complications		201 patients assessed pre-surgery, and monitored during admission for complications	No formal complications tool used		between preoperative frailty and development of postoperative complications in colorectal and cardiac patients	useful to help risk stratify patients.
Partridge et al 2013	Review definitions of frailty, methods to assess frailty in surgical population and its impact on this population	Older surgical patients	Review paper of available evidence to answer objectives	N/A	N/A	Frailty identified as an independent risk factor for surgical complications. Potential to modify aspects of frailty.	Frailty is potentially modifiable and may improve postoperative outcomes.
Mackary et al 2010	Determine if frailty predicts surgical complications	Elective general surgical patients, >65 years	Prospective study of 594 measured pre-surgery, 30-day complications, LOS and	Frailty measure, NSQIP complications	Not specified		

			discharge destination.				
Wolters et al 1996	Examine the strength of the association between ASA physical status, perioperative risk factors and postoperative outcome.	General surgical and vascular patients	Prospective study of 6301 patients assessed preoperatively and outcomes measured post-surgery.	Complications named, no formal tool used. ASA status.	Not specified	Significant correlation found between ASA score, particularly grades iii and iv, with perioperative variables, postoperative complications and mortality rate	ASA useful in predicting outcomes.

4. Investigate the evidence surrounding physical function assessment methods used to predict complications

Author/Year	Aims & research question	Subjects/Setting	Methods	Classification Tool	Surgical approach	Results/ Analysis	Comments
Lai et al 2013	Identify at anaerobic threshold (AT) of patients previously unable to perform cardiopulmonary exercise testing (CPET)	Elective colorectal surgery	269 patients tested using CPET bike and categorised as wither fit, unfit or unable to perform based on the AT they achieved.	AT, Nil complications tool specified	Open and laparoscopic	AT cut of values were highly predictive of mortality post colorectal surgery. increased fitness levels were associated with reduced LOS.	CPET may be useful in all patient's pre-surgery.
Moran et al 2016	Assess the ability of CPET to predict postoperative outcome	Systematic review of patients who underwent intra-abdominal surgery	37 studies reviewed	N/A	Not specified	Evidence to support CPET testing as a predictor was strong but added that cut off values for protective levels of fitness need to be	Useful tool that can predict post-surgical outcomes.

						established in this population	
Smith et al 2009	Review of predictive value of maximum oxygen consumption (VO_{2max}) and AT in relation to peri-operative morbidity & mortality	Review paper - Non-cardiopulmonary surgery	7 studies reviewed	N/A	Not specified	(VO_{2max}) and AT can predict mortality and morbidity peri-operatively	CPET should be used more frequently to aid risk prediction.
Moran et al 2016	Assess the ability of field exercise tests to predict postoperative outcomes following intra-abdominal surgery	Systematic review	6 full text articles included	N/A	N/A	Incremental shuttle walk test (ISWT) appears to be most superior.	Six-minute walk test (6MWT) and stair climbing require further validation.
Awdeh et al 2015	Determine if the SF-36 and 6MWT are useful predictors of	Elective major surgery including thoracic and upper abdominal surgeries	Prospective study of 117 patients, tested pre-operatively and followed up	Clavien Dindo SF-36, 6MWT, Spirometry, cardiac echo	Not specified	Patients unable to walk >300metres were associated with higher	6MWT may be useful in predicting outcome post

	postoperative morbidity		for 30-day complications			complication rates and LOS.	major surgical procedures
Keeratichananont et al 2016	Determine the 6MWT's ability to predict PPC's in patients undergoing major abdominal and thoracic surgeries	Elective abdominal and thoracic surgeries	Prospective study of 78 patients who were tested pre-surgery and reviewed up to 30 days post-surgery where complications were recorded	6MWT, spirometry, specific stated PPC's in study	Not specified	Patients unable to walk >335metres were associated with higher PPC rates	6MWT cut off available for prediction of outcomes in this cohort.
Moriello et al 2008	Provide evidence for the construct and longitudinal validity of the 6MWT as a measure of postoperative recovery	Elective colon resection patients	Data extracted from a previous RCT. Outcomes measured pre-operatively, 3 and 6 weeks post-surgery	6MWT, ASA, SF-36. No specific tool used in relation to complications	Not specified	6MWT is a valid marker of recovery in this cohort.	6MWT may be useful in both predicting and measuring recovery.
Pecorelli et al 2015	Contribute further evidence for the validity of the 6MWT as a measure of	Elective colorectal surgery patients.	Data taken from 3 previous 174 patients who	CHAMPS and 6MWT performed 4 weeks post-	Open and laparoscopic	6MWT construct validity was proven as a measure of post-operative	6MWT is useful as measure to evaluate

	postoperative recovery after colorectal surgery.		were enrolled in 3 prior RCT's.	surgery. Clavien Dindo		recovery after colorectal surgery.	postoperative recovery.
Nutt & Russell 2012	Use of the shuttle walk test to predict morbidity and mortality after colorectal surgery	Elective, major colorectal surgery	Prospective study of 121 patients. ISWT performed pre0surgery and followed up for 30 days	ISWT No specific tool used to capture complications, complications named	Open & laparoscopic	Significant differences in distance walked between those who developed complications & those who did not. 250m found to have good specificity to predict post-surgical morbidity.	Useful test as a risk prediction tool in this cohort.
Girish et al 2001	Determine of symptom led stair climbing can predict postoperative cardiopulmonary complications	Cardiothoracic and abdominal surgery	Prospective study of 83 patients asked to climb stairs and let their symptoms dictate how many	Complications mentioned, no classification tool used.	Open and laparoscopic	Inability to climb 36 steps was highly predictive of POC's in this cohort. Patients who climbed 7	Useful tool to predict post-operative outcomes.

	(POC) after high risk surgery.		to climb (max 7 flights). Assessed at 30 days for complications			flights had no POC's	
Reddy et al 2015	Determine the value of timed stair climbing to predict perioperative complications	Abdominal surgery patients	Prospective study of 362 patients who underwent a timed stair climb ,up and down 7 steps, and followed up for 90 days in relation to complications	Accordion severity grading system of complications	Open and laparoscopic	Those who had no complications completed the task in an average of 15 seconds whereas the others took an average of 22.9 seconds	A simple test which may be useful in this cohort but may not be suitable for all depending on physical abilities.
Kanat et al 2007	Examination of possible preoperative, intraoperative and postoperative risk factors on the development of early POC's	Elective upper abdominal surgery	Prospective study of 60 patients	Specific named POC's, no classification tool used	Open and laparoscopic	Complications rate of 58.3%. Their findings highlighted significant differences in forced expiratory volume in one second over FVC (FEV ₁ /FVC) when the groups	Detailed chest examination recommended prior to upper abdominal surgery.

						with and without complications were compared. PPC's occurred in 10 (45.5%) of 22 patients with normal PFTs and 25 (68.8%) of 38 patients with abnormal preoperative PFT's.	
Colucci et al 2015	Use of peak cough flow (PCF) to determine cough efficacy post upper abdominal surgery.	Elective upper abdominal surgeries	Prospective study of 101 subjects. PCF and spirometry measure pre-surgery and 1,3 & 5 days post-surgery.	Pre-determined PPC's.	Open	6% rate of PPC's. A significant relationship in PCF reduction compared to preoperative measures on days one (54%) three and five (72%) post-operatively. This was also strongly correlated with FVC on each day	Needs to be tested in lower abdominal surgeries also.

						but not with pain scores	
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5. Examine current guidance in preoperative assessment

Author/ Year	Guidance Document
Mellin- Olsen et al 2010	Helsinki declaration on improving patient safety
National Institute of Clinical Excellence 2003, 2016	The use of pre-operative tests for elective surgery. Updated version.
European Society of Cardiology – Poldermans et al 2009	Guidelines for pre-operative cardiac risk assessment and perioperative cardiac management in non-cardiac surgery.
Hepner 2009	HSE National Clinical Programme for Anaesthesia
AAGBI (2010)	Safety Guideline: <i>Pre-operative assessment and preparation of the patient. The role of the anaesthetist.</i>

Appendix III

Ethics Approval Letter



Ospidéal na hOllscoile, Luimneach
University Hospital Limerick

Quality & Patient Safety Department,
University Hospital Limerick
Dooradoyle
Limerick.

Tel: 061 482519
Fax: 061 482920

20th May, 2016.

Ms. Mary Flahive,
Senior Physiotherapist,
University Hospital Limerick,
Dooradoyle,
Limerick.

Re/ Protocol Title
Can Pre-Operative Functional Activity Screening Predict Morbidity and Recovery in Patients Undergoing Abdominal Surgery – A Prospective Study?

Dear Ms. Flahive,

The Research Ethics Committee at the University Hospital Limerick has received a submission for ethical approval for the above study.

The following documents were reviewed and approved by the Research Ethics Committee:

Application to the Research Ethics Committee	Approved
ASA Score	Approved
Letter to Participants	Approved
Patient Information Leaflet	Approved
Consent Form	Approved
Pulmonary Function Tests	Approved
Peak Cough Flow	Approved
Six Minute Walk Test	Approved
The 30 Seconds Sit to Stand Test.	Approved
Hand Held Dynamometry	Approved
MUST Score	Approved
Short IPAQ	Approved
Classification of Complications	Approved
Telephone Questions at 30 and 60 day's post-operatively	Approved
Telephone IPAQ	Approved
Physical Recovery	Approved

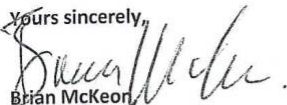
Ospidéal na hOllscoile, Luimneach
University Hospital Limerick

Quality & Patient Safety Department,
University Hospital Limerick
Dooradoyle
Limerick.

Tel: 061 482519
Fax: 061 482920

From an insurance perspective, please note that cover does not extend to those parties not employed by the Health Service Executive (HSE), or non-HSE Institutions unless working under a Principal Investigator who is a HSE employee in a site covered under the Clinical Indemnity Scheme.

Yours sincerely,



Brian McKeon

Planning, Performance & Business Information Manager.

(For and on behalf of the Research Ethics Committee & the QPS Department).

Appendix IV

Letter to Participants & Patient Information Leaflet

Department of Physiotherapy,
University Hospital Limerick,
St. Nessian's Road,
Dooradoyle,
Limerick.

Tel: 061 482151

Date:

Research Title: Can pre-operative functional activity screening predict morbidity and recovery in patients undergoing abdominal surgery- a prospective study.

Principle Researcher: Mary Flahive, Senior Physiotherapist.

To Whom It May Concern:

My name is Mary Flahive and I am conducting research, in conjunction with your Surgeon and Anaesthetist, in relation to people's exercise and activity levels before surgery in order to evaluate how this impacts on complications that may occur afterwards and also how fast you recover after the surgery. I am formally asking you to consider participating in this trial in order to help improve outcomes for patients.

Participation would involve the following:

- Attendance at your scheduled pre-operative assessment appointment.
- Consenting to participate in the trial.
- Approximately fifteen minutes extra of your time to do some questionnaires, a short walking test and a cough strength test.
- Allowing me to call you at thirty and sixty days after your operation for a quick questionnaire which should take no more than five minutes of your time.

If you are willing to participate, I will meet you in the clinic. Please bring comfortable shoes if you choose to participate.

If you choose not to participate, no pressure will be placed on you to do so and this will not affect your treatment in any way.

Thanking you for your consideration of participation in this study. I am happy to clarify any further information you may have regarding this study.

Warm regards,

Mary Flahive

Senior Physiotherapist



Patient Information Leaflet

Can pre-operative functional activity screening predict morbidity and recovery in patients undergoing abdominal surgery- a prospective study.

Principal Investigator's Name: Mary Flahive
Principal Investigator's Title: Senior Physiotherapist
(University Hospital Limerick)
Telephone No. of Principal Investigator: 061 482151

You are invited to take part in a research study about physical activity and functional screening before your operation, which is being carried out in the pre-operative assessment clinic in conjunction with the Physiotherapy Department at University Hospital Limerick. The purpose of this information leaflet is to give you all the information you need to help you to decide if you would like to take part in the study and to make sure that you know what is involved.

You are not obliged to take part in this study and if you decide not to take part this will not affect your treatment in any way. Likewise, if you decide to take part now, and then change your mind later on, this is also fine and will not affect your treatment in any way.

Before you decide to take part, you should read this information leaflet carefully and if you wish, discuss it with your family, friends or doctor. You can also ask the researcher questions about the study.

WHY ARE WE DOING THIS STUDY?

We are doing this in order to find out if we can predict complications such as chest infections for instance, in patients after abdominal surgery by looking at their activity and fitness levels before surgery. We would also like to know if this has an impact on how long it may take you to recover after your operation.

WHO IS ORGANISING THIS STUDY?

Mary Flahive, a Senior Physiotherapist in University Hospital Limerick is carrying out this study with Dr. Julie Broderick in Trinity College Dublin and the Anaesthetic team at the pre-operative clinics in the University Hospital Limerick. Your Surgeon will be aware if you are participating in the study.

HOW WILL THE STUDY BE CARRIED OUT?

The study will start in May 2016 and continue until June 2017. All patients who are planned to have abdominal surgery will be asked to participate.

WHAT WILL HAPPEN TO ME IN THE STUDY?

While you attend your clinic appointment, Mary Flahive will ask you to give your consent to participate in the study. If you agree, she will ask you to do a short walking test, a 30 seconds sit to stand test, a hand dynamometry (grip) test, a cough test and a short questionnaire on your activity levels. This should take no more than 15 minutes of your time. You will also be contacted at 30 and 60 days after your operation via telephone to repeat the activity questionnaire, ask you about your recovery and if you have had any complications.

WHAT OTHER TREATMENTS ARE AVAILABLE?

If you decide not to take part in the study, this will not affect your current treatment.

BENEFITS:

You will be given information in relation to your test results versus others of a similar age, height and weight.

RISKS:

There are no anticipated risks associated with any of the testing. You will be given clear instructions and supervised at all times by an experienced physiotherapist in a safe environment.

WHAT IF SOMETHING GOES WRONG IN THE STUDY?

If you experience any problems when you are in the study or if we discover any health issue, Mary Flahive will be responsible for contacting your General Practitioner (GP) and Consultant to inform them.

WILL THERE BE ANY COSTS INVOLVED?

There will be no cost incurred to any participants in the study.

WHAT ARE YOUR RESPONSIBILITIES AS A PARTICIPANT

As a participant in the study it is important that you follow the instructions provided to ensure your safety. You should also tell the physiotherapist about any changes in your health that may affect your ability to participate.

WHAT ARE THE RESEARCHER'S RESPONSIBILITIES TO YOU

The researcher, Mary Flahive, should be professional and courteous at all times, and conduct the study in the manner approved by the Ethics committee.

CONFIDENTIALITY ISSUES

Your Consultant will be aware that you are participating in the study. The research physiotherapist will look at your medical chart and will place a copy of your consent form in the chart.

Your results will be coded; this means your name will not appear on the assessment forms. Mary Flahive will have access to this code. The study records will be kept in a safe secure location at the Physiotherapy Department in

University Hospital Limerick, and the computer records will be stored on a password protected computer. The information will be destroyed after 5 years. We may contact you again following the study to see how you are, but this has not yet been decided.

IF YOU NEED MORE INFORMATION

If you have any other questions about the study you can contact the main researchers:

Mary Flahive, Physiotherapy Department, University Hospital Limerick.
Phone number: 061 482151

Appendix V

Consent Form



CONSENT FORM

Protocol Title:

Can pre-operative functional activity screening predict morbidity and recovery in patients undergoing abdominal surgery- a prospective study.

Please tick the appropriate answer.

I confirm that I have read and understood the Patient Information Leaflet dated _____ attached, and that I have had ample opportunity to ask questions all of which have been satisfactorily answered.

Yes No

I understand that my participation in this study is entirely **voluntary** and that I may withdraw at any time, without giving reason, and without this decision affecting my future treatment or medical care.

Yes No

I understand that my records may be viewed by individuals with delegated authority from _____

Yes No

I understand that my identity will remain confidential at all times.

Yes No

I am aware of the potential risks of this research study. **Yes** **No**

I have been given a copy of the Patient Information Leaflet and this Consent form for my records. **Yes** **No**

FUTURE USE OF ANONYMOUS DATA:

I agree that I will not restrict the use to which the results of this study may be put. I give my approval that unidentifiable data concerning my person may be stored or electronically processed for the purpose of scientific research and may be used in related or other studies in the future. (This would be subject to approval by an independent body, which safeguards the welfare and rights of people in biomedical research studies - the University Hospital Limerick Ethics (Medical Research Committee.)

Yes **No**

Patient

Signature and dated

Name in block capitals

To be completed by the Principal Investigator or his nominee.

I the undersigned have taken the time to fully explain to the above patient the nature and purpose of this study in a manner that he/she could understand. I have explained the risks involved, the experimental nature of the treatment, as well as the possible benefits and have invited him/her to ask questions on any aspect of the study that concerned them.

Signature:

Name in Block Capitals:

Qualification:

3 copies to be made: 1 for patient, 1 for researcher and 1 for hospital records.

Date:

Appendix VI

Data Collection Sheet

Code Number							
DOB							
Age							
Weight- current							
Weight 3-6 months ago							
Sex							
Height							
Co-morbidities							
Smoking status Y/N							
BMI							
Self reported function - I/A/D							
Planned Surgery							
Planned date of surgery							
Pulmonary Function Tests	FVC	VC		FEV1	PEFR		
		FEV1/FVC					
Peak Cough Flow							
6MWT	Metres		Predicted		% Pred		VO2 Peak
Sit-Stand	Reps						
Dynamometry	lbs						
ASA Score							
MUST Score							
IPAQ	METS		Mins sitting weekly				

Albumin						
Creatinine						
Surgical Grade						
Post Op						
Surgery						
Incision		Open		Lap		Lap assisted
Surgery date						
OT hours						
Analgesia		PCA		PCEA		Oral
Complications		Type		Grade		
Discharge Date						
30 Day Review						
IPAQ						
Self Recovery		%				
Complications		Type		Grade		
Follow up required		Y/N		Who		
60 Day Review						
IPAQ						
Self Recovery		%				
Complications		Type		Grade		
Follow up required		Y/N		Who		

Appendix VII

Charleston Co-Morbidity Index (Charlson *et al* 1994)

Score	Condition
1	Myocardial infarction (history, not electrocardiogram changes only) Congestive heart failure Peripheral vascular disease (including aortic aneurysm >6cm) Cerebrovascular disease: Cardiovascular accident with mild or no residual deficits of transient ischaemic attack Dementia Chronic pulmonary disease Connective tissue disease Peptic ulcer disease Mild liver disease (without portal hypertension, includes chronic hepatitis) Diabetes with end-organ damage (excludes diet controlled alone)
2	Hemiplegia Moderate or severe renal disease Diabetes with end organ damage (retinopathy, neuropathy, nephropathy or brittle diabetes) Tumour without metastases (exclude if ≥ 5 years from diagnosis) Leukaemia (acute or chronic) Lymphoma
3	Moderate or severe liver disease
6	Metastatic solid tumour AIDS (not just HIV positive)

NOTE: For each decade >40 years of age, a score of 1 is added to the above score.

Appendix VIII

Pulmonary Function Tests – Miller et al 2005

1. Patients will be positioned in standing with the device in their hands and a nose clip on.
2. They will be instructed that they will be asked to do each manoeuvre 3 times.
3. Initial instruction will be “ take as big a breath as you can, when you’re ready to exhale, place the device between your lips and blow out all the air in your lungs until they feel completely empty. Take the device out of your mouth before you take another breathe in. I will tell you when its time to repeat this again”.
4. The patient will be instructed to begin and will be encouraged until they take the device out of their mouth by saying “keep going, keep going, keep going.”
5. The same instruction will be repeated twice.
6. They will then do the next manoeuvre with instruction “ As before, take a as big a breath as you can place the device between your lips and this time blow as hard and as fast as you can, until you feel there is no air left in your lungs. Take the device out of your mouth before you take another breathe in. I will tell you when its time to repeat this again”.
7. The patient will be instructed to begin and will be encouraged until they take the device out of their mouth by saying “keep going, keep going, keep going.”
8. The same instruction will be repeated twice.
9. Results will be printed and noted – FEV1, FVC and PEFR.

Appendix IX

Peak Cough Flow – O Callaghan et al 2014

1. Place the participant in a sitting position and explain the aim of the test is to test the strength of their cough.
 2. Place the oro-nasal mask on to the peak flow meter and ensure it is set to zero
 3. Place the mask over the patients face and instruct the patient to inhale deeply and cough as strongly as possible.
Return the pointer to zero and repeat twice more.
 4. Record the highest score.
-

Appendix X

Six Minute Walk Test – American Thoracic Society Statement 2002

1. Repeat testing should be performed about the same time of day to minimize intraday variability.
2. A “warm-up” period before the test should not be performed.
3. The patient should sit at rest in a chair, located near the starting position, for at least 10 minutes before the test starts. During this time, check for contraindications, measure pulse and blood pressure, and make sure that clothing and shoes are appropriate
4. Pulse oximetry is optional. If it is performed, measure and record baseline heart rate and oxygen saturation (SpO₂) and follow manufacturer’s instructions to maximize the signal and to minimize motion artifact. Make sure the readings are stable before recording. Note pulse regularity and whether the oximeter signal quality is acceptable.
5. Have the patient stand and rate their baseline dyspnea and overall fatigue using the Borg scale
6. Set the lap counter to zero and the timer to 6 minutes. Assemble all necessary equipment (lap counter, timer, clipboard, Borg Scale, worksheet) and move to the starting point.
7. Instruct the patient as follows:

***“The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You will probably get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able.*”**

You will be walking back and forth around the cones. You should pivot briskly around the cones and continue back the other way without hesitation. Now I'm going to show you. Please watch the way I turn without hesitation.

Demonstrate by walking one lap yourself. Walk and pivot around a cone briskly.

“Are you ready to do that? I am going to use this counter to keep track of the number of laps you complete. I will click it each time you turn around at this starting line. Remember that the object is to walk AS FAR AS POSSIBLE for 6 minutes, but don't run or jog.

Start now, or whenever you are ready.”

8. Position the patient at the starting line. You should also stand near the starting line during the test. Do not walk with the patient. As soon as the patient starts to walk, start the timer.

9. Do not talk to anyone during the walk. Use an even tone of voice when using the standard phrases of encouragement. Watch the patient. Do not get distracted and lose count of the laps. Each time the participant returns to the starting line, click the lap counter once (or mark the lap on the worksheet). Let the participant see you do it. Exaggerate the click using body language, like using a stop- watch at a race.

After the first minute, tell the patient the following (in even tones): ***“You are doing well. You have 5 minutes to go.”***

When the timer shows 4 minutes remaining, tell the patient the following: ***“Keep up the good work. You have 4 minutes to go.”***

When the timer shows 3 minutes remaining, tell the patient the following: ***“You are doing well. You are halfway done.”***

When the timer shows 2 minutes remaining, tell the patient the following: ***“Keep up the good work. You have only 2 minutes left.”***

When the timer shows only 1 minute remaining, tell the patient: **“You are doing well. You have only 1 minute to go.”**

Do not use other words of encouragement (or body language to speed up).

If the patient stops walking during the test and needs a rest, say this: **“You can lean against the wall if you would like; then continue walking whenever you feel able.”** Do not stop the timer. If the patient stops before the 6 minutes are up and refuses to continue (or you decide that they should not continue), wheel the chair over for the patient to sit on, discontinue the walk, and note on the worksheet the distance, the time stopped, and the reason for stopping prematurely.

When the timer is 15 seconds from completion, say this: **“In a moment I’m going to tell you to stop. When I do, just stop right where you are and I will come to you.”**

When the timer rings (or buzzes), say this: **“Stop!”** Walk over to the patient. Consider taking the chair if they look exhausted. Mark the spot where they stopped by placing a bean bag or a piece of tape on the floor.

10. Post-test: Record the post walk Borg dyspnea and fatigue levels and ask this: **“What, if anything, kept you from walking farther?”**

11. If using a pulse oximeter, measure SpO₂ and pulse rate from the oximeter and then remove the sensor.

12. Record the number of laps from the counter (or tick marks on the worksheet).

13. Record the additional distance covered (the number of meters in the final partial lap) using the markers on the wall as distance guides. Calculate the total distance walked, rounding to the nearest meter, and record it on the worksheet.

14. Congratulate the patient on good effort and offer a drink of water.

Normative data was calculated using the equation below for 6MWD (Enright et al 1998) and VO₂ peak was also calculated (Ross *et al* 2010).

Men: 6MWD = (7.57 X height cm) – (5.02 X age) – (1.76 x weight kg) -309

Women: 6MWD = (2.11 x height cm) – (2.29 x weight kg) – (5.78 x age) + 667m

VO₂Peak mL.kg.min⁻¹ = 4.942 + (.023 x 6MWD)

Appendix XI

The 30 seconds sit to stand test - Rikli RE, Jones CJ (1999).

The 30 second chair test is administered using a folding chair without arms, with seat height of 17 inches (43.2 cm). The chair, with rubber tips on the legs, is placed against a wall to prevent it from moving.

The participant is seated in the middle of the chair, back straight; feet approximately shoulder width apart and placed on the floor at an angle slightly back from the knees, with one foot slightly in front of the other to help maintain balance. Arms are crossed at the wrists and held against the chest.

Demonstrate the task both slowly and quickly.

Have the patient practice a repetition or 2 before completing the test.

If a patient must use their arms to complete the test they are scored 0.

At the signal “go,” the participant rises to a full stand (body erect and straight) and then returns back to the initial seated position.

The participant is encouraged to complete as many full stands as possible within 30 seconds. The participant is instructed to fully sit between each stand.

While monitoring the participant’s performance to ensure proper form, the tester silently counts the completion of each correct stand. The score is the total number of stands within 30 seconds (more than halfway up at the end of 30 seconds counts as a full stand). Incorrectly executed stands are not counted.

The 30 second chair stand involves recording the number of stands a person can complete in 30 seconds rather than the amount of time it takes to complete a pre-determined number of repetitions. That way, it is possible to assess a wide variety of ability levels with scores ranging from 0 for those who cannot complete 1 stand to greater than 20 for more fit individuals.

Appendix XII

Hand held dynamometry – American Society of Hand Therapists statement on grip strength (Schechtman & Bhagwant 2002)

The tool:

- A. Grip strength should be measured using a calibrated dynamometer.
- B. The second rung of the classic dynamometer is the recommended handle position. If a different rung is used (e.g., for large hands) it should be noted and justified.
- C. The dynamometer's dial should be turned away from the client as no visual or auditory feedback should be provided regarding the score.
- D. The examiner should gently support the base of the dynamometer.

Standard position:

- A. The patient should be seated with the arm adducted at the side.
- B. The elbow should be flexed to 90°, the forearm should be in midprone (neutral), and the wrist should be positioned at 15-30° of extension (dorsiflexion) and 0-15° of ulnar deviation.

Procedure:

- A. The average of three repeated trials should be used as the test score. An exception is a painful grip, when a single trial may be reliable in some cases.
- B. Grip duration should be at least 3 seconds and until the dynamometer's dial drops.
- C. A rest period of at least 15 seconds should be provided between grip repetitions, which may be achieved by alternating hands.
- D. A practice trial should be given and standard instructions should be used, such as:
“ This test will tell me your maximum grip strength. When I say go, grip as hard as you can until I say stop.”

Appendix XIII

Short IPAQ - www.ipaq.ki.se

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the vigorous activities that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ days per week

No vigorous physical activities Skip to question 3

2. How much time did you usually spend doing vigorous physical activities on one of those days?

_____ hours per day

_____ minutes per day

Don't know/Not sure

Think about all the moderate activities that you did in the last 7 days. Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those

physical activities that you did for at least 10 minutes at a time.

3. During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ days per week

No moderate physical activities Skip to question 5

4. How much time did you usually spend doing moderate physical activities on one of those days?

_____ hours per day

_____ minutes per day

Don't know/Not sure

Think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?

_____ days per week

No walking Skip to question 7

6. How much time did you usually spend walking on one of those days?

_____ hours per day

_____ minutes per day

Don't know/Not sure

The last question is about the time you spent sitting on weekdays during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the last 7 days, how much time did you spend sitting on a weekday?

_____ hours per day

_____ minutes per day

Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

Appendix XIV

Protocol for IPAQ Short Form – “Guidelines for the data processing and analysis of the International Physical Activity Questionnaire” available from www.ipaq.ki.se

Scoring the IPAQ

Walking MET-minutes/week = 3.3 * walking minutes * walking days

Moderate MET-minutes/week = 4.0 * moderate-intensity activity minutes * moderate days

Vigorous MET-minutes/week = 8.0 * vigorous-intensity activity minutes * vigorous-intensity days

Total physical activity MET-minutes/week = sum of Walking + Moderate + Vigorous MET- minutes/week scores.

Category 1 Low

This is the lowest level of physical activity. Those individuals who not meet criteria for Categories 2 or 3 are considered to have a ‘low’ physical activity level.

Category 2 Moderate

The pattern of activity to be classified as ‘moderate’ is either of the following criteria:

a) 3 or more days of vigorous-intensity activity of at least 20 minutes per day
OR

b) 5 or more days of moderate-intensity activity and/or walking of at least 30 minutes per day OR

c) 5 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum Total physical activity of at least 600 MET-minutes/week.

Individuals meeting at least one of the above criteria would be defined as accumulating a minimum level of activity and therefore be classified as ‘moderate’.

Category 3 High

A separate category labelled 'high' can be computed to describe higher levels of participation. The two criteria for classification as 'high' are:

- a) vigorous-intensity activity on at least 3 days achieving a minimum Total physical activity of at least 1500 MET-minutes/week OR
- b) 7 or more days of any combination of walking, moderate-intensity or vigorous-intensity activities achieving a minimum Total physical activity of at least 3000 MET-minutes/week.

Sitting Question in IPAQ Short Form

The IPAQ sitting question is an additional indicator variable of time spent in sedentary activity and is not included as part of any summary score of physical activity. Data on sitting should be reported as median values and interquartile ranges. To-date there are few data on sedentary (sitting) behaviours and no well-accepted thresholds for data presented as categorical levels.

Appendix XV

ASA Score – NICE 2016

- I. Patient is a completely healthy fit patient.
 - II. Patient has mild systemic disease.
 - III. Patient has severe systemic disease that is not incapacitating.
 - IV. Patient has incapacitating disease that is a constant threat to life.
 - V. A moribund patient who is not expected to live 24 hours with or without surgery.
 - VI. Patient is brain dead
-

Appendix XVI

MUST score - http://www.bapen.org.uk/pdfs/must/must_full.pdf

<http://www.bapen.org.uk/screening-and-must/must-calculator> was used to calculate the score and categorise the patients risk status.

The 5 'MUST' Steps

Step 1

Measure height and weight to get a BMI score using chart provided. *If unable to obtain height and weight, use the alternative procedures shown in this guide.*

Step 2

Note percentage unplanned weight loss and score using tables provided.

Step 3

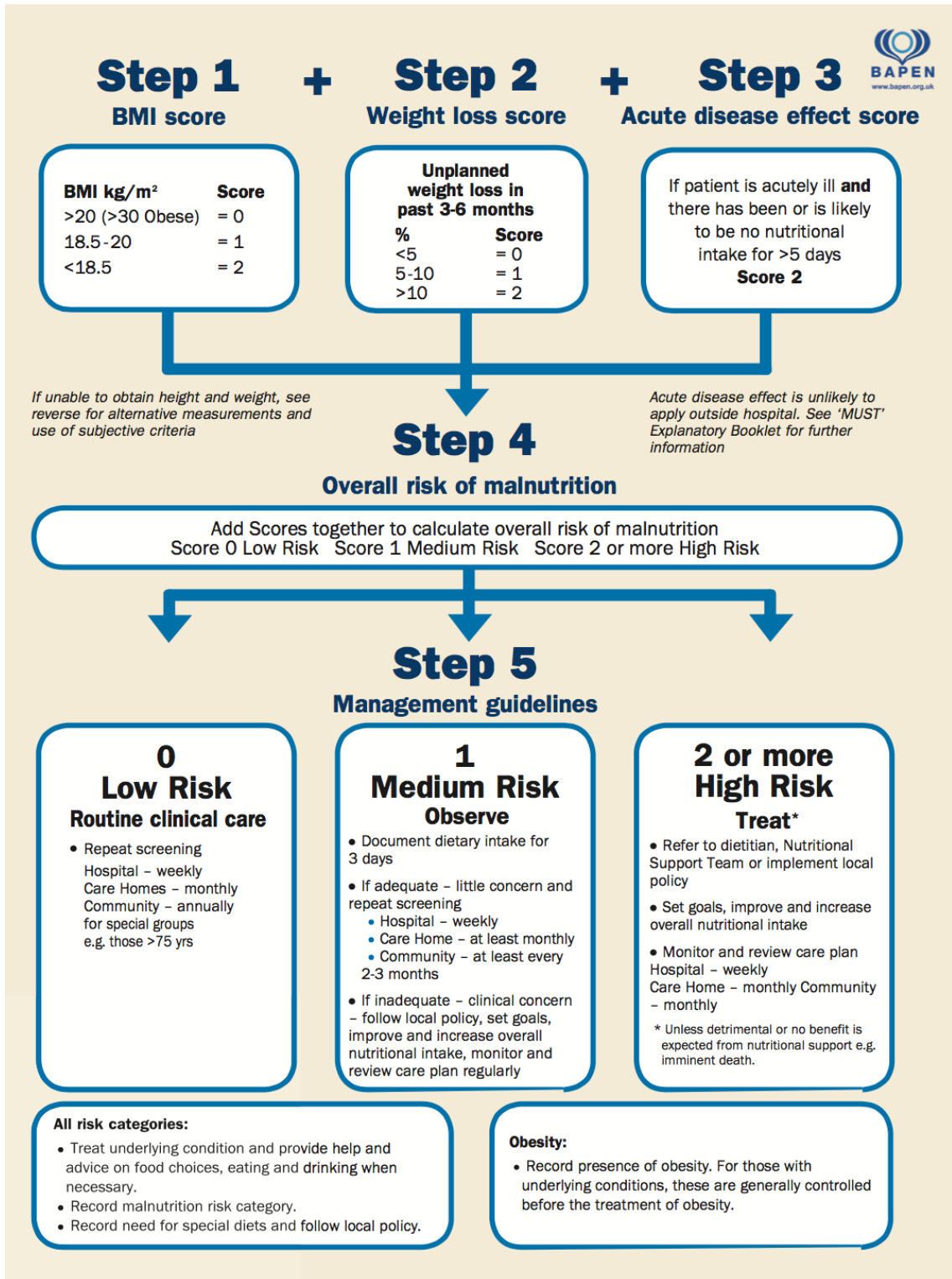
Establish acute disease effect and score.

Step 4

Add scores from steps 1, 2 and 3 together to obtain overall risk of malnutrition.

Step 5

Use management guidelines and/or local policy to develop care plan.



Appendix XVII

Classification of complications – Dindo et al 2004.

Grade 1 included minor risk events not requiring therapy (with exceptions of analgesic, antipyretic, antiemetic, and antidiarrheal drugs or drugs required for lower urinary tract infection).

Grade 2 complications were defined as potentially life-threatening complications with the need of intervention or a hospital stay longer than twice the median hospitalization for the same procedure. Grade 2 was divided into 2 subgroups based on the invasiveness of the therapy selected to treat the complication; grade 2a complications required medications only and grade 2b an invasive procedure.

Grade 3 complications were defined as complications leading to lasting disability or organ resection.

Grade 4 complication indicated death of a patient due to a complication.

TABLE – Surgical Complications

Grade

Grade I Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions

Allowed therapeutic regimens are: drugs as anti-emetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside

Grade II Requiring pharmacological treatment with drugs other than such allowed for grade I complications.

Blood transfusions and total parenteral nutrition are also included

Grade III	Requiring surgical, endoscopic or radiological intervention
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU management
Grade IVa	Single organ dysfunction (including dialysis)
Grade IVb	Multiorgan dysfunction
Grade V	Death of a patient
Suffix “d”	If the patient suffers from a complication at the time of discharge (see examples in Table 2), the suffix “d” (for “disability”) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

*Brain hemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks. CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.

Appendix XVIII

Telephone questions at 30 and 60 day's post operatively.

1. "Have you had any minor complications since your operation which have caused you to attend your GP?"
 - a. If yes, "what was the complication?"
 - b. "How was this managed?"

 2. "Have you had any complications since your operation that have caused you to attend the hospital – either via accident and emergency or the consultant's clinic?"
 - a. If yes, "what was the complication?"
 - b. "How was this managed?"
-

Appendix XIX

Telephone IPAQ - www.ipaq.ki.se

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

Short Last 7 Days Telephone IPAQ

READ: I am going to ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

READ: Now, think about all the *vigorous* activities which take *hard physical effort* that you did in the last 7 days. Vigorous activities make you breathe much harder than normal and may include heavy lifting, digging, aerobics, or fast bicycling. Think only about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities?

_____ Days per week
Don't Know/Not Sure

[**Interviewer clarification:** Think only about those physical activities that you do for at least 10 minutes at a time.]

[**Interviewer note:** If respondent answers zero, refuses or does not know, skip to Question 3]

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ Hours per day
_____ Minutes per day
Don't Know/Not Sure

[Interviewer clarification: Think only about those physical activities you do for at least 10 minutes at a time.]

[Interviewer probe: An average time for one of the days on which you do vigorous activity is being sought. If the respondent can't answer because the pattern of time spent varies widely from day to day, ask: "How much time in total would you spend **over the last 7 days** doing vigorous physical activities?"

_____ Hours per week

_____ Minutes per week [VWMIN; Range: 0-6720, 9998, 9999]

Don't Know/Not Sure

READ: Now think about activities which take *moderate physical effort* that you did in the last 7 days. Moderate physical activities make you breathe somewhat harder than normal and may include carrying light loads, bicycling at a regular pace, or doubles tennis. Do not include walking. Again, think about only those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities?

_____ Days per week [

Don't Know/Not Sure

[Interviewer clarification: Think only about those physical activities that you do for at least 10 minutes at a time]

[Interviewer Note: *If respondent answers zero*, refuses or does not know, skip to Question 5]

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

- _____ Hours per day
- _____ Minutes per day
- _____ Don't Know/Not Sure

[Interviewer clarification: Think only about those physical activities that you do for at least 10 minutes at a time.]

[Interviewer probe: An average time for one of the days on which you do moderate activity is being sought. If the respondent can't answer because the pattern of time spent varies widely from day to day, or includes time spent in multiple jobs, ask: “What is the total amount of time you spent over the **last 7 days** doing moderate physical activities?”

- _____ Hours per week
- _____ Minutes per week
- _____ Don't Know/Not Sure

READ: Now think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

- _____ Days per week
- _____ Don't Know/Not Sure

[Interviewer clarification: Think only about the walking that you do for at least 10 minutes at a time.]

[Interviewer Note: If respondent answers zero, refuses or does not know, skip to Question 7]

6. How much time did you usually spend **walking** on one of those days?

- _____ Hours per day

_____ Minutes per day
Don't Know/Not Sure

[Interviewer probe: An average time for one of the days on which you walk is being sought. If the respondent can't answer because the pattern of time spent varies widely from day to day, ask: "What is the total amount of time you spent walking over **the last 7 days?**"

_____ Hours per week
_____ Minutes per week]
Don't Know/Not Sure

READ: Now think about the time you spent sitting on week days during the last 7 days. Include time spent at work, at home, while doing course work, and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television.

7. During the last 7 days, how much time did you usually spend **sitting** on a **week day?**

_____ Hours per weekday
_____ Minutes per weekday
Don't Know/Not Sure

[Interviewer clarification: Include time spent lying down (awake) as well as sitting

[Interviewer probe: An average time per day spent sitting is being sought. If the respondent can't answer because the pattern of time spent varies widely from day to day, ask: "What is the total amount of time you spent **sitting** last **Wednesday?**"

_____ Hours on Wednesday
_____ Minutes on Wednesday
Don't Know/Not Sure

Appendix XX

Physical Recovery – Onerupp et al 2015

Subjects were asked “to what extent do you feel physically recovered?”. Answer categories were:

1. Not applicable, I don't feel recovered at all
 2. I feel recovered up to 25%
 3. I feel recovered up to 50%
 4. I feel recovered up to 75%
 5. I feel completely recovered
-

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