

**Assessment and Optimisation of
Wearable Activity Monitors within an
Enhanced Recovery Framework**

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Submitted for degree of Doctor of Philosophy

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DECLARATION OF ORIGINALITY

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Abstract

Enhanced recovery after surgery (ERAS) is a model of care that aims to improve patient recovery after surgery. Wearable activity monitors (WAMs) have the potential to provide possible solutions to a wide range of clinical challenges. The aim of this thesis was to assess whether physical activity, measured by a WAM, can be used as a measurable marker of peri-operative well-being and recovery after surgery, and whether the WAM can therefore be used to assess and help improve recovery after surgery.

A wrist-worn WAM was utilised to measure physical activity in a healthy normal cohort showing that it was feasible to monitor continuous physical activity in a healthy cohort in a free-living environment. Activity data were processed both at an individual level and as a group allowing further analysis and comparator with the surgical patient cohort. The WAM was used to measure objective physical activity data for a cohort of patients undergoing colorectal surgery. Activity was assessed pre-operatively at home, post-operatively on the in-patient ward and then on discharge home back into the community. The physical activity data gave insight into patients' baseline function and their progression and recovery following their surgical procedure, with more detailed analysis showing the WAM's ability to reflect the daily activities on the ward. There were statistically significant correlations between peri-operative physical activity and post-operative outcomes.

The results from the use of WAMs within this thesis provide an opportunity for refining the ERAS concept through continuous, objective physical activity monitoring as well as the potential to enhance patient/clinician communication, leading to more personalised care and an improvement in post-operative outcomes.

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List of Acronyms

A&E	Accident and Emergency
ACSM	American College of Sports Medicine
AHA	American Heart Association
BMI	Body Mass Index
CE	Conformité Européenne
CHAMPS	Community Health Activities Model Program for Seniors
COPD	Chronic Obstructive Pulmonary Disease
CRP	C-Reactive Protein
CSV	Comma Separated Values
CT	Computed Tomography
DVT	Deep Vein Thrombosis
e-AR	Ear-worn Activity Recognition Sensor
ECG	Electrocardiogram
EE	Energy Expenditure
EMBASE	Excerpta Medica DataBase
EORTC	European Organisation for Research and Treatment of Cancer
ERAS	Enhanced Recovery After Surgery
EU	European Union
FCS	Fatigue Consequence Score
GENEA	Gravity Estimator of Normal Everyday Activity
GI	Gastrointestinal
GP	General Practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HDU	High Dependency Unit

IMU	Inertial Measurement Units
iOS	iPhone Operating System
ITU	Intensive Therapy Unit
LOS	Length of Stay
LPA	Light Physical Activity
MDT	Multi-Disciplinary Team
MEMS	Microelectromechanical Systems
MESH	Medical Subject Headings
MET	Metabolic Equivalent of Tasks
MRI	Magnetic Resonance Imaging
MRSA	Methicillin-Resistant Staphylococcus Aureus
MVPA	Moderate Vigorous Physical Activity
NHANES	National Health and Nutrition Examination Survey
NHS	National Health Service
NOTES	Natural Orifice Transluminal Endoscopic Surgery
NRES	National Research Ethics Service
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
OMGui	Open Movement Graphical User Interface
PAL	Positional Activity Logger
PCA	Patient-Controlled Analgesia
PE	Pulmonary Embolism
POD	Post-Operative Day
PRISMA	Preferred Reporting Items for Systematic Review and Meta-analyses
PROMS	Patient Reported Outcomes
QOL	Quality of Life
QLQ	Quality of Life Questionnaire
RCT	Randomised Controlled Trial

ROC	Receiver Operating Characteristic
RTC	Real-Time Clock
SAGES	Society of American Gastrointestinal and Endoscopic Surgeons
SD	Standard Deviation
SF-36	Short Form 36 (Questionnaire)
SILS	Single Incision Laparoscopic Surgery
SVM	Signal Vector Magnitude
TAP	Transversus-Abdominis Plane
THA	Total Hip Arthroplasty
TV	Television
UK	United Kingdom
USA	United States of America
USB	Universal Serial Bus
VO2	Volume of Oxygen
VTE	Venous Thromboembolism
WAM	Wearable Activity Monitor

Chapter 1

Introduction

Many patients undergo surgical management, whether in the elective or emergency setting, for medical conditions and problems. Recovering from these procedures, back to baseline pre-operative levels, depend on many factors including patient pre-operative baseline, the procedure itself, patient physiology and post-operative course, as well as follow-up and support post-operatively. Clinicians are always striving for ways to help improve the patient recovery process and emerging technologies that monitor patient activity could provide a platform to monitor this recovery, as well as being used to improve it.

Enhanced Recovery after Surgery (ERAS)

Enhanced Recovery After Surgery (ERAS) was a concept initially proposed by Kehlet¹ who explored the possible factors of post-operative morbidity in the late 1990s. He identified several peri-operative aspects which needed to be recognised and treated to reduce surgical stress and its effects on the patient. He also supported the idea of clinicians working as a multidisciplinary team (MDT) using a multi-faceted framework. This has led to the formulation of standardised protocols that are formulated from a series of interventions that span a patient's entire journey through the surgical process. There are specific interventions in each of the pre-operative, intra-operative and post-operative phases.

The first specialty to implement ERAS, around the early 2000s, was colorectal surgery. Early studies with cohorts of patients undergoing elective colorectal surgery proved feasibility and demonstrated the benefits of shorter length of hospital stay, reduced post-operative ileus and fewer cardiopulmonary complications compared with standard care^{2,4}. ERAS was subsequently shown

to be feasible and safe in the emergency colorectal setting, leading to shorter length of stay and faster recovery of bowel function within this setting as well⁵.

The 2018 consensus review of ERAS guidelines for colonic surgery, the fourth updated guideline written by the ERAS society, examined the evidence base for each ERAS intervention and provided graded recommendations⁶. Though given strong recommendation grading, not all the interventions have high levels of evidence for their efficacy. Minimally invasive surgery is one element that has been strongly recommended with a high level of evidence for oncological outcomes and moderate evidence in terms of patient recovery.

Table 1.1 An example of a generic ERAS protocol⁷

Pre-operative	Intra-operative	Post-operative
Pre-admission counselling	Short acting anaesthetic agents	Mid-thoracic epidural anaesthesia
Fluid and carbohydrate loading	Mid thoracic epidural anaesthesia	No Nasogastric tubes
No prolonged Fasting	No drains	Prevention of nausea and vomiting
No/selective bowel preparation	Avoidance of salt and water overload	Avoidance of salt and water overload
Antibiotic prophylaxis	Maintenance of normothermia	Early removal of catheter
Thromboprophylaxis		Early oral nutrition
No Premedication		Early mobilisation
		Non-opioid oral analgesia
		Stimulation of gut motility
		Audit of compliance and outcomes

Minimally invasive surgery within ERAS

Undertaking surgery using the minimally invasive route has been shown to reduce post-operative complications, pain and length of hospital stay⁸⁻¹⁰. There have been a number of recent studies that have studied minimally invasive surgery within an enhanced recovery programme. For example, the LAFA-study¹¹ showed that, within an ERAS programme, laparoscopic surgery significantly shortened length of hospital stay compared with open surgery. Other outcomes were similar, including morbidity, readmission rates and quality of life. The EnROL Trial¹² found a statistically

significant difference between the laparoscopic surgery group compared to the open surgery group for length of hospital stay and the 30-day readmission rate, but no differences between the groups for other secondary outcomes including physical fatigue.

Single incision laparoscopic surgery (SILS) and natural orifice transluminal endoscopic surgery (NOTES) as well as robotic surgery are newer techniques that have emerged. Although in its infancy, SILS has been shown to reduce conversion rate to laparotomy and reduce the length of hospital stay¹³. Robotic surgery has some added advantages over laparoscopic surgery, including the ability for seven degrees of freedom and tremor filtration which could help surgeons performing more demanding surgery, e.g. rectal resections. Robotic surgery has been shown to be both safe and feasible, with short term outcomes comparable to conventional laparoscopic surgery but with a longer operative time and higher costs^{14, 15}. The ROLARR¹⁶ (Robotic versus Laparoscopic Resection for Rectal cancer) trial was a randomised controlled trial (RCT) that compared the benefits of robotic versus laparoscopic surgery. The results showed that there was no significant reduction of risk of conversion to open surgery in robotic versus laparoscopic surgery, and no other short-term benefits either.

Ultimately, both minimally invasive surgery and ERAS have the same aims, to improve post-operative patient outcomes and aid a quicker recovery. Laparoscopic surgery has been shown to improve outcomes both on its own merit, and together with the ERAS multi-modular structure, it can therefore be seen as a significant and integral component to any ERAS protocol.

ERAS as a multi-specialty tool

A wide range of specialties have adopted the ERAS principles for their own procedures and have formulated their own specific protocols and guidelines. The overall concept would include pre-operative, intra-operative and post-operative elements, but the actual interventions and evidence

base are specialty specific. Specialties with similar operative procedures, i.e. those within the lower abdominal/pelvic cavity, tend to have similar elements within their protocols, for example colonic surgery¹⁷ and gynaecological oncology surgery^{18,19} recommend no pre-operative bowel preparation, avoidance of nasogastric tube insertion and use of minimally invasive surgical techniques when expertise is available. Similar recommendations exist for urological surgery²⁰, however use of minimally invasive techniques are not standardised as results for long-term oncological results are still awaited.

The placement of intraperitoneal drains in pancreatic surgery has always been a controversial and highly debated element within ERAS protocols. Traditionally, intraperitoneal drains have been used to help recognise a pancreatic fistula or anastomotic leak after pancreatectomy. This leak of pancreatic fluid can cause erosion of vessels, haemorrhage and sepsis. A recent meta-analysis concluded that those patients without drains had higher mortality but lower overall complications²¹. Current ERAS guidelines recommend early removal of any post-operative drains in patients at low risk of pancreatic fistula, but these recommendations could change as further evidence is highlighted in future studies²². Within bariatric surgery the pre-operative features are thought to be more important for their post-operative benefits, these include pre-operative weight loss, pre-operative exercise and adequate nutritional supplementation²³. Studies have shown that pre-operative weight loss is a positive predictor of post-operative weight loss²⁴. Together with adequately improving known nutritional deficiencies, which are common in obese patients, these elements seem vital additional components to any bariatric ERAS protocol.

Thoracic surgery includes pre-operative respiratory physiotherapy prior to improve exercise capacity and lung function in patients who will lose lung volume after surgery²⁵. Use of pre-emptive analgesia and local anaesthetic infiltration within orthopaedic surgery ensures early mobilisation and increased limb movement^{26,27}.

In all the specialities generic elements are used as a basis for extra specialty guidelines ensuring a comprehensive ERAS protocol for each specific specialty with the intention of improving outcomes and patient recovery within each specialty.

1.1. Clinical Challenges

Barriers to the implementation of ERAS

Despite the evidence of improved post-operative outcomes and recovery, ERAS implementation varies in different centres. McLeod et al²⁸ reported only two of the 18 specific ERAS guideline recommendations reached a compliance rate of greater than 75%. Pedziwiatr et al²⁹ implemented an ERAS protocol over a period of time and found that compliance did gradually increase over time, initial compliance levels were 65%, and these rose to 89.6% by the third cohort. The ERAS Compliance Group found compliance with the ERAS protocol in elective colorectal cancer resections reached 75%, but there were variations between healthcare centres and between the recommendations used³⁰. Compliance with ERAS protocols are associated with improved outcomes and as compliance increases, complications decrease. Laparoscopic surgery and balanced intravenous fluid therapy were shown to be associated with a reduced risk of complications.

Certain recommendations are easier to implement than others, for example if they already form part of routine practice e.g. prophylactic antibiotics, thromboprophylaxis and using minimally-invasive techniques. Some elements are more difficult to implement despite increased efforts²⁹, due to surgeon or anaesthetic preferences, including: no bowel preparation, early urinary catheter removal, no opioids and restrictive fluid therapy. Despite the indication that compliance with ERAS protocols significantly influences post-operative outcomes in a positive manner³¹, it is still difficult to determine which specific recommendations have more of an influence on outcomes

than others. A review by Ahmed et al³² found that some research studies achieved similar post-operative outcomes despite not including all of the recommended ERAS protocol. Furthermore, a systematic review³³ looking at RCTs of ERAS versus standard care was unable to show whether ERAS protocols with more elements were more successful than those with fewer elements.

Factors thought to encourage the implementation of ERAS and improve compliance include engaging the wider MDT and having specific ERAS units, appointing specific ERAS coordinators, specific teaching sessions about the benefits of ERAS and regular auditing^{29, 31, 32}..Given the barriers to implementation of ERAS protocols in full and the difficulty in determining each individual components worth within the protocol, an idea has emerged for each hospital and specialty to design their own protocol which is flexible and can be individualised, adding in components based on their population until more research in the area has been developed^{31, 33, 34}. Whichever recommendation are included it is essential to audit compliance with the ERAS protocol, as well as measure patient outcomes¹⁷.

ERAS outcome measures

The motivation behind ERAS is improving post-operative recovery, and therefore recovery needs to be objectively measured. There are already many outcome measures and the most frequently reported is length of hospital stay³⁵. However, this is a surrogate measure of recovery and is highly influenced by external conditions, for example patients' expectations of discharge date, social or support networks not being in place or even hospital administration issues (inability to process discharge summaries or dispense necessary medications). Furthermore, the patient is often not back to their functional baseline despite meeting the necessary clinical markers required for discharge, e.g. blood tests and physiological observations, since hospital discharge is based on the patient being safe to convalesce in the community. Other clinical outcomes that are used as measures of recovery include thirty-day mortality, thirty-day re-admission and post-operative

complications^{36,37}. These outcomes are often recorded as part of the clinical notes and can be used in conjunction with length of hospital stay. However, they do not offer the day to day recovery of patients, only highlighting patients with major post-operative complications or readmission to hospital, rather than how recovery improves in the long-term.

In the United Kingdom the NHS has asked patients to complete a patient reported outcomes (PROMs) questionnaire after hip replacement, knee replacement, groin hernia and varicose vein surgery. Questionnaires like these measure patients' health status and health-related quality of life at a single point in time, they tend to be completed at two separate time periods; before and after the procedure. This has been introduced to provide an indication of the quality of care being delivered to patients and how patients are affected following the procedure. The questionnaires focus on the patients themselves, how they live in their own environment and their return to normal function. King et al³⁵ assessed the influence of an ERAS protocol on quality of life. A validated QOL questionnaire (EORTC QLQ-C30) was completed by patients undergoing surgery within an ERAS protocol led department and this was compared to a historic control group. There were no statistically significant differences between the two groups in terms of quality of life. Another study measured post-operative fatigue as a long-term outcome to compare ERAS versus conventional care³⁸. Post-operative fatigue levels increased in both groups significantly and reached a maximum level just before patient discharge. However, the ERAS group reached a significantly smaller peak level than those patients in the conventional care group. They also exhibited a significantly smaller Fatigue Consequence Score (FCS) during the first thirty post-operative days. More recently supporters of ERAS have started to focus their research on patient experience³⁹, and qualitative studies have highlighted areas for improvement including post-discharge support and follow-up care in the community⁴⁰.

It is also important to consider the economic potential of ERAS. Studies have shown that

implementing an ERAS protocol is cost effective⁴¹. Recent systematic reviews by Lemanu et al⁴² and Lee et al⁴³ however, highlight that there are few RCTs documenting cost data, and draw attention that there are also inconsistencies in the reporting of cost data. This suggests that there is further for well-designed trials in order to fully determine the true cost-effectiveness of ERAS.

Validated outcome measures are lacking for recovery within an ERAS setting, Neville et al⁴⁴ performed a systematic review that found that multiple different outcome measures are currently in use and they seem to reflect mainly short-term recovery focusing more on the biological and physiological outcomes. The lack of outcome measures in the longer term was highlighted, e.g. few studies report any outcomes after thirty days post-surgery. A suggestion has been made to focus on patients' functional status including physical activity measurement and exercise capacity in the long-term in order to help quantify recovery after surgery more fully. Another review by Feldman et al⁴⁵ suggests that stages of recovery actually overlap and cannot be defined as a single event within a specific time frame. Therefore, different outcome measures would be relevant at different time periods, and no single outcome measure is currently sufficient to quantify total recovery. A different method is therefore proposed, using a set of core outcome measure at each different stage of recovery, which would reflect the different stages of recovery as well as the inputs from each MDT member, including the patient.

One measure of recovery that is poorly represented by current outcome measures is physical activity. This is an important indicator of functional recovery, both in hospital when the patient is on the ward and once they have been discharged home back into the community. There is a potential to fill this gap by providing a means of continual measurement of physical activity in a non-invasive and objective manner.

1.2. Proposed solutions

Technology is now used for a multitude of reasons in the peri-operative period, for example oesophageal Doppler for monitoring fluid balance⁴⁶, pneumatic calf compression to provide thromboprophylaxis⁴⁷ and the use of forced air warming units to maintain normothermia⁴⁸. Furthermore, recent advances in technology have led to the emergence of small, wearable sensors that can measure, store and transmit large amounts of patient and environmental data^{49, 50}. These sensors have been used to objectively and continuously monitor physical activity in the home environment following discharge from hospital⁵¹ and within the hospital setting⁵².

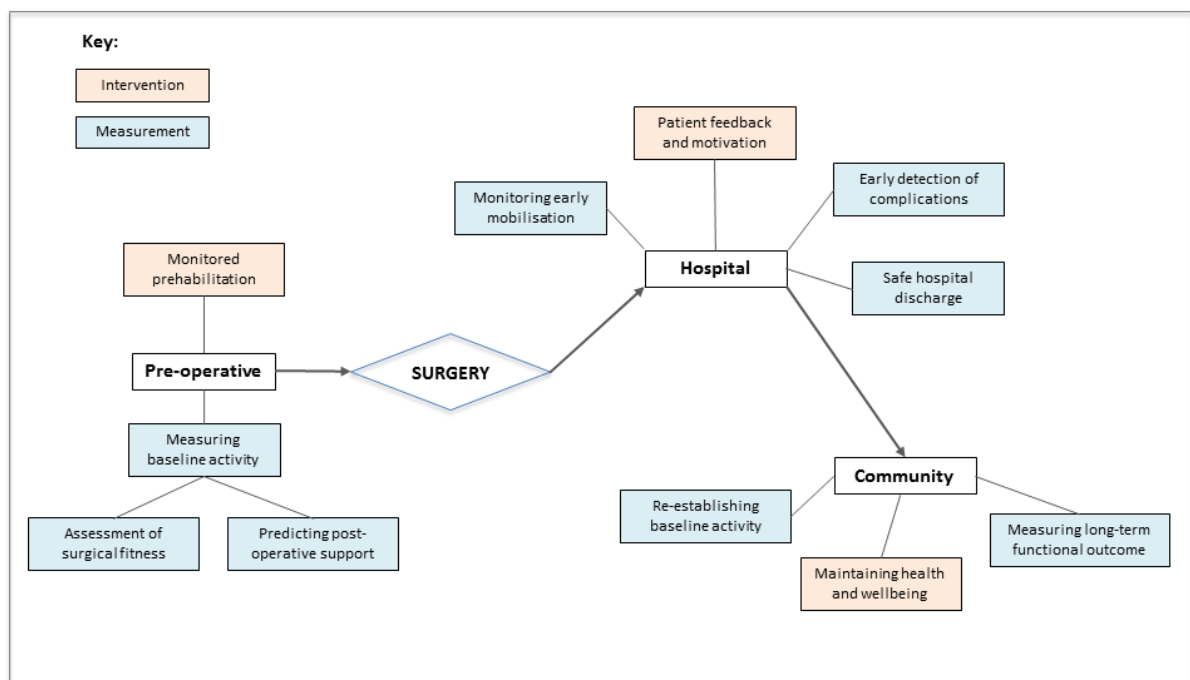


Figure 1.1. Uses of physical activity monitoring in the peri-operative period⁷

Cook et al⁵³ monitored patient steps after elective cardiac surgery and found an association between the number of steps a patient took and their length of hospital stay and post-operative discharge destination. Wasowicz-Kemps et al⁵⁴ measured daily physical activity following laparoscopic cholecystectomy in a controlled study, where advice was given to resume normal

activity quickly following their operation. Sixty four percent of patients took over a week to recover to their baseline daily activity, however, the women in the intervention group resumed normal daily activity more quickly than those in the control group. One study comparing laparoscopic with open distal gastrectomy used an objective physical activity monitor to evaluate post-operative recovery⁵⁵ and showed that patients in the laparoscopic group increased their activity more on each post-operative day. There have also been studies assessing longer-term physical activity monitoring^{56, 57} and these have shown that it is feasible to collect this data and that there are added benefits for longer-term outcomes.

An RCT of young healthy Finnish men⁵⁸ showed that providing feedback on activity levels to participants increased their physical activity. A further RCT which assessed interventions for patients with intermittent claudication⁵⁹ showed that patient who wore a feedback-enabled wearable activity monitor (WAM) improved claudication and walking distance as well as quality of life scores after three months.

This has shown that there is the potential to use sensor technology to enhance and improve the ERAS paradigm, with the potential to improve patient experience and outcomes. Knowledge of a patients' pre-operative activity levels may help correlate their baseline function and wellbeing, which could help indicate what support the patient may require post-operatively on the ward and in the community. Monitoring physical activity in the hospital post-operatively can also help monitor compliance with post-operative mobilisation recommendations, as well as measure inpatient activity, providing an indication of functional recovery and could also help detect and complications. Over time, discretely monitoring physical activity could give useful feedback and long-term outcome measures which truly reflect the patient's recovery in the community⁶⁰. Giving feedback about patient activity to patients both in hospital and in the community may help to encourage them to increase their activity levels, as well as motivate them to be more engaged in

their own recovery and care. Sensor technology could, therefore, help overcome some of the identified barriers to ERAS by assessing and improving patient outcomes and experience throughout the surgical period.

1.3. Thesis overview

Hypothesis - Physical activity is a measurable marker of peri-operative well-being which can be used to assess and optimise recovery within an Enhanced Recovery After Surgery (ERAS) framework.

Chapter 2 - Physical activity and post-operative length of hospital stay: A systematic review

- Hypothesis – There is a relationship between in-patient physical activity and the post-operative outcome measure length of hospital stay.

A systematic review of the relationship between physical activity and post-operative length of stay highlights the close association between recovery after surgery and physical activity, which can be monitored using sensor technology.

Chapter 3 – Wearable Activity Monitors (WAMs): technology and analytical methods

- Hypothesis - Sensor technology is a valid method of assessing physical activity within a healthcare setting.

In this chapter, sensor technology, hardware and data analysis methods are described and reviewed. Sensors within a healthcare setting are compared, specifically sensor types, outputs and analysis methods.

Chapter 4 – Wearable activity monitors (WAMs) in a free-living environment

- Hypothesis – Continuous objective activity using a wearable activity monitor (WAM) is feasible, providing objective physical activity data and insight into daily activity in a normal healthy control cohort.

The ability to monitor the physical activity of a normal, healthy control cohort is shown using a WAM. Different types of activity output are described and analysed showing that using the WAM is a feasible way to continuously monitor physical activity in a free-living environment.

Chapter 5 – Wearable activity monitors in the peri-operative setting

- Hypothesis - Wearable sensor technology to monitor activity in the whole peri-operative period is feasible, showing a decrease in activity following surgery, a small increase on each post-operative inpatient day and greater increase back to baseline once discharged home.

Building on the previous clinical study, the WAM is used to monitor physical activity in patients during the peri-operative period at home, as an inpatient following surgery and recovering at home following discharge. The activity data is assessed, and patterns of activity are investigated. The relationship between activity and clinical input is explored with the potential to individualise ERAS for each patient based on their activity profile.

Chapter 6 – Peri-operative activity and patient outcomes within an enhanced recovery setting

- Hypothesis - Physical activity, as measured by a WAM, correlates with post-operative outcomes, specifically length of hospital stay, after elective colorectal surgery.

Post-operative outcomes and their relationship with peri-operative physical activity are

investigated. Correlation between activity and length of hospital stay, post-operative complications and other outcomes are described. The possibility of peri-operative physical activity predicting patient outcomes is discussed along with the ability to aid clinical management and facilitate early discharge within an ERAS setting.

Chapter 7 – Wearable activity monitors peri-operatively: patient and clinician perspectives

Hypothesis - Patients and clinicians have positive, but differing, opinions on the utility and value of wearable activity monitors to measure physical activity in the peri-operative period.

The final chapter investigates clinician and patient perceptions of wearable technology, with a focus on WAMs, and their role in a healthcare and surgical setting. A mock-up application presenting physical activity data collected was shown to clinicians and patients, and qualitative, semi-structured feedback interviews were used to understand how sensor technology is viewed, as well as its utility and usability within a surgical healthcare setting and as an ERAS tool.

1.4. Original contributions of the thesis

1. Recruited 65 participants to a clinical trial.
2. Piloted the use of a WAM in patients undergoing colorectal surgery and objectively measured physical activity over the peri-operative period including at home following discharge.
3. Evaluated the relationship between objective physical activity data and post-operative outcome measures, showing significant correlation.

The contents of this thesis have resulted in the following publications and conference presentations:

- *Publication:* Abeles A, Kwasnicki RM, Pettengell C, Murphy J, Darzi A. (2017) The relationship between physical activity and post-operative length of hospital stay: A systematic review. *International Journal of Surgery*. 44; 295-302.
- *Publication:* Abeles A, Kwasnicki RM, Darzi A. (2017) Enhanced recovery after surgery: Current research insights and future direction. *World Journal of Gastrointestinal Surgery*. 9(2); 37-45.
- *Conference oral presentation and published abstract:* Abeles A, Kwasnicki RM, Geoghegan L, Pratt P, Darzi A. (2017) Wearable activity sensors: Using physical activity to predict length of hospital stay? Association of Surgeons of Great Britain and Ireland (ASGBI) (Glasgow, UK). *British Journal of Surgery*. 104 (Issue supplement S6): 1-243
- *Conference presentation:* Abeles A, Kwasnicki RM, Geoghegan L, Pratt P, Darzi A. Predicting post-operative outcomes: Utilisation of wearable activity sensors. Poster Presentation. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), Houston, Texas, USA, March 2017

- *Conference presentation:* Abeles A, Kwasnicki RM, Geoghegan L, Darzi A. Enhancing recovery after surgery: Wearable technology and the future. Sowerby eHealth Symposium. London, UK, Sept 2016
- *Conference presentation:* Abeles A, Kwasnicki RM, Darzi A. Physical Activity and Technology in ERAS. Enhanced Recovery after Surgery (ERAS) UK Conference. Edinburgh, UK, Nov 2015

Chapter 2

Physical activity and post-operative length of hospital stay: A systematic review

2.1. Introduction

Recovery from surgery is often quantified using specific outcomes measures from both short and long-term follow up. The most frequently used include complication and readmission rates, re-operation rates, 30-day mortality and morbidity, with the most commonly used measure being length of hospital stay^{36, 44}. Not only are these standardised metrics, these measures are also easily available, do not require any extra contribution from the patient themselves, and are therefore relatively easy to obtain and use. However, patients often only return to their baseline function after the inpatient stay has been completed and can quite often run a varied course⁶¹. A study by Carmichael et al⁶² quantified patient recovery ‘trajectories’ for patients undergoing inguinal hernia surgery, laparoscopic abdominal, open abdominal and thoracic surgery. They found that patients had a significant decrease in steps taken after all types of surgery, and that their recovery to baseline number of steps per day differed depending on their operation type. More recent studies have used quality of life (QoL) questionnaires as surrogate functional outcome measures. These aim to assess at what point in time patients were able to return to their everyday life and function following surgery^{63, 64}. QoL questionnaires, which often detail activities of daily living, offer an insight into physical function but can be subjective⁶⁵.

Physical activity is thought to be an important factor in recovery after surgery, both as a way to reduce post-operative complications, e.g. pneumonia and venous thromboembolism (VTE)¹, and as an indication of functional recovery⁶⁶. Until recently researchers wanting to assess physical

activity have had to use self-reporting questionnaires or physical function tests^{67, 68}. These tests often only assess activity and function at one point in time. Furthermore, self-reporting can be biased or inaccurate and therefore can give misleading results. Daskivich et al⁶⁹ measured patient daily step counts after eight types of inpatient surgical procedure and assessed the accuracy of clinician assessment of activity versus the objective step count. They found that there were substantial variations in step count and surgeon estimates. However, developments in the technology sector have led to the arrival of devices that can measure objective physical activity both unobtrusively and continuously over a longer period of time⁷⁰. These wearable activity monitors (WAMs) are small and light-weight and have been used in a multitude of clinical settings including during the peri-operative period^{49, 52, 71, 72}.

Until now, there has been no agreement in the literature with regard to whether objective physical activity data correlates with the more traditional outcome measures, in particular, length of hospital stay. The benefits to researchers and clinicians in knowing whether accurate objective physical activity data correlate with the more traditional outcome measures currently used, could be sizeable and may provide a way to better understand and enhance patient recovery. It would also help to understand whether wearable activity monitors could be used during the post-operative period and help in detecting patients at risk of a slower recovery, or with possible poorer long-term outcomes, therefore highlighting the need for further clinical support and care at an appropriate stage.

The aim of this systematic review was to determine the relationship between objective physical activity data, measured by wearable activity monitors and length of hospital stay in the acute surgical inpatient setting.

2.1.1. Hypothesis

There is a relationship between in-patient physical activity and the post-operative outcome measure length of hospital stay.

2.2. Methods

2.2.1. Literature search

A systematic review was conducted in accordance with the guidelines for the 'Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA)'⁷³. A literature search was performed using Medline, EMBASE and the Cochrane Library, from inception to January 2017, combining MESH and all-field search terms for “physical activity” AND “accelerometer” AND “postoperative”. Detailed search criteria are presented in the Appendix. The full texts of original articles and relevant reviews were obtained. Additional studies relevant to this review were identified through reference lists.

2.2.2. Inclusion criteria

The search included any study that evaluated patients' physical activity or body movement in the peri-operative period. Studies were only included if body movement was monitored by a wearable activity monitor. Papers were only included if there was physical activity data available for the in-patient stay as well as hospital length of stay data. The search was restricted to articles written in English. RCTs, observational studies and case series were included. Study authors were contacted when extra data or information was required to be able to determine whether the study was eligible for inclusion.

2.2.3. Exclusion criteria

Studies involving children and adolescents were excluded. Studies where physical activity was only measured pre-operatively or just post-operatively in the community were excluded. Studies where sensor equipment was placed on structural equipment only, e.g. on a wheelchair, on furniture or walls were excluded. Conference abstracts and single case-reports were excluded.

2.2.4. Study selection

Two reviewers conducted the literature search and independently reviewed the titles and abstracts to select potentially relevant articles (A.A. and C.P.) and a consensus was reached. Any discrepancies between reviewers were referred to a third reviewer (R.M.K.) before a final decision was made on whether to include that study. Endnote was used to manage the bibliographic searches.

2.2.5. Study quality

The quality of each selected article was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system⁷⁴. The GRADE system classifies quality of evidence into four levels: high, moderate, low, very low. The design of study is evaluated along with evidence of study limitations, inconsistencies, indirectness, imprecision and publication bias⁷⁵. This tool was utilised since it assesses the quality of randomised controlled trials as well as observational studies.

2.2.6. Data extraction

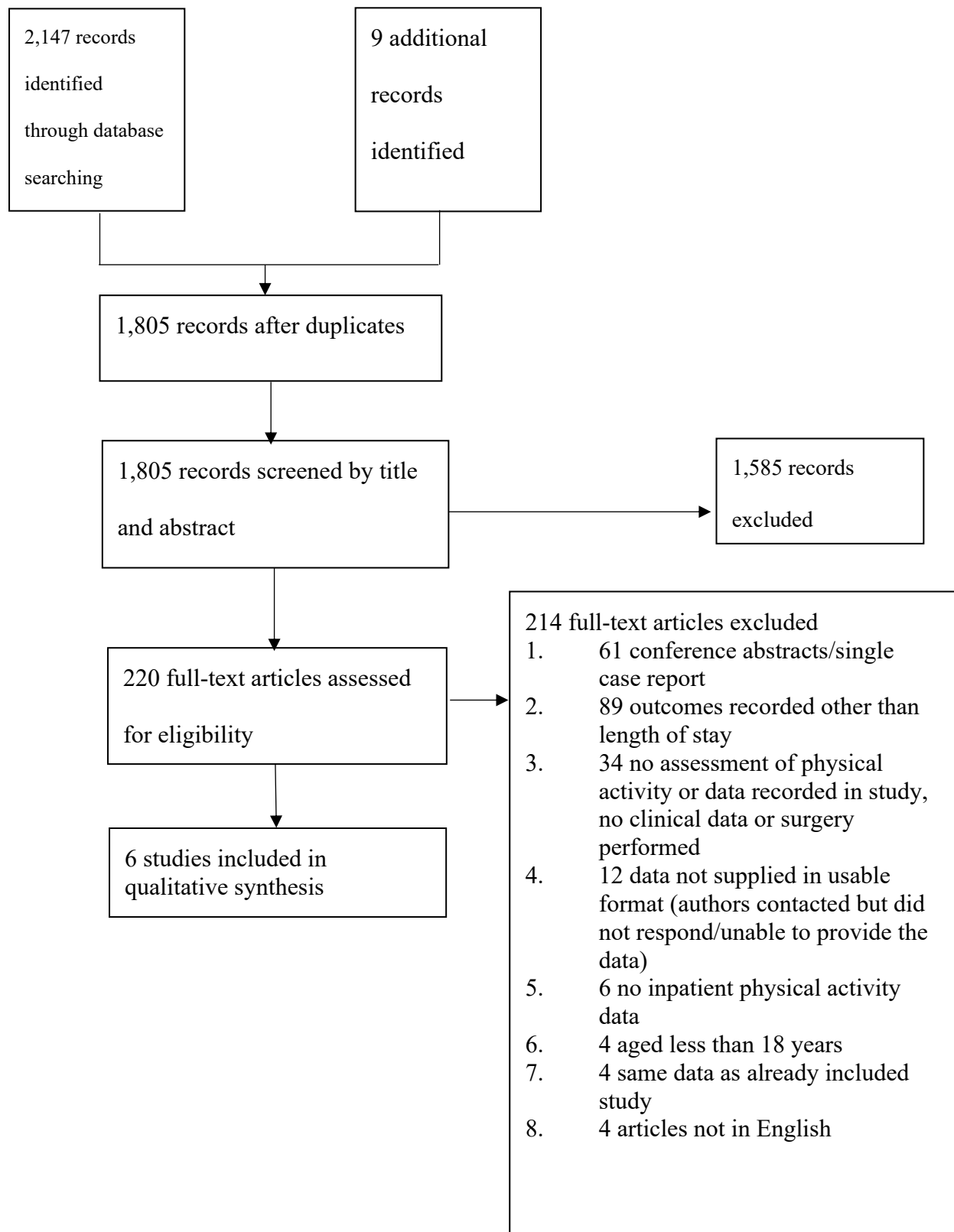
The following data were extracted: (1) study features including study design, number of patients, patient demographics; (2) wearable activity monitor (WAM) details including type of sensor, body placement, length of time sensor worn, sensor output measures e.g. time spent at activity level, Metabolic Equivalent of Tasks (METs) hours, number of steps, energy expenditure; (3) length of hospital stay.

2.3. Results

2.3.1. Search results

Initially 2,147 potentially relevant titles were identified. After removal of duplicates 1,805 titles and abstracts were screened and 1,585 records were excluded. Full texts were obtained for the remaining 220 studies. The inter-rater agreement between reviewers was good (kappa score 0.651, $p < 0.0005$). Eighteen eligible studies were found. Four studies included the full data necessary to meet the inclusion criteria of this review⁷⁶⁻⁷⁹. Authors of the remaining fourteen studies were contacted in an attempt to obtain additional analyses or full data sets. Contact details for authors of two studies could not be obtained^{80, 81}. Of the authors we were able to contact, one provided additional data, but it transpired that no in-patient activity data had been recorded, only out-patient activity, and therefore the study was excluded from the review⁸². Two authors were unable to provide the study data^{83, 84}, two study authors^{85, 86} sent us the extra data needed, while the remaining eight authors did not respond to our communication⁸⁷⁻⁹³. Therefore, six studies were ultimately included in this review (Figure 2.1.).

Figure 2.1. PRISMA diagram for literature search⁹⁴



2.3.2. Study design and quality

The GRADE tool was used to assess study quality and all six studies were rated as low-quality. The low-quality grading was due to the studies all being observational and there being no evidence of a large magnitude of effect as well as a high potential for confounders, which would minimize any effects seen.

2.3.3. Study characteristics

The six studies included in this review were published between 2007-2016 and studied four different types of surgical cohort. Two studies assessed cardiothoracic patient cohorts, two studies enrolled an orthopaedic patient cohort, one study included a general surgical patient cohort (including upper GI, hepatobiliary and colorectal) while one study reported on a vascular patient cohort. Five studies monitored physical activity after elective surgery and one study monitored patient activity after emergency surgery. Of the six studies, five had in-patient physical activity monitoring for the entire cohort, while one study only had in-patient activity data for half the cohort and therefore only those data were included in this review. In total, 343 patients were included in this review, with the largest assessed study having recruited 149 patients. The mean age of participants in all six studies was 68.3 years of age. The characteristics of the study populations are shown in *Table 2.1*.

Authors	Year	Study design	Emergency/Elective	Specialty	Surgery types performed	Number of participants	Age Mean (SD) [Range]	Males N (%)	GRADE quality
Agostini et al ⁷⁹	2014	Prospective observational study	Elective	Cardiothoracics	Pneumonectomy 10 Lobectomy 57 Wedge resection 19 Segmentectomy 4 Exploratory thoracotomy 4 Sleeve resection 4	99	67 (10)	46 (46)	Low
Browning et al ⁷⁶	2007	Prospective observational study	Elective	General Surgery (including colorectal, hepatobiliary and upper GI)	Anterior resection 14 Hemicolectomy 7 Small bowel resection 8 Pancreatic resection 7 Liver resection 4 AP resection 2 Gastrectomy 2 Oesophagectomy 1 Splenectomy 1 Cholecystectomy 2 Reversal of Hartmann's 2	50	61 (12)	29 (58)	Low
Cook et al ⁷⁷	2013	Prospective observational study	Elective	Cardiothoracics	Valvular surgery 43% CABG 32% Valvular surgery and CABG 14% Repair of ascending aortic aneurysm 4% Septal myectomy 5% Other 1%	149	67.8 (9)	98 (67)	Low
Davenport et al ⁷⁸	2015	Prospective observational study	Emergency	Orthopaedics	Femoral intra-medullary nail 3 Cannulated screws 1 Dynamic hip screw 7 Hemi-arthroplasty 3 Total hip replacement 6	20	79.1 (9.3)	2 (10)	Low
Matsuo et al ⁸⁵	2015	Prospective observational study	Elective	Vascular	Aortobifemoral bypass 1 Iliofemoral bypass 2 Femoropopliteal bypass 9 Popliteal-popliteal 1	13	73 [65-81]	11 (85)	Low
Schotanus et al ⁸⁶	2016	Prospective observational study	Elective	Orthopaedics	Total Knee Arthroplasty	10	67 [53-76]	5 (50)	Low

Table 2.1. Study characteristics⁹⁴

2.3.4. Study aims and outcomes

Only one study explicitly stated an aim of determining whether length of hospital stay was associated to physical activity⁷⁶. One study documented physical activity as their primary outcome measure and length of stay as their secondary outcome measures⁷⁸. Four studies mentioned physical activity and length of hospital stay as outcome measures but did not state if they were defined as primary or secondary outcomes^{77, 79, 85, 86}.

2.3.5. Sensor characteristics

Different wearable activity monitors were used in each of the six studies; full WAM details are included in *Table 2.2*. Five of the WAMs were accelerometers (one uni-axial⁷⁸, four tri-axial^{77, 79, 85, 86}), and the sixth study used the Positional Activity Logger (PAL)⁷⁶, a position sensor which uses three mercury tilt switches. Each study used only one WAM per patient and these were attached to the lower limb in four studies (the thigh in three^{76, 78, 86} and the ankle in one⁷⁷), the upper arm in one study⁷⁹ and the waist in the last study⁸⁵. The WAM was worn both pre and post-operatively in two studies^{85, 86}, otherwise monitoring was only undertaken post-operatively. WAMs were worn continuously in five of the studies, but only during waking hours in one study⁸⁶, for a time period ranging from four to seventeen days. In two studies the WAM was worn until day of discharge^{77, 85}, in three further studies the WAM was worn until day four post-operatively^{76, 79, 86} and in the final study the WAM was worn up to seven days post-operatively (or earlier if discharged prior to this)⁷⁸.

Authors	Year	Wearable Activity Sensor (WAM) Name (Manufacturer)	Type of sensor	Number of WAMs worn	Where WAM worn	WAM output	When WAM is worn	Total length of time WAM worn
Agostini et al ⁷⁹	2014	SenseWear Pro 3 (APC Cardio-vascular Ltd, Crewe, UK)	Triaxial accelerometer	1	Upper arm	1. Total steps per day 2. Time spent in activity of differing intensities as defined by METs 3. Energy expenditure	Post-operative days 1 to 4	4 continuous days
Browning et al ⁷⁶	2007	Positional Activity Logger Version 1 (Gorman ProMed Pty Ltd, Australia)	Position sensor via 3 mercury tilt switches	1	Thigh	1. Amount of time spent in upright position (uptime)	Post-operatively for 4 days	4 continuous days
Cook et al ⁷⁷	2013	Fitbit (Fitbit, Inc, San Francisco, CA, USA)	Triaxial accelerometer	1	Ankle	1. Total steps per day	Post-operatively after ITU stay until discharge	5-7 continuous days
Davenport et al ⁷⁸	2015	ActivPal Activity Tracer (PAL technologies Ltd; Glasgow, Scotland, UK)	Uniaxial accelerometer	1	Thigh	1. Total steps per day 2. Time spent lying, sitting, upright, walking 3. Estimate of net energy expenditure	Post-operatively until discharge	7 continuous days
Matsuo et al ⁸⁵	2015	Active Style Pro. HJA-3501T (Omron Healthcare, Japan)	Triaxial accelerometer	1	Waist	1. Total steps per day 2. Daily physical activity - MET's hours per day	2 days pre-operatively until day of discharge	7-17 continuous days
Schotanus et al ⁸⁶	2016	GC dataconcepts LLC, Waveland, USA	Triaxial accelerometer	1	Thigh	1. Total steps per day 2. Time spent lying, sitting, upright, walking	4 days pre-operatively and 4 days post-operatively	8 days during waking hours only

Figure 2.2. Wearable activity monitor characteristics⁹⁴

2.3.6. Physical activity outputs

The outputs of objective physical activity data varied for each WAM and within each study. Most studies presented two or more variables which had been derived from the WAM. No single variable or output was used in all six studies. The most common output used was total number of steps per day, which was reported by five of the studies^{77-79, 85, 86}. Other outputs included time spent taking part in activities of differing intensities^{78, 79, 86}, energy expenditure (EE)^{78, 79} and time spent in an upright position ‘uptime’⁷⁶ or daily physical activity as METs hours per day⁸⁵.

2.3.7. Length of stay and physical activity

Four studies reported a relationship between physical activity levels and length of hospital stay^{76, 77, 79, 85}. Browning *et al.*⁷⁶ demonstrated that the amount of time patients spent sitting upright increased each day over the four post-operative days ($p < 0.001$) and that this ‘uptime’ predicted length of hospital stay ($r^2 = 0.5, p < 0.001$). Cook *et al.*⁷⁷ reported that patients who walked more on their first and second recovery days had shorter hospital stays ($p < 0.05$). Agostini *et al.*⁷⁹ demonstrated that patients who were less active had a significantly longer median post-operative length of hospital stay (6 days vs 5 days, $p = 0.013$). We analysed the raw data received from Matsuo *et al.*’s study⁸⁵ using Spearman’s rank-order correlation, and found a strong negative correlation between length of hospital stay and total number of steps taken on the fourth post-operative day ($r_s = -0.599, p = 0.03$). However, there was no significant correlation between total number of steps taken on any other post-operative day (1-3, 5-7) or METs-hours on any post-operative day and length of stay ($r_s = -0.403 - 0.378, p > 0.05$). We analysed the data from Schotanus *et al.*⁸⁶ using Spearman’s rank-order correlation. This was a small cohort of ten patients and no correlation was found between length of stay and number of steps taken on days one, two or three post-operatively ($r_s = -0.394 - 0.248, p > 0.05$). Davenport *et al.*⁷⁸ concluded that no measures of activity, either total number of steps per day or amount of time spent in different activities, were associated with length of hospital stay ($r = 0.18 - 0.34, p > 0.05$).

2.4. Discussion

This is the first systematic review that explores the relationship between objectively measured physical activity, as recorded by WAMs, in the inpatient post-operative setting and length of hospital stay. This systematic review has identified six studies in both the elective and emergency setting, in cohorts of surgical patients covering multiple surgical specialties. Overall the findings seem to suggest that the amount of physical activity performed whilst an inpatient on the ward following surgery negatively correlates with length of hospital stay. However, a meta-analysis could not be performed due to the heterogeneity of WAMs used, and the outcomes reported.

A systematic review looking at physical activity levels in healthy older adults living at home compared with those who were residing in a healthcare setting showed similar heterogeneity in the type of WAM, and the types the data outputs used⁹⁵. Within these six studies, the most common data variables that were reported were energy expenditure, total time walking and total time in all activity and many of the WAMs reported more than one output variable. A more recent review by Montoye et al.⁹⁶ also highlighted that a wide range of WAMs were used in different studies and that a range of physical activity data outputs were used, cut-points and counts per minute being the most reported. This demonstrates that although our study has heterogenous data, this is a widespread problem in the literature, given there are so many accelerometer devices on the market, and unfortunately there is currently not enough compatibility between the different devices to allow comparison of these multiple different physical activity outputs.

Although only six papers were included in this review, other studies were found in the literature search which did not fit the inclusion criteria, however, they still described activity monitoring in the peri-operative period, and also showed similar heterogeneity to the studies included in this review. Ten out of twenty studies used tri-axial accelerometers^{62, 69, 90, 97-105}, with eleven different WAMs used in total. WAM output included activity counts^{90, 106, 107}, steps^{62, 69, 97, 98, 101-105, 108-110}, energy

expended¹¹¹, time spent upright¹⁰⁸, raw accelerometry data/ cumulative acceleration^{89, 99, 100, 112} and time spent in activity/ activity intensities^{104, 105, 110}. Again, there was no single output measure within these studies, and some studies used multiple output measures. Surgical specialties studied included Cardiothoracics (4), Colorectal (2), Upper GI Surgery (2), HPB (3) Orthopaedics (3), Transplant Surgery (1), Urology (1) and multiple heterogenous cohorts (4). WAM placement varied by study and included ankle, wrist and waist.

WAMS have also been used to monitor patients undergoing laparoscopic and open surgery in some studies comparing these two groups. The laparoscopic group had a shorter length of stay as well as a quicker return to pre-operative activity levels as compared to the open group^{87, 88}. Although these findings are similar to the present study, and suggest a relationship between objectively monitored physical activity and length of hospital stay, there are other recent studies which did not show any significant difference. A study by Basse et al.¹⁰⁶ looking at functional recovery in open, compared with laparoscopic, resections and showed that both groups had a two-day median length of hospital stay with an equally high degree of mobilisation on the first post-operative day. Zutshi et al.⁸⁴ compared a traditional post-operative care protocol to an enhanced recovery/fast-track approach. They did not find any differences in physical activity, which seems to suggest that there may be other factors that are also associated with length of hospital stay other than just levels of physical activity. Furthermore, although length of hospital stay is one of the most commonly used outcome measures following surgery, it is still only seen as a substitute indicator for actual recovery from surgery. There are many factors that can influence length of hospital stay, including the specific operation, and whether it is performed laparoscopically or open, the hospital discharge policy, patient preference, the availability of family and community support on discharge, and lastly, surgeon preference. It is, however, a measure that is easily gathered and is frequently reported in policy, reports and studies, thereby allowing comparisons to be made between clinicians, institutions and regions. Although fitness for discharge would

probably give more evidence about patients' functional recovery, this data is less easily collected and is also subjective in nature. Other, less subjective markers of recovery include the previously mentioned mortality, 30-day re-admission and complication rates. Although these are useful in highlighting shifts in the recovery process, they do not measure functional recovery itself. This is where objective markers of recovery, physical activity levels, could supplant these other, more traditional and subjective markers. Physical activity data could help clinicians and researchers measure recovery from surgery from the moment a patient leaves the operating theatre, continuously whilst an in-patient on the ward prior to discharge, and then up until baseline activity levels are reached back at home in the community.

There are limitations to this review. Only six studies were included, all of which were low quality according to the GRADE tool. Three of the studies, which showed little or no correlation between physical activity and length of hospital stay, had very small numbers of participants. Of the six studies, four different surgical specialty patient cohorts were used, which contributed to the heterogeneity of the data. Participants of each study wore the WAM for varying amounts of time and on different body locations, although there have been previous studies which have shown that there is a similarity in activity output measured at different anatomical sites^{113, 114}. All six studies were only observational in nature, nevertheless, the results are encouraging and describe the use of a new technological device that has only recently been introduced to the clinical arena.

The findings from this systematic review suggest that the amount of physical activity undertaken as an in-patient following surgery, negatively correlates with length of hospital stay. However, since there were so few studies, with small cohorts in some of the studies and the data was heterogeneous it is necessary to investigate this further. The next step is therefore a study with specific aims and objectives, investigating the relationship between physical activity and patient outcomes after surgery, using WAMs to objectively monitor physical activity in the peri-operative period.

The role for WAMs and the physical activity data they provide could be highly beneficial if these finding were to be proven, with the possibility of predicting functional recovery post-operatively as well as being used as a tool to help clinicians identify patients who need additional clinical input.

Chapter 3

Wearable Activity Monitors (WAMs): technology and analytical methods

3.1. Introduction

Physical activity is defined as ‘any bodily movement produced by skeletal muscles that results in energy expenditure’¹¹⁵. Its importance in a healthy daily life is manifold, the ability to move and function affects people’s everyday life; living independently, performing their occupation and enjoying social and family relationships. Physical activity can also be used as a descriptor of behaviour and daily habits.

The benefits of physical activity are highlighted in the advice given by the American College of Sports Medicine (ACSM) and the American Heart Association (AHA)¹¹⁶ which suggest that engaging in moderate-intensity aerobic activity for thirty minutes on five days each week can promote and maintain health, as well as reduce the risks of chronic disease and premature death.

Physical activity type, character or amount can change suddenly when a person becomes unwell with an acute illness, or more slowly with chronic conditions, with physical activity often decreasing before a formal diagnosis or recognition of illness occurs. As patients recover, physical activity increases back to normal baseline values. However, this can take a period of time, and may not return completely to previous baseline levels depending on other comorbidities, previous mobility issues and the possibility of a new lower level of chronic disease state. Some conditions e.g. osteoarthritis of the hip and knee specifically affect the character of a person’s movement and activity.

Being physically active plays an important role in primary and secondary prevention of chronic

diseases, for example diabetes, cardiovascular disease, chronic kidney disease and cancer¹¹⁷, with one review showing that physical activity gave a risk reduction of 75% for breast cancer, 49% for cardiovascular disease, 35% for diabetes and 22% for colorectal cancer¹¹⁸. Physical activity can therefore be seen as both a measure of wellness and health, as well as an intervention that can be used to enhance and improve these.

Physical activity can be measured in a multitude of ways ranging from basic self-reporting tools to complex gait laboratories and video recordings (Figure 3.1).

Questionnaires or self-reports, e.g. the CHAMPS (The Community Health Activities Model Program for Seniors) physical activity questionnaire, can be used to estimate time spent in a range of activities and has been shown to correlate with other methods of estimating physical activity in assessing post-operative recovery in patients following a laparoscopic cholecystectomy⁶⁸. Patients fill out the questionnaires themselves, or together with a researcher. However, self-reporting is highly subjective, susceptible to inaccuracy and recall bias.

Validated functional tests or simple timed measures, e.g. the timed 'up and go' test¹¹⁹ or six-minute walk test⁶⁷ aim to assess mobility that relates to activities of daily living, thereby giving a marker of functional activity. However, these are often time consuming, may require special equipment and often don't reflect actual mobility or activity at home.

Newer technology with video recordings and use of force plate analysis in a laboratory or research facility allows assessment of gait analysis and the identification of impaired gait patterns. Although a large amount of data can be gained from these tests, multiple equipment is needed within a large space, the equipment is large, expensive and cumbersome and the testing itself is time-consuming. As the testing is all done in the laboratory setting it may not fully reflect every-day life activity in a

free-living environment.

The ideal activity measure is collected continuously in a natural, free-living environment, using low cost, objective measurements. Wearable activity monitors (WAMs) are becoming increasingly useful to meet those requirements. They can be worn unobtrusively throughout the day and are able to monitor activity in the home environment. They do not impede movement or activities of daily living and can therefore assess activity and functional status in an unsupervised, free-living environment over a long period of time. These WAMs can also be used to prompt behaviours or as an intervention, for example a wrist-worn step counter as motivation for weight loss behaviour or to encourage ongoing activity. With advances in technology, more sophisticated WAMs are emerging that can collect different types of data such as heart rate, electrocardiogram (ECG) trace, temperature and ambient light. These multi-faceted WAMs provide a wealth of data about people in their normal living environment and could be used in the healthcare setting to monitor patients remotely from hospital and detect deteriorations in chronic disease as well as acute instances of illness, especially in cardiovascular disease.

3.1.1. Hypothesis

Sensor technology is a valid method to assess physical activity within a healthcare setting

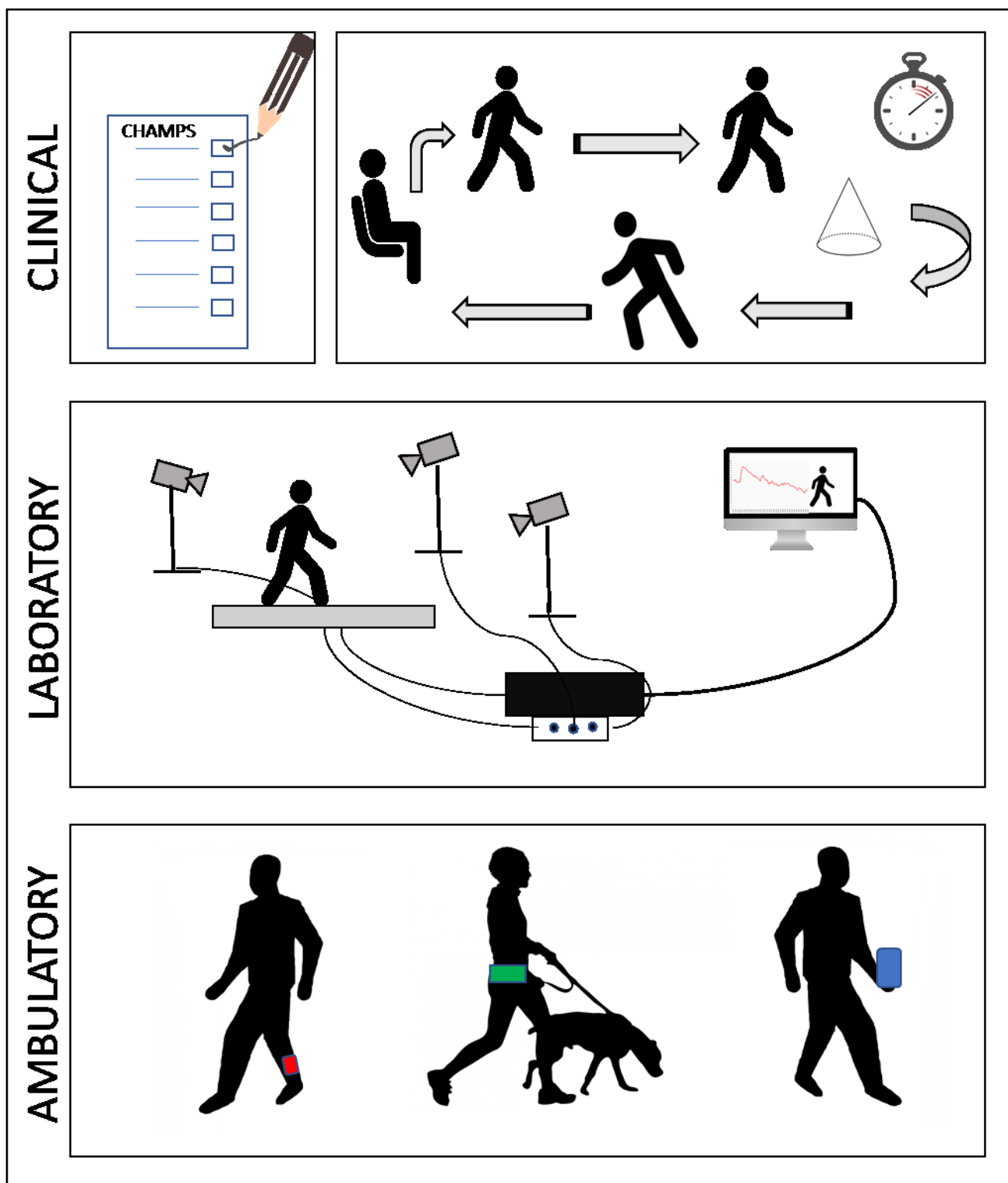


Figure 3.1. Different modes of collecting physical activity data

3.2. Sensor hardware

Different types of WAMs can measure different aspects of human body movement and/or measure similar movements from a different approach (Figure 3.2).

- Gyroscopes
- Goniometers
- Pedometers
- Accelerometers
- Combination sensors/Inertial measurement units (IMUs)

Gyroscopes measure angular velocity, relative joint angle and inclination. They monitor the orientation of an object in motion and can be used to provide information on ambulatory gait analysis and abnormal gait patterns. These WAMs can be placed on the lower leg and foot and have been used to detect normal and pathological gait¹²⁰. Gyroscopes use the microelectromechanical systems (MEMS) and measure in degrees per second.

Goniometers are used for direct measurement of joint angles. They are useful to help determine the function, or conversely, dysfunction of the joint for example in post arthroplasty patients¹²¹. The manual Universal Goniometer (Chattanooga, CA) is the traditional tool to measure range of joint motion but newer technology within smartphones means that different applications have been developed, including the Simple Goniometer app for Apple iOS. This has been shown to be both valid and reliable for knee joint angle measurement when compared with the Universal Goniometer¹²². Wearable goniometers have also been produced which are able to measure joint angle changes throughout the walking cycle¹²³.

A pedometer is a device which detects the steps taken by a person. It can be mechanical or

electronic. With mechanical pedometers, a pendulum swings and this causes the lever to change gear by one position, which counts a step. With mixed electronic and mechanical pedometers, the pendulum moves and completes a circuit so current flows and this counts a step. The distance travelled can be calculated by first calibrating steps to a specific distance or length and then calculating the distance from number of steps walked. The pedometer is cheaper than an accelerometer but does not allow the differentiation between intensity of activity nor is it sensitive to non-ambulant activity e.g. swimming or cycling. Pedometers are used in fitness tracking and monitoring physical activity e.g. The Stepwatch 3 which has been used to measure the walking activity of patients after a stroke¹²⁴. The inclusion of MEMS technology within smartphones means that both Android and Apple smartphones can be used as pedometers.

Accelerometers measures acceleration, the rate of change of velocity. A uni-axial accelerometer records accelerations in a single plane but a triaxial accelerometer records in three dimensions and so gives a more holistic measure of global body movement. Technological advances have facilitated the use of MEMS which allow the accelerometers to be small and low cost. Accelerometers can be one of three types piezo-electric, piezo-resistive or capacitor accelerometers.

- Piezo-electric: A piezo-electric element acts as a spring and damper. The element generates an electrical charge in response to a mechanical force.
- Piezo-resistive: Silicon resistors are present which change electrical resistance in response to an applied mechanical load. This produces a voltage proportional to the amplitude and frequency of the acceleration.
- Capacitor accelerometers: Capacitative plates, some attached to springs, move as an acceleration force acts on the sensor. As these plates move in relation to each other the capacitance changes and therefore acceleration can be determined.

Combination sensors, often called inertial measurement units (IMU), are combinations of multi-

axial gyroscopes, accelerometers, magnetometers and pressure sensors. This allows the calculation of orientation, position and velocity. The use of multiple sensing modalities can sometime improve the overall utility of the data.

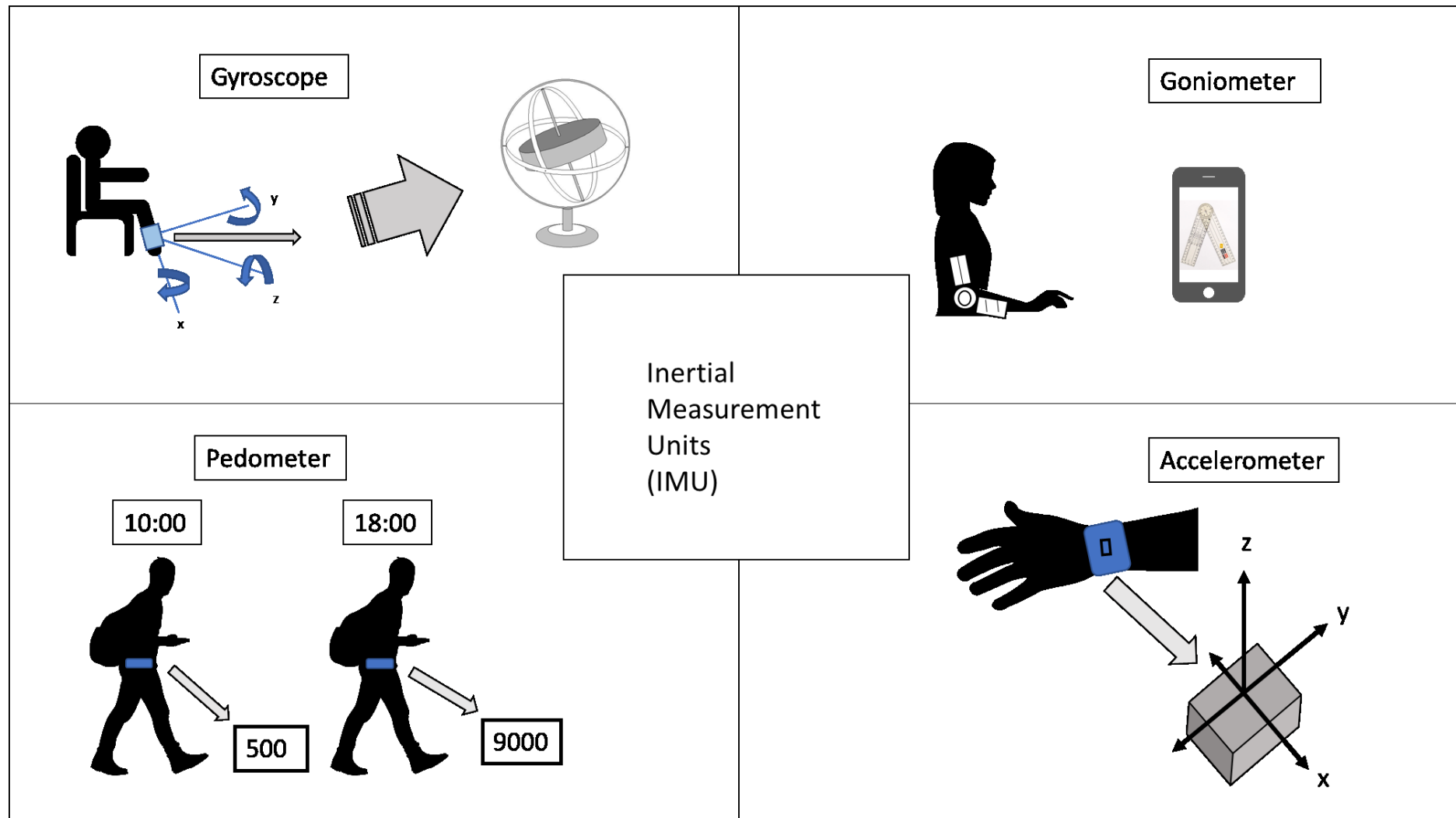


Figure 3.2. Different types of wearable activity monitors

3.3. Accelerometers

Although accelerometers have been used as a tool to assess human body movement in the free-living and clinical settings from the 1950s¹²⁵, it wasn't until the 1970s¹²⁶ that accelerometry started to be used more widely, due to the newer technology enabling small, light-weight devices. Modern accelerometer devices have a relatively low current draw which allows data to be recorded continuously for a period of days, weeks and even months¹²⁷. The data output from an accelerometer depends on four factors⁷⁰; the position the WAM is placed, the orientation of the WAM, the posture of the subject and the activity being performed.

3.3.1. Wearable activity monitor placement

WAM placement is an important issue to consider when thinking about monitoring physical activity (Figure 3.3). The WAM must be easy to place, must not interfere or obstruct body movements, and must show consistency and reliability in its results. The WAM should also be in a position that takes into account gravity and other noise due to external vibrations. Initial designs focused on the WAM being worn as close to the centre of mass of the body e.g. the back, waist or central chest¹²⁸. The e-AR sensor, which has been validated to measure gait in normal participants and those after knee surgery, is worn behind the ear. This site was chosen as although the head does move increasingly with increased activity, it moves less than the limbs because of the stability provided by the neck and trunk¹²⁹. A number of studies have since examined the optimal location for WAMs. Fortune et al¹³⁰ compared placement and number of tri-axial accelerometers used to detect posture and movement. They concluded that when only one accelerometer was used the best position (out of thigh, ankle and waist) was the thigh to identify movement and static postures, walking, fidgeting and jogging. They also suggested that posture related tasks would require two accelerometers at the waist and thigh, but for movement only, one accelerometer is enough. This study used data from a previous study that was re-analysed, on 12 patients who had performed a five-minute protocol of static and dynamic postures. However, three other studies seem to suggest

that the location of the WAM does not cause a significant difference in WAM output. One study¹¹³, recruited 16 nursing facility residents, who wore accelerometers simultaneously on their ankle, wrist and waist for four days, they found that there was no difference between the ankle, waist and wrist site for activity intensity, activity duration and activity frequency. Another study¹¹⁴ recruited 8 male students and staff from one university. Participants wore six tri-axial accelerometers at different body locations (chest, wrist, lower back, hip, thigh and foot) whilst performing seven different activities, each lasting two minutes. The study showed that there was similar accuracy from all the different locations of placement of a single WAM, although the hip seemed to provide a small but significantly better accuracy than the other locations. Heil et al¹³¹ also evaluated three locations for placement of WAMs (ankle, hip, wrist) and concluded that they provide similar physical activity outcome measures. An important consideration in WAM placement within a clinical trial is practicality of use. The WAM needs to be in a comfortable position so that it is worn continually and needs to be in a position that allows reproducibility within and between subjects.

The level of evidence for WAM placement is low, with level 4 studies, mainly case control or cohort studies, with few participants.

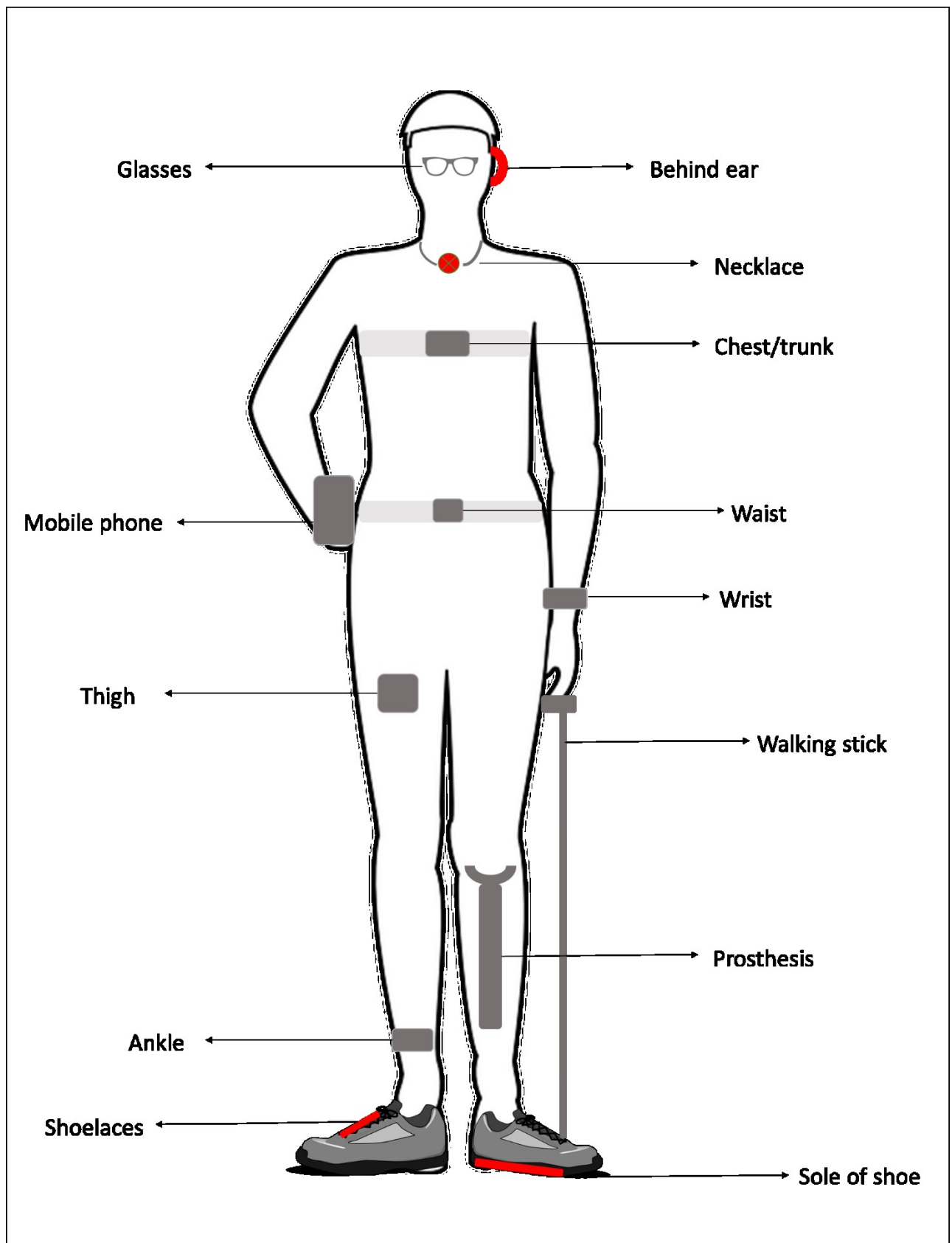


Figure 3.3. Wearable activity monitor placement

3.3.2. Acceleration signal

When the accelerometer is motionless the acceleration is the projection of gravitational force onto the WAM, whereas, when moving, the measured acceleration is the vector sum of the gravitational and movement forces. Several different components make up the acceleration signal, body movement being the main factor but soft tissue movement and external vibrations also contribute. Linear, centripetal and coreolis accelerations makes up the factors in translational and rotational movements^{70, 127}.

Signal filtering can be used to minimize the spurious vibrations and soft tissue movement that is more akin to static orientation than actual body movement, generally this is achieved by using a filter with a cut off frequency between 0.1-0.5Hz⁷⁰. The rate of data acquisition is determined by the sampling frequency. Accelerometers are either pre-configured to a specific sampling rate, or are constructed to allow the researcher to choose the most appropriate sampling frequency for their study, within a certain range. A sampling frequency of 50Hz means 50 recordings a second are taken of acceleration readings. The higher the frequency the more data points recorded and, generally, a higher sampling frequency is used to capture more precise and delicate movements. The acceleration data is then filtered using a band pass filter, which allows a specific level of frequencies, set between a certain range, to pass (i.e. to be ignored) whilst all the others are captured. This is thought to help increase the linearity of the measured acceleration compared with the actual body movement signal¹³². A wide bandwidth allows non-physiological noise or artifact and vibrations to be included in the signals, and so may not truly encapsulate actual body movement, but, conversely, a narrow bandwidth could miss out on acceleration data from actual movement or activities. A judgement needs to be made with regard to the type of activities being monitored as to which frequency of sampling and what bandwidth filters should be used. The data recorded can be stored on the sensor's internal memory or sent in real-time to a local processing unit, e.g. smartphone or laptop, via Bluetooth, radiofrequency or other low power communication

method. The information stored or transmitted can be the raw accelerometry signal or some simple electronics can allow processing ‘on the node’ before a smaller, more user-friendly data set is sent.

3.3.3. Accelerometer outputs and data analysis

There are multiple ways to transform the raw accelerometer data into usable outputs of physical activity measures. All of them have strengths and weaknesses and the ideal measure for each study must be chosen to help meet the aims of the specific study in question. The many potential outputs from the accelerometer sensor data analysis vary from low level data mining for determining gait abnormalities or sport technique e.g. golf swing, all the way to high level analysis for gross movements such as in physical activity measurement (Table 3.1).

Basic interpretation of accelerometry data uses mathematical methods including mean and standard deviation of accelerometer signal to determine static versus dynamic activity¹³³. These, together with specific thresholds can define activities e.g. sitting, standing, lying or walking. Other mathematical and statistical features used include skewness, kurtosis and eccentricity of the accelerometer signal and these can also help to distinguish between physical activities¹³⁴.

The acceleration signal, which is both positive and negative (i.e. bi-directional), is filtered and sometimes amplified. It is then sampled at a pre-fixed frequency to convert the analog voltage signal to a digital series of numbers (A/D conversion). Once this data string reaches the processor, different analysis techniques can be performed:

- The number of instances that the signal crosses the pre-set threshold is counted. The threshold is chosen as zero or another value thought to be significant with regard to movement. This is also called the Zero-crossing method.
- An algorithm is used that works out the maximum value reached over a defined time period (an epoch) and that represents the activity ‘count’ over that specified time period.

- An algorithm is used that averages or integrates the area under the curve. Negative acceleration is often converted into positive, so that integrations do not include both the negative and the positive data.

Each digitized signal is summed over a user specified time interval (epoch) e.g. 60 seconds. So that activity counts can be expressed as average physical activity counts per minute¹³⁵, i.e. acceleration over time. There are no current standards that currently exist for units of physical activity counts between accelerometers and manufacturers¹³², these depend on whether there is analogue or digital conversion, amplification and sensor type.

The accelerometer data can be calibrated by recording accelerometer data simultaneously with a physiological variable i.e. METs or maximum volume of oxygen (VO₂) in a lab setting. The relationship is then determined using linear regression. Ranges of accelerometer output correspond to different levels of physical activity. These 'cut-points' are then applied to accelerometer data collection in free-living environments where time spent in various intensities of physical activity is estimated. Cut points divide activity into sedentary, light, moderate and vigorous intensity. Within calibration studies the cut points are developed by analysing the relationship between the accelerometer count and energy expenditure (which had been objectively measured) using regression or ROC curves e.g. Freedson¹³⁵ or Troiano¹³⁶. Different equations are used for different population types.

Another output that is used to differentiate between physical activity levels is Energy Expenditure (EE). This is the estimation of metabolic energy expended due to the physical activity performed. This can be estimated using the area under the curve of body movement acceleration over time, which is related in a linear manner to and is proportional to energy expenditure⁷⁰. The most accurate estimation of energy expenditure is via integration and summation of each accelerometer's

axis' output¹²⁸.

More specific analysis can be performed on the raw accelerometer data itself, allowing analysis of periods of activity framed with preceding and succeeding specific postures i.e. sitting to standing. The accelerometer data can be presented as wave forms and these can be analysed and interpreted, e.g. detection of peaks, or using continuous or discrete wavelet transformations to give information about step counts.

Table 3.1. Table showing examples of WAM output measures

WAM output	Type of WAM	Output measure	References
Steps	Accelerometer, pedometer	Step count	Lord et al ¹³⁷ , Mudge et al ¹²⁴ , Wolin et al ¹³⁸
Energy	Accelerometer, gyroscope	Metabolic Equivalent of Tasks (METs), energy expenditure (EE)	Bassett et al ¹³⁹ , Kim et al ¹⁴⁰ , Bouten et al ¹²⁸
Gait	Accelerometer, gyroscope	Postural stability, sway, trunk movements, gait cycle time	Atallah et al ¹⁴¹ , Adkin et al ¹⁴² , Yang et al ¹⁴³
Activity	Accelerometer	Signal Vector Magnitude (SVM), cut-points, time in activity type	Camhi et al ¹⁴⁴ , Berglind et al ¹⁴⁵ , Troiano et al ¹³⁶

3.4. Assessment of physical activity within a healthcare setting

The different output measures derived from the various sensors can be used to investigate physical activity and movement within an assortment of clinical settings and with diverse cohorts of patients (Figure 3.4). One way to divide these different data types is into those that analyse specific movement types e.g. tremor quantification in the patient with Parkinson's Disease, compared with the gross analysis of physical activity e.g. monitoring activity and inactivity in patients during a hospital stay. In patients with Parkinson's Disease the ability to measure the specific activity of the patient's hand, and therefore their tremor, and the change in movement that occurs over time in the home setting, allows assessment of disease progression and alteration of medication and treatment¹⁴⁶. The ability to monitor and measure patient movement whilst an inpatient helps clinicians assess how active patients are when hospitalised. This can indicate how well or unwell they are, or whether they require extra motivation or physiotherapy support⁵².

Other ways to define the sensor output data is by disease type itself. Some diseases are movement specific, e.g. Parkinson's Disease, dystonia, cerebral palsy. The characterisation of movement itself describes the disorder. However, other illnesses can cause inactivity as a secondary problem, e.g. having a cerebrovascular event, or suffering with an acute exacerbation of heart failure or Chronic Obstructive Pulmonary Disease (COPD). Furthermore, a review of the literature looking at WAMs within the healthcare setting describes an additional use for activity monitoring, assessing patients within the surgical setting¹⁴⁷.

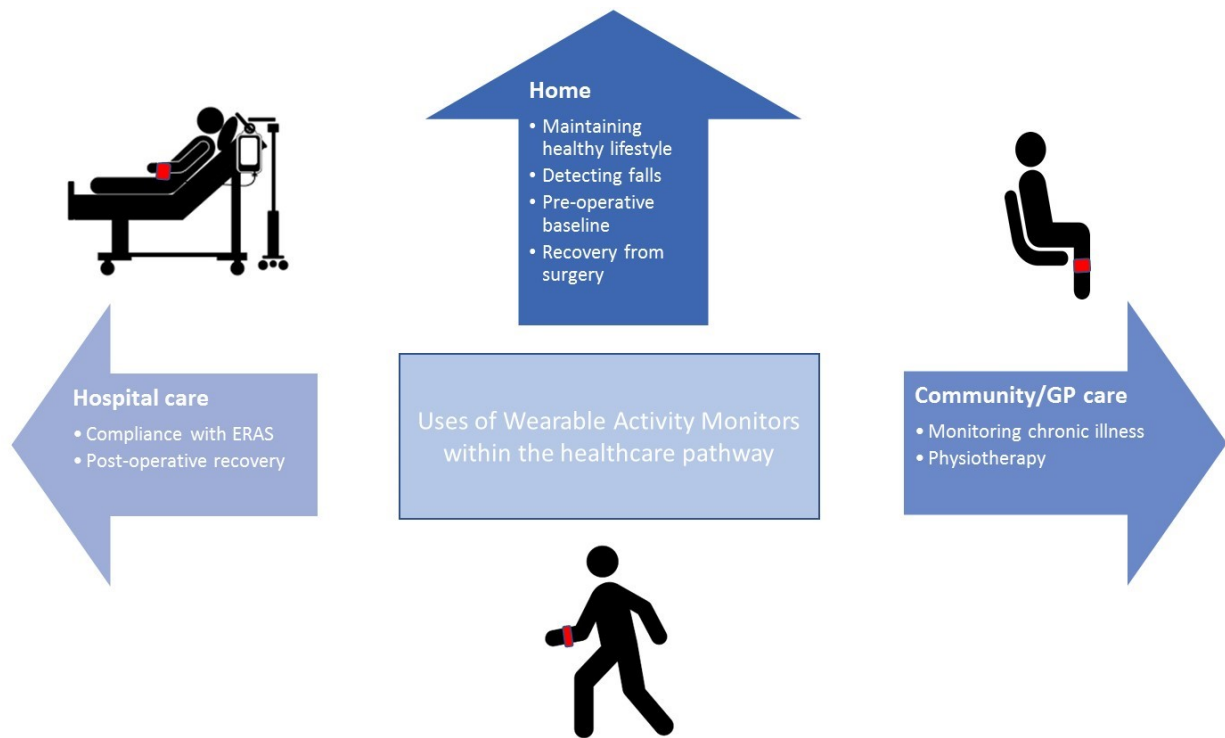


Figure 3.4. Wearables within the healthcare pathway

3.4.1. Assessment of movement disorders

As well as monitoring the tremor of patients with Parkinson's disease, WAMs can assess long term changes in movement as well as short term fluctuations. WAMs have been worn during normal activities of daily living and have been shown to be able to monitor the activity status of these patients¹⁴⁸ as well as trunk sway measurements¹⁴².

One specific disorder of movement is a fall, where a person has an unintended fast change of posture from standing/sitting to sitting/lying down. This is an important use of activity monitoring with the ability to detect and prevent falls in the elderly population. Because falls can be classified by a fast change in posture, generally from standing to lying, an accelerometer can detect this change in orientation and posture. Fall detection systems have been studied and include monitoring postural (in)stability and sway as well as walking speeds¹⁴³. Higher frequency and larger amplitudes indicate postural instability and the increased likelihood of falls⁷⁰. One fall detection

system measured acceleration in three planes of young, healthy males who wore a waist mounted tri-axial accelerometer whilst falling onto a 30cm height soft bed, they found that they were able to detect falls reliably, from normal activities of daily living¹⁴⁹.

A large cohort of patients who undergo orthopaedic treatment have disorders in movement either prior to or following surgical management. One observational study monitored 20 patients following fixation of acute hip fractures on the orthopaedic ward of an acute general hospital. A uni-axial accelerometer, ActivPal, was worn on the thigh for a maximum of seven days, the output measurement used was steps taken, and patients were found to be only minimally active on the ward post-operatively¹⁵⁰.

A study by Reininga et al. performed gait analysis on patients who had total hip arthroplasty (THA). Patients were randomly allocated to either a minimally invasive THA (35 patients) or conventional THA (40 patients). Gait parameters and trunk movements were monitored by two triaxial WAMs which contained gyroscopes, accelerometers and magnetometers (MTx Motion Tracker, Xsens Technologies, B.V., Enschede, The Netherlands). One WAM was worn on the back between the two posterior superior iliac spines, and the other in the midline of the thorax, below the 7th cervical vertebrae. Gait activity was assessed pre-operatively and at 6 weeks and 3 and 6 months post-operatively. Walking speed, step length, cadence and angular movements of the pelvis and thorax were determined based on the gait data. Minimal differences were found between the minimally invasive and control group, but improvement in walking speed and step length were observed in both groups following the THA¹⁵¹.

3.4.2. Assessment of activity in chronic illness

Activity often decreases in patients suffering with chronic diseases, both as the disease progresses, and when an acute exacerbation occurs. One example is COPD, where an exacerbation can lead

to increased shortness of breath and therefore a decrease in movement and activities of daily living. One study attempted to characterise physical activity in COPD patients to see if an acute exacerbation could be determined by change in activity¹⁵². Eight patients wore a tri-axial accelerometer on their waist during waking hours for over 100 days. The mean vector magnitude per minute was used to quantify activity, but the small sample, and infrequent exacerbations meant that no significant correlation could be made.

A systematic review of WAMs showed that as well as in healthy subjects, the WAMs had been validated against indirect calorimetry in studies of patients with chronic diseases including diabetes mellitus type II, COPD, chronic heart failure, chronic back pain and chronic organ failure¹⁵³.

Wolin et al¹³⁸ studied patients following colonic polyp removal at screening colonoscopy to assess whether a physical activity programme could help increase patient activity levels. Patients were randomised to either meet 30-minutes of walking per day target, or 60-minutes of walking per day target. Patients attended group sessions and were coached to help achieve their targets and physical activity was monitored prior to the intervention and in the last week of the intervention. Patients wore the Omrom HJ 720 IT pedometer (Omrom HealthCare, IL) as well as an Actigraph GT1M accelerometer (Actigraph, Penascola, FL). Activity output measures were steps per day and moderate/vigorous physical activity per week. There was no significant difference between groups at follow-up but both groups significantly increased objective activity levels over the course of the intervention¹³⁸.

3.4.3. Assessment of patient activity in the surgical setting

Surgical management of conditions is undertaken for differing reasons, e.g. bariatric surgery to improve weight-loss, surgical excision of a malignancy in order to remove a tumour or transplant of an organ to allow normal functioning of physiological processes. For some of these conditions

patient activity may already have been reduced to the nature of the disease or chronicity, in others, activity levels may have remained the same. Following surgery patients' activity levels will decrease as recovery from physical wounds takes place, but should increase again and could even over-take pre-operative levels if surgical management has been successful. Monitoring in the surgical setting can help determine objective levels of physical activity prior to operative management, e.g. in the obese cohort/bariatrics patients, where self-report often over-estimates physical activity performed¹⁵⁴. One study compared 38 bariatric patients and 20 normal weight controls, who wore a tri-axial accelerometer on their waist during waking hours for seven consecutive days. They showed that the bariatric surgery cohort performed significantly less activity per day than the normal weight control group¹⁵⁵.

In a different trial, 56 female patients who underwent a Roux-en-Y gastric bypass surgery were monitored with an Actigraph GT3X+ tri-axial accelerometer (Penascola, FL) on their right hip for seven consecutive days three months pre-operatively and nine-months post-operatively. The vector magnitude for activity counts was analysed and calculated as the square root of the sum of the three axes. Activity outputs used were moderate/vigorous physical activity (MVPA), light physical activity (LPA) and ten or more minute bouts of MVPA. No difference in physical activity was found pre to post-surgery¹⁴⁵.

One study looking at 18 patients undergoing surgical re-vascularisation for critical limb ischaemia measured energy expenditure using the Caltrac vertical accelerometer, which was worn by the participants for five days. Although energy expenditure was shown to be grossly improved following surgery it was not found to be statistically significantly¹⁵⁶.

The level of evidence for the use of WAMs within a healthcare setting is mixed. There is a randomised controlled trial, a level 2 study, and a non randomised controlled study, a level 3 study,

but the other studies are more varied level 4 or 5 studies, mainly observational case-control or cohort studies. There are no multi-centre trials or systematic reviews, which would upgrade the levels of evidence. This is because the adoption of sensors into healthcare is still in the early stages with studies working out the more basic issues prior to starting larger, multi-centre trials.

3.5. Broader utility of physical activity data

WAM data can also be used in a variety of other non-clinical health settings. Physical activity can be seen as a measure of frailty. The ability to measure objective physical activity allows patient monitoring to occur with the possibility of prediction of patient deterioration. This could benefit by highlighting when extra community support may be necessary. E.g. post-operatively, or following an illness or fall, when patients are discharged home. It can flag up when a patient may require further medical, social or physiotherapy input and could help prevent unnecessary admission to hospital by highlighting early a problem and enabling help to be given before a major deterioration occurs necessitating hospital admission.

Physical activity can be used to detect human and societal behaviours. The ability to objectively monitor physical activity allows the quantification of human behaviour and the comparison of this behaviour with health outcomes. The UK Biobank study collected and analysed accelerometer data for over 100,000 participants¹⁵⁷. The UK Biobank study is a large prospective epidemiological study collecting extensive data with longitudinal follow-up and phenotypic and genotypic details about its 500,000 participants. A subsection of participants were asked to wear an accelerometer for seven days. The Axivity AX3 (Newcastle, UK) wrist-worn triaxial accelerometer was used. This sensor was used as it allowed transparent data processing analysis due to its open source software, as well as the ability to process the raw data itself. They found that that women were more active than men, younger people were more active than older people, and that there were differences in activity by time of day. With studies like this, which also include a wealth of physiological,

biochemical and genomic, as well as other health data, further study into physical activity and health outcomes is available. For example, looking at daily routines within the working week and how these change with unemployment, mental illness or physical illness, and more widely the ability to describe the behavior of communities, and how this could promote wellbeing.

Changes in behaviour can often lead to health benefits e.g. stopping smoking, cutting down on alcohol consumption. Behaviour has been shown to be influenced by the environment, as well as via incentives and information giving. Dolan et al¹⁵⁸ describes MINDSPACE, an acronym which encompasses nine ways that influence behaviour from the environment itself. People are influenced by who it is that communicates information to them, with responses to incentives shaped by predictable shortcuts e.g. strongly avoiding losses. People are strongly influenced by what others do and also tend to 'go with the flow'. People's attention is drawn to new and relevant things with actions influenced by subconscious cues and shaped by emotions. People generally act consistently and in a style that makes them feel better.

Improving physical activity and exercise in patients with peripheral arterial disease is a behavioural change that forms a significant part of the treatment plan for these patients by improving their walking distances and quality of life. However, supervised exercise programmes are expensive, and compliance has been found to be low. Drawing on a number of elements from the MINDSPACE work Normahani et al¹⁵⁹ investigated whether patients who wore a feedback-enabled wearable activity monitor improved their walking distances and quality of life. Patients were randomly assigned to either wear a *Nike+ FuelBand* or not, and were followed up at 3, 6 and 12-months. The *Nike+ Fuelband* has a built-in accelerometer with output measures of number of steps take, calorie expenditure and 'fuel-points'. The *FuelBand* allows personalised goal settings and output measures are displayed in real-time. Reminders can be sent to the wearer to keep active and overall activity can be compared within specified communities of users. This study found that those patients

wearing the *Nike+ FuelBand* significantly improved their walking distance and claudication distance, as well as having an increased quality of life.

In summary, there are many different types of wearable activity monitors that have been studied and used in a wide variety of environments, including the healthcare setting, both in hospital and in the community. This has ranged from detecting falls, to monitoring activity amounts in patients with Parkinson's disease to alter medication as appropriate. Physical activity monitoring in the surgical setting has also been undertaken. There is, however, a need for further study of patient activity in the peri-operative setting using appropriate WAMs and output measures to answer specific clinical questions.

Different WAMs can be used to ascertain different information about body movement in these different settings, with some WAMs being more appropriate or useful than others. Output measures from WAMs are varied and different environments and clinical situations require different output measurements.

3.6 Sensor requirements for thesis studies

The sensor requirements for the thesis studies were a small, light-weight sensor which could be worn continuously. The sensor needed to be unobtrusive, but worn on the body continuously, so that it could detect all movement any time of the night or day. A long battery life was important as it was more likely that the participant would continue wearing the sensor if they did not have to take it off to charge it at regular periods. The data recorded needed to be stored easily and then downloaded into a useable format to allow comparison and analysis.

The Axivity AX3 (Newcastle, UK) is a light weight (11g), wrist worn, sensor containing a tri-axial Micro-Electro-Mechanical-Systems accelerometer (ADXL345). It has a non-volatile flash memory

chip, which is used for secondary (long-term) storage of data and can retain stored data even if the power is off. A temperature sensor, ambient light sensor, real time clock (RTC) and lithium polymer battery are also integrated into the sealed polycarbonate puck, sensor casing. The product is CE marked, i.e. it is compliant with EU safety, health and environmental requirements.

The Axivity AX3 has been validated for use in monitoring physical activity in the free-living environment. Ladha et al.¹⁶⁰ performed a shaker table validation of the AX3 accelerometer and also compared it to the GENEa device. The GENEa accelerometer has been previously validated in comparison to physical activity questionnaires¹⁶¹, and Ladha's study showed that the AX3 and the GENEa demonstrated equivalent output on the shaking table test. They also confirmed that the AX3 device's inter- and intra-device variability was suitably stable for the purpose of capturing data on human movement. Khan et al.¹⁶² used the AX3 accelerometer to investigate whether it was possible to identify which activity a person was performing (lying, sitting, walking, running, standing, cycling, ascending and descending stairs) with the sensor worn in three locations on the back. Their results showed that a single accelerometer can identify activity types independent of BMI or age with the upper part of the back giving better accuracy. Clarke et al.¹⁶³ tested the validity of the AX3 in an older population recruiting twenty-three patients. Overall, the correlation between the AX3 and RT3 sensor was high, and this was stronger for walking activities than non-walking activities. There were moderate bivariate correlations for the different placements of the AX3 sensor (wrist, ankle, hip and thigh) and the AX3 device was shown to be a valid tool to objectively measure walking in older, functionally impaired adults. The AX3 has also been used to quantify gait during continuous walking, Godfrey et al.¹⁶⁴ performed a within test validity and reliability of the AX3 sensor. They validated the sensor for quantifying gait during continuous walking by estimating the gait parameters of step time, stride time, step length and step velocity.

Current large trials using the AX3 sensor include the INTERVAL study¹⁶⁵ and the UK Biobank¹⁶⁶.

The INTERVAL study is looking at the interval of time needed between blood donations and how this can safely be decreased to optimise blood supply but maintain health of donors. The AX3 sensor was chosen due to its open-source software and the ability to extract the raw data. The UK Biobank study has collected accelerometry data from more than 100,000 UK adults, enabling researchers to investigate links between physical activity and multiple health outcomes.

The sensor can be configured to record different bandwidths, i.e. accelerations at different sample rates, ranging from 25Hz to 400Hz (Table 3.2.). This means that between 25 to 400 recordings a second can be taken of reliable acceleration readings. Vibration readings require higher bandwidths, but human movement can be measured with 40-60Hz bandwidths. We chose 50Hz as there is an improved battery life of up to 31 days, and the data points are large enough to give accurate readings of human movement, but not too numerous to be unable to analyse and manipulate easily.

Table 3.2. Sample rate and battery life
(Axiivity User Guide <http://axivity.com/userguides/ax3/settings/>)

Sample Rate (Hz)	Typical Battery Life (days)	Low Power Battery Life (days)
400	5	5
200	9	10
100	14	18
50	21	31
25	34	47

The sensor can measure a range of forces from +/-2g to +/- 16g (Table 3.3.). The smaller the range the more sensitive the readings. So, for example, detecting small vibrations would need +/-

2g range whereas more crude movements and activity would require a larger range. We chose +/- 8g in order to account for moderate, crude activity likely to be performed in our normal and patient cohort.

Table 3.3. Acceleration ranges and applications
(Axivity User Guide <http://axivity.com/userguides/ax3/settings/>)

Sensitivity	Example Use Case
$\pm 2g$	Fine movements such as hand writing or painting
$\pm 4g$	Mild activities such as walking
$\pm 8g$	Moderate activities such as sprinting, jumping
$\pm 16g$	High intensity activities such as boxing

The decision to use the AX3 accelerometer, rather than e.g. the FitBit or other more commercial WAMs was due to a number of factors. The commercial WAMs do not allow for raw data to be viewed or processed, the activity data is presented back to the user via the WAM in whichever unit of activity has been programmed which could be steps, energy expended or an invented unit, e.g. *Nike Fuelband* points. There is also no choice for configuring the sample rate or the acceleration ranges on the commercial WAMs, whereas the AX3 allows this, thereby allowing to increase battery life, which is important in a patient setting where they may not be able to charge the WAM daily. The AX3 also uses an open source application software which has the ability to record, store and download the data easily, allowing analysis of the raw data and drilling down to the nature of activity/intensity performed.

Chapter 4

Wearable activity monitors (WAMs) in a free-living environment

4.1. Introduction

The focus on physical activity as a health benefit has increased, more recently, with growing evidence in the literature. Activity behaviour has been linked with a population's general health, mental wellbeing and been shown to provide insights into these for patients and their healthcare providers. Guidance has been given from both the UK and the USA for the adult population regarding optimal physical activity that should be performed each week. A suggestion of 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity, or a combination of the two is recommended over a period of a week, with a suggestion to be active every day and spread the time in activity across the course of a week^{167, 168}. Performing this amount of activity is thought to improve mental and physical health. This will be discussed in more detail, specifically:

- Morbidity and all-cause mortality
- Mental well being
- Behavioural insights
- Frailty and the elderly population

4.1.1. Morbidity and All-Cause Mortality

Performing physical activity is thought to reduce risks of acquiring or exacerbating health conditions. A systematic evidence review has shown that the more active people were the higher their median risk reductions were for developing coronary heart disease and cerebrovascular disease, up to 30-40%^{169, 170}. A systematic review and meta-analysis of physical activity and the risk

of acquiring Type 2 Diabetes¹⁷¹ showed that activity of any type was associated with a statistically significant reduction in risk of Type 2 diabetes. Those that increased their physical activity over time had an even greater reduction in risk. Vigorous activity seemed more strongly associated with decreased risk than walking. Musculoskeletal health, specifically osteoporosis, has also been shown to benefit from increased physical activity. A randomised controlled trial showed that women who participated in a two year back-strengthening exercise programme had significantly lower incidence of vertebral fractures (1.6%) than the controls (4.3%)¹⁷². Moderate physical activity has been shown to reduce cancer specific and overall mortality in patients with colorectal cancer¹⁷³ as well as being related to improved patient quality of life (QOL) in colorectal cancer survivors¹⁷⁴. Specifically looking at all-cause mortality, a large number of observational studies have been performed. These have shown that there is an inverse relationship between being physically active and all-cause mortality, with a 30% reduction in risk of mortality compared with those who are least active¹⁷⁰.

4.1.2. Mental Wellbeing

The relationship between physical activity and mental health has been examined within the literature with much evidence to support the premise that increased physical activity is associated with better mental health^{175, 176}. A review of articles investigating physical activity and various mental health problems in children and adolescents¹⁷⁷ found that physical activity was inversely associated with symptoms of depression and anxiety and, although limited evidence, it seems that there are beneficial effects of physical activity to reduce depression, anxiety and improve self-esteem, mainly in the short term. An association was also found between the amount of time spent sedentary and poorer mental health. Kim et al.¹⁷⁸ investigated the dose-response relationship between physical activity and mental health. They found that between 2.5-7.5 hours of physical activity a week conferred mental health benefits.

A further study involving university students showed that those who met the physical activity

recommendations for vigorous activity were less likely to report mental health problems than those who did not¹⁷⁹. An ongoing Finnish Public Sector Study looking at physical activity and future mental health in women has shown that there is an inverse relationship between amount of physical activity performed and future symptoms of mental health¹⁸⁰. This is consistent with the idea of a protective effect of physical activity, and that increasing physical activity levels may be beneficial in improving mental health in women who are middle aged or older. The Whitehall II study, in London, has shown an association between mental health and activity in adults from mid-life to old age, with those subjects performing more physical activity having better mental health outcomes¹⁸¹.

4.1.3. Behavioral Insights

As well as providing health benefits, physical exercise can help provide insight into a person's behaviour and potentially highlight health issues or changes. Anecdotally, people suffering from sudden acute illnesses will perform less physical activity than usual, e.g. suffering with a viral upper respiratory tract infection or gastroenteritis. But even those people with chronic illnesses may display subtle changes in their activity levels. One study looking at physical activity in patients with Multiple Sclerosis compared activity levels to a healthy control group. A statistically significant difference between the activity levels of the groups was found, those with Multiple Sclerosis were moderately less physically active than the controls¹⁸². In a further study, comparing physical activity levels and self-reported health status, a significant difference was found between the levels of reported health status and moderate physical activity¹⁸³.

4.1.4. Frailty and the Elderly Population

Frailty is a term referring to age-related decline across a number of physiological, homeostatic systems with a reduced capacity to combat stress, and more vulnerability to falls, hospitalisation and mortality¹⁸⁴. Impaired physical function is a major indicator of frailty. The Rockwood scale

discusses an accumulation of ‘deficits’, for example the number of medications taken, comorbidities, the amount of times medical intervention has been necessary and other psychosocial indicators¹⁸⁵. The Fried Frailty Phenotype describes frailty as people who present with at least three of the following five conditions: unintentional weight loss; low physical activity levels; slow gait speed; exhaustion, and weakness¹⁸⁴.

One study has shown that elderly people who spend more time in physical activity, either higher moderate/vigorous physical activity (MVPA) or a decreased amount of sedentary time, show improved ability to perform normal everyday activities with improved functional fitness¹⁸⁶. A review of the literature looking at physical activity in post-menopausal women¹⁸⁷ showed that higher rates of physical activity in these women were associated with lower rates of cognitive and physical decline, as well as an associated reduction in all-cause mortality. The NHANES cohort study showed an association between sedentary behaviour or MVPA and frailty¹⁸⁸. They found that older people tend to spend more time sedentary and that the more time spent sedentary the higher likelihood of increased frailty and adverse health outcomes. They also found that few people met the weekly recommended levels of MVPA, and that the healthier individuals tended to rest in evenings and on Sundays, whereas the frail group did not show this pattern and were sedentary at all time frames. One study investigated which activity parameter best identified a group of pre-frail, frail and non-frail subjects. They found that the number of steps per day and percentage of sitting were the most accurate¹⁸⁹. This may be useful in setting up an objective screening tool for identifying frailty in older adults.

4.1.5. Clinical research using wearable activity monitors

Physical activity is an important component of a healthy lifestyle and can allow an understanding of healthy behaviours. Although there have been many studies reporting and analysing healthy behaviour, most have relied on self-reported activity. They also tend to classify activity in many

different ways, with different frequencies and durations being reported. Trying to determine activity intensity can also be difficult, and it is often unclear how much activity is being performed within each intensity category. Most studies discuss leisure time activity rather than total daily activity, but some subtle activity changes occur more with regard to housework and ambulation than, for example, amount of recreational activity performed.

As discussed above use of WAMs has been beneficial in recording objective activity in a variety of settings that have shown the advantages of patients being active for their mental health, medical well-being and even reducing all-cause mortality, as well as providing behavioural insights into patients with chronic diseases and the elderly and frail. Prior to investigating the changes in activity and physical behaviours of patients within a surgical setting it is important to establish that of a normal population, this helps to provide a reference of a healthy cohort for comparison with patient cohorts and will be used as the control group for further analysis in chapter 5. Furthermore, capturing data from a healthy cohort can help identify practical challenges with wearable devices being used for data collection free from the added pressures and complexities of the clinical setting. The normal data will also provide an opportunity for development and refinement of analytical methods.

This study is a pilot study which aims to quantify physical activity patterns in healthy adults which gives insight into normal daily activity in the home environment, as well as allow future comparison between this healthy control cohort and the patient cohort in future studies.

4.1.6. Hypothesis

Continuous objective activity using a wearable activity monitor (WAM) is feasible, providing objective physical activity data and insight into daily activity in a normal healthy control cohort.

4.2. Methods

4.2.1. Outline

A WAM was used to continually assess eleven healthy volunteers for five days. Activity data was analysed allowing detailed quantification of physical activity in a normal, healthy cohort.

4.2.2. Conducting the clinical trial

Ethical approval

Ethical approval was sought and granted from the NRES committee London - City Road and Hampstead (September 2015 – Ref 15/LO/1038).

Registration of the clinical trial

The study was registered at *clinicaltrials.gov*, which is an open, worldwide database providing information about current ongoing clinical research studies. The study was registered under ‘The Step Home Trial: Utilising Physical Activity Data in the Acute Post-Operative Setting – ID NCT02583711’

Recruitment and eligibility

Volunteers were recruited via a poster advert and through word of mouth. Participants were eligible over eighteen years old and able to mobilise independently, with no known movement disorder e.g. Parkinson’s disease.

Data collection

People who expressed an interest in the study were contacted and initial eligibility criteria were checked. The participant information sheet was provided and any questions were answered. If they were happy to take part written consent was gained. Participants were given a WAM (AX3, Axivity, Newcastle, UK) and asked to wear it continuously, only removing it if having a bath or going

swimming. They were advised to go about their usual activities and daily life. The sensor was returned after five days.

4.2.3. Data analysis

Wearable Activity Monitor

The Axivity AX3 (Newcastle, UK) (Figure 4.1.) is a light weight (11g), wrist worn, sensor containing a tri-axial MEMS accelerometer (ADXL345). It has a non-volatile flash memory chip, which is used for secondary (long-term) storage of data and can retain stored data even if the power is off. A temperature sensor, ambient light sensor, real time clock (RTC) and lithium polymer battery are also integrated into the sealed polycarbonate puck, sensor casing. The product is CE marked, i.e. it is compliant with EU safety, health and environmental requirements.



Figure 4.1. Axivity AX3 tri-axial accelerometer.
(Axivity user guide: <http://axivity.com/product/ax3>)

The puck/sensor casing is placed into an Axivity wrist band (Figure 4.2.), which allows the sensor to be worn on the wrist.



Figure 4.2. Sensor inserted into Axivity wrist band
(Axivity User Guide: <http://axivity.com/userguides/ax3/using/>)

Sensor data analysis

Physical activity data is recorded and stored within the AX3 sensor itself but the data is downloaded and analysed using an open source application software, OMGui (Open Movement Graphical User Interface). The OMGui configuration and analysis tool (version 28) aids in the setup and configuration of the AX3 sensor prior to recording physical activity and is also used to download and visualise the recorded data from the AX3 device. The OMGui software needs to be installed on a computer together with its drivers, the AX3 is then connected to the computer via a micro USB cable. The OMGui software uses an interface to allow visualisation and downloading of the data. Once a device is connected it appears in the 'Device Browser Pane', the data on the sensor can be previewed in the 'Data Preview Window' which is part of the OMGui interface. The data can be downloaded into the 'working folder' by clicking on the 'download' button. This downloads the raw data into a binary format which can then be exported to an external analysis package or analysed using validated integrated algorithms within the application. The data is checked in order to ensure that the device has recorded data over the expected time period and that the battery power lasted until device return. The signal vector magnitude (SVM) and cut point analysis algorithms are useful ways to analyse the raw data and the analysis toolbar within the OMGui interface enables this analysis to be performed and the output exported as a CSV excel

file (Table 4.1).

Table 4.1. Raw accelerometer data as presented in an excel CSV file format

Time (mm:ss:0)	x-axis	y-axis	z-axis
38:00.0	0.234375	-0.4375	-0.92188
38:00.0	0.234375	-0.45313	-0.92188
38:00.0	0.234375	-0.45313	-0.92188
38:00.0	0.234375	-0.4375	-0.90625
38:00.1	0.25	-0.4375	-0.92188
38:00.1	0.234375	-0.4375	-0.90625
38:00.1	0.234375	-0.4375	-0.90625
38:00.1	0.234375	-0.45313	-0.90625
38:00.1	0.234375	-0.45313	-0.90625
38:00.2	0.234375	-0.45313	-0.90625
38:00.2	0.234375	-0.45313	-0.92188
38:00.2	0.234375	-0.4375	-0.92188
38:00.2	0.234375	-0.4375	-0.90625
38:00.2	0.234375	-0.4375	-0.92188
38:00.3	0.234375	-0.4375	-0.92188
38:00.3	0.234375	-0.4375	-0.92188
38:00.3	0.234375	-0.4375	-0.92188
38:00.3	0.234375	-0.4375	-0.92188

The signal vector magnitude is the magnitude of acceleration (the rate of change of velocity per unit of time) in three directions which gives a measure of activity in three axes, which can be plotted on a line graph (Figure 4.3.). The accelerometer vector length from the Euclidean distance of the three accelerometer axes is calculated and the 1g expected from gravity while stationary is subtracted. The signal can be improved by applying a fourth-order Butterworth band-pass filter between 0.5Hz to 20Hz, which filters for frequencies of human movement only. Negative values are treated as ‘absolutes’ and the value is combined into a mean measurement over a user-defined epoch length (seconds) leading to an equation: $SVM-1 = \text{sum}(\text{abs}(\sqrt{x^2 + y^2 + z^2}) - 1)$ which can be plotted as one single line graph (Figure 4.4.).

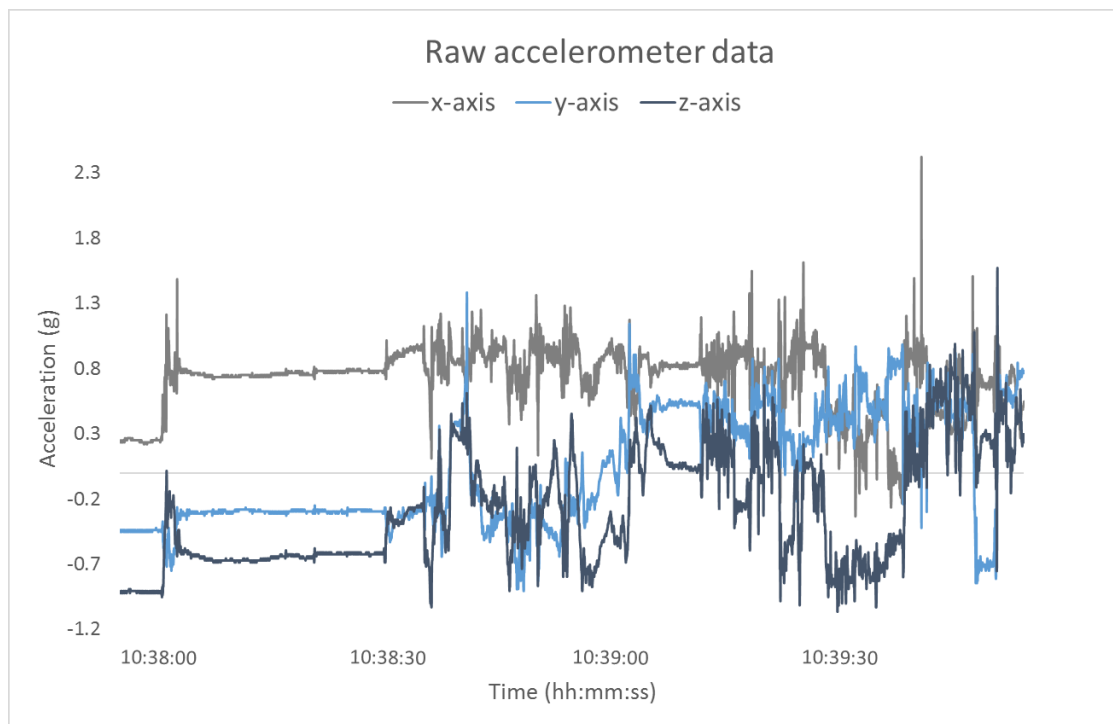


Figure 4.3. Line graph representing three axes of raw accelerometer data

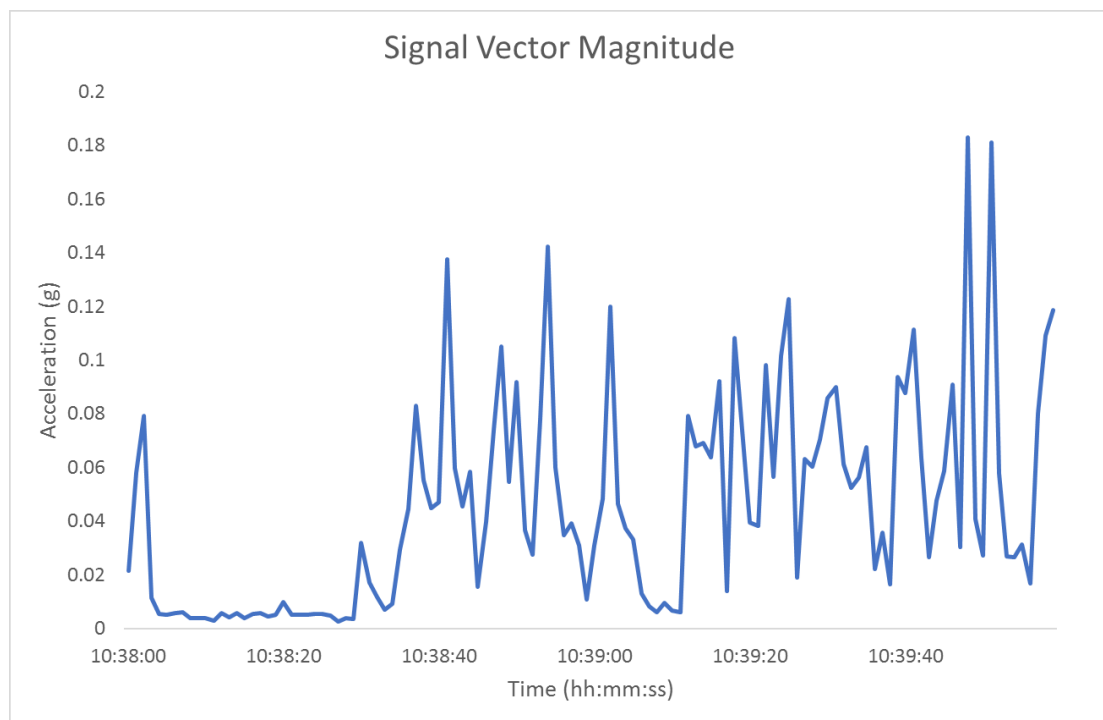


Figure 4.4. Line graph representing the signal vector magnitude

Further analysis of the activity data can be performed by comparing the SVM to known Metabolic Equivalent of Tasks (METs). 1 MET is equivalent to the rate of energy produced per unit surface area of an average person seated at rest. Different equations are used for different sensors, based on previous calibrations and validation studies. The AX3 was validated against the GENEA accelerometer which uses Eslinger et al's¹⁹⁰ calibration equation. The maximum oxygen uptake (VO₂) was measured using the Cosmed K4b2 metabolic gas analysis system. The VO₂ is converted to METs using the standard conversion of 1 MET = 3.5mL/Kg/min. There are four absolute-intensity categories, sedentary, light, moderate and vigorous. Total activity is defined as any non-sedentary behaviour, i.e. any activity above a 1.5 MET threshold. Table 4.2 sets out the comparison of METs with activity intensities. Studies evaluating the standard error of the estimate using multiple regression models have shown that the mean standard error of the estimate (SEE) was 0.613 with a standard deviation of residual errors was 0.709¹⁹¹.

Table 4.2. Activity type and corresponding Metabolic Equivalent of Tasks (METs)

Activity type	METs
Sedentary	<1.5
Light	1.5 - 4
Moderate	4 - 7
Vigorous	>7

The separate activity intensities are known as 'cut-points'. Receiver operating characteristic (ROC) curve analyses were performed to examine the use of these thresholds to discriminate between the four different intensity categories. This was found to have almost perfect discrimination (ranging from 0.97 to 0.98)¹⁹⁰. The mean SVM over 60 seconds is then compared against these known cut-points to allow identification of activity intensity type, giving a non-linear relationship between SVM and METs (Figure 4.5).

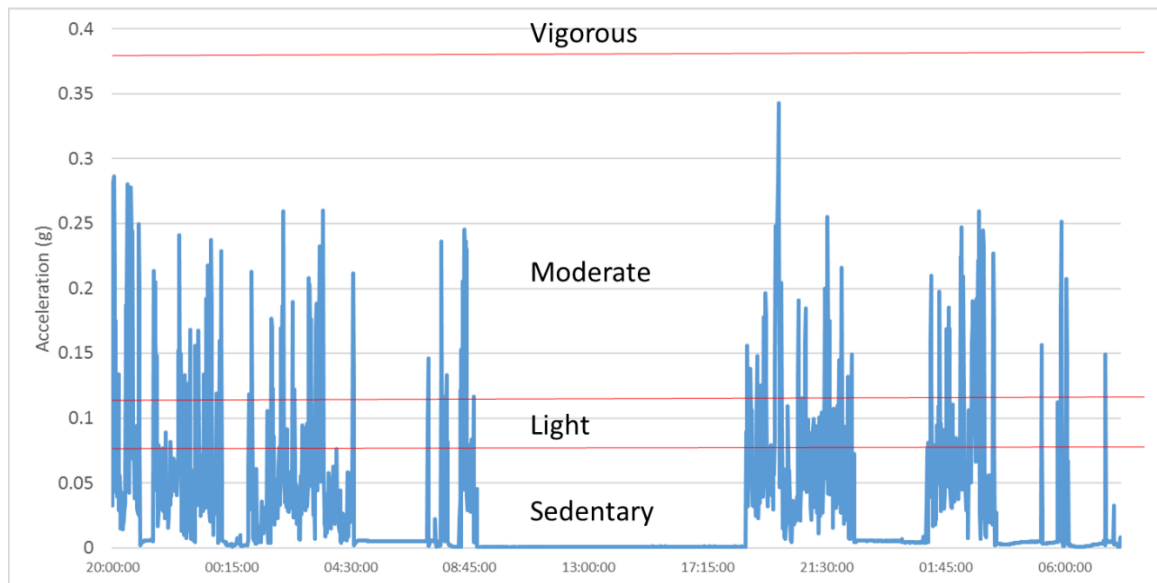


Figure 4.5. Line graph showing the cut points for SVM accelerations

Statistical analysis

Descriptive statistics (mean, standard deviation) were calculated for subject demographics and activity output measures. Independent samples t tests were performed to compare activity between males and females. A Pearson's correlation was performed to assess correlation between physical activity levels and participant age. A Friedman test was performed to compare amount of activities over all days. Statistical analysis was performed using the Statistical Package for Social Sciences version 23.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY).

4.3. Results

4.3.1. Study participants

In total, eleven normal, healthy participants were recruited, six females and five males. They had a mean age of 65 years (SD 7.26, range 52-73). Average WAM wear time was 4.6 days. The WAM was worn by all participants on both weekdays and one weekend day (and/or Bank Holiday Monday). Table 4.3 shows the baseline demographics and comorbidities of the study participants.

Table 4.3. Baseline demographics and comorbidities of study participants

Characteristics	Participants (n = 11)
Gender (male:female)	5:6
Age (years), mean	65
Comorbidities, (%)	
Hypertension	36
Hypercholesterolaemia	45
Diabetes	18
Previous malignancy	18
Musculoskeletal	64
Previous intra-abdominal operation	45
Other	18
Smoking History, (%)	
Non-smoker	100
Alcohol History, (%)	
No alcohol	64
Minimal alcohol	36

4.3.2. Main findings

Total daily activity

The mean total activity per 24-hour period was 177 minutes (SD 43). Males had a slightly greater daily mean total activity (179 mins SD 50) than females (175 min SD 41) but this was not statistically significant ($p = 0.499$) (Figure 4.6.).

Activity types

Activity was broken down into light, moderate and vigorous intensities. The total mean light activity performed was 95 minutes per 24-hour period (SD 24). Mean moderate activity was 87 minutes per 24-hour period (SD 25). There was no sustained vigorous intensity activity recorded within this cohort of participants. Males performed more daily mean moderate activity, but this was not found to be statistically significant ($p = 0.058$). There were no other significant differences between males and females (Figure 4.6.).

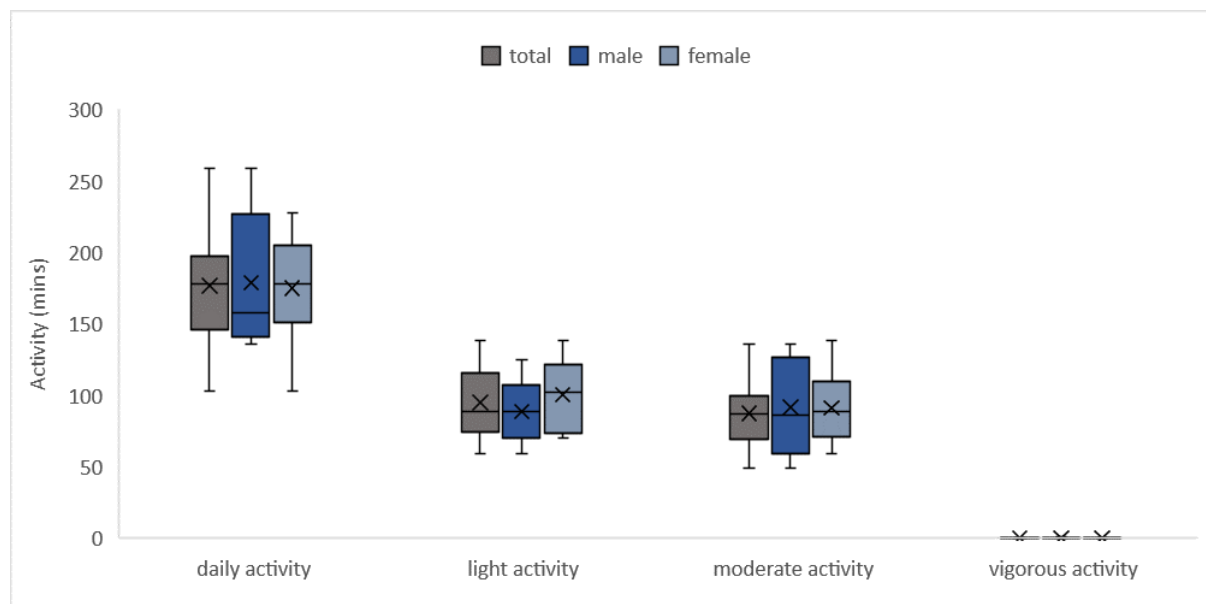


Figure 4.6. Bow and whiskers plot showing time spent in total activity and different activity levels, and split by gender

There was no statistically significant difference in activity (all types) by age of participant ($p = 0.127 - 0.949$).

Activity broken down by time-points

Mean total night activity (23:59 – 05:59) was 6 minutes per 24-hours (SD 6, range 0-21). Males had higher activity levels at night (9 mins SD 8) than females (2 mins SD 2) $p = 0.052$. Mean total morning activity (05:59 – 11:59) was 73 minutes per 24-hour period (SD 20, range 48-104). Mean total afternoon activity (11:59 – 17:59) was 70 minutes per 24-hours (SD 25, range 36-114). Mean total evening activity (17:59 – 23:59) was 33 minutes per 24-hours (SD 16, range 17-63) (Figure 4.7).

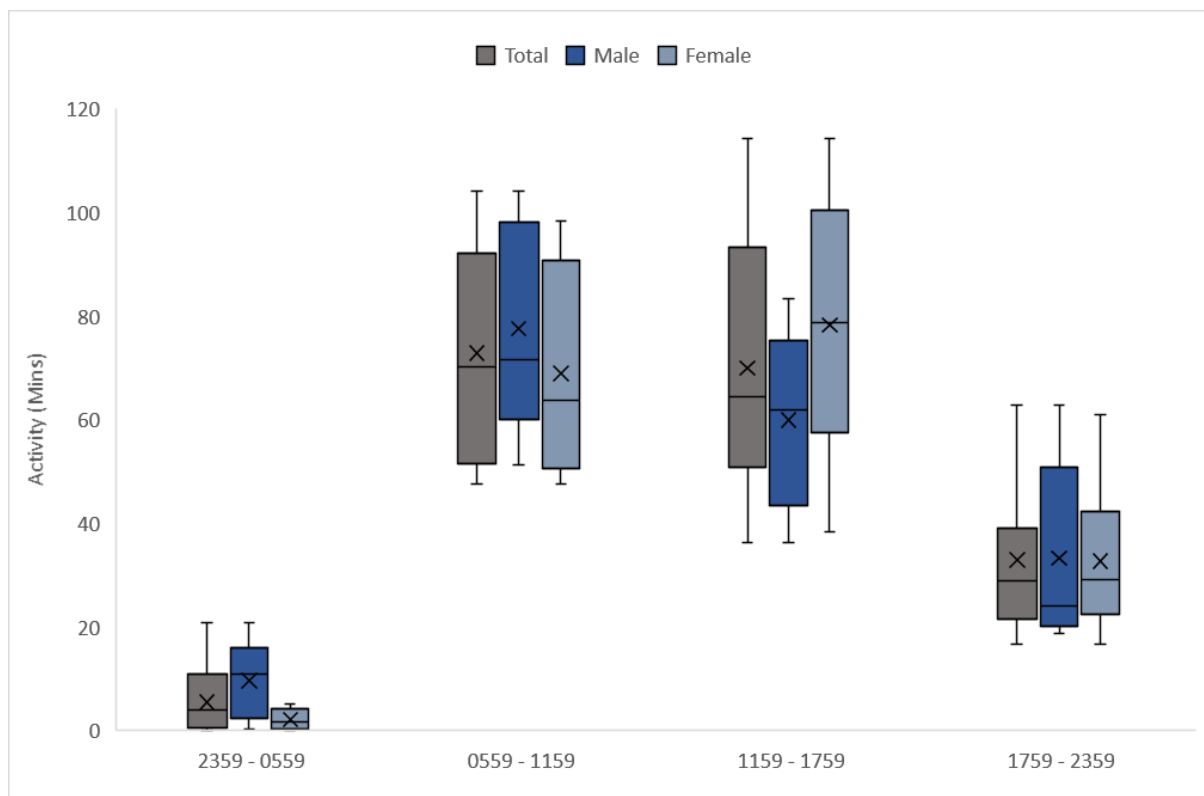


Figure 4.7. Box and whisker plots showing total activity over four time-periods in the day

Activity bouts

A bout of activity is a period of continuous activity without pause. Over the whole sensor wear period the mean total number of activity bouts of more than ten mins was 11 (range 3-23 SD 7). The mean number of moderate activity bouts of more than ten mins was 2 (range 0-8 SD 2). Bouts of two minutes in length were the most common, and the longest bout length was 40 mins of total activity (Table 4.4.). Total bouts are made up of light and moderate bouts, and can be made up of any amount of time spent in these two different intensities, that adds up to be two minutes or more. For example, a bout would not be included in light intensity if less than two minutes, however if the activity is a mixture of less than two minutes of light intensity activity and just over two minutes of moderate intensity activity that would equal one bout of total activity of four minutes. Hence, total activity bouts are not simply the addition of the light and moderate activity bouts.

Table 4.4. Mean number of activity bouts performed in total, in light activity and in moderate activity

<i>Bout length (mins)</i>	2	3	4	5	6	7	8	9	10 or more
Total activity	60	33	19	16	10	6	6	3	11
Light activity	56	19	6	3	1	0	0	0	0
Moderate activity	41	21	10	5	3	3	2	1	2

Difference in activity levels between wear days

A Friedman test was performed and showed there was no statistical differences in total activity or type of activity performed between days (Total activity; $p = 0.212$) (Figures 4.8 & 4.9.).

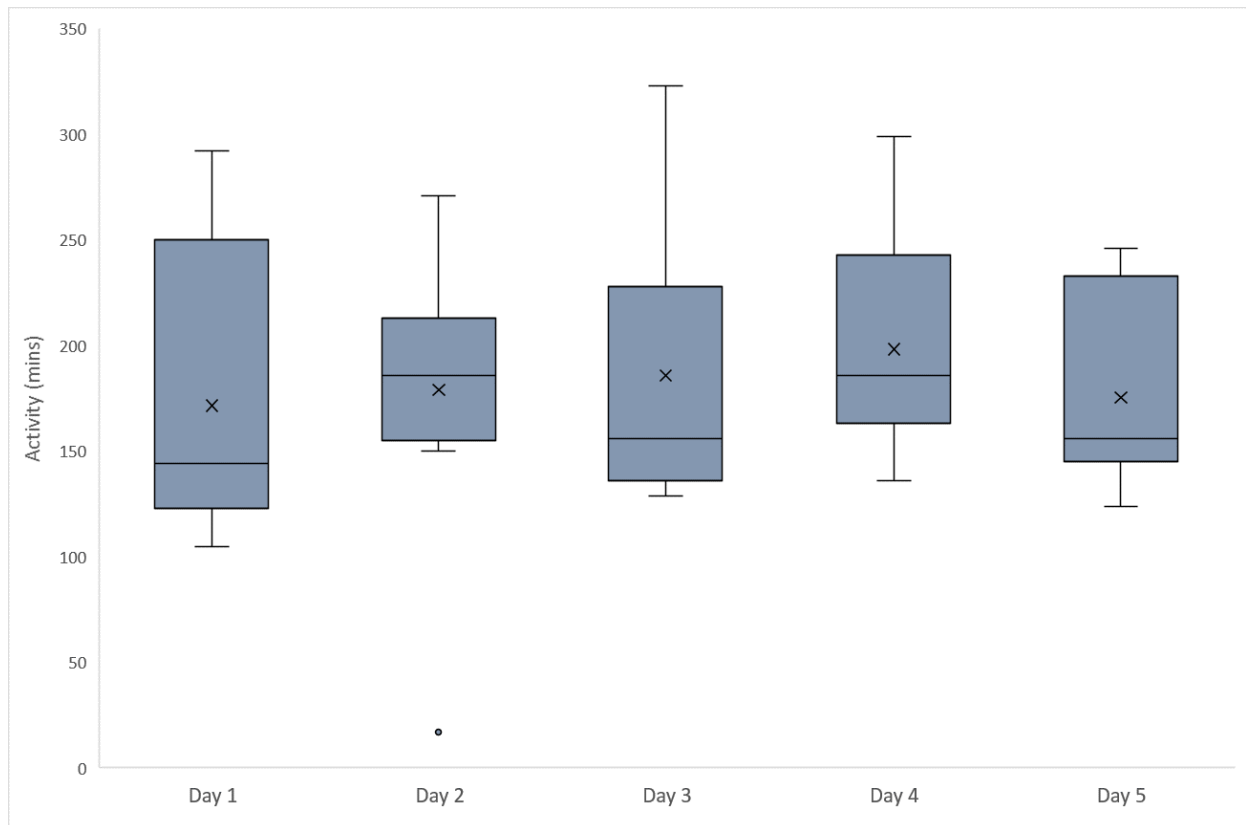


Figure 4.8. Box and whisker plot showing difference in total activity levels between all five days of wear

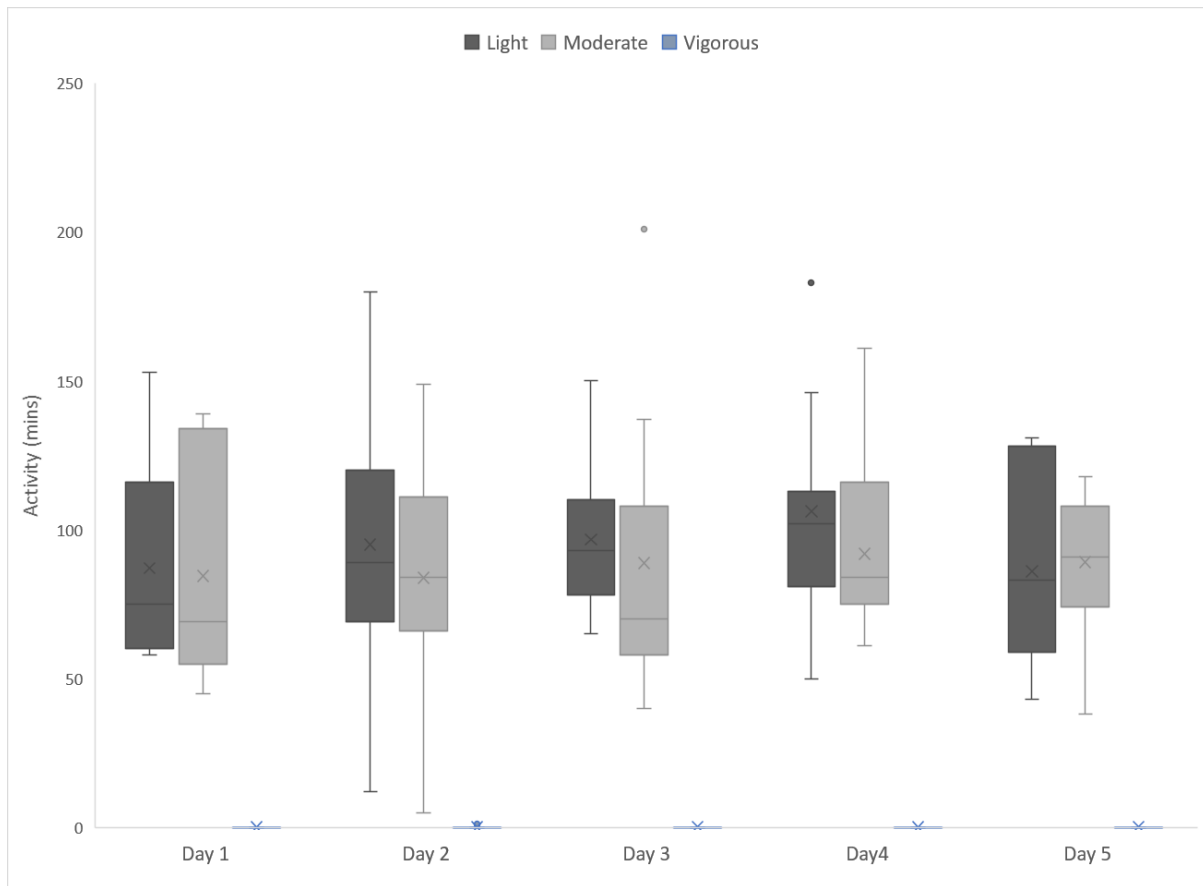


Figure 4.9. Box and whisker plot showing difference in activity type between all five days of wear. Circular dots show outliers.

Individual participant activity

Individual participant data were reviewed and activity displayed in different ways. An overview of the total activity over the intended wear time can help identify any unusual patterns in activity, or conversely, allow identification of typical activity routines (Figure 4.10.).

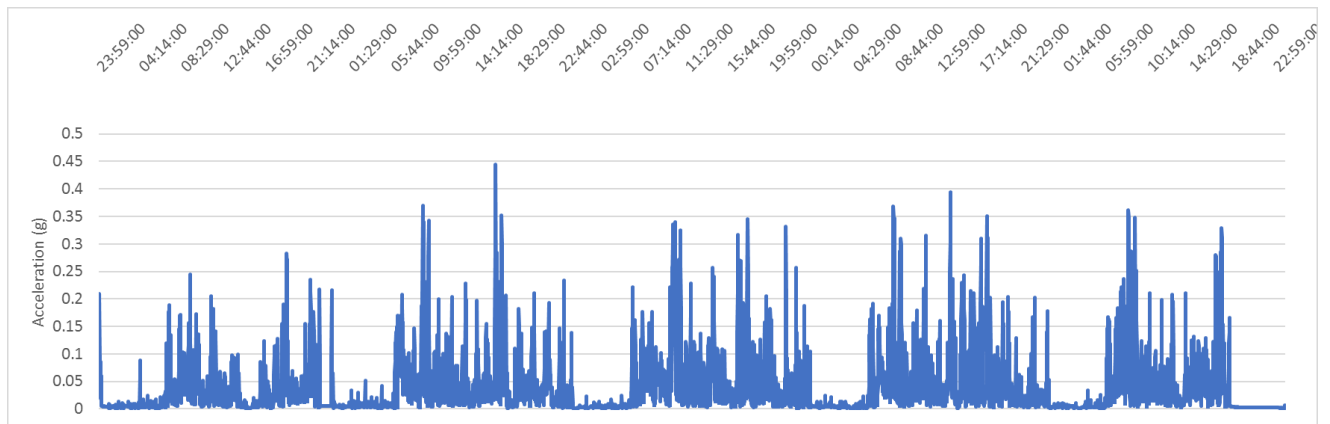


Figure 4.10. Line graph showing SVM acceleration over total wear time, Participant C

Comparison of SVM across specific time points on different days allowed the recognition of a ‘signature’ of a specific activity, (Figure 4.11.) showing activity between 0800 to 0830 for one participant on all five days. It is also possible to compare different participants across the same time points (Figure 4.12.) and this can help identify differences in waking or bedtime routines, increased activity during the normal day, or where abnormal activity occurs during night time hours. This way of viewing the data also allows analysis of wear-time. Even though a person may be stationary or asleep, they often move small amounts that will be picked up by the WAM, and therefore transmitted into data output. The SVM is not high enough to be included in light intensity activity, it is still classed as sedentary, but movement can be seen. However, when the graph line is completely horizontally flat, no movement at all is detected, this means that the device is not moving, and therefore can be classified as non-wear time, i.e. the participant is not wearing the device.

Two participants were found to have non-wear times during night time hours, Participant E for two of the nights and Participant H for all nights. Participant G had a period of non-wear time on one day from 11.00 to 21.00.

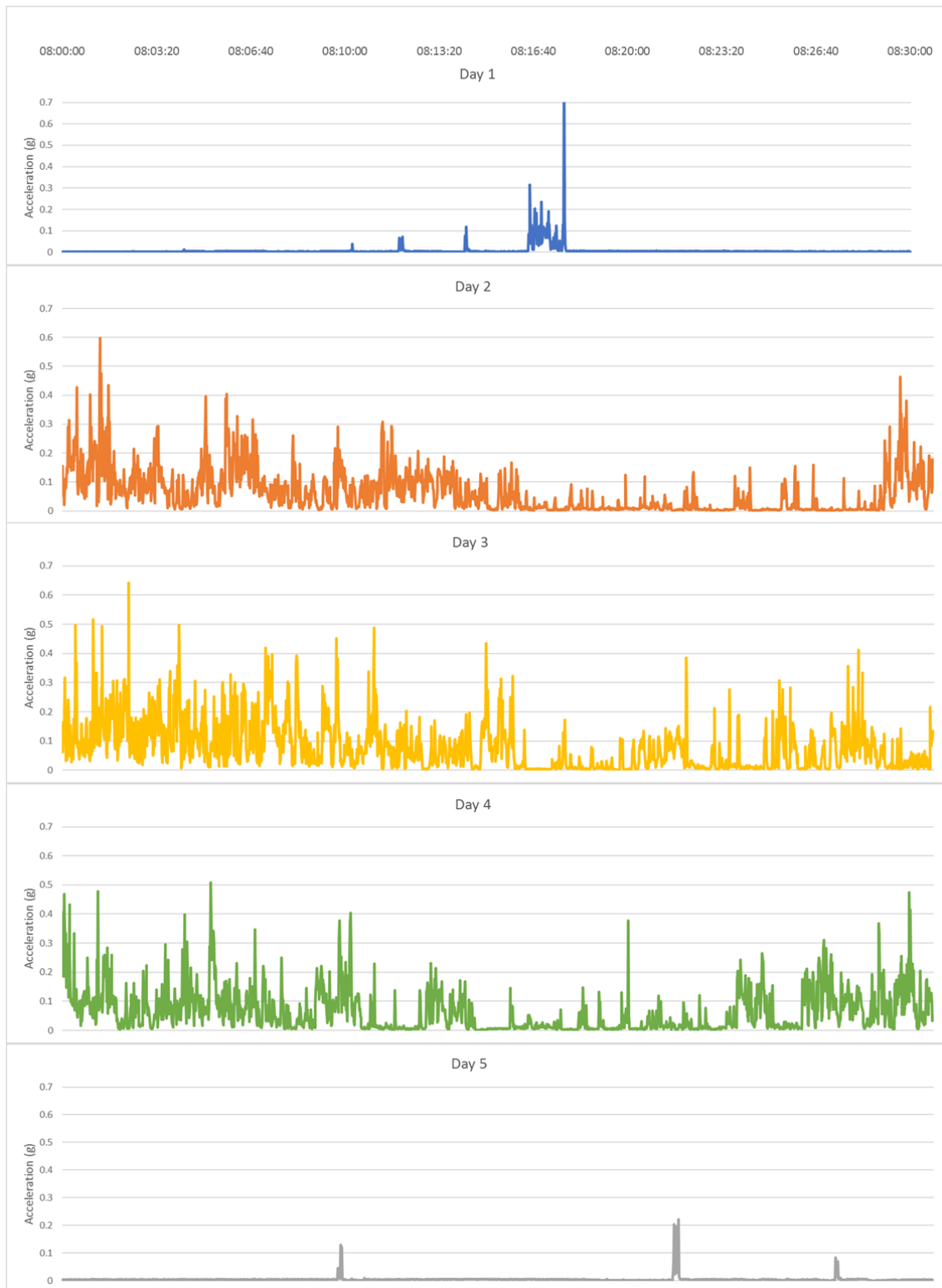


Figure 4.11. Comparison of activity (SVM) for each day between 0800 to 0830, Participant A



Figure 4.12. Comparison of activity (SVM) between participants (A, B, E, H, K) over a 24-hour period

Data can be viewed to compare each day's activity, and the activity intensity, (Figure 4.13.), this allows easy identification of the days on which more activity took place, and the intensity of activity on these days. Furthermore, the day can be broken down into twenty-four sixty-minute periods, (Figure 4.14.), and the amount of activity performed within each hour can be ascertained. This allows easy comparison of activity, to identify time-periods when most activity and least activity are performed.

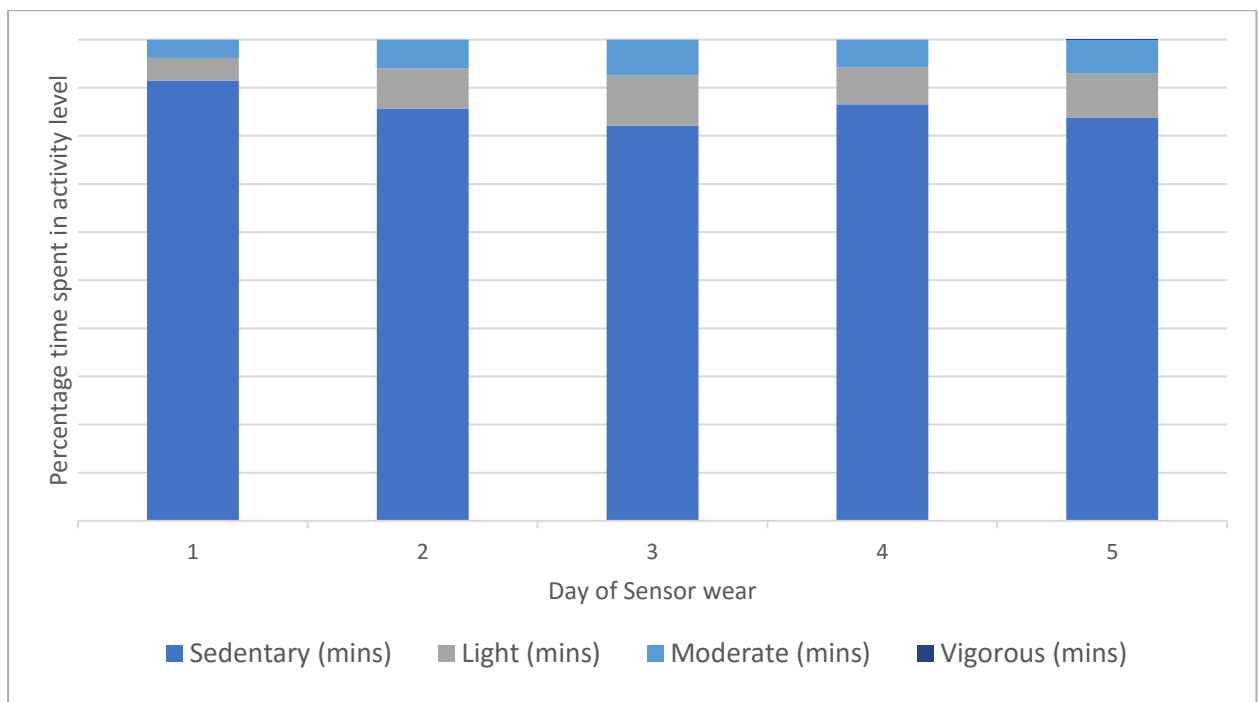


Figure 4.13. Stacked bar chart showing percentage of activity types performed each day, Participant A

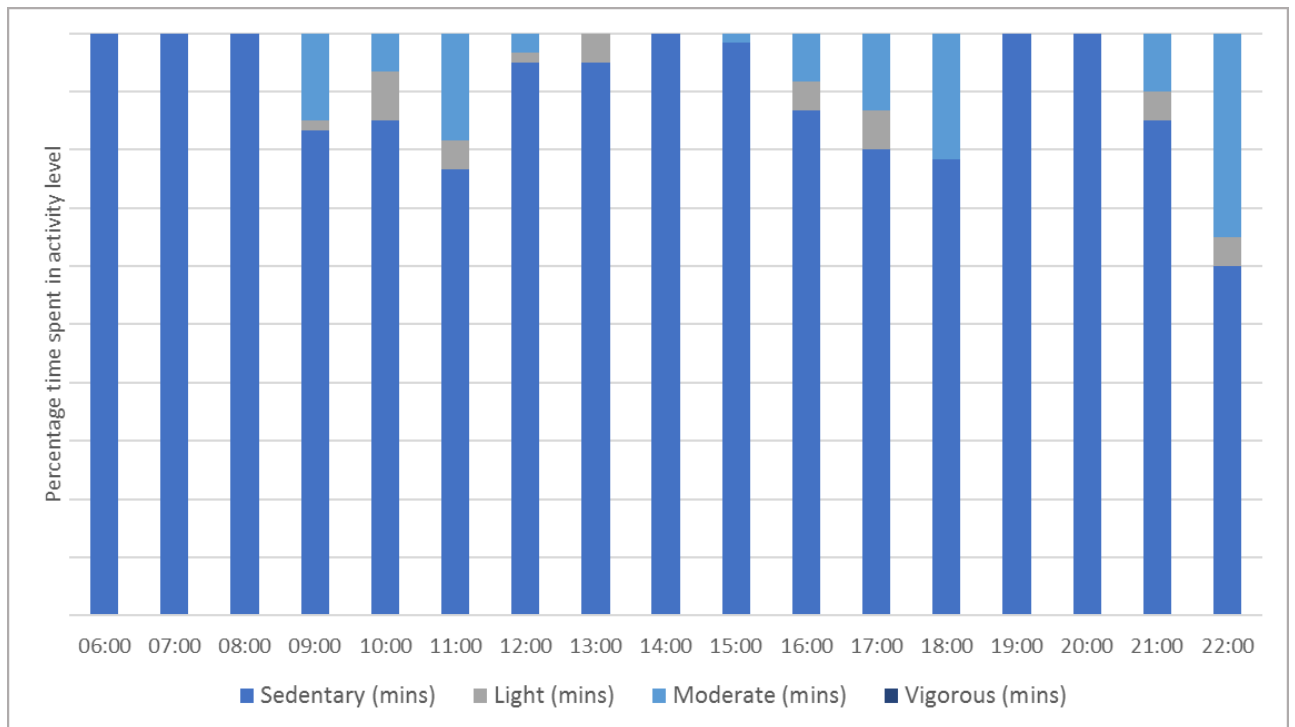


Figure 4.14. Stacked bar chart showing percentage of activity type per hour during normal waking hours, Participant A

4.4. Discussion

This study demonstrates the feasibility of using the AX3 Axivity (Newcastle, UK) to objectively measure continuous activity in a normal healthy cohort, which will then be used as a control cohort to compare with the patient cohort data. Physical activity data were collected, showing that participants were more active in the day than during the night, and more light and moderate activity performed, with minimal vigorous activity. The WAM data was continuous and this is reflected in that there are data for all days and time periods, showing that the WAM technology measures continual everyday physical activity. Activity data were processed both at an individual level and as a group, this allows analysis of participants within a cohort as well as helping to identify individual participant's activities and daily routines.

Activity at night, though minimal which is to be expected, still occurred but more often in the male participants. This could be due to an older cohort, with possible prostatic symptoms, who wake at night needing to urinate. Almost no vigorous activity was performed in this cohort, one possibility could be due to the age of participants, with minimal running and vigorous leisure activity being performed, rather walking and lighter activity types instead, however, the cohort performed more daily moderate activity than Department of Health recommendations¹⁶⁸. Bouts of activity performed most commonly were two minutes in length, this could suggest that the activity performed is just part of their daily routine and not scheduled or extra activity e.g. exercise class, going for a run or playing tennis. There were no statistical differences in total activity or type of activity intensity between all five days the WAM was worn, this seems to suggest that activity on all days were similar and that five days' worth of data probably is representative of the participants general daily activity. Looking specifically at each participants data, it is possible to see the times they wake up in the morning and go to sleep at night, as well as time periods where they may wake during the night.

Although this study only included eleven participants, the intention was to prove that continual physical activity monitoring was feasible and analysis of the data possible, picking up any possible issues or problems prior to monitoring a peri-operative clinical cohort. Our results are similar to those from the UK Biobank Study¹⁵⁷, which showed that there were differences in activity by time of day, but not any differences between weekend days and week days. Their study also found that there were age related differences in activity, with the older participants performing less physical activity in total. Both weekend and week days were monitored in our study, with the Bank Holiday Monday counting as a weekend day allowing us to analyse if there were any differences in activity between the weekend and the week days.

The Hawthorne effect¹⁹² describes a change in behaviour of a participant in a study due to their awareness that they are being observed within a study. Wearing a WAM is a constant reminder to the participants of this study that they are being monitored and observed, and could therefore change their behaviour, performing more physical activity, because they know that the study is monitoring them. It is, however, difficult to perform blinding for these sort of trials as the WAM must be worn by the participant and are therefore continually aware they are taking part in a trial. However, the length of time the WAM is used hopefully helps to negate this effect, as the participants get used to wearing it over time and then go about their daily lives as usual.

The data collected within this study showed a good overview of participant activity over the five-day observed period. However, there were a couple of limitations. Two participants did not wear the WAM overnight, and the data clearly shows activity prior to taking it off and once it has been put on again in the morning. Therefore, we were unable to assess night-time activity for these participants. This could be due to discomfort of wearing the WAM in bed, or that the participant is used to taking off their watch, for example. This makes analysis more difficult as there will be some participants with night-time data, and others without. One participant was shown to have

non-wear time over a day time-period, when activity would have been expected to occur. Non-wear time started at 11:00 and the next time activity was detected was at 21:00. Possible explanations for these are if the patient had taken a bath, or gone swimming, and had taken the WAM off as directed but then forgotten to put it back on again. This can skew the data, both because it may miss activity done e.g. if swimming was being performed, or because a large proportion of the daytime activity has been missed. Furthermore, intention to treat for non-wear time creates a potential bias in the data.

Practically going forward with the peri-operative study, reminders need to be given to patients to keep the sensor on at all times, and to put it back on again if the WAM has been taken off for some reason, e.g. during the operation itself.

4.4.1. Clinical Implications

The analysis performed in this cohort gave data that will be useful to understand healthy adult individuals and allow comparison with the surgical cohort in the next study. Specifically, analysing the amount of activity on each day is important, in this cohort there were statistically similar activity levels on all days, knowing this for a peri-operative cohort could help in understanding how patients recover on each post-operative day. The ability to see SVM traces for each individual over specific time periods allows easy analysis and comparison to see at which time points most activity occurs, and if there are activity ‘signatures’ that can be recognised, both as a normal pre-operative activity, or post-operatively as a patient recovers. It will also be important to recognise non-wear time within the clinical cohort to allow us an insight into when the WAM is worn and what clinical and practical barriers there are to wearing them.

Chapter 5

Wearable activity monitors in the peri-operative setting

5.1. Introduction

Admission to hospital, whether for an elective procedure or as an emergency admission, changes people's surroundings and daily routine in more ways than just the illness or procedure being done. For some patients their hospital experience will be a wait in the Accident & Emergency department for a number of hours before being discharged home. Other patients will require admission into a hospital ward itself, either overnight or for a number of days whilst investigations are performed, and a diagnosis is given. A smaller subsection of patients are admitted for a longer period of time, whether due to acute illness management or frailty. These interactions with healthcare provision can change a person's actions and how they interact with their surroundings.

Because of the wait, normal meal times may be disregarded, with people often buying food from vending machines in the A&E department, furthermore, people must sit in the waiting room, unsure when they will be called through to see the medical team. If a patient is admitted to the ward, either electively post-surgery, or as an emergency admission their environment and daily routines can be very different from their usual lifestyle and activity.

Some procedures and operations can now be performed either as a day case, where a patient can go home on the same day, or as a 24-hour stay, the patient stays in overnight and is then discharged home. However, many patients still stay in hospital for longer periods of time, ranging from a couple of days to many weeks. The average length of hospital stay in the UK is 7.1 days¹⁹³. In England during 2016-2017 there were 23.4 million attendances recorded at Accident and Emergency¹⁹⁴ and 19.7 million total hospital admissions¹⁹⁵.

5.1.1. Hospital in-patient wards

Structure of wards

Nightingale wards, named after Florence Nightingale, contain a large room/corridor without any subdivisions and contains between 24 to 36 beds, these were a common ward layout until the 1960s¹⁹⁶. Racetrack wards, which have 4-6 bedded bay areas became more popular with the more modern hospital buildings¹⁹⁶. Although the NHS Service providers are encouraged to provide higher proportions of single room accommodation (of about 50%) in new hospital builds¹⁹⁷, this has not yet come into fruition, and therefore most wards are set out in the racetrack ward design with 4 - 6 beds in a bay area, with curtains that can be pulled around the bed space to give some privacy. There are several side rooms, for patients with infectious diseases or in need of privacy e.g. end of life care.

The nurses' station is often situated in the middle of the ward, with those patients who are more unwell placed nearer to this station, and those who are more ambulatory with less need of input placed further away. There are uni-sex bathrooms/toilets, usually per 4-6 bedded bay area, with ensuite bathrooms in single rooms. Other areas on the ward include treatment rooms, supply/storage room, clean and dirty utility rooms, clinical administration area, education/training facilities, visitor/relatives' room. Sometimes there is also a communal space for patients e.g. a communal TV room¹⁹⁸.

Daily life on an inpatient ward

Although each patient will have a different reason for their hospital stay, and often follow different trajectories and lengths of stay, the daily life as an inpatient is often very similar. From the early morning waking for observations and medication giving, to set meal times, ward rounds and investigations. Patients may see the physiotherapist, the social worker and the occupational therapists as well as other specialty reviews (Figure 5.1.).

Figure 5.1. Generic daily inpatient routine on ward

Basic Daily Ward Routine	
06:30	Medication round Observations checked
07:30	Blood tests Breakfast Shower/wash
08:30	Ward round by clinical team
09:30	Investigations e.g. X-ray, CT scan, MRI, Endoscopy Surgical procedures
10:30	Review by physiotherapy/occupational therapy/social worker Observations checked
11:30	Review by other specialty
12:30	Lunch Medication round
14:30	Visitors Re-review by clinical team
16:30	Observations checked
17:30	Supper
18:30	Medication round
20:30	Observations checked
22:30	Medication round Light out

Most of these daily inpatient routines take place at or near the patient bedside and there is almost a clinician expectation that the patient is never far away from their bed space for blood tests, investigations, or a review by other specialties. Even meal times take place with the patient either in bed or sat out next to their bed. Rarely is there provision or space to eat somewhere else on the ward/communal space. Similarly, patients often expect to convalesce in hospital, remaining in pyjamas in bed and not moving around or leaving their bed space except to use the bathroom. This may be because they are not feeling well enough to move around, they do not think about moving into the chair or walking around the ward or, they may not be encouraged by their clinical

teams/nursing staff.

Some patients need to be isolated due to infection risk, e.g. C. Difficile or MRSA, and are therefore not allowed to mobilise into the main part of the ward to prevent other patients from contracting the same pathogens. Other patients are too unwell and so cannot mobilise, especially if they are needing higher dependency care e.g. HDU/ITU.

In Spring 2018 a social media campaign called #EndPJPParalysis was launched by NHS England with the view of making sure patients are up and dressed each morning and move around as they usually would at home. This was a response to the greater understanding about deconditioning – that patients who sit or lie in bed for too long eventually lose their muscle strength. Kortebein et al.¹⁹⁹ showed that healthy older adults, who rested in bed for ten days had a substantial loss of lower limb strength, power and aerobic capacity, as well as a reduction in physical activity. A study by Brown et al.⁵² where hospitalised medical patients were monitored with wireless accelerometry showed that on average 83% of the hospital stay was spent lying in bed, despite being able to walk independently prior to admission.

Decreased mobility is also a risk factor for venous thromboembolism (VTE), which includes deep vein thrombosis and pulmonary embolism. In 2005 VTE was shown to be the underlying cause of death in more than 6500 patients²⁰⁰.

One study looking at older medical patients has shown that those patients that had an increase by 50% in mobility (step count) whilst an inpatient had a 6% reduction in length of stay²⁰¹.

5.1.2 Recovery after surgery

Recovery from surgery occurs at different rates for different aspects of recovery. Some patients

and procedures do not require a hospital stay, e.g. day case laparoscopic cholecystectomy. Some require an overnight stay, especially if a patient lives on their own at home. Others, however, require longer hospital stays. Short term recovery involves recovery from the anaesthetic and physiological recovery of the stressors of surgery and anaesthesia on the heart and circulation. Wound healing comes together with pain control as body tissue repairs itself. These tend to begin in hospital but can continue after discharge and at home. Patients are encouraged to eat and drink from early stages post-operatively especially in elective cases, and fluid restriction prior to the operation is also minimised, as fluid balance has an important role in patient recovery.

Medium and longer-term recovery involves patients getting back to their normal everyday life. In hospital this will start with them getting out of bed to sit in a chair, walk around the ward and to the bathroom. They may not be as steady on their feet, as fast or as confident in their mobility, but this improves slowly over time and into the time-period after discharge home or to a rehabilitation centre. This process of functional recovery, will depend on the person themselves, their pre-operative function, the operation they have had, any complications and how they engage with their recovery and how motivated they are. Part of ERAS is the encouragement of the nursing, clinical and physiotherapy teams and to help the patients mobilise and begin their functional recovery whilst still in hospital. However, recovery still occurs at home, and it can be many weeks or months before patients are functioning back to their baseline levels, performing all their activities of daily living, going to the gym or performing other higher levels of activity. Furthermore, patients who undergo hernia repair surgery or open abdominal surgery are recommended not to go to gym or lift heavy weights for six-to-eight weeks after surgery, to allow sufficient wound and tissue healing to prevent hernia formation.

Once home, patients continue to recover, this can be emotionally as well as physically. They may play the 'sick role' at home, needing support from family or even care workers, or may 'bounce

back' quickly and settle back into their old routines or way of life. This is dependent on their previous baseline, as well as the operation they have had and how they recover. Currently there are ideas about 'pre-habilitation' – improving patients baseline reserves and physical fitness prior to any higher risk and extensive operations, e.g. operations to remove cancer. The idea behind this is that with a better functional reserve, these patients do better post-operatively and recover quicker.

5.1.3 Clinical Problem

Understanding a patient's baseline activity is a useful determinant of how fit and healthy they are prior to hospital admission as well as recognising their daily routine and levels of activity. This can help the clinical team to be aware of their underlying physical function and how they may recover after an insult to their physiological function after surgery.

Whilst an inpatient the amount of physical activity performed by the patient is estimated by the clinical teams, and is often used to help with discharge planning, whether a patient is fit to be discharged, whether they need extra help at home to aid mobilisation, or if they require further intense physiotherapy assessment and input e.g. rehabilitation. The amount of activity performed is only estimated subjectively though, as there has been little, or no, objective data available to clinicians about patient activity on the wards. Recent studies have used wearable activity monitors to objectively measure physical activity in the in-patient setting. A study by McCullagh et al.²⁰¹ measured average daily step counts in hospitalised medical patients and showed that steps taken during the hospital admission were low, but seemed to increase slowly on each subsequent day of admission. There have been other studies^{62, 69, 76, 82, 83, 89, 90, 92, 97-112, 150, 202} looking more specifically at activity in patients following surgery on the ward, whilst in hospital. One study found that activity levels were low in patients after surgical intervention for hip fractures¹⁵⁰. Whereas, Wickerson et al.⁸² found that post lung transplant patients had similar activity levels pre-operatively and at

discharge.

There have also been a number of studies looking at physical activity levels after discharge from hospital. Often this is not the immediate post-operative period that is monitored, rather at three, six, twelve or more months post-operatively^{56, 203}. These studies help to quantify longer term recovery, but do not necessarily help with understanding the recovery path in the early post-operative days, and how recovery can differ whilst in hospital compared with at home.

No study has looked at the full peri-operative period, including the pre-operative time period (at home prior to the operation), as an in-patient recovering from the operation in hospital, and then at home following discharge from hospital in a colorectal cohort. WAMs have the potential to fulfil a role that would allow objective activity data to be recorded and analysed for patients undergoing surgery. This would allow assessment of pre-operative baseline function, determination of any pre-existing functional issues that may need to be addressed post-operatively, quantification of in-patient activity and whether baseline levels are being met prior to discharge, as well as giving insight into patient recovery at home in the immediate post-operative period.

This study aims to capture objective physical activity data in the full peri-operative period, for patients undergoing colorectal surgery, pre-operatively at home, post-operatively on the ward and post-operatively after discharge.

5.1.4. Hypothesis

Wearable sensor technology to monitor activity in the whole peri-operative period is feasible, showing a decrease in activity following surgery, a small increase on each post-operative inpatient day and greater increase back to baseline once discharged home.

5.2. Methods

5.2.1. Outline

A wearable activity monitor (WAM) was used to assess patients undergoing elective colorectal surgery peri-operatively. Patients wore the wearable activity monitor continuously both at home, pre-operatively, and on the ward following their operation until they were discharged home. A further cohort also wore the WAM at home after discharge. The objective activity data was recorded, viewed and analysed to present a picture of patient activity prior to surgery, on the ward post-operatively and at home recovering.

5.2.2. Conducting the clinical trial

Ethical approval

Ethical approval was sought and granted from the NRES committee London - City Road and Hampstead (September 2015 – Ref 15/LO/1038).

Registration of the clinical trial

The study was registered at *clinicaltrials.gov*, which is an open worldwide database providing information about current ongoing clinical research studies. The study was registered under ‘The Step Home Trial: Utilising Physical Activity Data in the Acute Post-Operative Setting – ID NCT02583711’

Recruitment and eligibility

Patients who were seen in the colorectal clinic and booked for an elective surgical procedure at St Mary’s Hospital were identified and assessed in line with study eligibility criteria. The first cohort were recruited between October 2015 and October 2016, and the second between May 2017 and September 2017. Patients were excluded if they were dependent on someone else to mobilise, this is because any activity performed could not be solely attributed to the patient and would be majorly

dependent on the help being given. Furthermore, those patients with movement disorders, e.g. Parkinson's disease may have an added tremor or other bodily movements which would be picked up by the sensor and would not be specific to mobilisation and ambulatory activity levels. See Table 5.1 for a full list of inclusion and exclusion criteria.

Table 5.1. Eligibility criteria for recruitment

Inclusion	Exclusion
Undergoing elective colorectal surgical procedure at St Mary's Hospital, Paddington	Unable to mobilise independently i.e. Walk with stick/frame or dependent on another person to mobilise
	Have medical condition characterized by movement disorder e.g. Parkinson's Disease
	Unable to understand and complete the SF-36 (unless interpreter present) or lack capacity to consent
	Severe uncontrolled psychiatric disorder e.g. psychosis, schizophrenia
	Aged less than 18

Data collection

During a pre-operative outpatient clinic appointment, a member of the direct healthcare team (i.e. doctor or nursing staff managing the clinical aspect of the patient's care) introduced the study protocol and gained verbal consent for the researcher to discuss the study in detail. This was either done at the end of the clinic appointment or arranged for another time when the patient was having their pre-assessment clinic or specialist nurse clinic appointment. Patients received a participant information sheet and were given time to ask any questions. If they were happy to take

part in the study written consent was gained.

Wearable Activity Monitor (WAM)

The patients were given a wearable activity monitor (AX3, Axivity, Newcastle, UK) and asked to wear it continuously, from the time of consent (approximately one to two weeks prior to surgery), only removing it if they were having a bath or going swimming (see Chapters 3 & 4 for further WAM details). They were advised to go about their usual daily life and activities as normal. The WAM was collected back from the first cohort of patients when they were discharged from hospital, and from the second cohort of patients when they came back for their two-weeks post-operative outpatient clinic review.

Control Group

The control group for this study is the cohort of healthy participants from the study in Chapter 4. The activity data from that chapter is used to compare activity between those healthy participants and the patient cohort within this chapter/study. Healthy volunteers were recruited via a poster advert and through word of mouth. Participants were eligible over eighteen years old and able to mobilise independently, with no known movement disorder e.g. Parkinson's disease. People who expressed an interest in the study were contacted and initial eligibility criteria were checked. The participant information sheet was provided and written consent was gained. Participants were given a WAM and asked to wear it continuously, only removing it if having a bath or going swimming. They were advised to go about their usual activities and daily life. The sensor was returned after five days.

5.2.3. Data analysis

Sensor data

The sensor data was processed using the OMGui interface whereby raw motion data was transformed into measures of physical activity including total activity and subgroups of activity intensity (see Chapters 3 & 4 for full description).

Statistical analysis

Descriptive statistics (mean, median, standard deviation, range) were calculated for subject demographics and outcome measures. Statistical analysis was performed using the Statistical Package for Social Sciences version 23.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY). As the data was non-parametric, the Friedman Test was used to determine if there were any differences in activity between the pre-operative and post-operative days. The Mann Whitney U test was used to compare the control cohort to the patient cohort, as well as to compare data from males and females. The Wilcoxon signed rank test was used to determine if there was any significant difference in activity between the pre-operative average and activity on day of discharge.

5.3. Results

5.3.1. Study participants

Two cohorts of patients were recruited, the first wearing the WAM at home pre-operatively and post-operatively in the hospital (n=38) and the second wearing the WAM at home pre-operatively, in hospital post-operatively and then at home post operatively (n=10).

Cohort I

Between October 2015 and October 2016, 38 patients undergoing elective colorectal resection at St Mary's Hospital were recruited. There were 23 males and 15 females, with a mean age at the time of surgery of 66.4 (SD 11.3, range 29-90).

Three patients withdrew from the study. Four patients did not wear the sensor post-operatively, and one patient's sensor had not recorded any data, with possible sensor malfunction. Two patients did not return the sensor on discharge and we were unable to recover them. One patient had only post-operative data but no pre-operative data recorded. There were therefore 28 patients with full post-operative data and 31 patients with full pre-operative data. Table 5.2 shows full patient demographics and clinical characteristics for these 28 patients.

Table 5.2. Cohort I - Participant baseline demographics and clinical characteristics

Characteristic	Participants (n = 28)
Gender (male:female)	16:12
Age (years), mean (SD) [range]	67 (11.2) [29-90]
Body Mass Index (kg/m ²), mean (SD)	26.1 (4.7)
Comorbidities, number (%)	
Cardiovascular	14 (50)
Respiratory	9 (42)
Diabetes	4 (14)
Musculoskeletal	7 (25)
Other	14 (50)
Smoking History, number (%)	
Current	4 (14)
Non smoker	8 (26)
Ex smoker	16 (57)
Clinical diagnosis, number (%)	
Adenocarcinoma	21 (75)
[Dukes A]	6 (21)
[Dukes B]	7 (25)
[Dukes C]	9 (32)
[Dukes D]	0 (0)
[mucinous adenocarcinoma]	2 (7)
Medullary carcinoma	1 (4)
High Grade dysplasia	1 (4)
Benign	4 (14)
Approach, number (%)	
Laparoscopic (including SILS)	15 (54)
Laparoscopic assisted/conversion to open	6 (21)
Open	7 (25)
Type of Surgery, number (%)	
Right hemicolectomy	9 (32)
Anterior resection	8 (29)
Panprocto/subtotal colectomy/completion proctectomy	3 (11)
Abdominoperineal resection	3 (11)
Left hemicolectomy/sigmoid colectomy	2 (7)
Ileostomy reversal	3 (11)
Stoma formation, number (%)	
No stoma	16 (57)
Ileostomy	9 (32)
Colostomy	3 (11)
Length of stay (days), median [range]	7 [3-33]

Cohort II

Between May 2017 and September 2017, ten patients undergoing elective colorectal resection at St Mary's Hospital were recruited. There were five males and five females, with a mean age at the time of surgery of 65 (SD 9.2, range 42-75).

No patients withdrew from the study, but one patient did not wear the sensor at home on discharge. There were, therefore, ten patients with full pre-operative data, ten patients with full post-operative in-hospital data, and nine patients with full post-operative data at home. Table 5.3 shows baseline demographics and clinical characteristics for Cohort II.

Table 5.3. Cohort II – Participant baseline demographics and clinical characteristics

Characteristic	Participants (n = 10)
Gender (male:female)	5:5
Age (years), mean	65
Body Mass Index (kg/m ²), mean	28.58
Comorbidities, number (%)	
Cardiovascular	7 (70)
Respiratory	2 (20)
Other	3 (30)
Clinical diagnosis, number (%)	
Adenocarcinoma	6 (60)
Mucinous adenocarcinoma	1 (10)
Neuroendocrine tumour	1 (10)
Benign	2 (20)
Approach, number (%)	
Laparoscopic	5 (50)
Open	5 (50)
Type of Surgery, number (%)	
Right hemicolectomy	3 (30)
Anterior resection	2 (20)
Subtotal colectomy	1 (10)
Sigmoid colectomy	2 (20)
Other	2 (20)
Length of stay (days), median [range]	8 [4-13]

5.3.2. Main Findings

The main findings are presented with regard to:

- Total activity
- Activity type
- Activity dependent on time of day
- Control vs Patient cohort
- Individual patient activity

Total Activity

Physical activity, as measured by a WAM, decreased after surgery for both cohorts and slowly returned to normal post-operatively (Figure 5.2. Cohort I and Figure 5.5. Cohort II), almost reaching baseline activity in Cohort II when recovering at home.

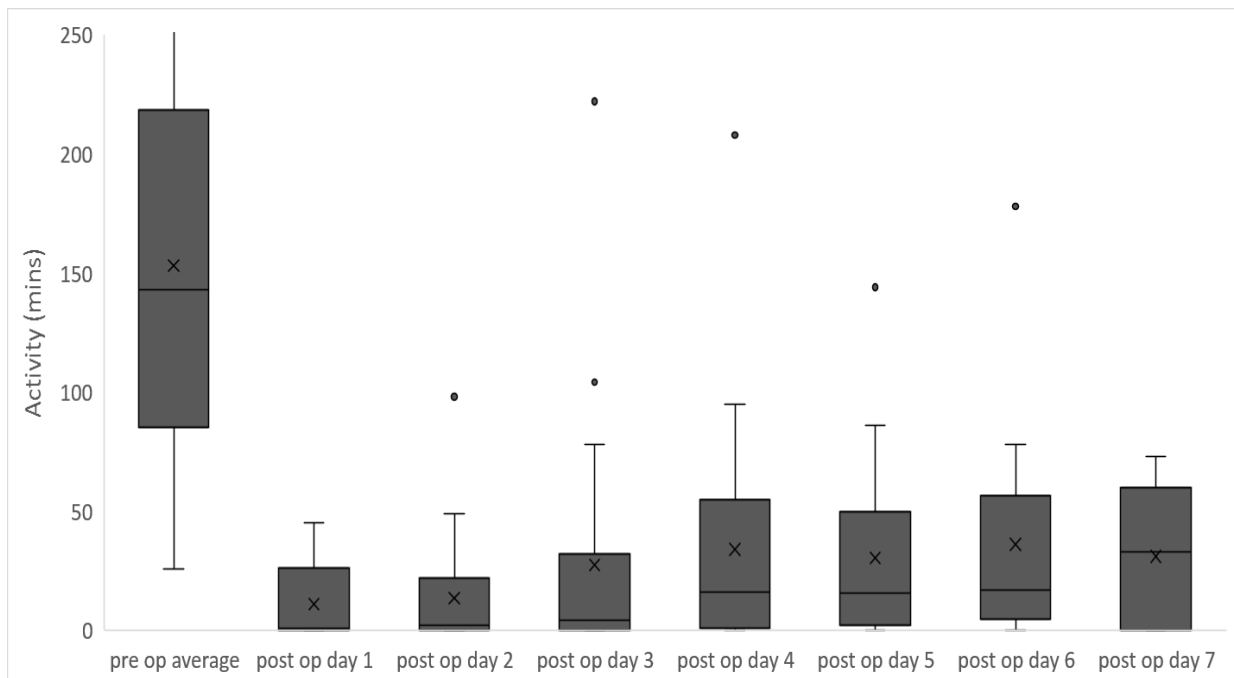


Figure 5.2. Box and whiskers plot showing total activity over peri-operative period for Cohort I

The biggest changes in activity were between the pre-operative average and the first few post-

operative days, with minimal change until discharge and further recovery of activity at home, after a median length of stay (LOS) of seven days. Figure 5.3. shows total activity on each post-operative day for Cohort II and shows an increase in activity each day. Figure 5.4. shows the rate of increased activity i.e. recovery by day, with the higher gradient occurring for activity performed once discharged home from hospital. The r squared also indicates that there is a better fit of trendline to the data for activity once home after discharge. Table 5.4 shows descriptive statistics for Cohort I for mean pre-operative and each post-operative day and Table 5.7 shows these for Cohort II.

For Cohort I the mean pre-operative activity (mins) was statistically significantly different to activity on each post-operative day. (Friedman Test: $\chi^2(2) = 30.186$, $p < 0.0005$). Pairwise comparisons were performed with a Bonferroni correction for multiple comparisons. Total activity was statistically significant between mean pre-operative total activity and total activity on post-operative day one ($p = 0.015$), day two ($p=0.012$), day 3 ($p=0.010$) and day four ($p=0.008$), but there was no significant difference thereafter, (5th post-operative day; p value = 0.056).

For Cohort II there was statistically significant difference between mean pre-operative and each post-operative hospital day. (Friedman test: $\chi^2(2) = 24.759$, $p = 0.01$). There was no statistically significant difference between mean pre-operative activity and activity at home. Pairwise comparisons were performed with a Bonferroni correction for multiple comparisons which were statistically significant for the mean pre-operative mean activity and activity on post-operative day two ($p= 0.004$) and day three ($p= 0.017$). A Wilcoxon signed rank test was performed and showed that there was a significant difference total activity preoperatively and total activity on the day of discharge ($T = 1.500$, $p = 0.021$).

The average return to baseline activity was 30% for Cohort I and 43% for Cohort II whilst inpatients but increased to 82% by day three at home (Table 5.5). Table 5.6 shows the amount of

activity bouts performed pre-operatively and post-operatively, showing a reduction in the immediate post-operative period, with an increase after discharge to almost baseline levels.

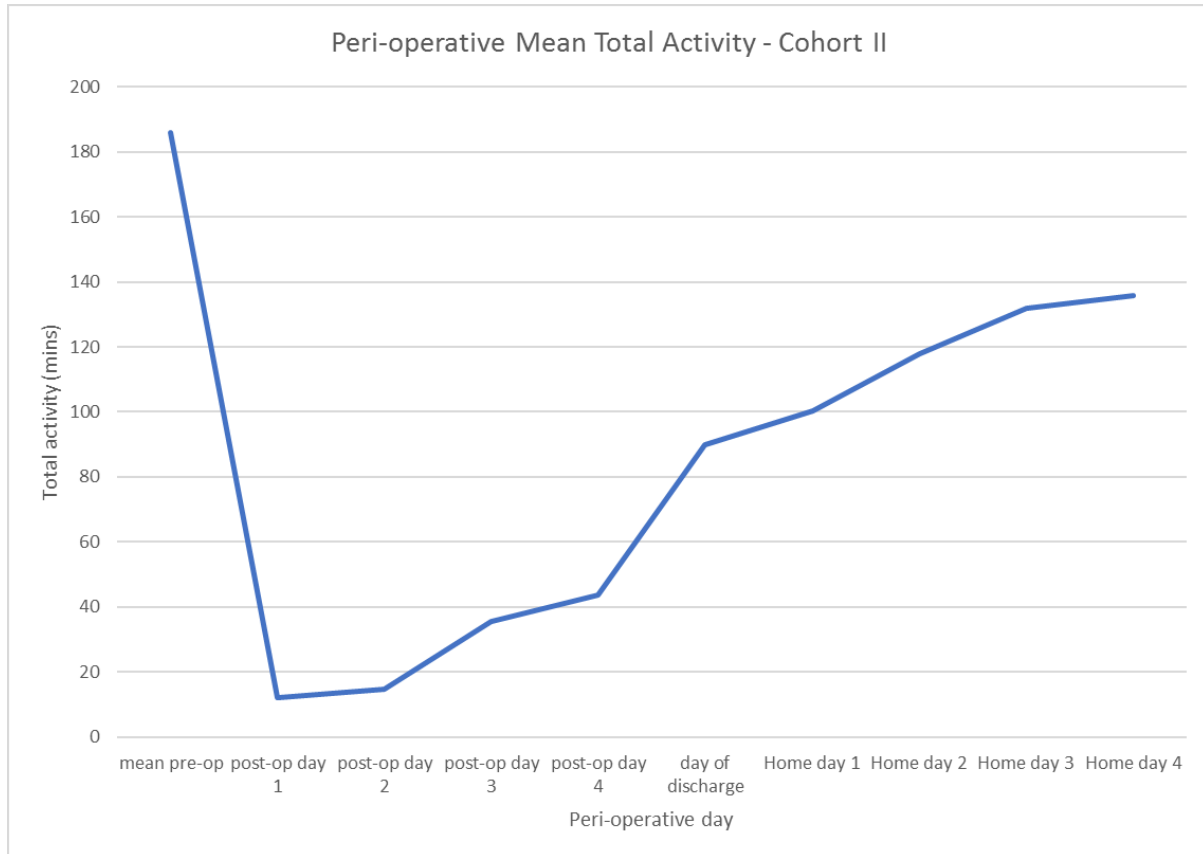


Figure 5.3. Mean total peri-operative activity for each peri-operative day

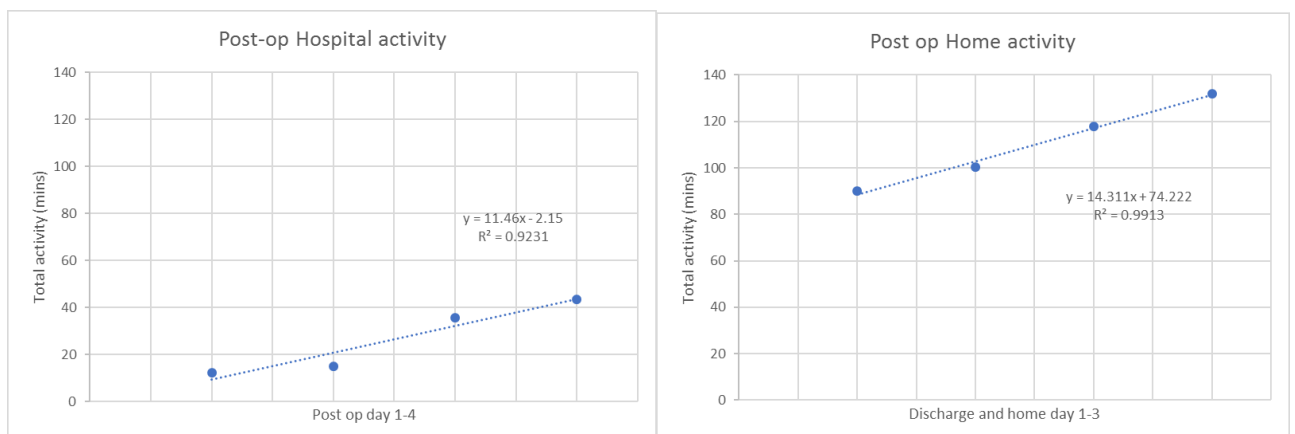


Figure 5.4. Trendlines for post-operative activity on the ward and at home

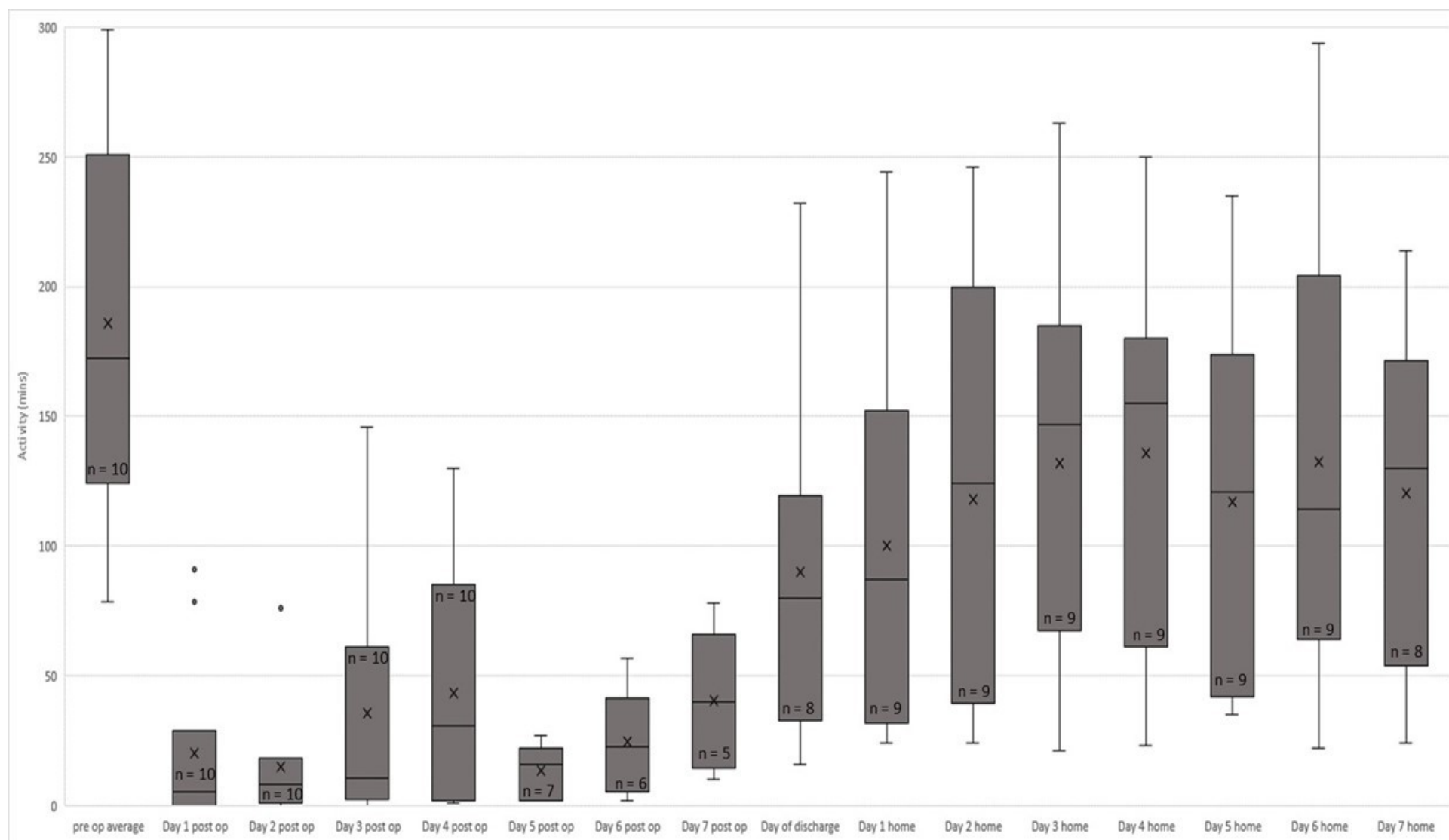


Figure 5.5. Box and whiskers plot showing total activity over peri-operative period for Cohort II

Table 5.4. Cohort I: Total activity - descriptive statistics

TOTAL Activity (mins)	Mean	Median	Min	Max	Standard Deviation
Mean Pre-op	154	117	26	403	88
Post-op Day1	12	1	0	45	15
Post-op Day2	14	2	0	98	23
Post-op Day3	26	4	0	222	48
Post-op Day4	34	16	0	208	49
Post-op Day5	30	16	0	144	39
Post-op Day6	38	21	0	178	50
Post-op Day7	34	42	0	73	30

Table 5.5. Percentage off baseline from pre-operative average for Cohort II

	Day of discharge	Home day 1	Home day 2	Home day 3	Home day 4
Percentage off baseline	43	57	61	82	81

Table 5.6. Activity bouts - mean number and longest for both cohorts (*only cohort II)

	Pre-Op	Day of operation	Post-Op In-patient	Day of discharge*	Post-Op Home*
Mean bouts >5 mins per day	10	3	1	3	5
Longest bouts (mins)	29	11	8	12	24

Table 5.7. Cohort II: Total activity - descriptive statistics

TOTAL Activity (mins)	Mean	Median	Min	Max	Standard Deviation
Mean Pre-op	186	172	78	299	73
Post-op Day1	0	5	0	2	1
Post-op Day2	15	8	0	76	23
Post-op Day3	36	11	0	146	49
Post-op Day4	44	31	1	130	50
Post-op Day5	13	16	2	27	11
Post-op Day6	24	23	2	57	20
Post-op Day7	40	40	10	78	27
Day of discharge	90	80	16	232	68
Home day 1	100	87	24	244	74
Home day 2	118	124	24	246	83
Home day 3	132	147	21	263	79
Home day 4	136	155	23	250	73
Home day 5	117	121	35	235	71
Home day 6	132	114	22	294	87
Home day 7	120	130	24	214	68

Activity intensities

Categories of activity intensity, (light, moderate and vigorous), were obtainable from the WAM. Again, there was a marked drop in activity in Cohort I from the pre-operative average activity to the initial post-operative period, with a gradual increase of activity over the successive post-operative days. There was no sustained vigorous intensity activity recorded within this cohort of participants (Figure 5.6.).

Table 5.8. shows the descriptive statistics for Cohort I broken down into activity intensity. There was a statistically significant difference in activity intensity types between the mean pre-operative activity and activity on each post-operative day. (Friedman test; Light activity; $\chi^2(2) = 32.520$, $p < 0.0005$, Moderate activity; $\chi^2(2) = 29.722$, $p < 0.0005$, Vigorous activity $\chi^2(2) = 32.923$, $p < 0.0005$).

Pairwise comparisons were performed with a Bonferroni correction for multiple comparisons. There was statistical significance between mean light activity performed pre-operatively and on post-operative day one ($p = 0.018$), day two ($p = 0.005$), day three ($p = 0.002$) and day four ($p = 0.012$). There was statistical significance between mean moderate activity performed pre-operatively and on post-operative day one ($p = 0.008$), day two ($p = 0.022$) and day four ($p = 0.008$). There was no statistically significant pairwise comparison for vigorous activity.

Similarly, Cohort II showed a marked drop in all activity types from the pre-operative average to the initial post-operative period (Figure 5.7). Table 5.9. shows the descriptive statistics for Cohort II broken down into activity intensity. There was a statistically significant difference between the mean pre-operative and activity and activity on post-operative inpatient days for light and moderate activity (mins). (Friedman test: Light; $\chi^2(2) = 27.845$, $p < 0.0005$, Moderate; $\chi^2(2) = 30.654$, $p < 0.0005$).

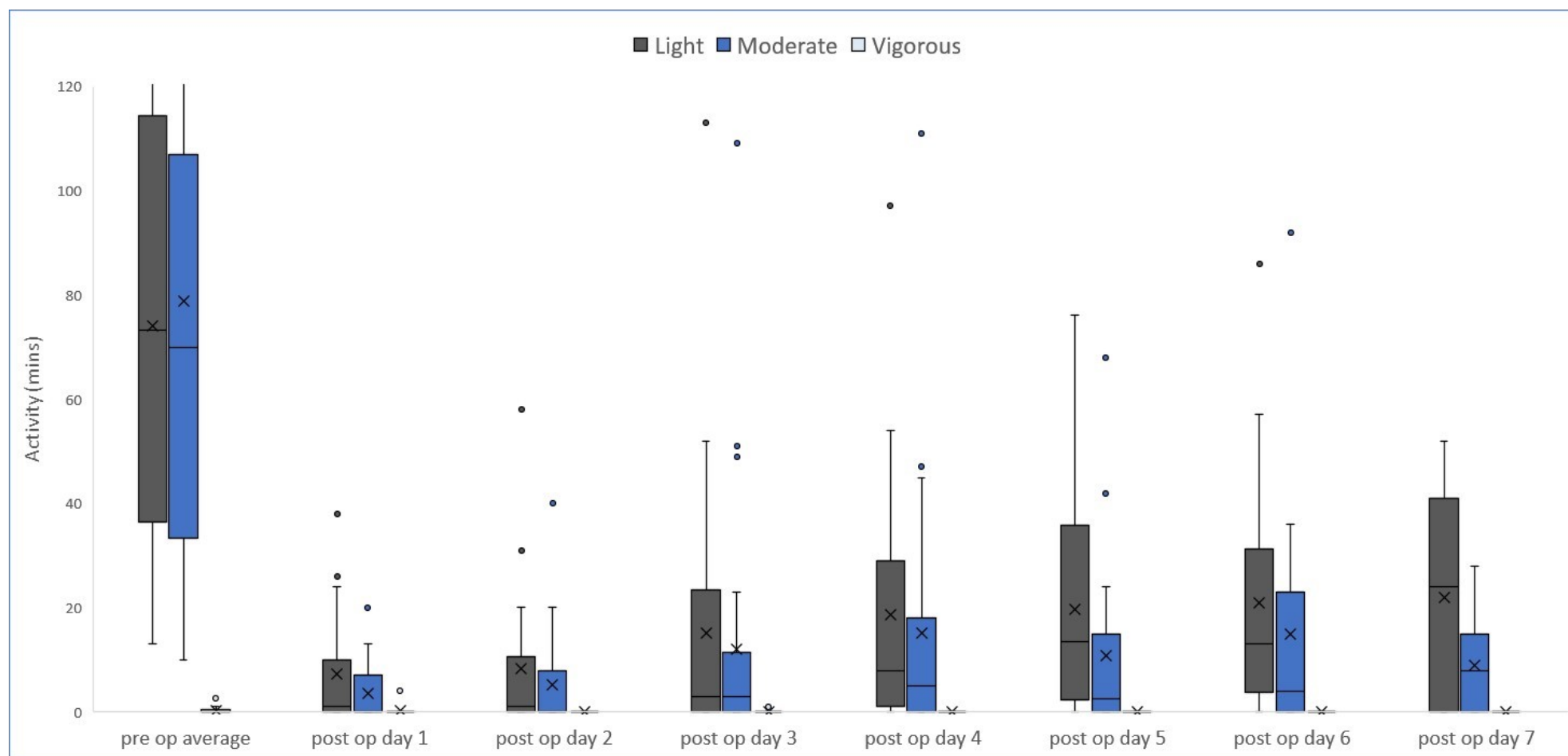


Figure 5.6. Box and whiskers plots showing activity break down over peri-operative period for Cohort I

Table 5.8. Cohort I: Light, moderate and vigorous activity – descriptive statistics

	LIGHT Activity (mins)					MODERATE Activity (mins)					VIGOROUS Activity (mins)				
	Mean	Median	Min	Max	Standard Deviation	Mean	Median	Min	Max	Standard Deviation	Mean	Median	Min	Max	Standard Deviation
Mean Pre-op	75	55	13	159	41	80	49	10	244	56	0	0	0	3	1
Post-op Day1	7*	1	0	38	11	4*	0	0	20	6	0	0	0	4	1
Post-op Day2	8*	2	0	58	14	5*	0	0	40	10	0	0	0	0	0
Post-op Day3	15*	3	0	113	25	12	2	0	109	24	0	0	0	1	0
Post-op Day4	19*	8	0	97	25	15*	5	0	111	25	0	0	0	2	0
Post-op Day5	20	14	0	76	22	11	3	0	68	18	0	0	0	1	0
Post-op Day6	22	14	0	86	26	16	3	0	92	26	0	0	0	0	0
Post-op Day7	24	30	0	52	21	10	9	0	28	10	0	0	0	0	0

* = statistically significant difference between pre-operative activity and activity on post-operative day using Friedman Test and Bonferroni Correction for multiple comparisons.

Pairwise comparisons were performed with a Bonferroni correction for multiple comparisons. Light activity was statistically significant between mean pre-operative activity and activity on inpatient post-operative day one ($p = 0.008$), day two ($p = 0.008$) and day three ($p = 0.014$). Moderate activity was statistically significant between mean pre-operative activity and post-operative activity on day one ($p = 0.007$), day two ($p = 0.017$) and day four ($p = 0.014$). There was no statistically significant difference between pre-operative and post-operative vigorous activity.

There was a statistically significant difference between mean moderate activity pre-operatively and moderate activity at home (Friedman test: $\chi^2(2) = 17.856$, $p = 0.013$). There was no statistically significant difference between mean pre-operative light or vigorous activity and post-operative light or vigorous activity at home.

A Wilcoxon signed rank test was performed and showed that there was a significant difference between mean pre-operative activity and activity on the day of discharge for light ($p = 0.036$) and moderate activity ($p = 0.012$).

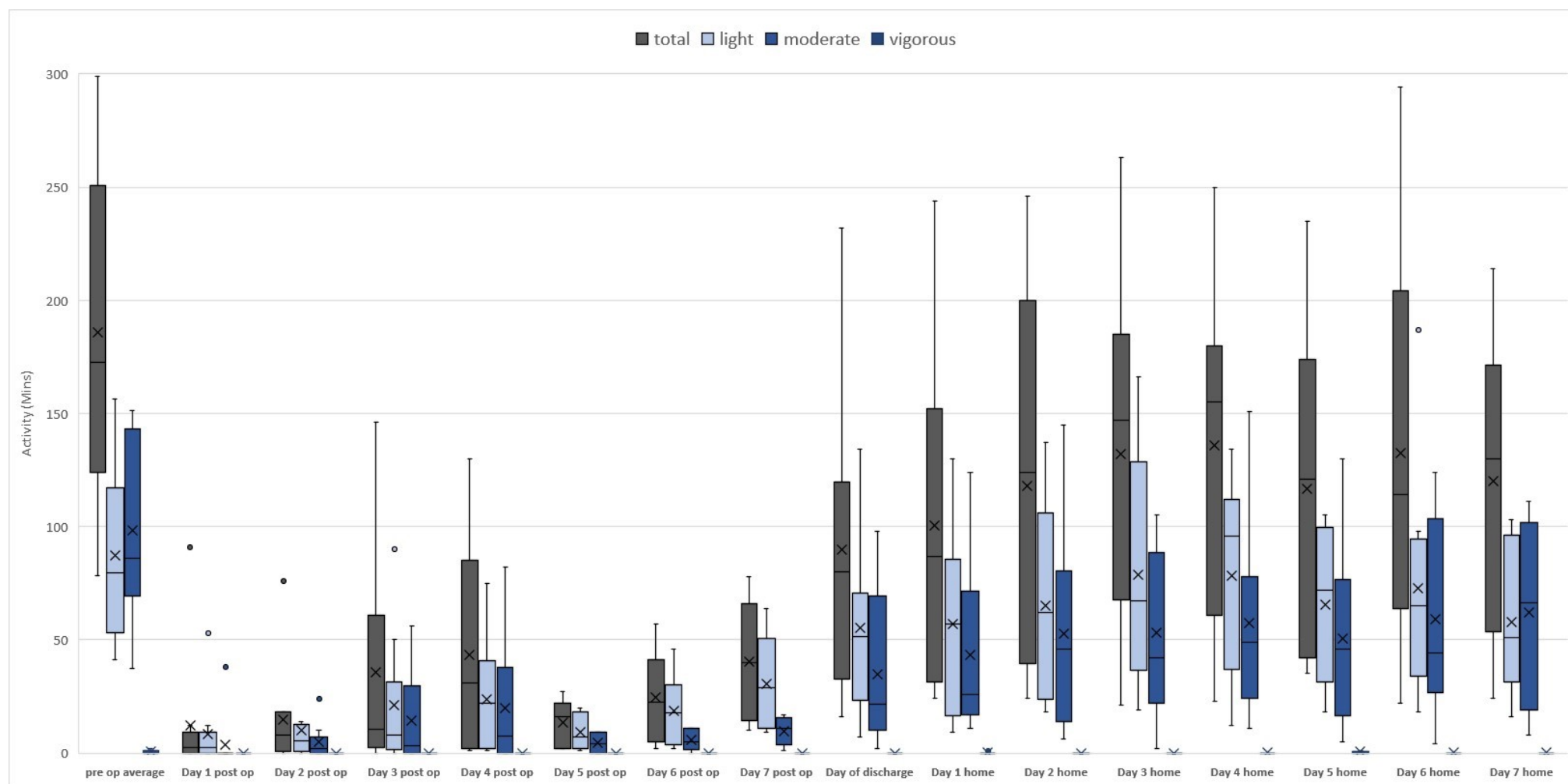


Figure 5.7. Box and whiskers plot showing activity break-down over peri-operative period for Cohort II

	LIGHT Activity (mins)					MODERATE Activity (mins)					VIGOROUS Activity (mins)				
	Mean	Median	Min	Max	Standard Deviation	Mean	Median	Min	Max	Standard Deviation	Mean	Median	Min	Max	Standard Deviation
Mean Pre-op	87	79	41	157	38	98	86	37	151	40	0	0	0	2	1
Post-op Day1	8	3	0	53	16	4	0	0	38	12	0	0	0	0	0
Post-op Day2	10	6	0	52	16	5	2	0	24	8	0	0	0	0	0
Post-op Day3	21	8	0	90	29	14	3	0	56	21	0	0	0	0	0
Post-op Day4	24	22	1	75	24	20	8	0	82	28	0	0	0	0	0
Post-op Day5	9	7	1	20	8	4	4	0	9	4	0	0	0	0	0
Post-op Day6	19	18	2	46	16	6	5	0	11	5	0	0	0	0	0
Post-op Day7	30	29	9	64	22	10	11	1	17	6	0	0	0	0	0
Day of discharge	55	52	7	134	39	35	22	2	98	36	0	0	0	0	0
Home day 1	57	57	9	130	40	43	26	11	124	43	0	0	0	1	0
Home day 2	65	62	18	137	44	53	46	6	145	45	0	0	0	0	0
Home day 3	79	67	19	166	52	53	42	2	105	36	0	0	0	0	0
Home day 4	78	96	12	134	42	57	49	11	151	42	0	0	0	2	1
Home day 5	66	72	18	105	34	51	46	5	130	41	0	0	0	3	1
Home day 6	73	65	18	187	51	59	44	4	124	42	0	0	0	2	1
Home day 7	58	51	16	103	33	62	67	8	111	40	0	0	0	1	0

Table 5.9. Cohort II: Light, moderate and vigorous activity – descriptive statistics

Activity broken down by time of day

There was a significant statistical difference between pre-operative activity and post-operative activity at all time points for Cohort I ($p < 0.0005$) (Figure 5.6.), a Bonferroni Comparison was performed and the only statistically significant pairwise comparison was for the night time-period (2359-0059) which was statistically significant between pre-operative activity and activity on day one post-operatively ($p = 0.009$) (Figure 5.9.).

But there was a statistically significant difference between pre-operative activity and post-operative hospital activity at all time points for Cohort II (Night $p < 0.0005$, Morning $p = < 0.0005$, Afternoon $p = 0.014$, Evening $p = 0.004$).

There was no statistically significant difference for pre-operative activity and post-operative home activity at night. But there was statistically significant difference in activity for the morning ($p = 0.008$), afternoon ($p = 0.002$) and evening ($p = 0.044$). There was statistically significant difference in activity between the morning pre-operative activity and the morning activity on home day one ($p = 0.028$). There was also statistically significant difference in activity between the afternoon pre-operative activity and the afternoon activity on the day of discharge ($p = 0.045$), home day one ($p = 0.004$) and home day two ($p = 0.033$).

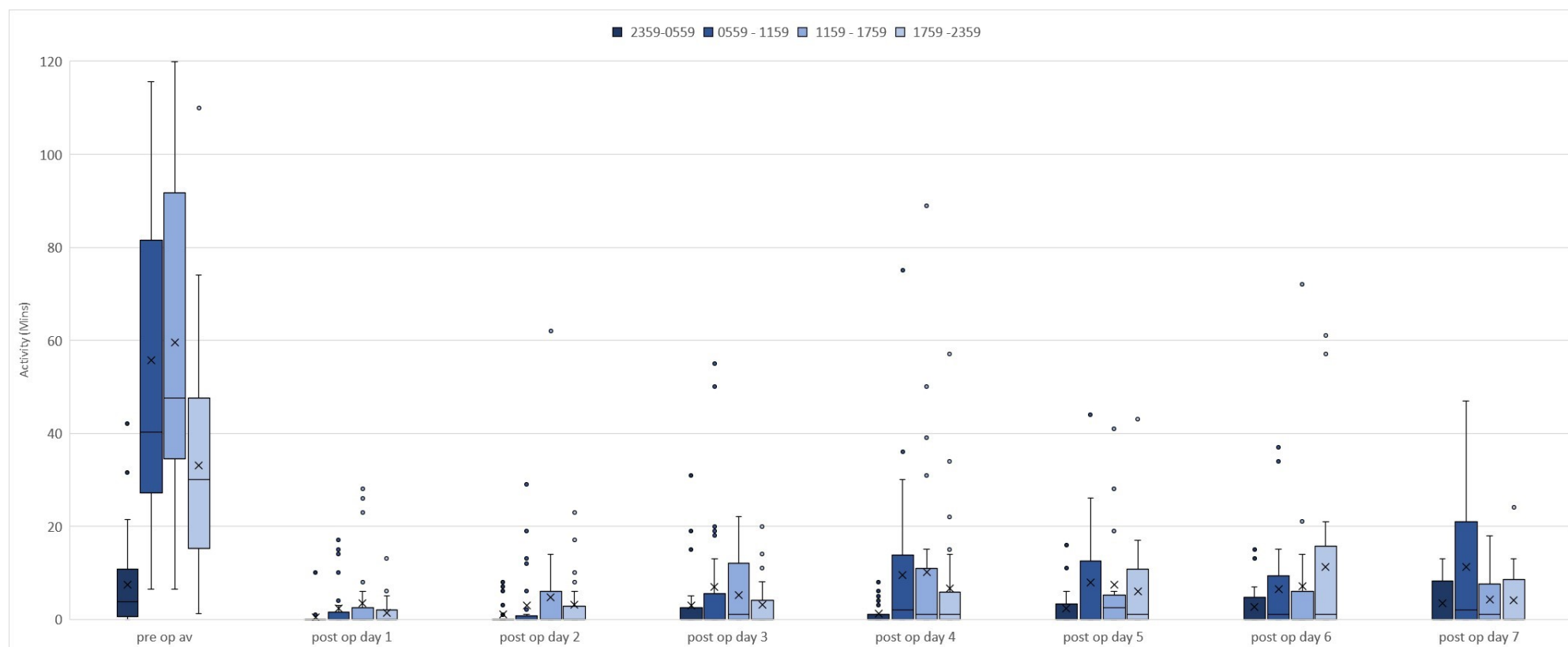


Figure 5.8. Cohort I – Activity (mins) by time point

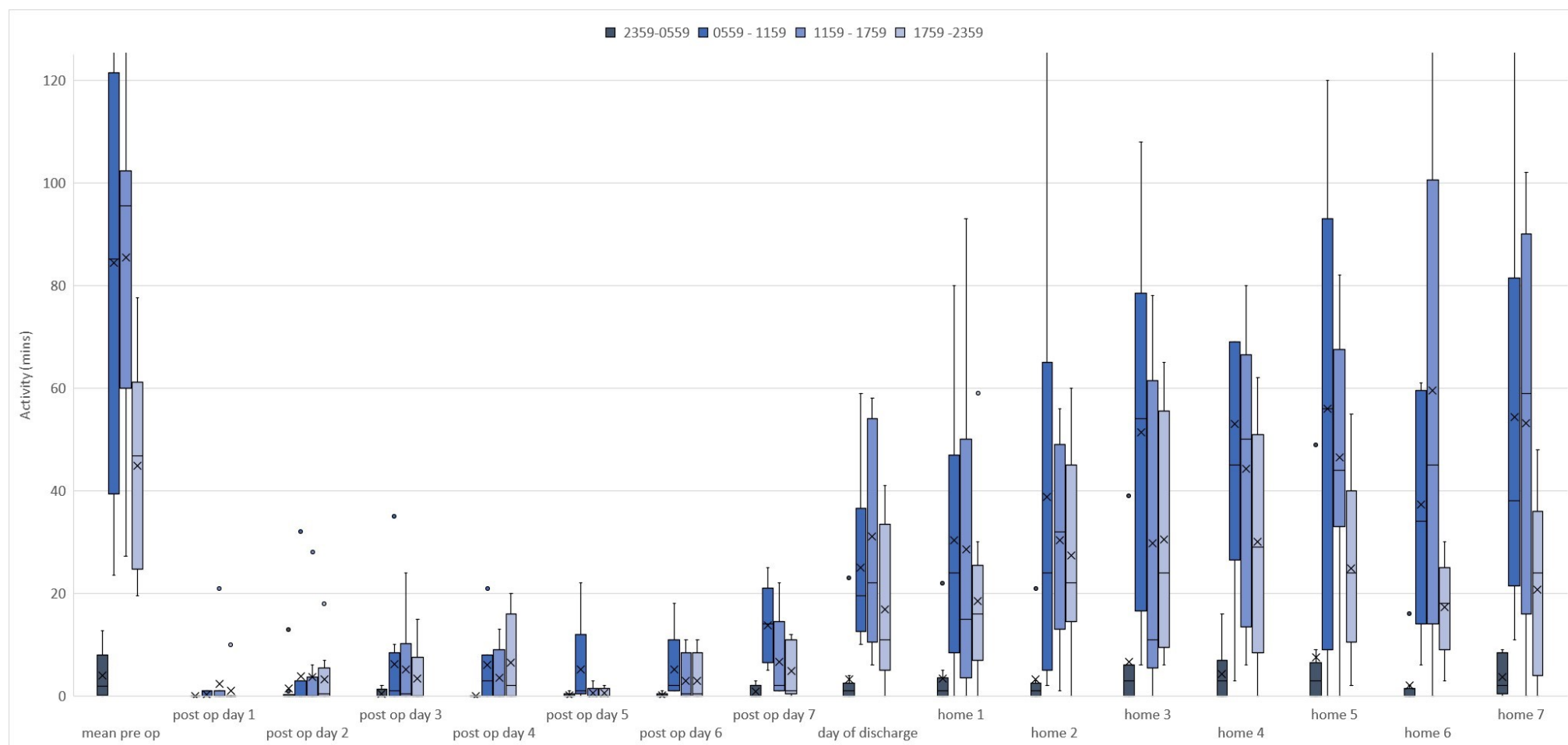


Figure 5.9. Cohort II – Activity (mins) by time point

Comparison of control group vs patient cohort

There was no significant difference in activity (total, light, moderate and vigorous) between the control group and the patient cohort pre-operatively. There was a significant difference ($p < 0.0005$) between the total, light and moderate activity performed between the control group and patient cohort on all post-operative days, including the day of discharge. By the time the patients were at home on day three, there was again no significant difference in activity (total, light, moderate and vigorous) between the control cohort and the patient cohort (Table 5.10.).

Table 5.10. Comparison of control group and patient cohort for activity pre- and post-operatively

		Total Activity	Light Activity	Moderate activity	Vigorous activity
Pre-op average	Mann Whitney U Score	188.5	157.5	199.5	300
	P value	0.407	0.128	0.56	0.053
Post-op Day 1	Mann Whitney U Score	10	0	0	176
	P value	0.000 *	0.000*	0.000*	0.785
Post-op Day 2	Mann Whitney U Score	0	0	0	175
	P value	0.000 *	0.000 *	0.000 *	0.666
Post-op Day 6	Mann Whitney U Score	6	4	7	95
	P value	0.000 *	0.000 *	0.000 *	0.703
Post-op Day 7	Mann Whitney U Score	0	1	0	75
	P value	0.000 *	0.000 *	0.000 *	0.721
Day of Discharge	Mann Whitney U Score	11	13	12	40
	P value	0.005*	0.009*	0.007*	0.778
Home Day 1	Mann Whitney U Score	18	20	19	50
	P value	0.016*	0.025*	0.020*	0.941
Home Day 2	Mann Whitney U Score	28	29	22	45
	P value	0.112	0.131	0.038*	0.766
Home Day 3	Mann Whitney U Score	35	33.5	24	45
	P value	0.295	0.23	0.056	0.766
Home Day 4	Mann Whitney U Score	32	41	19.5	51
	P value	0.201	0.552	0.020*	0.941
Home Day 5	Mann Whitney U Score	24	26	19.5	56.5
	P value	0.056	0.08	0.020*	0.603
Home Day 6	Mann Whitney U Score	29	29	29.5	51
	P value	0.131	0.131	0.131	0.941
Home Day 7	Mann Whitney U Score	23	17	30	45
	P value	0.091	0.026*	0.272	0.904

Individual patient activity

Looking more specifically at individual patients, and their activity throughout the perioperative period, allows us to see trends of daily activity, and specifically how activity changes depending on time of day, whether they are in hospital, or discharged home. Night time activity can be viewed, and disturbed sleep /activity over night can be identified. From the figure below (Figure 5.10.) we can see the gradual increase in activity on each post-operative day, until day of discharge, and then this being maintained and improved upon once recovering at home. In the early post-operative period, the day time hours have minimal activity, a possible area for an intervention to increase activity as an inpatient. Total activity on each post-operative day can also be viewed, this gives an idea about recovery both in hospital and at home (Figure 5.11.). Activity does not steadily increase day by day, rather there are peaks and troughs with activity higher on some days and lower on others.

Patient notes are written electronically and time-stamped. Using this data we can compare clinical activity, nursing notes and physiotherapy with ongoing patient activity (Figures 5.12a, 5.12b & 5.12c.). Nursing and clinical staff have encouraged the patient to mobilise on their rounds, and we can see an increase in activity following this.

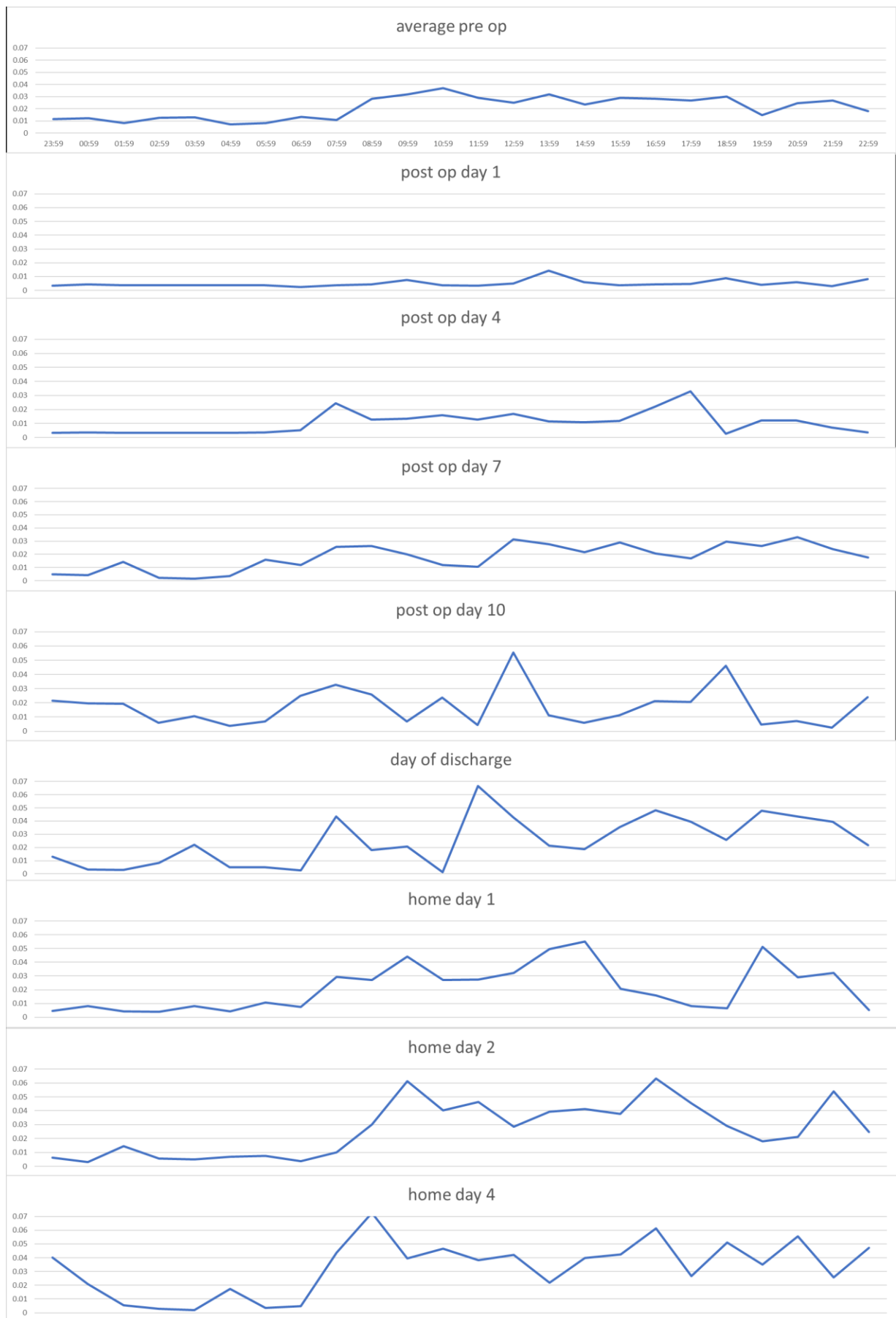


Figure 5.10. Individual patient (20004) activity through peri-operative time period: SVM over time

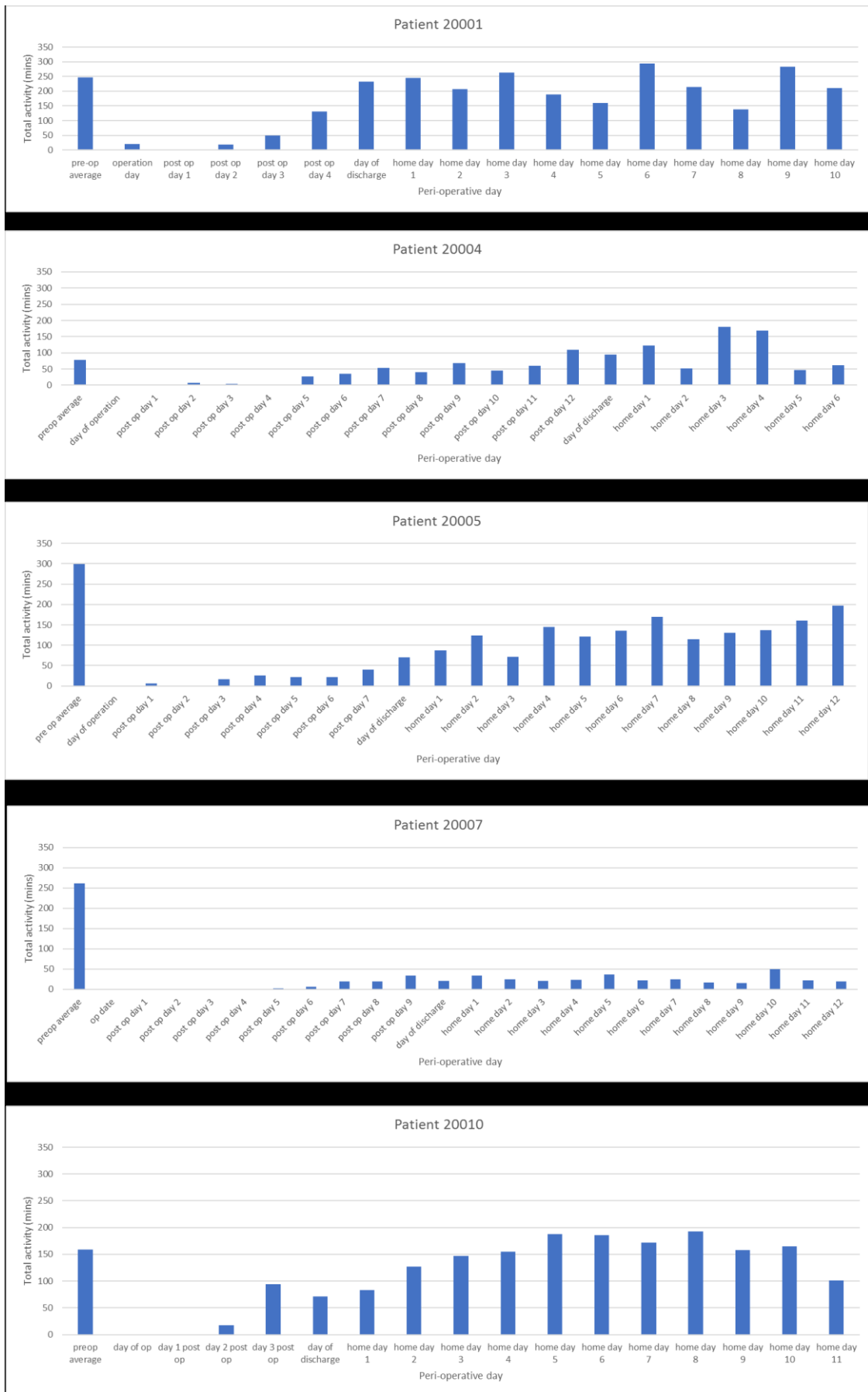


Figure 5.11. Individual patient total activity levels post-operatively.

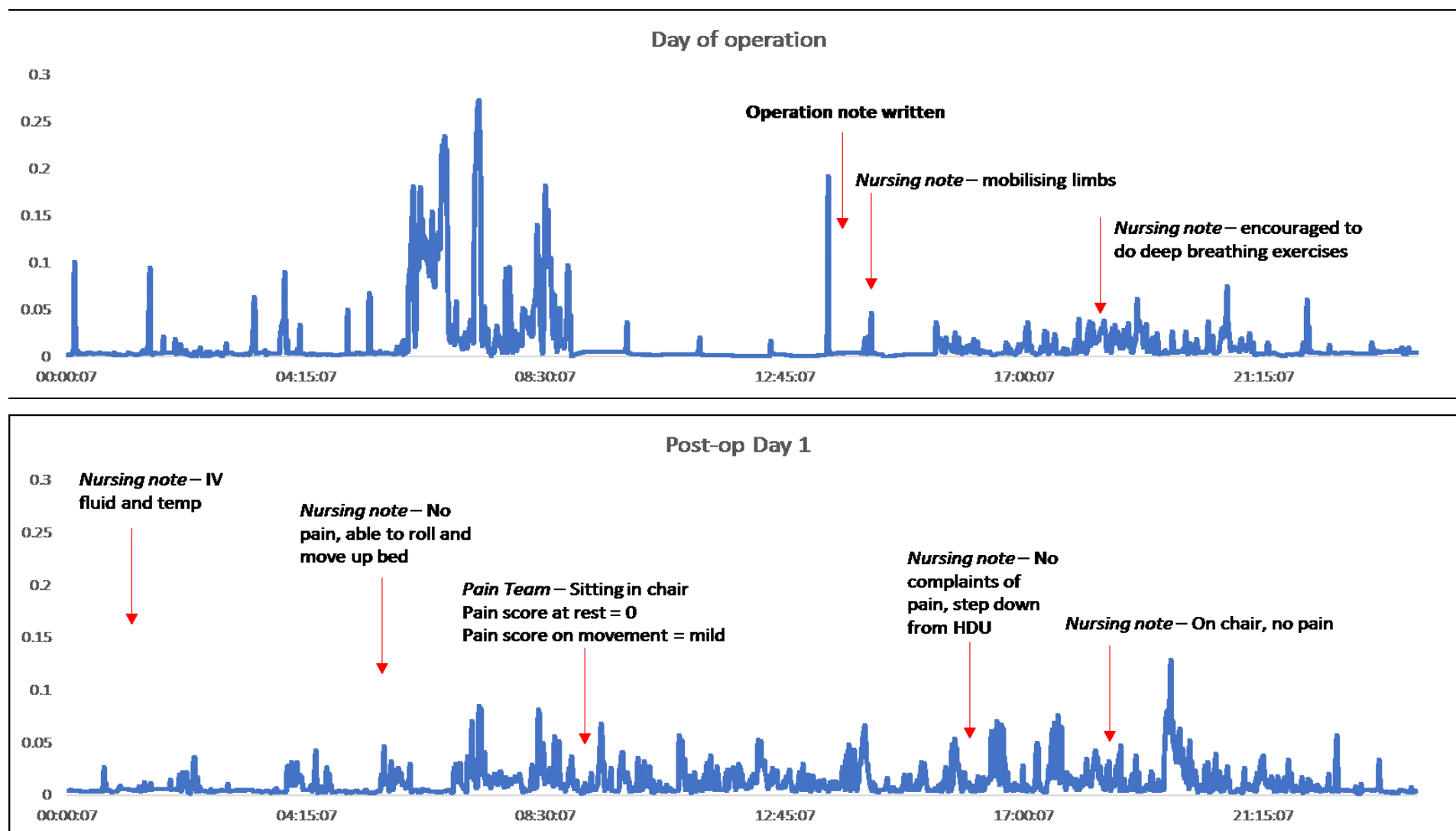


Figure 5.12. a. Activity of individual patient with Cerner notes superimposed on Day of operation and post-op day 1

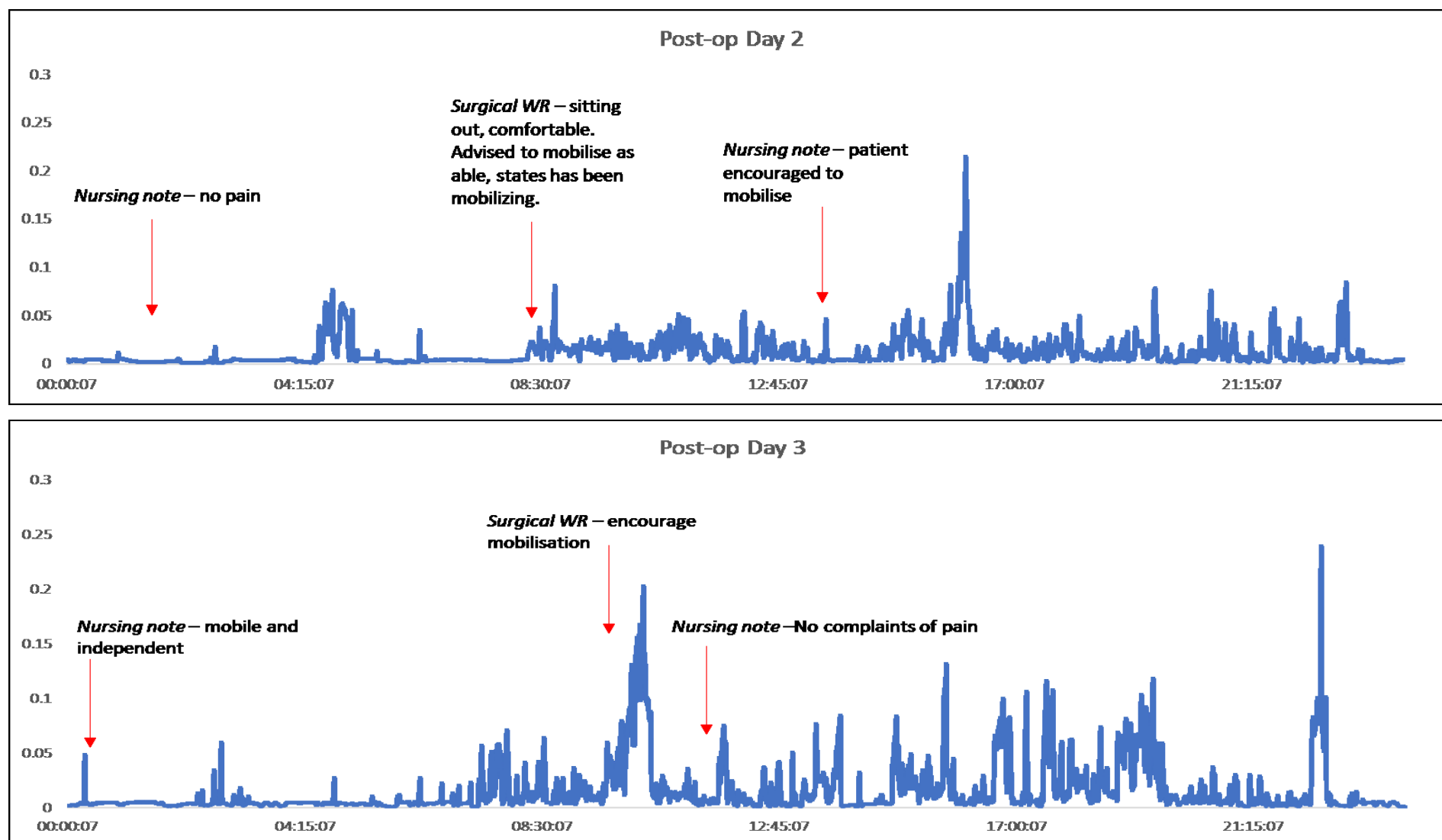


Figure 5.12. b. Activity of individual patient with Cerner notes superimposed post op day 2 &3

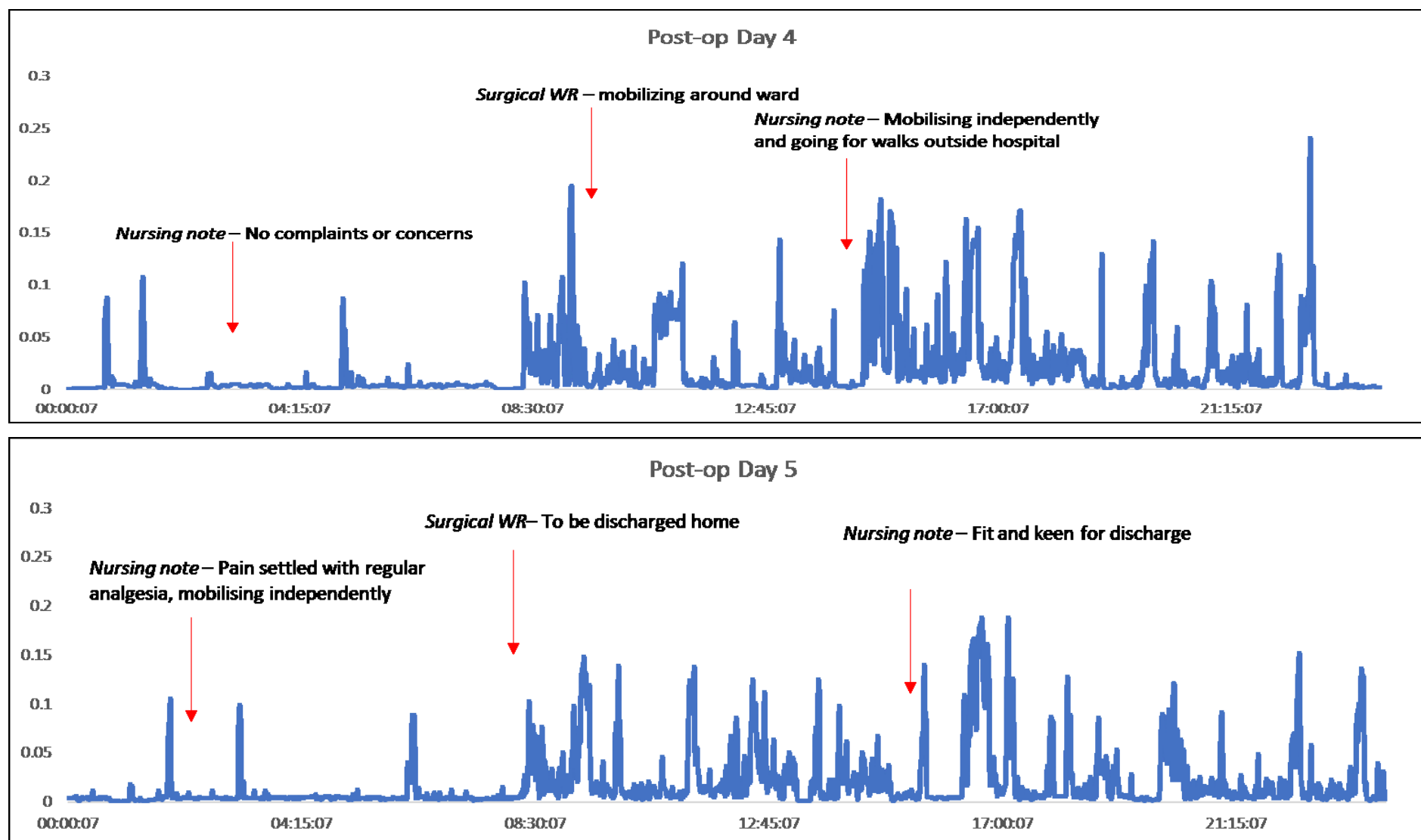


Figure 5.12. c. Activity of individual patient with Cerner notes superimposed post-op day 4 &5

5.4. Discussion

This study demonstrates the feasibility of using a WAM to objectively monitor, quantify and evaluate patient activity pre-operatively and post-operatively both in hospital and on discharge home in the community. To our knowledge, this is one of the first few studies to monitor patients undergoing colorectal surgery, continuously and unobtrusively, with a WAM throughout the peri-operative period, including once home after discharge. The on-going monitoring and evaluation of this physical activity data gives insight into patients' baseline function as well as their progression and recovery following a surgical procedure.

There was a significant reduction in activity between the pre-operative period and post-operative inpatient period, with low post-operative activity in general. These results are similar to the relatively sparse, but related literature. Bisgaard et al.²⁰² monitored patient activity with a WAM one week pre-operatively and one week post-operatively following a laparoscopic cholecystectomy. They found that physical activity levels, as measured by activity counts per minute, were significantly reduced on the first and second post-operative day, but normalised by the third post-operative day. One of the few studies looking specifically at patient activity after gastrointestinal surgery, measured post-operative upright mobilisation (uptime) using the 'Positional Activity Logger'⁷⁶. They found that uptime was very low on the first post-operative day, with a total duration of 3.0 minutes. This slowly increased on each post-operative day, rising to 34.4 minutes of total uptime by the fourth post-operative day. They had not, however, measured uptime or activity in the pre-operative period and so comparison to pre-operative baseline function is unavailable. Basse et al.'s study⁸³ looked at physical activity in patients undergoing laparoscopic and open colorectal surgery. Although they found a high degree of mobilisation in both groups of patients, with a median of ten hours out of bed on the first post-operative day, increasing to fourteen on the second post-operative day and plateauing on subsequent post-operative days, this was a subjective assessment recorded by the nurses and patients. They had, however, also

monitored patients using a WAM for two days pre-operatively and six days post-operatively. Patients in both the laparoscopic and open group appeared to have similar pre and post-operative activity, with 100 activity counts per minute on all pre-operative and post-operative days. It is difficult to fully compare this study with our data, given that one measure was only subjective notes, and furthermore, the physical activity data has only been presented as a small summary graph which can be difficult to pull all data from. It is also not implicit in the study details if patients who went home continued to wear the WAM or if they took it off on discharge. However, given that the median length of hospital stay was two days, it could be that this was a more active cohort in general, with a shorter recovery and discharge time than our study cohort, with a median LOS of 7 days. Although our study did not show that the difference in activity levels on the fifth post-operative day were significant, the p value is approaching significance. Furthermore, given that some patients were discharged by the fifth post-operative day, the number of patients in the cohort still in hospital being monitored on the fifth post-operative day had reduced to 18, this would also alter the significance.

During the first week at home, following discharge, activity levels were not statistically significantly different to those pre-operatively. This could suggest that a significant part of recovery is happening at home, and not in hospital. Conversely, behaviour at home and behaviour in the hospital are very different, and it could be that the patients' post-operative behaviour was different in hospital due to the constraints of the hospital environment itself, but that on returning home their behaviour could return to normal. It is difficult to pinpoint the exact reasons for this, but it is important to consider post-operative pain, disability, recovery and environment as possible multi-factorial causes. The variation in activity once home, as shown by the increase in range of minutes of activity each day, shows that some patients recover more quickly and are more active than others once back home in their own environment. Looking at individual patient data each post-operative day was variable with some days greater activity, and some days less, this could be

due to being over active on one day and the patient not feeling strong enough to then be as active the next day. Conversely, because in the home environment the patient can be as active as they like when they like, it could be normal variations in day to day life. However, it is clear that the rate at which activity improves overall is greater once at home than when they were in hospital post-operatively.

This study has shown there was a statistically significant difference between all activity intensities performed pre-operatively compared with activity on each post-operative day. This indicated that not only has moderate and vigorous activity stopped whilst an in-patient, but also light activity. Interestingly, by the time the patients reach home, activity levels are heading back to pre-operative levels, but not at as high an intensity, as there was no statistically significant difference between total pre-operative activity and activity post-operatively at home, but there was statistical significance for moderate activity. Van der Meij et al.²⁰⁴ studied patients undergoing laparoscopic general and gynaecological surgery. They measured light, moderate and vigorous activity, using an Actigraph wGT3X-BT, for seven consecutive days at four different time points; the week before surgery, one week after surgery, and then three and five weeks after surgery. They found that all activity intensities dropped from the pre-operative time period to the week following surgery. And that there was still statistically significant differences between light and moderate activity intensities in the third post-operative week, but that by the fifth post-operative week moderate intensity activities were no longer statistically significantly different. These results are similar to our study, although in their study light activity was still significantly different at both three and five weeks following surgery. The cohort of patients in van der Meij et al.'s study was significantly different, their patients underwent minor (laparoscopic hernia repair, laparoscopic cholecystectomy, laparoscopic adnexal surgery) and intermediate surgery (laparoscopic hysterectomy), whereas our patients underwent major surgery (laparoscopic or open colorectal resections).

The amount of activity performed at different time points were analysed showing that activity at all times of the day were reduced post-operatively as an inpatient. Once discharged back home night time activity returned to normal levels much quicker than those in the morning or afternoon. This could be because night times were more restrictive as an in-patient, with even less ability to mobilise around the ward, or that on the ward they did not need to look after themselves e.g. make their own tea or food, given assistance with washing at the bed-side rather than walking to the bathroom. Once back home patients were able to follow their normal routines without restrictions on their movements.

This study has shown that activity over the entire peri-operative period can be plotted for each patient. This allows an overview of their activity with a visual representation of how they improve and recover to their functional baseline. This can be useful to determine if a patient is not returning to their expected activity levels, or if they are exceeding their anticipated trajectory. Plotting the physical activity levels together with the ward round activities and nursing documentation allows corroboration between the different ways of monitoring patient activity and wellness. A nursing note commenting that a patient is independent and mobilising well can be shown via an activity graph and the high level of activity can be visualised and objectively measured. Conversely, if nurses note that the patient does not seem to mobilise, or requires excessive encouragement, the graph shows poor activity levels. Barriers to mobilisation can also be identified as documentation of bedside reviews, investigation or blood tests can be seen to occur at times when patients are not mobilising, or a spike in activity when the physiotherapist attends the patient. This can also help with ERAS protocols, both to monitor compliance with suggested mobilisation protocols, and to monitor whether patients are improving and recovering.

This study has shown patterns of patient activity both pre-operatively, in normal everyday life, and then post-operatively as they recover. This pattern of activity shows the clinical course of the

patients' peri-operative journey. Those patients who are more unwell or slower to recover, are less active, often staying in bed due to catheters or drains in situ. Furthermore, all patients are different, and are active at different times, and in different ways. This can be evidence by different pre-operative and post-operative activity throughout the cohorts. However, once admitted to hospital patients tend to be treated in the same way, with access to physiotherapists only at specific times, regimented meal times and minimal opportunities to mobilise around the ward. Using a WAM means that each patient can be viewed individually, and also allows for individualised variations of ERAS mobilisation protocols for each patient.

Other models for in-patient care have been suggested, with more use of communal spaces, including a shared social area, e.g. an area to watch television together or eat together. Hokstad et al.²⁰⁵ found that patients admitted to Norwegian hospitals that had communal areas for serving and eating meals had increased activity levels. Other considerations include more individualised care. A team of Paediatric Intensive Care doctors at John Hopkin's Hospital looking at barriers to early mobilisation put together a program that individualised each patient, and their activity goals/requirements each day²⁰⁶. They showed that individualising care and identifying safe activities and levels of activity for each patient based on their needs and abilities. Wasowicz-Kemp et al.⁵⁴ designed a study where physical activity was objectively monitored using a WAM in patients undergoing laparoscopic cholecystectomy. They split the patients into two groups, one received standard post-operative care and the second were given advice and individualised activity goals to encourage quick resumption of activity following surgery. Their results showed that only 36% of patients in the control group reached their baseline pre-operative activity levels in one week, compared with 50% in the activity group.

5.4.1. Limitations of study

There were some limitations within this study. The data was processed as a whole for each post-

operative day, however, some patients had been discharged early, e.g. on day three or four post-operatively, and so smaller patient numbers were used in the analysis on those post-operative days. Four patients did not wear the sensor post-operatively and the WAM failed on one occasion and was not handed back to the clinical team on two occasions. This gave a smaller number of data points to analyse, in an already heterogeneous and small sample size. This made subgroup analysis impractical for laparoscopic relative to open procedures. Future studies need larger numbers to fully compare the difference in peri-operative activity levels for different surgical approaches. The attrition rate was low, and there were no statistical differences between those who withdrew from the study and those that took part. Although it may have seemed logical to combine the two cohorts together for data analysis the two cohorts were distinct and recruited separately, with different intended aims and outcomes, at different time periods and as stand-alone cohorts. Ethics was gained separately for each cohort and therefore the data was analysed separately for each distinct cohort.

Another limitation is the recruitment process. Initially, eligible patients were approached by the clinical team, and then the research team gave further information and recruited them if they were happy to proceed. However, there were instances where the clinical team thought the patient not appropriate to be recruited, whether due to the severity of their condition, their frailty or other reasons. This can lead to a selection bias, which could skew the results. Furthermore, patients with walking impairments or needing to use walking aids were not eligible to be included in this study. However, this means that those patients are not represented and so the findings are not generalisable to the wider population. It is important to be aware of the recovery time and activity pattern of these patients, possibly even more so than those without mobility issues, in order to facilitate their recovery and give them the help they require post-operatively.

Finally, one further issue is that when patients know that their activity is being monitored they may

end up being more active than if their activity was not monitored. This Hawthorne effect was hopefully, at least partially mitigated, by the fact that the activity was not shown to the patients, rather their WAM was blank and they were unable to see their daily activity.

5.4.2. Potential clinical impact

A number of questions arise from this study. Why do patients recover their activity at home, rather than as an inpatient? Is this because recovery only happens after a certain time? Or is it because once back in their own home environment they are able to behave more naturally and therefore perform more activity? If the answer is the latter, then there is the possibility to improve recovery and patient activity whilst they are still in-patients. For example, bringing a 'home' environment onto the ward to allow people to mobilise and recover more quickly, this could be a communal room in which to socialise or eat meals. Patients are individuals and they need individualised exercise programmes and graded activity that is suitable to their pre-operative function and based on their abilities and need as well as at a time that is suited to them.

Wearable activity monitors can be utilised in this setting as a device that objectively records patient activity providing data on patient baseline, allowing personal interventions to be given, e.g. physiotherapy if activity levels are flagged up as low. Pervasive monitoring can provide evidence of compliance with medical advice given, especially in the context of ERAS as well as providing insight to the patient as to their own activity levels. Smart wearables that can prompt the wearer to be more active could be useful to remind the patient to get up and move around, ensuring they are up and away from their bed being as active as possible. The wearable monitors could also give more specific and individualised advice and activity prompts that encourage and push patients within specified limits to help them recover at a faster pace, again enabling and improving the ideals of ERAS. Wearing these devices at home after discharge give a wealth of knowledge about

ongoing recovery and return to functional baseline for clinicians, with the possibility of flagging up if the normal trajectory is not being met, allowing clinical review as necessary.

Chapter 6

Peri-operative activity and patient outcomes within an enhanced recovery setting

6.1. Introduction

6.1.1. Enhanced Recovery After Surgery (ERAS)

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) discusses four ‘pillars’ of ERAS which are seen as the most important elements of the ERAS ideal to help improve recovery from gastrointestinal surgery. They are early enteral feeding, multi-modal non-opioid analgesia, goal directed fluid therapy and early mobilisation.

Early Enteral Feeding

Previous guidance to patients about oral intake prior to surgery strictly prohibited eating and drinking from midnight on the day of the operation, with enteral feeding often not starting again until 24-48 hours into the post-operative period. The ERAS protocol, however, encourages patients to drink clear fluid up to two hours prior to their operation, as it has been shown there is no increased risk of aspiration in healthy adults²⁰⁷. Some studies have also shown that a carbohydrate-rich drink two hours pre-operatively can reduce hunger and thirst and reduce insulin resistance^{208, 193, 194, 22}. Early post-operative nutrition can also reduce insulin resistance as well as prevent loss of muscle strength and has been shown to be associated with significant reductions in post-operative complications²⁰⁹. Patients are encouraged to have clear fluids in the immediate post-operative period and to move on to a low residue diet within the first post-operative day.

Multi-modal non-opioid analgesia

Managing post-operative pain with more than one type of analgesic aims to ensure optimal pain

relief whilst minimising use of opioids, which can cause undesirable effects and hamper recovery, e.g. post-operative ileus, nausea and vomiting. The range of analgesics includes paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs), systemic local anaesthetic blocks, thoracic epidurals, spinal anaesthesia and patient-controlled analgesia (PCAs).

A local anaesthetic block, e.g. rectus sheath or transversus-abdominis plane (TAP) block, can be infiltrated by the surgeon at the end of the operation before closing the abdominal cavity. They have been shown to reduce the need for morphine use as well as decrease post-operative nausea and vomiting²¹⁰. Thoracic epidural anaesthesia is thought to reduce the surgical stress response and provides good analgesia especially in an open approach but has been shown to increase recovery time within a laparoscopic setting, where a spinal anaesthetic or patient controlled analgesia may be a better modality to use²¹¹.

Goal directed fluid therapy

The goal of fluid management is to ensure that the patient is well hydrated and in a euvolaemic state. A meta-analysis has shown that those with balanced fluid state have less complications than those in imbalance²¹². It is thought that worse outcomes occur in patient who gain more than 2.5Kg in weight, due to the salt and water overload²¹³. Maintenance fluid using a balanced crystalloid solution, e.g. Ringer's lactate (Hartmann's solution), provides daily physiological fluid and electrolyte requirements for those patients who are unable to drink but have no other fluid or electrolyte losses²¹⁴. Once fluid and electrolytes are lost e.g. vomiting, diarrhoea, drain output or fistula, then like for like replacement of the lost fluid and electrolyte is required. In a hypovolaemic state fluid boluses need to be given, with a debate about the benefits of a colloid solution over crystalloid. Although colloid solutions e.g. hydroxyethyl starch are thought to reduce the total volume of fluid required, a randomised trial showed that there was no evidence of benefit of colloid over crystalloid²¹⁵. Devices have been used to monitor and direct goal-directed fluid therapy

including transoesophageal doppler monitoring, and central venous pressure measurements. The ability to monitor fluid status more accurately allows fluid replacement to be more specific to the patient and prevent overload and oedema from possible excessive intravenous fluid.

Early Mobilisation

Immobilisation post-surgery can increase the risk of pneumonia, venous thromboembolism and post-operative ileus as well as lead to loss of muscle mass and deconditioning²¹⁶. A study by Maessen et al showed that mobilising out of bed on the day of surgery and on the first post-operative day were significantly related to a decreased length of hospital stay³¹. Other studies which have included early mobilisation within enhanced recovery protocols have also shown an improvement in post-operative outcomes^{4, 11}. ERAS guidelines for elective colonic surgery give a strong recommendation grading for early mobilisation, however, the evidence is weak¹⁷. There is still a lack of information regarding how early mobilisation helps improve recovery outcomes, nor how best to monitor this activity. Different enhanced recovery protocols have used different activity goals e.g. time not sedentary, time spent in different activities or distance moved.

6.1.2. Colorectal Surgery

Surgical resections of the colon and rectum are performed to treat diseases arising from these areas, with the aim to remove the diseased tissue and ensure continuity of healthy bowel if possible. In the UK, between 1st April 2000 and 31st March 2008, the total number of primary colorectal resection performed was 246,469. Sixty-four percent of these were elective resections (158,847), with 148,716 open (93.5%) and 10,131 laparoscopic cases (6.5%). The resections were performed for colorectal cancer in 111,025 cases (70%) and benign colorectal disease in 47,822 (30%) including diverticular disease and inflammatory bowel disease²¹⁷.

Recovery after surgery is a complex process which involves many factors with many potential complications in the immediate and short-term post-operative period which can prolong recovery.

Colorectal Disease

Colorectal Cancer

Colorectal cancer is one of the commonest cancers in the UK with around 40,000 new cases each year with 75% occurring in people aged 65 or over²¹⁸. The incidence in the last decade has increased by 2% in the UK but is expected to fall by 11% by 2035. In 2014 there were 15,900 deaths from colorectal cancer in the UK, but mortality rates have been decreasing over last decade by 12%. In England and Wales survival at 10-years is 57%, 59% at 5-years and 76% at 1-year (2010-2011 data). Colorectal cancer survival is improving and has more than doubled in the UK in last 40 years²¹⁹.

62% of patients with colorectal cancer received a major surgical resection as part of their cancer treatment²²⁰. Other treatment options include radiotherapy and chemotherapy, these can shrink tumour size prior to surgery, reduce risk of recurrence post-operatively or be used as primary treatment for metastatic/advanced disease.

Benign Colorectal Disease

Colonic diverticular disease occurs when colonic mucosa develops outpouchings, thought to arise secondary to a western diet with low fibre. It is more common as patients get older and can either be asymptomatic, cause infection and inflammation (diverticulitis) or lead to a diverticular haemorrhage. Although most cases do not require surgical intervention, there is a place for resection in patients with recurrent attacks or complicated diverticulitis or in a diverticular bleed that is not controlled with endoscopic or radiological procedures. Inflammatory bowel disease encompasses ulcerative colitis and Crohn's disease. Surgical management is often indicated when medical management fails for these patients.

Anatomy of the Colorectal Tract

The gastrointestinal tract begins to form from the second and third week of gestation as the foregut, midgut and hindgut. The midgut develops into the duodenum, jejunum and ileum as the small intestine and as the caecum, appendix, ascending colon and proximal two-thirds of the transverse colon as the large intestine. The hindgut develops into the distal third of the transverse colon, descending colon, sigmoid, rectum and upper part of the anal canal (Figure 6.1).

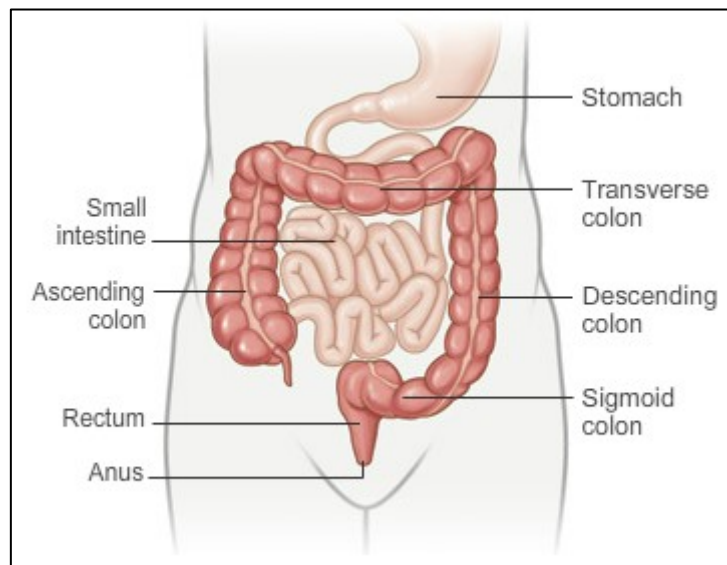


Figure 6.1 Anatomy of Colon and rectum (Images courtesy of Calprotectin.co.uk)

Branches of the superior mesenteric artery and inferior mesenteric artery supply the large intestine, they anastomose within the mesentery and form the marginal artery, meaning that the bowel has a collateral blood supply. Venous drainage follows the arteries and drains into the portal vein. The role of the large intestine is to absorb water and salt, solidify waste and store faecal matter until evacuation.

Surgery of the Colon and Rectum

The diseased part of the colon and/or rectum is resected together with the vasculature that supplies that part of the bowel. A right hemicolectomy involves resection of the caecum, ascending colon and first part of the transverse colon, whereas a left hemicolectomy is a resection of the second half of the transverse colon and the descending colon. (See figure 6.2 for illustration of colorectal resections)

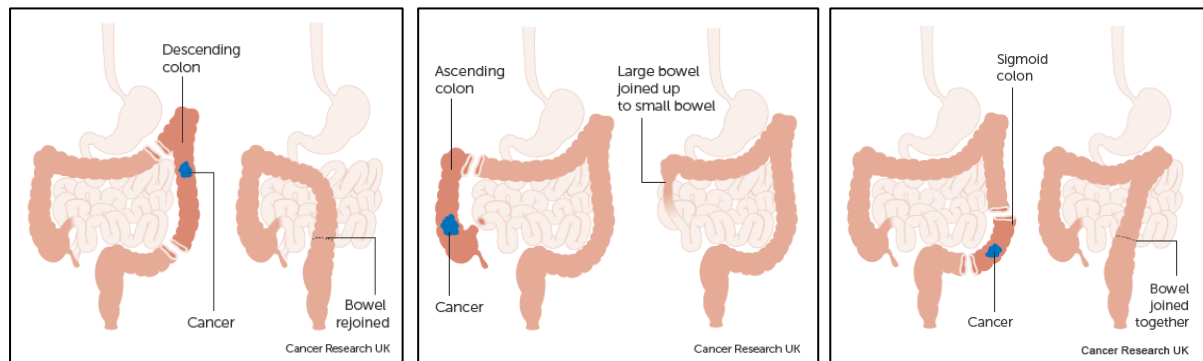


Figure 6.2. Colorectal resections types (Images courtesy of Cancer Research UK)

The abdominal cavity is accessed either through a traditional laparotomy incision, vertical through the anterior abdominal wall, or through laparoscopic port insertions into the anterior abdominal wall at the umbilicus and other points in the abdominal wall. The bowel is resected together with its blood supply and lymphatic drainage, a cancer resection requires a bigger margin of tissue than benign disease. The cut bowel ends are then anastomosed, connected again, either using a stapler

device or sewn by hand. If bowel continuity is thought to be at risk of breaking down or leaking, then a covering ileostomy may be formed. This allows the anastomosed bowel to rest and heal whilst the small bowel contents can be eliminated through the small bowel via the anterior abdominal wall. Sometimes when the sigmoid or descending colon is resected the bowel is not re-joined together and a colostomy is formed. The colostomy is the cut end of the colon brought up through the anterior abdominal wall allowing large bowel contents to be evacuated. After the operation patients are often cared for in a high-dependency ward until they can be stepped-down to a normal hospital ward.

Post-operative Recovery

An important part of recovery is the physical healing of the wound and soft tissues that have been disrupted by the surgical procedure. There are various factors which affect wound healing including immunosuppression, malnutrition, older age, use of steroid drugs, localised infection and poor tissue oxygenation. Smoking and obesity are also known to affect wound healing. A wound which takes longer to heal is at a greater risk of infection and breakdown.

Following a colorectal resection, recovery of bowel function and its coordinated propulsive activity can take time. This functional delay in recovery is called an ileus. There is no clear pathophysiology, but the parasympathetic, sympathetic and intrinsic nervous system are thought to play a role. Factors influencing an ileus are thought to be use of opioid analgesia, naso-gastric tube insertion and fluid excess. Longer term recovery of baseline function and resumption of normal activities is termed functional recovery. This occurs in the weeks and months following surgery and can be measured using QOL questionnaires.

6.1.3. Clinical problem

Mobilisation and physical activity are also used as a marker to assess recovery itself. Patients who are unwell or recovering post-surgery often move much less than normal, healthy individuals. They tend to have increased pain post-operatively as well as decreased energy and possible nausea/vomiting. Although an ileus post-operatively can be prolonged and worsened by inactivity it can also make the patient unwilling to mobilise. Developing an infection post-operatively will further cause systemic processes which can lead to decreased mobilisation. The anecdotal evidence seems to suggest that physical activity is highly sensitive to illness and post-operative complications, but that it is not particularly specific. Mobilisation/activity is rarely recorded formally, rather, a subjective report is gained from the nursing staff and junior doctors on the wards. The specific amount of activity performed is rarely known, although the subjective impression is used in conjunction with physical examination and patient observations to assess a patient's progress and plan for their discharge home.

Measures of recovery and outcomes during the post-operative period are important to assess how best the actions implemented improve patient care and recovery. There are multiple outcome measures used at different times of the post-operative period. These include complication rates, readmission to hospital, morbidity and mortality. There are also longer-term outcomes focusing on functional recovery, i.e. patient returning to their baseline function, and patient reported outcomes. The most commonly used outcome measure in the short-term surgical setting is hospital length of stay^{36, 44}. There is no consensus as to which optimal outcomes should be used or which better reflect recovery. Assessing recovery is vital to help with the clinical management of post-operative patients and give an indication as to which patients need extra clinical input/physiotherapy to prevent or treat complications, and which could be discharged early, allowing them to return home back to their normal lifestyle. Although different outcome measures may be relevant at different time periods within the recovery process, the possibility of a single

outcome measure that traverses the peri-operative period is a highly attractive concept. Using physical activity as a marker of functional recovery, both in the short and long-term, could be the outcome measure that can achieve this ideal.

Wearable activity monitors have been used to investigate patient activity recently including those undergoing ambulatory pH monitoring⁷², and in the development of an objective mobility assessment tool after lower limb reconstruction²²¹. Following on from the previous chapter and the systematic review in chapter two, this chapter assesses the relationship between patients' activity, monitored using a wearable activity monitor, and current recovery outcome measures following colorectal resection surgery. The aim of this chapter is to assess the relationship between physical activity, as measured by a WAM, and post-operative outcome measures, most specifically length of hospital stay, but also other post-operative outcomes that are used to measure recovery after colorectal surgery.

6.1.4. Hypothesis

Physical activity, as measured by a WAM, correlates with post-operative outcomes, specifically length of hospital stay, after elective colorectal surgery.

6.2. Methods

6.2.1. Outline

A wearable activity monitor was used to assess 38 patients undergoing elective colorectal surgery peri-operatively. Patients wore the wearable activity monitor continuously both at home, pre-operatively, and on the ward following their operation until they were discharged home. The objective activity recorded was analysed and compared to several known patient outcome measures in order to evaluate its use as a surrogate marker of patient recovery and the potential for using the data to predict short and longer-term outcomes.

6.2.2. Conducting the clinical trial

Ethical approval

Ethical approval was sought and granted from the NRES committee London - City Road and Hampstead (September 2015 – Ref 15/LO/1038).

Registration of the clinical trial

The study was registered at *clinicaltrials.gov*, which is an open worldwide database providing information about current ongoing clinical research studies. The study was registered under ‘The Step Home Trial: Utilising Physical Activity Data in the Acute Post-Operative Setting – ID NCT02583711’

Recruitment and eligibility

This cohort of patients is the same cohort as in chapter 5. Patients who were seen in the colorectal clinic and booked for an elective surgical procedure at St Mary’s Hospital were identified and assessed in line with study eligibility criteria between October 2015 and October 2016. Patients were excluded if they were dependent on someone else to mobilise, this is because any activity performed could not be solely attributed to the patient and would be majorly dependent on the

help being given. Furthermore, those patients with movement disorders, e.g. Parkinson's disease may have an added tremor or other bodily movements which would be picked up by the sensor and would not be specific to mobilisation and ambulatory activity levels.

Table 6.1. Eligibility criteria for recruitment

Inclusion	Exclusion
Undergoing elective colorectal surgical procedure at St Mary's Hospital, Paddington	Unable to mobilise independently i.e. Walk with stick/frame or dependent on another person to mobilise
	Have medical condition characterized by movement disorder e.g. Parkinson's Disease
	Unable to understand and complete the SF-36 (unless interpreter present) or lack capacity to consent
	Severe uncontrolled psychiatric disorder e.g. psychosis, schizophrenia
	Aged less than 18

Data collection

During a pre-operative outpatient clinic appointment, a member of the direct healthcare team introduced the study protocol and gained verbal consent for the researcher to discuss the study in detail. This was either done at the end of the clinic appointment or arranged for another time when the patient was having their pre-assessment clinic appointment or specialist nurse clinic appointment. Patients received a participant information sheet and were given time to ask any questions. If they were happy to take part in the study written consent was gained.

Wearable Activity Monitor (WAM)

The patients were given a wearable activity monitor (AX3, Axivity, Newcastle, UK) and asked to wear it continuously, only removing it if they were having a bath or going swimming (see Chapters 3 & 4 for further WAM details). They were advised to go about their usual daily life and activities as normal. The WAM was collected back from the patients when they were discharged from hospital.

Short Form Health Survey (SF-36)

In order to acquire a reliable quality of life metric, the patients were asked to complete the Short Form health survey (SF-36) at the initial outpatient clinic appointment, at their first follow-up appointment (two to four weeks following discharge) and at three to six months' post discharge. The SF-36 is a generic health-related quality of life questionnaire which comprises of 36 questions which are scored together and divided into eight subscales which represent specific health domains (physical functioning, role functioning physical, pain, social functioning, role functioning emotional, energy, mental health and general health perception). These eight composite score can then be combined to produce a physical and a mental score, as well as an overall health score.²²² The SF-36 is one of the most common tools used to assess post-operative recovery and has been validated in the post-operative setting as a measure of recovery for elective colorectal surgical patients.²²³

6.2.3. Data analysis

Sensor data

The sensor data was processed using the OMGui interface and raw data was transformed into signal vector magnitude and cut-points/time spent in activity types (see Chapters 3 & 4 for full description).

Moderate vigorous physical activity (MVPA), where time spent in activity with METs of four or more is combined, is a commonly used metric of activity in the literature in both self-reported activity questionnaire and accelerometer studies^{79, 203, 224, 225}. However, there is also increasing focus on ‘non-sedentary’ activity, i.e. time spent in any type of activity, with a METs intensity of over 1.5. Light intensity activity is also called lifestyle activity and is important in delineating activities of daily living¹⁴⁴. Older adults and those with moderate/severe comorbidities commonly perform more light physical activity than moderate/vigorous²²⁶, and performing light physical activity has been shown to provide health benefits in patients unable to perform these higher levels of activity²²⁷. Therefore, MVPA is used as a marker of activity prior to surgery, and total activity (including light activity) is used for the analysis of post-operative activity.

Statistical analysis

Descriptive statistics (mean, standard deviation) were calculated for subject demographics and outcome measures. Spearman’s rho correlation coefficients were calculated between physical activity levels and continuous outcome measures (length of stay, SF-36 score and blood C-reactive protein level). This test was chosen to account for the data which had a non-parametric and monotonic distribution. A Mann Whitney U test was performed for non-continuous outcome measures (readmission and complications). Statistical analysis was performed using the Statistical Package for Social Sciences version 23.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY).

6.3. Results

6.3.1. Study participants

Between October 2015 and October 2016, 38 patients undergoing elective colorectal resection at St Mary's Hospital were recruited. There were 23 males and 15 females, with a mean age at the time of surgery of 66.4 (SD 11.3, range 29-90). The mean Body Mass Index (BMI) was 26.8 (SD 5, range 15.8 – 38.6).

Three patients withdrew from the study. Four patients did not wear the sensor post-operatively, and one patient's sensor had not recorded any data, with possible sensor malfunction. Two patients did not return the sensor on discharge and we were unable to recover them. One patient had only post-operative data but no pre-operative data recorded. There were therefore 28 patients with full post-operative data and 31 patients with full pre-operative data. Table 6.2 shows the baseline demographics and clinical characteristics of the study participants.

Table 6.2. Baseline demographics and clinical characteristics of study participants

Characteristic	Participants (n = 28)
Gender (male:female)	16:12
Age (years), mean (SD) [range]	67 (11.2) [29-90]
Body Mass Index (kg/m ²), mean (SD)	26.1 (4.7)
Comorbidities, number (%)	
Cardiovascular	14 (50)
Respiratory	9 (42)
Diabetes	4 (14)
Musculoskeletal	7 (25)
Other	14 (50)
Smoking History, number (%)	
Current	4 (14)
Non smoker	8 (26)
Ex smoker	16 (57)
Clinical diagnosis, number (%)	
Adenocarcinoma	21 (75)
[Dukes A]	6 (21)
[Dukes B]	7 (25)
[Dukes C]	9 (32)
[Dukes D]	0 (0)
[mucinous adenocarcinoma]	2 (7)
Medullary carcinoma	1 (4)
High Grade dysplasia	1 (4)
Benign	4 (14)
Approach, number (%)	
Laparoscopic (including SILS)	15 (54)
Laparoscopic assisted/conversion to open	6 (21)
Open	7 (25)
Type of Surgery, number (%)	
Right hemicolectomy	9 (32)
Anterior resection	8 (29)
Panprocto/subtotal colectomy/completion proctectomy	3 (11)
Abdominoperineal resection	3 (11)
Left hemicolectomy/sigmoid colectomy	2 (7)
Ileostomy reversal	3 (11)
Stoma formation, number (%)	
No stoma	16 (57)
Ileostomy	9 (32)
Colostomy	3 (11)
Length of stay (days), median [range]	7 [3-33]

6.3.2. Main findings

Length of stay

There was a statistically significant correlation between total time spent in activity on all post-operative days, including total activity on day of discharge, and LOS (Table 6.3). Furthermore, the mean amount of time spent in pre-operative moderate/vigorous physical activity (MVPA) was significantly correlated to LOS ($r_s = -0.457$, $p = 0.01$) (Table 6.4. & Figure 6.3.). Figure 6.4. shows a scatter plot correlation of total activity on the first post-operative day and length of hospital stay, indicating that the more active on the first post-operative day, the shorter the length of stay. This could indicate that both pre-operative and post-operative activity may help to predict length of hospital stay.

Table 6.3. Correlation between total time spent in total physical activity level post-operatively and length of hospital stay. * $P < 0.05$ statistically significant
LOS length of hospital stay, POD post-operative day.

LOS v total activity on	Spearman's rho (r_s)	p value
POD 1	-0.448	0.017*
POD 2	-0.457	0.014*
POD 3	-0.455	0.015*
POD 4	-0.533	0.005*
POD 5	-0.451	0.046*
POD 6	-0.581	0.018*
Day of discharge	-0.491	0.038*

Table 6.4. Correlation between time spent in MVPA pre and post-operatively and length of hospital stay. *P<0.05 statistically significant
LOS length of hospital stay, POD post-operative day.

LOS v MVPA on	Spearman's rho (rs)	p value
Mean pre-operative days	-0.457	0.01*
POD 1	-0.376	0.07
POD 2	-0.347	0.089
POD 3	-0.414	0.036*
POD 4	-0.473	0.019*
POD 5	-0.387	0.113
POD 6	-0.454	0.089

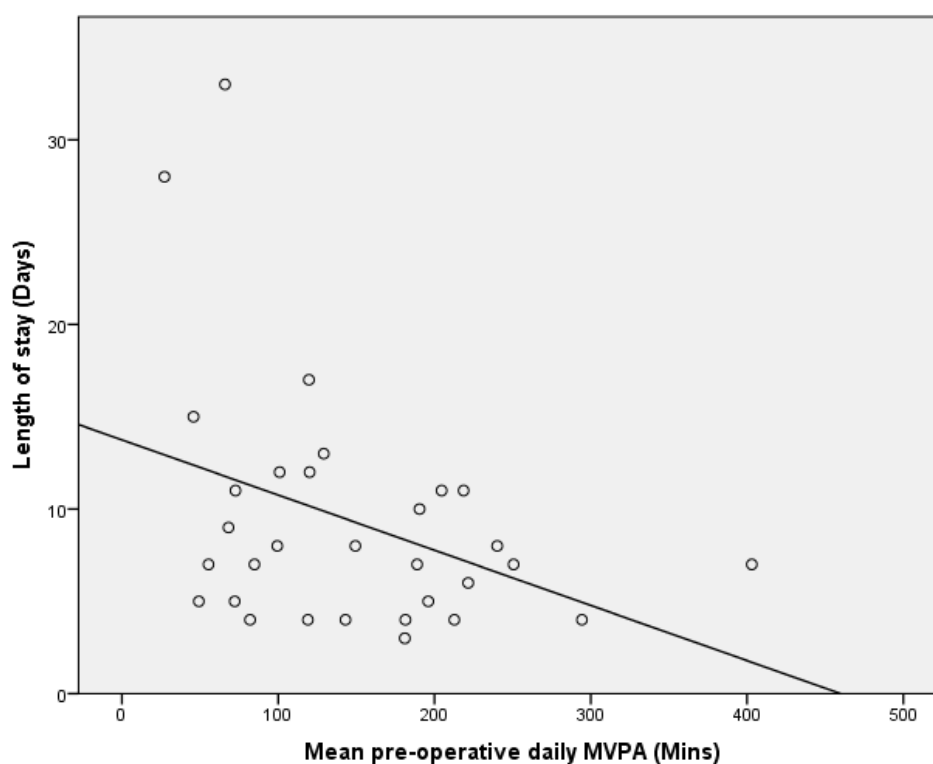


Figure 6.3. Scatter plot showing correlation between mean pre-operative MVPA and LOS

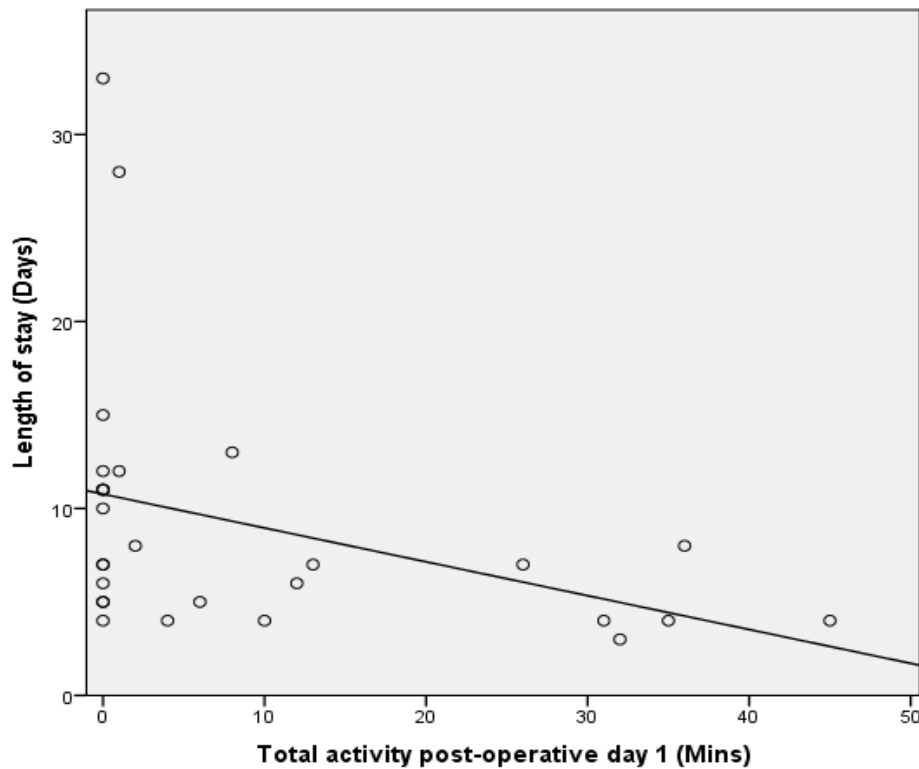


Figure 6.4. Scatter plot showing correlation between total activity on the first post-operative day and LOS

Complications

There were no statistically significant differences between mean pre-operative MVPA and the presence of complications (mean rank = 13.07) or none (mean rank = 18.75), $U = 76$, $z = -1.739$, $p = 0.086$.

Total time spent in physical activity on the first post-operative day, for patients with complications (mean rank = 10.57) was statistically significantly lower than for those without complications (mean rank = 18.43), $U = 43$, $z = -2.664$, $p = .011$ (Figure 6.5). Total activity was also significantly lower on the second post-operative day for those patients who went on to have complications (mean rank = 10.61) compared with those who did not have complications (mean rank = 18.39), $U = 43.5$, $z = -2.677$, $p = .011$ (Figure 6.6). There were no statistically significant differences between physical activity on post-operative days three ($U = 60$, $z = -1.788$, $p = 0.085$) and four ($U = 51$, $z = -1.723$, $p = 0.095$) and the presence of complications. Figure 6.7. shows activity on the

first post-operative day and complications, broken down by their Clavien Dindo severity.

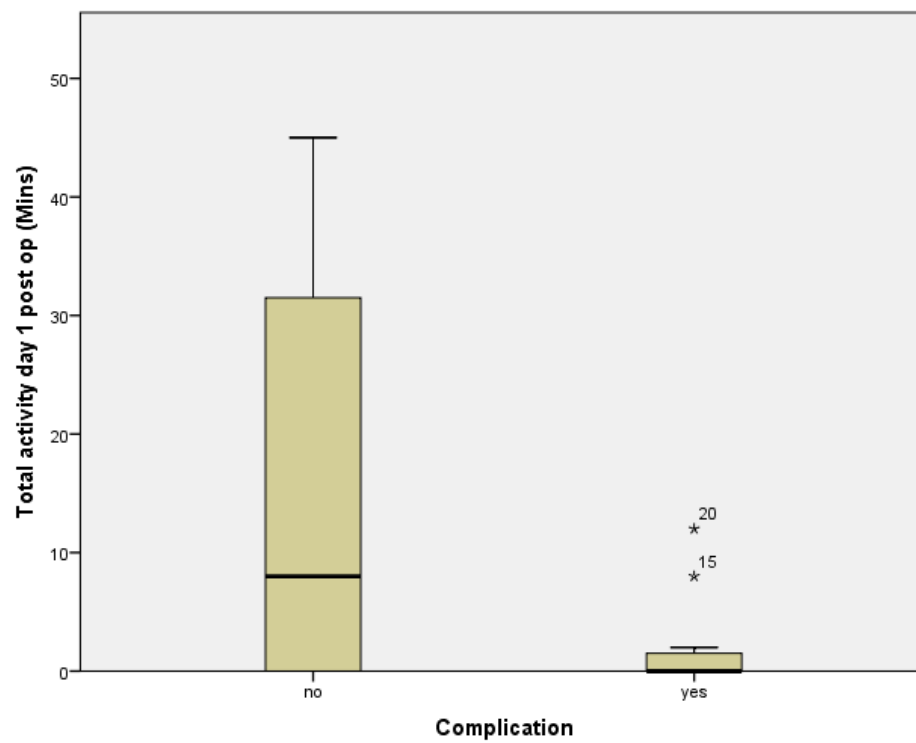


Figure 6.5. Boxplot showing activity day one post-operatively and presence of complications

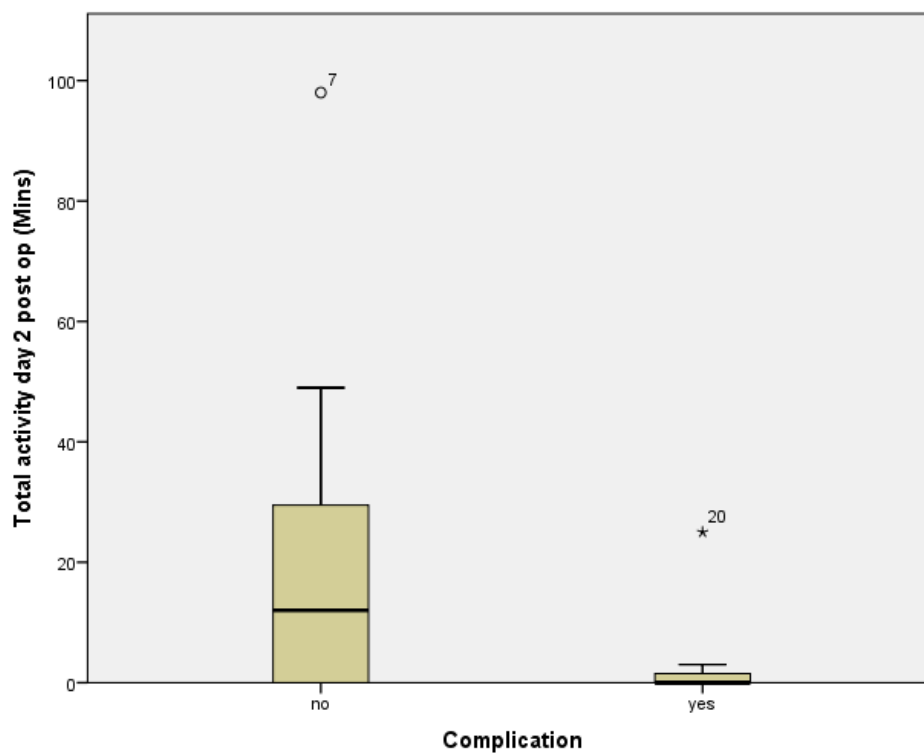


Figure 6.6. Boxplot showing activity day two post-operatively and presence of complications

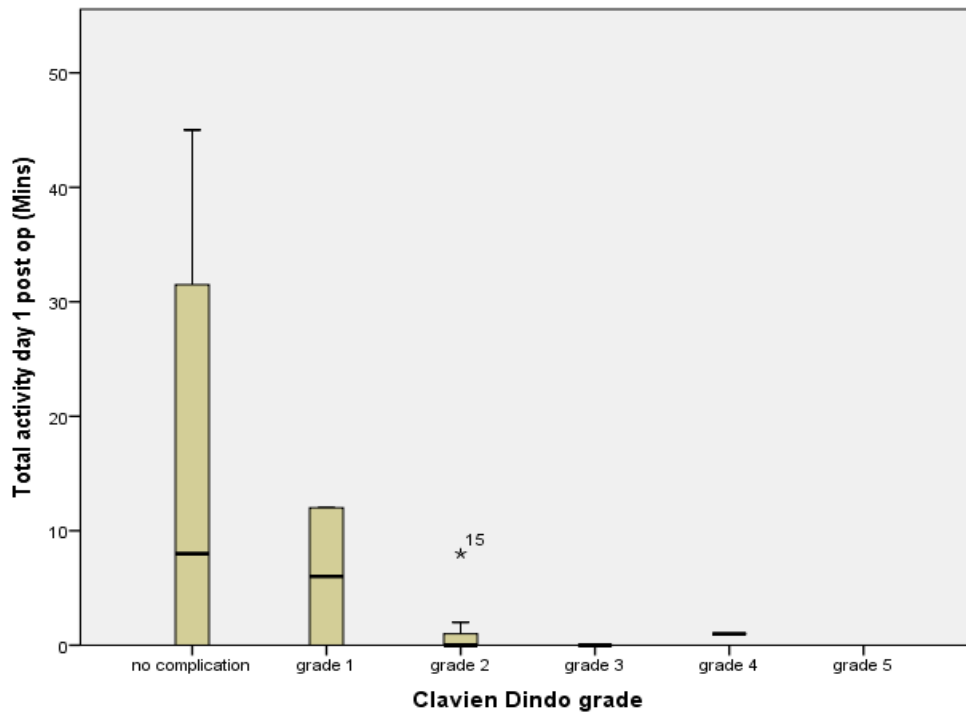


Figure 6.7. Boxplot showing complications broken down into severity (Clavien Dindo grading) and physical activity on the first post-operative day.

Readmission

There were no statistically significant differences between mean pre-operative MVPA and readmission within thirty days of discharge (mean rank = 14.80) or not (mean rank = 16.23), $U = 59$, $z = -0.322$, $p = 0.775$. There were no statistically significant differences between time spent in total activity on post-operative days one to four and patients who were readmitted to hospital within thirty days and those that were not ($p > 0.05$).

C-Reactive Protein (CRP)

There was no significant correlation between physical activity on the first post-operative day and the CRP level on either that day or any subsequent days. There was significant correlation between activity on the second post-operative day and the CRP on that day ($r_s = -0.407$, $p = 0.035$), as well as the CRP on the fifth ($r_s = -0.562$, $p = 0.024$) and sixth ($r_s = -0.572$, $p = 0.033$) post-operative

day. There were also significant correlations between activity on post-operative days three, four and five and the CRP on post-operative days two and six (Table 6.5.).

Table 6.5. Correlation between total activity on first five post-operative days and C Reactive Protein levels. *P<0.05 statistically significant, **P<0.01 statistically significant

		CRP day 1 post op	CRP day 2 post op	CRP day 3 post op	CRP day 4 post op	CRP day 5 post op	CRP day 6 post op	CRP day 7 post op
mins of LMV activity day 1 post op	Correlation Coefficient	.040	-.316	-.091	-.144	-.128	.010	-.007
	Sig. (2-tailed)	.839	.108	.679	.494	.636	.972	.985
	N	28	27	23	25	16	14	10
mins of LMV activity day 2 post op	Correlation Coefficient	.112	-.407*	-.209	-.379	-.562*	-.572*	-.467
	Sig. (2-tailed)	.571	.035	.339	.062	.024	.033	.173
	N	28	27	23	25	16	14	10
mins of LMV activity day 3 post op	Correlation Coefficient	.098	-.392*	-.195	-.281	-.176	-.456	-.335
	Sig. (2-tailed)	.621	.043	.372	.173	.515	.101	.345
	N	28	27	23	25	16	14	10
mins of LMV activity day 4 post op	Correlation Coefficient	-.349	-.669**	-.450*	-.302	-.376	-.616*	-.321
	Sig. (2-tailed)	.080	.000	.035	.151	.151	.019	.366
	N	26	25	22	24	16	14	10
mins of LMV activity day 5 post op	Correlation Coefficient	-.044	-.566*	-.247	-.126	-.371	-.565*	-.584
	Sig. (2-tailed)	.854	.011	.323	.597	.173	.044	.099
	N	20	19	18	20	15	13	9

Quality of life

Quality of life, as measured by the SF-36 questionnaire, did not correlate with physical activity for either physical or mental function apart from between total activity on the day of discharge and physical function and energy/fatigue (Physical function $r_s = 0.806$, $p = 0.005$, Energy or fatigue $r_s = 0.713$, $p = 0.021$), and emotional wellbeing ($r_s = 0.661$, $p = 0.038$) at three to six months post-operatively.

6.4. Discussion

This study demonstrates that objectively recorded pre-operative and post-operative patient activity levels correlate with post-operative outcomes, particularly length of hospital stay. This is, to our knowledge, the first study to show this within a colorectal cohort and will be a useful addition to the ERAS literature, giving objective evidence that mobilisation and activity correlate with post-operative outcomes. Although it seems obvious that patients who are more active both prior to, and immediately following, an operation are more likely to have better outcomes than those who are less active, our study has shown this objectively in a colorectal cohort. Patients who were more active pre-operatively in the community and post-operatively on the ward recovered quicker and were discharged sooner than those who were less active. Patients who were less active had a greater risk of developing a complication post-operatively. These findings could lead to the ability to predict patient length of stay or other post-operative outcomes, with larger participant numbers needed within a randomised controlled trial.

Our results are similar to recent, but limited, literature within the cardiothoracic, orthopaedic and vascular domains. In-patient steps have been shown to be a risk factor for cardiac re-hospitalisation following cardiac surgery⁹², a decrease in adverse events was noted in the more active cohort after lower limb bypass for claudication²²⁸, and a significant relationship was seen between the number of steps taken in the early post-operative period, after thoracic surgery, and length of stay as well as discharge destination⁵³. Only one other study has looked at activity levels and clinical outcomes within abdominal surgery, with the activity metric of ‘uptime’ (amount of time spent in upright position) being used. Uptime correlated with length of stay but not with other post-operative outcomes⁷⁶.

Pre-operatively, patients with a lower level of physical function in the community have been shown to have worse outcomes post operatively with higher complication rates and readmission²²⁹. Pre-

operative physical activity levels are an objective way of stratifying patients' baseline physical function. Mobilising post operatively is important, forming one of the four 'Pillars of ERAS', and is significant in the prevention of some post-operative complications, including chest infections and thromboembolic events (PE/DVT)²³⁰. Furthermore, minimal activity, or a decrease in activity, on the ward post-operatively could also indicate a problem in the post-operative course, highlighting an impending complication that could be prevented or flagging up where an early intervention could prevent ongoing complications. Knowledge of patients' activity both pre and post-operatively, and the awareness of poorer outcomes with lower activity levels, is an essential area where ERAS ideals can be integrated and improved upon.

Although our results did not show any significant difference between activity levels and readmission to hospital within 30 days, only a few of the patients in our cohort were readmitted, making the analysis limited. Furthermore, readmission within 30 days may be more associated with a person's comorbidities or the type of operation performed, rather than solely on the amount of activity performed pre-or post-operatively. A larger patient cohort may help us to explore this in more depth.

Post-operative activity was shown to correlate with the level of post-operative C-reactive protein. CRP is a blood inflammatory marker that rises when tissues are inflamed or infected and has also been shown to be a useful negative predictive test for the development of an anastomotic leak in colorectal surgery²³¹ and a predictor of poorer outcome on the first day post-operatively after abdominal surgery.²³² CRP is known to have a lag time,²³³ and our data is in keeping with this. Activity levels correlated to CRP level two to three days later. This could be because any infection or inflammation affects the patient more immediately, whereas the CRP which lags will only show up two to three days later. Therefore, good levels of physical activity on the day of discharge will likely correspond with a low, or falling, CRP in the community, thereby facilitating and supporting

safe early hospital discharge.

This study showed a correlation between total activity on the day of discharge and the physical functioning and fatigue scores post-operatively at three to six months, but not at two to four weeks. Similarly, the mean MVPA scores did not correlate with the pre-operative physical component scores. The mental health component scores showed comparable results to the physical health component scores. In a study²²³ where a 6-minute walk test was performed post-operatively at one and two month the SF-36 physical functioning scores were shown to significantly correlate with activity post operatively. Another study showed that the SF-36 correlated well with pre-operative and post-operative activity⁶⁷. Within our study however, pre-operatively the SF-36 questionnaires were completed within a few days or weeks from diagnosis, which was a cancer diagnosis in 82% of our patient cohort. Although their objective physical function may be at a certain level, their perceptions and health beliefs could alter how well they view their function subjectively, and so they record their physical function at a lower level on the SF-36 questionnaire. This perceived lack of physical capability, even though physically able, has been discussed previously along with other beliefs about physical activity in cancer patients²³⁴. Further confounders include that the SF-36 is completed post-operatively, in our study, at 3-6 months after their inpatient stay. This lengthy time period means there are potential recall biases, the patient may also be undergoing other treatments, e.g. chemotherapy or radiotherapy for their colorectal tumour, or biological treatment for inflammatory bowel disease.

6.4.1. Limitations of study

Although 38 patients were recruited, the drop-out rate was 7% and the number of unreturned WAMs or those with data malfunction was also 7%. This left us with a smaller sample size, and more difficulty in statistical analysis, especially with regard to patients with complications and those needing readmission. A number of patients did not wear the WAM on the first few days post-

operatively, this was because of invasive intravenous/arterial lines within their arms, or swelling following the removal of these. Although we included these with intention to treat, i.e., a recording of zero activity in these patients was included as zero activity within the analysis, it may have significantly underestimated the amount of activity that was performed on those post-operative days. The battery life in the WAMs (up to thirty days) meant that patients with an extended pre-operative course and a lengthy post-operative course did not have their total activity recorded whilst an inpatient. Although this only occurred in a small number of patients, it could affect the comparison between outcomes and amount of activity on day of discharge, thereby underestimating recovery at the time of discharge.

6.4.2. Potential clinical impact

Our results show the potential to highlight the less fit patients pre-operatively who have a smaller functional reserve and may therefore benefit from increased physiotherapy or input prior to undergoing any surgical intervention in order to mitigate against poorer recovery post-operatively, thereby ensuring that the patients' recovery is improved as per the ERAS paradigm. It will also enable intervention in the early post-operative period for those patients who are less active, or who deteriorate, as complications can be recognised earlier and clinical input instigated quicker, thereby again ensuring improved patient recovery in line with the ERAS ideal. Our data seems to suggest that those with higher pre-operative and post-operative activity are discharged earlier than those less active. This knowledge could help with discharge planning and facilitate early discharge. Patients with a high level of pre-operative activity who achieve high enough levels of activity on post-operative days one and two could be discharged home at that point knowing they are recovering at the expected trajectory and are less likely to have complications. This could also help predict bed availability for the hospital management who need to plan for subsequent patient admissions for elective surgery and emergency admissions.

Wearable activity monitors peri-operatively: patient and clinician perspectives

7.1. Introduction

The recent advancements in wearable technology has led to the manufacture of devices able to measure multiple parameters and subsequently the application of such devices within the healthcare setting has risen exponentially. WAMs are generally small, body worn devices that can monitor patients in a hospital and home environment, providing patients and clinicians with data about their health and wellbeing and track their progress and recovery from illness or following an operation.

In the last decade or so patients have increasingly become active partners in health research, one example is their involvement in the design and conduct of controlled trials, which has been thought to improve the relevance of the questions asked as well as the end results from the trials²³⁵. Patients are said to possess ‘experiential knowledge’²³⁶, that is, they have lived through their illness and have the experience and knowledge first hand. They are therefore seen to have both insight and expertise, with the ability to give wider perspectives and opinions on the research aims and questions.

Translational research is the connection and translation of biomedical/scientific research into clinical practice and the healthcare setting²³⁷. Involving users at an early stage of technology development has been shown to help anticipate and address any issues or problems, as well as increasing the uptake of the technology²³⁸. Although studies have shown the benefit of using WAMs for longer term monitoring of patients and for reducing healthcare costs^{239, 240}, there

remains a gap between research and clinical service applications. Patients recruited into clinical trials often don't wear the WAMs for the full study period or drop out altogether. Although it seems obvious that patient participation and involvement within technology research is key to translating the objective scientific findings and research into clinical practice, there is little research with regard to the attitudes, perceptions and concerns of patients surrounding WAM technology.

It is important to understand the impact that technology has on patients, whether it empowers them and motivates them, or if, conversely it is detrimental to their recovery. There have been studies which have shown that patients with chronic conditions who take greater control of their own management in certain ways have an overall benefit in their health and wellbeing²⁴¹. Thinking about the psychosocial factors that may affect patients' use of technology are as important as understanding the practical issues of WAMs. These include the appearance and comfort of the WAM as well as the technical side and functional use.

Equally, it is important to know how clinicians view this newer technology, whether they want or would use the data that can be collected and how they would want the data to be shown to them in the clinical setting.

There have only been a small number of studies to date looking at wearable technology in a qualitative manner from either the patient or the clinician perspectives. A systematic review by Bergmann et al²⁴² showed that there was a lack of high-quality studies within this area, and that user acceptance and preference was often overlooked when designing WAMs. Although there have been no studies, to our knowledge, exploring patient perspectives of WAMs within a surgical cohort, there have been a handful of studies within other medical specialties.

One study explored the perceptions of the use of wearable technology in patients suffering from

epilepsy and Parkinson's disease²⁴³. Patients and healthcare professionals participated in focus group interviews and qualitative analysis was performed. Most participants identified a benefit for the wearable technology and this benefit outweighed the potential inconvenience of wearing the sensor. A different study²⁴⁴ looking at WAMs in patients with Parkinson's disease asked patients to wear bilateral WAMs on their wrists for four hours in the research facility and then for one week at home. A questionnaire about patient experience was completed and free responses were analysed qualitatively. The main qualitative results showed that there was increasing discomfort with increased length of wear as well as issues with the WAM strap, but that most participants preferred wearing the WAM to completing symptom diaries.

One study used WAMs to collect continuous activity data from pregnant women from the beginning of their second trimester until one-month post partum²⁴⁵. Phone interviews and questionnaires were used to collect qualitative data. Most of the participants did not report any long-term permanent effects of the WAM on their behaviour but overall, they found the WAM easy and comfortable to use. Another study looked at patients following treatment for endometrial cancer²⁴⁶. The patients wore a *Fitbit* for 30 days at home and then completed a Technology Acceptance Questionnaire. There was a high level of acceptance of the *Fitbit* by the patients.

One qualitative study looked at both the perceptions and preferences of WAMs in patients suffering with osteoarthritis, as well as the impact of wearable technology on these patients^{247, 248}. Their study only used a prototype sensor, and the patients did not actually wear the sensor at all, rather looked at it and discussed the potential positives and negatives based on their ideas, rather than their experience. The participants did perceive benefits to the WAM especially for rehabilitation purposes and as a tool to monitor their progress. The participants also commented on the appearance and comfort of the WAM.

One study²⁴⁹ reviewed clinician preferences with regard to WAMs, again in a patient population with osteoarthritis, where the patients did not wear the WAM in any clinical setting. They found that clinicians supported the use of WAMs within a healthcare setting, and perceived many benefits including monitoring compliance, evaluating treatment and enhancing their relationship with patients.

Looking at the bigger picture it is important to consider how WAMs could be used within the surgical setting, and which healthcare professionals would want to see the data. Knowledge of activity levels and baseline function pre-operatively may be useful for the surgical team in order to help quantify a patient's pre-operative fitness level. There may also be a benefit for prehabilitation, to try and improve baseline function prior to any operative stress^{250, 251}. Patient and healthcare professional opinions would be beneficial to work out how long prior to the operation the patient should start wearing the WAM, how the information could be relayed to the clinical team, and whether there are any other types of information that could be linked to it, e.g. GP notes. Furthermore, it would be useful to know whether this activity data could or should alter the date of operation.

Post-operatively on the ward the nursing staff, physiotherapists and the direct clinical care team would want to know if the patient is being active and if so, how active they are being. It is important to understand what type of data these healthcare professionals would want to view and how they would want to view it, whether via paper chart, through the WAM, or on a separate device. Additionally, it would be helpful to know how frequently the healthcare professionals would want to view the data, as well as whether the data should be combined with any other parameters that are already or could be measured. Lastly, it would be interesting to understand if the physical activity data itself would change any of the healthcare professionals' management plans or encourage discharging patients home earlier.

Following discharge, the surgical team could use the WAM activity data to observe recovery of patients at home. It is helpful to know if the healthcare professionals think this is a useful parameter to be measured, and whether they would want the data to be available to them in real-time whilst the patient is at home or just available to be reviewed at the follow-up clinic post-operatively.

It is important to understand if healthcare professionals believe they would benefit from the activity data available, and if they do perceive a benefit, then in what way they would want the data presented to them and at what time periods. It is possible that different healthcare providers would want to see patient activity data at different times of the operative pathway and in different ways.

The aim of this chapter is to gain further insight into the user experience and acceptance of wearing the WAM whilst undergoing clinical care in the hospital and the community. This will give invaluable understanding of how patients perceive the WAMs, how they interact with them and how to improve the design and implementation of sensors in future research and clinical practice. We also aim to gain insight and understanding into how healthcare providers view wearable technology, physical activity data, and its use in the healthcare setting.

7.1.1. Hypothesis

Patients and clinicians have positive, but differing, opinions on the utility and value of wearable activity monitors to measure physical activity in the peri-operative period.

7.2. Methods

7.2.1. Outline

A qualitative study was undertaken using semi-structured feedback interviews to understand how WAMs and wearable technology were viewed by patients and healthcare professionals.

7.2.2. Conducting the clinical trial

Ethical approval

Ethical approval was sought and granted from the NRES committee London - City Road and Hampstead (September 2015 – Ref 15/LO/1038).

Registration of the clinical trial

This study formed part of ‘The Step Home Trial: Utilising Physical Activity Data in the Acute Post-Operative Setting’ registered at *clinicaltrials.gov*, which is an open worldwide database providing information about current ongoing clinical research studies, ID NCT02583711.

Participants

Patients who had been recruited to wear the WAM at home pre and post-operatively were also approached to take part in the feedback interviews. Consultant surgeons and clinical nurse specialists were approached and recruited to take part in feedback interviews, as they had had direct care with these patients from pre-operative clinic appointments to post-operative review in clinic after the surgery. Both the patients and healthcare professionals were given written information and then provided written informed consent before taking part in the study.

Interviews

Semi-structured interviews were conducted, and recorded, with consent of the participant. The recordings were then transcribed verbatim. Participants were asked a series of open-ended

questions which helped to explore their knowledge and views on wearable technology in everyday life and within a healthcare setting. Each patient was shown their own collected and analysed activity data (example in figure 7.1.). The clinicians were shown one patients' activity data. Further questions were asked to gain an understanding of how they viewed the data itself, and which types of analysis/visualisation of data they understood and preferred. The semi-structured interviews were based on the focus group, questions and work done by Papi et al^{247, 249} and are included in the appendix. Papi et al used focus groups to understand the main themes and responses of patients with osteoarthritis and their understanding and perspective on wearable technology within a surgical setting. They also studied clinician views on wearable health technologies for patients with osteoarthritis within a surgical setting using semi-structured feedback questionnaires. Although the clinical context is different, the underlying concept of using WAMs within a surgical setting was similar and therefore was adapted slightly to fit the patient and clinician cohort for this study.



Figure 7.1. Different ways the activity data was presented and shown to patients and clinicians

7.2.3. Data analysis

Study design and analysis

This was a qualitative study based on interviews with patients and clinicians on their perspectives about wearable technology used in the healthcare setting within the peri-operative period.

Qualitative research is the *‘development of concepts which help us to understand the phenomena in natural (rather than experimental) settings, giving due emphasis to the meanings, experiences and views of the participants’*²⁵².

There are four main types of qualitative research design²⁵³:

- Ethnography – A study of a people or culture in order to develop cultural awareness and sensitivity.
- Phenomenology – A study of individuals who have lived the experience of events/phenomena.
- Grounded theory – A study where a theory is developed and derived from the field data itself.
- Case study – An in-depth investigation into a single unit/individual over a period of time.

Once captured, qualitative data can be analysed in different ways:²⁵⁴

- Content analysis
 - Categorising verbal or behavioural data in order to classify or summarise and tabulate it. This can be analysed descriptively – ‘what is the data?’, and interpretatively – ‘what was meant by the data?’
- Narrative analysis
 - The narrative, or story, is reformulated based on the person’s different experiences and the different contexts.

- Discourse analysis
 - A method to analyse naturally occurring spoken interaction and written text. Focusing on how language is used differently according to the context.
- Framework analysis
 - A highly systematic method of categorising and ordering qualitative data. Often used as it is a flexible tool that can be adapted to qualitative studies that wish to generate themes between and within cases.

There is also a difference between deductive versus inductive analysis. Which approach to use when analysing qualitative data can depend on the nature of the research question itself. The deductive approach is used if the research question is based on previous existing theories, or when a yes/no answer is required. Inductive analysis however is used to allow themes to be generated from the data itself, with further refinement of themes as the process continues²⁵⁴.

For the current study, an inductive thematic analysis was conducted using Framework Methodology²⁵⁵. This was chosen to allow for the development of the theory from the data itself, meaning no pre-existing theory about use of technology and WAMs in the peri-operative period was needed, this was necessary given there has been little research into this area prior to our study. Themes were generated by comparing interview data between patients, providing a structured overview of the summarised data.

Firstly, familiarisation with the data occurred, then the interview data were examined, and preliminary themes were extracted. Classification of patients' responses in the different themes was carried out in Microsoft Excel spreadsheets. These themes were then re-analysed and main recurrent themes were established. The data were continually interpreted thematically, with indexing and charting of the key points and findings, until the data had been fully clarified.

7.3. Results

7.3.1 Study participants

Six patients were recruited, (4 female, 2 male), out of a total cohort of ten, as saturation of themes was met after the sixth patient. Patient ages ranged from 66 to 75 years. Five healthcare professionals were recruited, two consultant colorectal surgeons and three colorectal nurse specialists, (3 female, 2 male) and no further healthcare professionals were recruited due to saturation of themes.

All participants were recruited between June 2017 and October 2017 at St Mary's Hospital, Paddington, London. The interviews lasted between 11 and 25 minutes and occurred in a private setting, however, if a patient requested a family member to sit in this was permitted.

7.3.2 Main results - Patient study

General knowledge of wearable sensors

Four of the six patients had either personal use of, or awareness of, wearable technology within the fitness industry, but only one patient described wearable technology in the healthcare setting. Two patients mentioned the *Fitbit* specifically and two just the generic description of a wearable activity monitor. Three patients described heart rate and blood pressure monitoring, whilst four of the patients described activity, steps or fitness being monitored. Two patients mentioned use of an *app* (smartphone or tablet application) to look at the results from the WAM. One patient mentioned the use of a panic call button, used to let medical professionals and family know if the wearer has fallen over and needs help.

Data analysis revealed four main themes: practicality, functionality, value and holistic tool. These themes are described below together with verbatim comments, which use the notation P to indicate patient, and a number to indicate which specific patient.

Practicality

One of the key areas discussed with the practicality of the WAM, including the wearability, comfort, attractiveness and discretion of the sensor as well as how it interacted with other hospital devices (figure 7.2.).

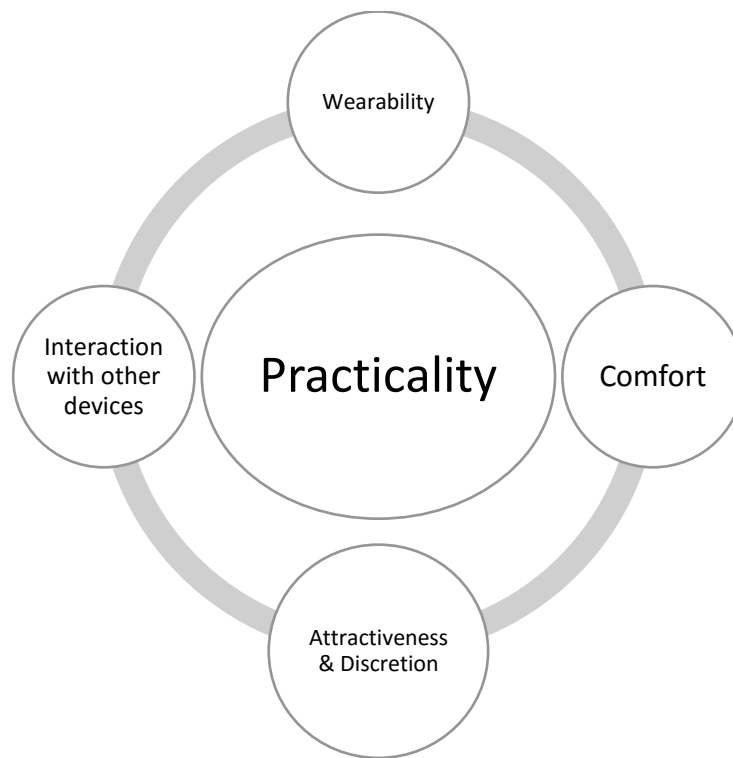


Figure 7.2. Patient views on the practicality of the WAM

Four out of six patients were happy to wear the WAM again:

I was very happy.... No problems whatsoever (P3) I can't see any reason why not to, yes (P5)

But two of the patients did not think they would wear the WAM again:

Not normally I don't think (P2) No, not really. I'm not the sort of person that can do things like this. I'm terrible about putting things on my wrist (P4)

This led into a discussion about the comfort and design of the WAM. In general patients found the WAM acceptable to wear:

It wasn't difficult to do up (P6) It was not uncomfortable.... no problem whatsoever there.... all positive (P3)

But others wondered if the design could be altered, making it lighter and slicker;

Is it possible to make it less chunky, less heavy?... I found it cumbersome. It wasn't a terribly comfortable thing to wear... it was quite chunky.... And I found that the strap where you flicked it into the second bit... to keep it flat... it kept riding towards the metal bit, so you had things sticking out... so if you were taking clothes on and off, it got caught... and it tore towards the end.. (P1)

Perhaps a bit smaller, or different kinds... not made out of rubber (P5)

Two patients commented on some skin irritation after wearing the WAM:

It started making my arm sore.... it was like a rash.... And I was itching (P4)

The only problem was it was quite hot, and it got a bit sweaty.... I think I got a little bit of a rash (P5)

Wearing the WAM in the shower caused some inconvenience, necessitating either removing it, or trying to keep it out the way of the water:

Perhaps the showering bit was troublesome because I did try and keep it out of the shower (P1)

I always took it off when I had a shower and I washed my hair (P5)

There did not, however, seem to be any issues with it being particularly obvious when worn, or attracting too much attention, rather it seemed relatively discrete and unobtrusive:

I don't think one person remarked on it, not one (P6)

Although one participant did comment that it wasn't particularly appealing if one was going out somewhere:

It doesn't look very attractive (P5)

The biggest obstacle to the WAM was its interaction with other medical devices, often needing to be change from wrist to wrist, depending on where cannulas, medication and other medical equipment was being used on:

I think I moved it from one wrist to the other, only because of the drips I had (P6)

I think I may have switched it earlier because of the cannula (P1)

It did become intrusive because, uh, they were continually.... fitting new inputs into me, and I'd say for eight days I had to have a drip... for food... other drugs, morphine, and all intravenously, so they were grafted on the wrist as well (P2)

Value

The majority of patients identified benefits of using the WAMs in the peri-operative period, although often this was not necessarily for them in the current time period, rather for future patients, or for healthcare professionals. The themes that were explored included utility of the data, reinforcement and encouragement as well as generalisability and accuracy of the data (figure 7.3.).

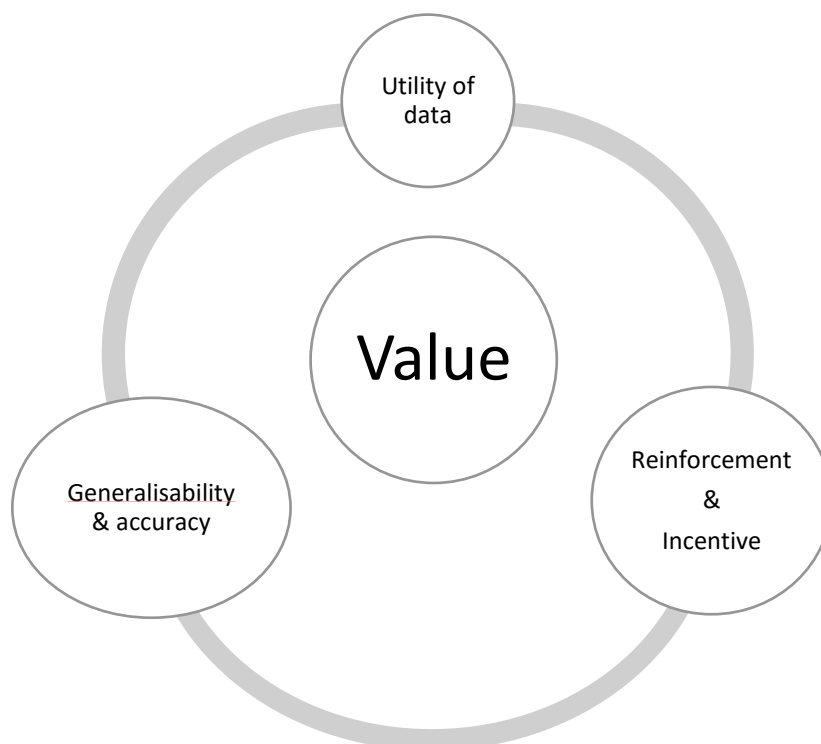


Figure 7.3. Patient views on value of using WAMs in the peri-operative period

Patients were keen to have the data from the WAM and identified being able to use the data in order to observe their on-going progress and as a guide to their activity in the peri-operative period:

I think it would be quite useful... because I think, um it's really like a sort of little reminder of how you've, you know, well done. This is what you have done today (P1)

I think if I'd, if I'd had, I'd had a little bit more information and a little bit more encouragement, I think I might have walked even further (P3)

Some patients, however, did not think there was a use for the data in their own circumstances, rather for other patients in the future:

Maybe for the benefit of others later (P2)

Interestingly, they felt the benefit of the WAM data may only be for specific subsections of patients that either needed more of a boost due to their inactive lifestyle, or those who were already quite active pre-operatively:

My opinion would be... I think it would help some people, who are mentally not so strong and maybe the slightly overweight or well overweight. I think it would show them that they need to do something (P3)
Maybe some people, yes.. probably if they were more active and then they've had an operation and everything changed (P4)

Others felt that the data was more useful for healthcare professionals rather than patients themselves:

Not for me, but for, maybe professionals. What am I going to gain from knowing what I'd done already? I know what I'd done already... I feel it's more for the clinicians' side of it benefit, than for mine (P6)

The WAM technology was seen as a major way to incentivise and encourage patients to be physically active:

I think in a way it prompted you to keep going ... I think I was aware I needed to move about.. A reinforcement, maybe, to where one was at I think actually it's a positive reinforcement to keep going (P1)
I would look at it and then I would most probably do a bit more, maybe. You know, to make it so every day that you, you, sort of improved on the day before (P5)
I'd probably be encouraged to be a bit more active then if I was, because I'd probably look at it on the computer and go ooooooh yes. Yes I think I might be encouraged a little bit more (P6)
I think the more information you're given, I think it, it, it makes you want to do more (P3)

This was highlighted especially in those who may not have been as active as they could or should have been post-operatively:

Well I would say that it looks very low... it may have, um, motivated me to be more active, yes... At the time, if you had come up on the wards, you'd have only done, sort of, 10% of your normal activity... you may have been incentive to be more active (P2) I think it would encourage people to get off the, get out of the bed (P3)

Leading to the observation that the WAM data could be used by the healthcare professionals, providing them with objective physical activity data that they can use to encourage and motivate patients to be more active post-operatively, especially those who are not meeting the

recommended activity guidelines:

Well, if it's, if after four, five days I was only doing, sort of, 2% of my normal activity, then they would have said look, you need to be more active... and that would've, I would've agreed with them.... It would be a question of them saying to you you're not being active enough (P2)

An example would, in my opinion, is that the nurse if she's seeing that you're not moving by the clock, you could say, you know, Mr B, please can you do a little more. Would you like some assistance? Would you like me to walk with? Encouragement, I think would work. It's the encouragement (P3)

However, some patients did not feel that they were personally motivated by wearing the WAM, either because they were going to be as active as they could anyway, or because they would listen to a healthcare professional more, perhaps, than the device itself being a motivator:

It didn't really motivate me to try and be more active because I wanted to try to be more active from the start anyway... The more activity I had, well you see, that the quicker I was going to get out (P2)

Well no, I mean... I can do it. If I'm told I've got to do it, but I, it wouldn't make any difference to me having anything to motivated myself (P4)

Patients were understandably intrigued as to how their level of activity was perceived, and whether they met a certain 'criteria' or baseline and how they compared to other individuals:

Is there an average for people? (P3)

But, in general, the data was thought to accurately assess physical activity levels and participants commented that it seemed to mirror what they actually experienced:

I think it reflects how it was.... Obviously, some days were busier than others. I did try to increase the activities each day (P1)

Functionality

One of the largest themes that was developed was if / how the data captured on the WAMs should be presented to patients and clinicians. This led to discussions about data feedback and interpretation. The visualisation and graphics of how the data was presented as well as data privacy were touched upon (figure 7.4.).

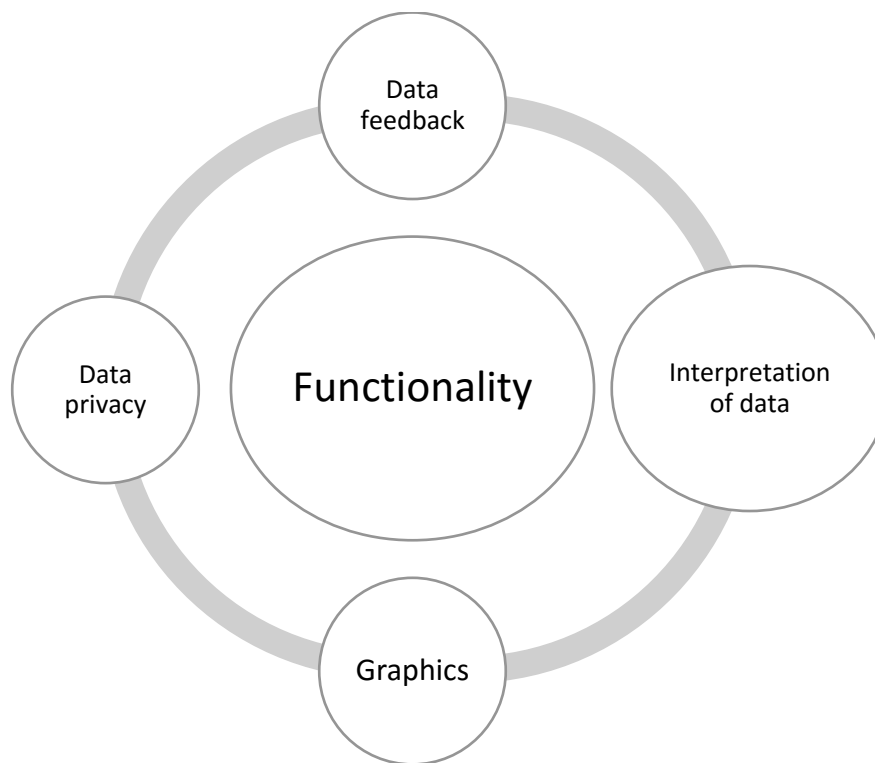


Figure 7.4. Patient views on the functionality of the WAMs

Some of the patients were unsure what the sensor was actually monitoring:

Did this register sort of walking or all types of movement?.... I mean if I was scrubbing the floor?.... one is doing different things (P1)

Most patients wanted the data to be presented to them via the WAM in real-time, giving them information instantly to help them understand their current physical activity levels:

I'd say you'd have to be giving me information at the time, rather than finding it out later, for me to be able to interact with them... if it was giving results there and then, you know, more like... a modern watch or something, you know, digital figures... and then you just press a button and it would tell you whatever it was meant to be telling you... that would be of far greater benefit (P2)

I think they would need to know the results as they were wearing it, rather than it was a blank screen, I didn't

know what it was reading or what it was saying (P2)

Interestingly, one patient described the Hawthorne effect, and thought it better not to be able to see the information, as it may mask what the patient would otherwise truly be doing, whereas with a WAM they may alter their behaviour and perform more activity if they were aware that their levels were falling short for the day:

I think if, you're getting a much more true picture by not having anything showing because you are, you think you're just carrying on as normal.. the minute you put on something with a reading, you in a way, you don't get a true reaction because you're doing, you're saying, oh, I'm doing too much so I'll sit down now, right? Where normally you wouldn't do that. Or you would have an opposite effect and you would say, I am not doing enough, I better do more. But once you take that off, then you back to normal. So, I think it's better personally, not to show it. I think that's better because you're getting a much truer picture (P3)

All the patients were able to understand the data that had been derived from the WAM when it was presented to them:

On day one it's 91, day two 76, three 146. So it is, yes, it seems funny how one day seems high and then the next one. Really interesting... on day one, I spent 91 minutes doing something... active (P3)

They often interpreted the data presented through their mood and frame of mind in the post-operative period:

*It's increased... quite busy... interesting how it seems to drop.... And then up again... because one was weary. Having done perhaps more than one should the day before..... high low low high low low high (P1)
Why was I more active then? That's I don't know, I know on day two I felt really fed up. It's gone up and down, hasn't it... I suppose these were the days when, I mean a couple of days I didn't go out for a walk did I.. (P5)*

Some aligned the data they saw with their actual movements/ non-movements on the ward post-operatively:

*That's when I was in bed all the time, that was the day of the operation, day two I didn't do much at all, neither the following two days. And then it started, I was gradually... It just tells me that I'm getting more active. I'm doing a bit more (P4)
I was just lying in bed... up to ten days after it still looks fairly minimal... I thought it was a bit more than that (P2)
Oh gosh, it suddenly goes up there, doesn't it, day six... Because day one, what is eight minutes on day one, I thought that was the day I slept all day (P6)*

Patients were split as to how they would prefer to visualise their physical activity data. Some

preferred seeing numerical digits:

I think it was simpler with the numbers (P2) I'd choose... the numbers (P5)

Whereas others preferred looking at the pie charts:

*It's easier to see it as a pie chart ... I could see a more interesting variation with the bar chart (P1)
I think I would choose... The pie chart, I think purely because you can see that I did very little compared to that..
I think that, as you know, I think it's easy to understand very quickly.. I think the average person would probably
understand the pie much quicker (P3) It's much easier to understand the pie chart, I think (P6)*

One patient also liked the multi-coloured bar chart that showed activity and also distinguished between different activity levels:

It just goes to show how, as I was getting better, look at the grey, you know, and the orange, you know it's increasing... I, quite like this one... with the three different colours (P3)

Only one person commented on the notion of data privacy, but was happy to share data with the healthcare professional team:

Some people would say, oh, it's privacy... I'm very open to share with any surgical team, I just felt it was great (P3)

Holistic tool

The WAM was seen as a device that could potentially impact healthcare in a more holistic way, leading to better communication and teamwork with healthcare professionals, giving individualised treatment plans and helping in decision making processes. The use of the WAM as an educational tool and as a forum to consider peri-operative fitness was also discussed (figure 7.5).

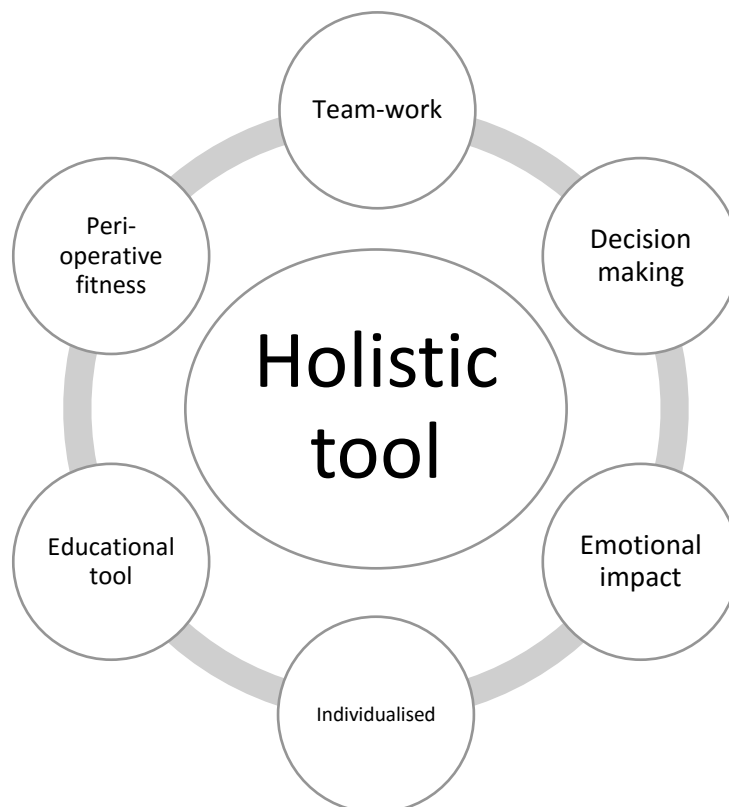


Figure 7.5. Patient views of the WAM as a holistic tool

Patients identified an emotional aspect tied in to the peri-operative period itself, and the use of a WAM:

In my opinion, the reason why I recovered very quickly, as I was operated on the Wednesday and I was out Sunday morning, was... my mental state was very, very good (P3)

I might be anxious. I might think, ooh why am I not doing... or I just feel tired today (P1)

There was a sense that the WAM could support patients to become part of the healthcare team, ensuring they had a role to play in their own recovery:

I just wanted to walk straight away... because I knew that was monitoring me, I wanted to make sure you knew

that I was doing my bit to get better, so you see, that was encouraging yes... I, personally... would feel part of a team (P3)

Most patients thought that giving the WAM data to healthcare professionals was advantageous, although some commented on the possible overloading of information for the healthcare team:

I think, you know, it would, well, you, there could be benefits to the doctors having that information (P2)
I think it may be useful for them if they, you know, they already have a welter of stuff to take in. If it could be made concise for them, I think it would be very helpful, yes (P1)

One benefit seemed to be that healthcare professionals would be able to see the results of any interventions through the data, but that they would need to be informed of the activity levels in real-time:

It might tell them how well one's feeling or how one has responded to their operation, their drugs, whatever it is that they've given you (P1) I think they would need to know the results as they were wearing it (P2)

It was thought that having the activity information could allow the healthcare professionals to alter patient management plans and treatment decisions:

I think if the [Clinical team] found that a person was, was very weak in, in movements and everything, I think they, they would have to be, in no doubt, they would take a different action (P3)
Medical professionals... I think it's to their advantage... It took the medical profession to discover what advantage it is and also recovery rates and things like that I'm sure is affected (P6)

Others, however, were less convinced, and maintained that the activity data would only be a small part of information used to make patient management and treatment decisions:

Well, I think there's a lot more taken into consideration. Like, you know, from a clinical point of view... So I don't think they would use that as the main thing to judge you on, no. It might be useful for doctors, yes, but whether they, you know, whether sort of define at the end of the day what decision they make, I don't know really (P5)

The WAM brought up patients' ideas and experiences surrounding peri-operative fitness, and what they perceived they ought to be doing activity wise post-operatively, and how this may or may not affect their recovery. One patient who had been told not to lift things post-operatively, was worried that all other activity may lead to lifting and therefore thinks she did less post-operative activity than she otherwise might have:

The operation that I had was,... I'm not meant to lift anything, so that makes you instantly think, ah, mustn't do too much, mustn't be too energetic because that tends to bring in perhaps, other activities that would incur lifting (P1)

An idea emerged to use the WAM as an educational tool, to give over information to patients about activity in the peri-operative period:

I think it's essential that time is spent explaining to people. I think it's lack of information. This is the problem, you know, is that not enough information is given to some people (P3)

And that each patient could have an individualised activity plan and regime:

What works for individuals?.. I would say, you know, how many steps would you like me to do to make sure I get better? (P3)

But that it was necessary to really tailor any recommendations that would be made to ensure each patient's operation type and pre-operative fitness was taken into account:

But then at the end of the day, you know, you can't say to somebody you've got to do that much, or you've got to do that much. You can only do what you're capable of, can't you (P5)
You may think, oooh good, I've gone up and then you might think, well I'll do another burst, and you find you just can't (P1)

Interestingly, one patient recognised the importance of being physically fit prior to an operation in order to improve the recovery process post-operatively:

Is it because I have a personal trainer, and I train two/three times a week? So that's represented there. You know, my mental state was very good because I felt very, very strong because I felt very fit. And the reason I felt fit is this going back because I, I train regularly. I do lots of walking. So that reflects back on that. So, in a way, the recovery of surgery is all to do how fit you are before you go in (P3)

Figure 7.6. and Table 7.1. show a summary of words and ideas expressed by the patients within their interviews.



Figure 7.6. Word cloud based on patient feedback transcripts

Table 7.1. Top 20 most frequent words used within patient feedback interviews

Think	Operate	See	Doing
Know	Go	Make	Use
Day	Well	Wear	Understand
Active	Look	Right	Average
More	Data	Way	Show

7.3.3. Main results - Clinician study

General knowledge of wearable sensors

Prior to this trial all healthcare professionals had been aware of wearable technology, mainly within the fitness domain, but one healthcare professional knew about the use of activity tracking in the healthcare setting within a different research environment from our own. The most commonly known WAMs were the *Fitbit* and the *Apple watch* and four of the healthcare professionals had used the physical trackers/step counters on the *Apple/Samsung* mobile phone apps.

Three themes emerged from the data analysis: value, MDT relationships and functionality. These themes are described below together with verbatim comments, which use the notation HP to indicate healthcare professional, and a number to indicated which specific healthcare professional.

Value

All healthcare professionals viewed wearable technology in a positive light with many important benefits identified for use within their clinical practice. The main uses were thought to be as objective evidence, to monitor patients remotely, giving motivation and encouragement to patients, goal setting and as an ERAS tool (Figure 7.7.).

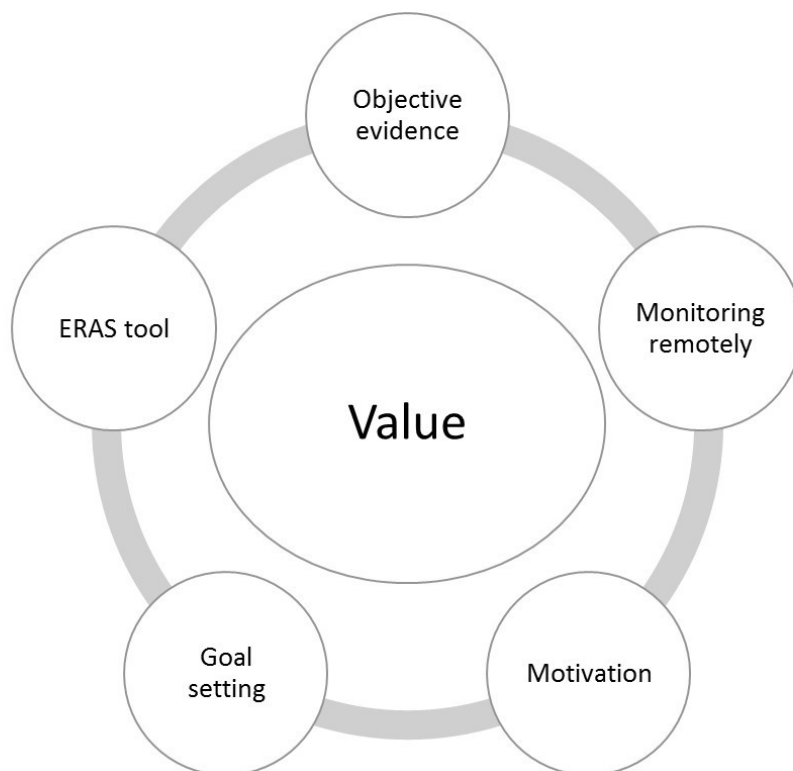


Figure 7.7. Healthcare professionals' views at to the value of WAMs

All the healthcare professionals identified WAMs as devices that provide an objective measurement of physical activity levels and patient wellbeing:

*It gives hard physical evidence and it's not just us speculating or thinking. It's judgement based upon facts (HP3)
I think they're valuable because they can actually give you a good overview of your actual movement. So, it's all numerical than you judging or thinking that you've done more or less. It's, kind of, a bit more accurate (HP3)*

This was seen as valuable for current patients to be able to know how much activity they performed:

Um, I think it definitely has potential to be... beneficial. And purely because it will provide hard data of, um, the actual level of movement that the patient has (HP3)

It would also provide evidence for prospective patients, allowing better care for them and individualised management plans:

That data I think can help us to plan for future patients (HP2)

Clinicians identified the benefit of monitoring patients remotely, when not on hospital grounds:

The main benefit would actually probably be out of hospital monitoring. So, if we are going to the point where we're discharging patients and they are... going home very early. So, for example on passage of first flatus then, um, the benefit would obviously be if we had the infrastructure... being able to monitor them remotely (HP5)

This could give the patients the extra confidence they need on discharge:

Enhanced recovery after surgery... one aim of that, obviously, is to get patients home early. Now they get discharged when they're ready, not when they're not ready. So, I think wearables would just help give the patient and the clinicians, to an extent, reassurance that they are continuing to do well at home (HP4)

A major benefit was the ability of the WAMs to both motivate and encourage patients to perform physical activity post-operatively:

I think, with saying to them, you know, this is our way of getting you home as quick as possible, and by, you know, following these steps, then I think it's really beneficial because patients will be motivated to actually do something. And instead of just sitting in a chair at the end of their bed for the whole day, they can actually get up and do something (HP1)

One interesting proposal that was identified was to set goals for patients using the WAM in order to reinforce their physical activity:

You know, they say do 10,000 steps a day. It's actually getting you to do the 10,000 steps because you can see it (HP1)

I've got to do this and I need 1000 steps today or a 100 steps then they've got something to aim for rather than just, oh, I've got to do another lap around the ward. At least they've got a goal (HP1)

Yeah, because you could say oh look I know you had a bad day or you weren't feeling so well yesterday you did this many steps why don't you try and do that today. And then maybe the next day, you know, setting goals with them (HP2)

And it'll help them to, kind of, gauge how much more movement or, you know, give them, give them an avenue to create goal around their movement (HP3)

However, one disadvantage is that patients may only try to hit their target, and not push themselves

further, if they are capable, limiting the potential for increased activity:

I've heard problems with people thinking that, um, if they do their limit of 6,000 steps a day they think that's okay. And I don't think it encourages people necessarily to do more steps. So, I think that's one of the... the bad side, the down side of them (HP2)

Some of the healthcare professionals identified the WAM technology as a tool to help improve recovery after surgery, an ERAS tool:

And because the patient can see what they're doing and they feel motivated and not to actually carry on doing it, then they would actually reduce that length of stay because they wouldn't have chest infection, so it wouldn't have, you know, formability after surgery. They wouldn't be sitting there going oh, I'm not sure what happens next. (HP1)
If we can prove that the more level of activity that they have, then the faster they'll recover (HP3)

Evaluating recovery after surgical intervention

I think the sensor will... obviously it shows you how they were before and the impact of surgery (HP2)
If you optimise fitness, hopefully the body will recover quicker, and that's what we know. But I think this will actually give us something a bit more quantifiable (HP3)

And identifying those who comply with ERAS:

It's useful to know because it'll give me an idea if they're actually complying to the ERP [ERAS] protocol as well in that sense (HP3)

Multi-disciplinary relationships

The majority of the healthcare professionals thought that the WAM could change the way they delivered healthcare in a beneficial way, with no reservations that it could interfere with the healthcare professional-patient relationship. A focus on the use of resources and how the WAM could help improve a low resourced system was discussed. Most importantly it was felt that the WAM could make patients feel like part of the team, allowing better communication and empowering the patients, who could be treated in a more individualised manner (Figure 7.8).

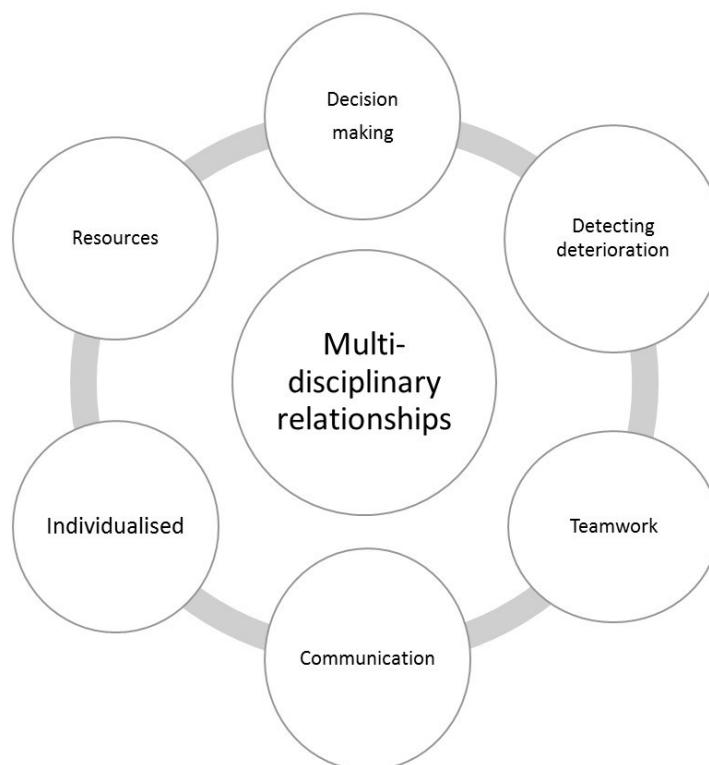


Figure 7.8. Healthcare professionals' views on WAMs and multi-disciplinary relationships

Some healthcare professionals didn't think there would be much change in management or decision making with use of the WAM:

I don't think it will change it because we do, like, our patients, you know, keep themselves busy, in fact, before they have surgery (HP3)

Others considered there was a role for the WAM in supporting discharge planning:

I don't think it'll, it will make us get them home that much faster because if they're not ready to go, they can't go... It will give us a greater degree of confidence to send somebody home who, where we're thinking well, they might be ready, but it depends on how confident they are. And if it can give the patient confidence that they'll, they haven't severed their links with the hospital. I think that's a big issue with enhanced recovery discharges (HP4)

I think if I had a technology that I could rely on to give me reliable results and I had a mechanism by which I could be warned early then, yeah, it would certainly make me more likely to discharge patients who I thought there was... it was a 50/50 thing and they may be okay. It may even be useful in an emergency setting as well (HP5)

An important aspect of the WAM as to detect those patients that were deteriorating, either on the ward or back at home:

It's a huge opportunity for us, passively monitoring our patients, or rather, we are monitoring them very actively without them having to do anything, i.e., they're passive in that. But, um, I think it offers huge scope for detecting a clinical deterioration early whilst they're in hospital, but also facilitating early discharge and then monitoring them remotely, picking up problems and then bringing them back in as required. I think there may be a benefit to actually having continuous monitoring of all of our patients to understand how the conditions that lead to a clinical deterioration, whether that's an anastomotic leak or a hospital acquired pneumonia, come about (HP4)

The technology itself was viewed as a way to help improve the healthcare system and allow increased efficiency:

I think, you know, a big opportunity would be if it's possible to link that into sonar. You can make some real efficiency savings and save the nurses' time, you know, having pulse ox and heart rate data, at least, um, feed into their groups, save them a huge amount of work (HP4)

Conversely, some healthcare professionals recognised the potential for the WAM and its technology to use up more resources in an already resource poor area or potentially even become a clinical risk if the monitored data isn't fed through to the correct healthcare professionals in a timely manner:

It may in some ways generate actually more need for resource to look after them. Say if we had an ERS [ERAS] nurse, as we will do soon in the trust, um, it might generate a whole lot more work for her or him through just taking calls about things that are fine, and reassuring people that they are fine (HP4)

Especially given we're working in a healthcare environment where we are stretched.... again the key is being able... there's no point recording the data if you are not going to use it or not going to be... it's not going to warn you early or you don't have the system to deal with it because then it's just a clinical risk (HP5)

Using the WAM was seen as a way to incorporate the patient into the healthcare team and empower them to play a bigger role in their own health care:

It gives some of the power back to the patient. If a patient knows what's going on with him, then they can report that to you and they become a, they become a much more active partner in their recovery and... And also in any reintervention (HP4)

If the patients are more aware that we're expecting them to be as active as possible, and the fact that we are actually monitoring how active they have been, it gives them some sort of psychological kick (HP1)

I think that they actually feel quite empowered to do something. So, you're going well, actually, I've got my monitor, I've seen that my heart rate was a bit high, or I've done this many steps, I'm going to do more. (HP1)

And maybe if they used it before their operation and afterwards they could say, oh, look I'm getting back to my baseline now so it's empowerment and encouragement for them (HP2)

However, it was stressed that it was important to treat each patient as an individual:

So, maybe you could look at it a different way instead of setting the goal you can just go, okay, we're going to see how you do today. And see what they did and then the next day go, ah, should we try and beat this by a little bit more rather than having a set number they could just have their own goals. So, then they may not feel so much pressure to actually achieve what everybody else has to achieve because obviously everybody responds to surgery differently. Their age is different; their comorbidity is different so it would be hard actually thinking about it to set an actual goal for everybody that's generic (HP2)

I mean, I think it's hard to, kind of, put all patients in the same box. I think it would have to be a case by case (HP3)

The issue of psychological distress to patients was discussed, particularly if the patient felt that they needed to push themselves more than they should, which could possibly reduce, rather than build their confidence:

Just psychologically it might make some patients feel that they have to push themselves and move more than they would've done normally. I think that's the only thing, I think, psychologically (HP3)

If they were particularly a bit like me a competitive person and had to reach that goal each day but they were unwell and couldn't do it they may feel a little bit downhearted about it. And it may, um, may reduce their confidence because they haven't done what they were supposed to do (HP2)

Another consideration was to those patients that could become obsessive or anxious due to being monitored and seeing their data continuously:

I think you have to be careful though because people could become obsessed with it and could be, like, oh my God, my heart rate is 90 today I need to go and see my GP whereas they've just walked up the stairs. So, I think we have to be careful of how far we go (HP2)

I think it has the potential to induce anxiety amongst patients because, um, when you're aware of what your heart rate is all the time, if it's fed back to you as the patient, stuff might make you question every day whether you are okay. So, there'd be... I think one would need to manage that anxiety somehow (HP4)

Some people will be interested inevitably, err, some people will obsess about it, some people won't care. I think it, you know, it's like all there'll be a variety of, err, opinions on it (HP5)

The WAM was seen as a good way to start conversations about physical activity, goal setting and

enhanced recovery:

So, if we give them something, another aspect to talk about, because they can say well, actually, you know, that really helped me, in fact I probably wouldn't have been this active if I was not wearing the monitor. So, you know, I think it's probably quite a nice conversation they could be having too so that, you know, it incorporates in part recovery, but it also makes it a broader spectrum rather than just oh yeah, you're on enhanced recovery (HP1)

I think it would make a good conversational piece to, you know, kind of, encourage patients to keep active and to improve their level of fitness. Um, yes, like... (HP3)

The communication that started in hospital could be continued on discharge, giving a channel that is open when needed back to the healthcare professionals:

They feel like they've, they are disconnected from the hospital once they home. And if you can say, look, you have an electronic umbilical cord to us... Whereas we're saying... We're not saying goodbye. We're just saying see you later when you need us (HP4)

The healthcare professionals thought it was beneficial for all patients to have these monitors, but also identified some sub groups that could have a greater advantage for, and other patient groups that could struggle to understand or benefit:

I think they should all be offered the monitor... I suppose certain age groups might say well, I'm a bit confused with what, what it is (HP1)

I don't know, I think people who are having, small minor day surgeries probably not because they're going to go home. But anybody who's in... yeah, over 24 hours, 48 hours then, yeah, I think it would be useful (HP2)

If funding is an issue then yes, one might focus on the more high-risk patients.. But I think the real value lies, in the end, looking at everyone. (HP4)

I think if you have it you would roll it out for everyone. There may be an issue about older people, you know, and their ability to use technology but I think from the perspective of the clinician I think if you have this facility and it's resourced appropriately then you'd use it for everyone (HP5)

One concern was the reliability of the data, with a worry that it may not be accurate, or may have fluctuations that alter how a patient would be assessed:

Err, if it's unreliable, if it causes... if it has occasional fluctuations in the recordings. If it gives you aggregate results then it could increase the workload potentially of what would be hard to fund, err, support for patients being remotely monitored. So, I think it would... that's my main concern is the reliability (HP5)

Functionality

The healthcare professionals identified practical issues that were associated with the WAM in both positive and negative regards. They also discussed how the data itself could be viewed along with what they would want from any extra functions that could be added to the WAM, with nursing observations being the most popular (Figure 7.9).

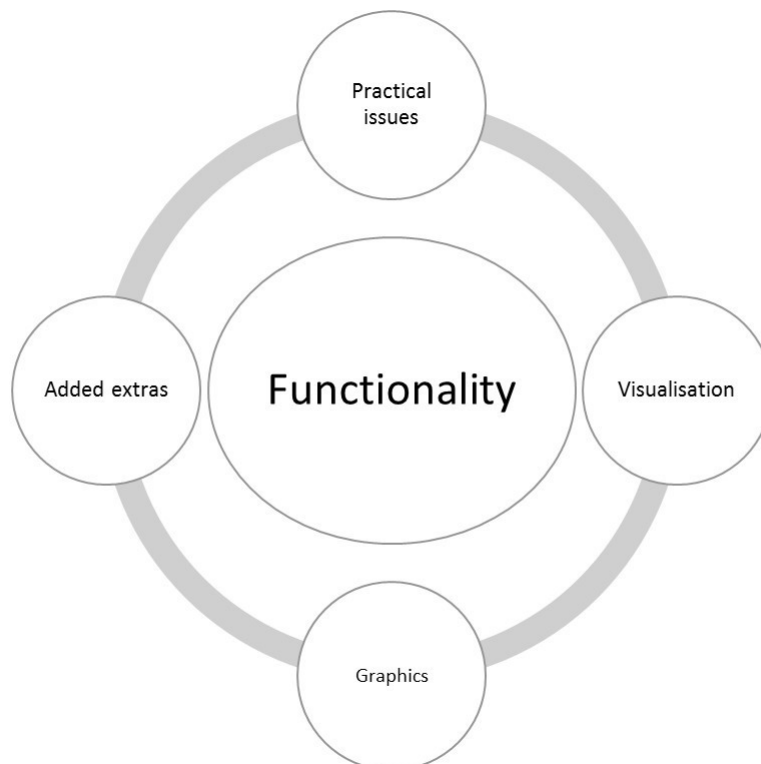


Figure 7.9. Healthcare professionals' views on the functionality of the WAMs

In general, the WAMs were thought to be satisfactory in terms of appearance, although there were issues with the size /bulkiness and problems with the strap:

No, because they were quite slick, they fitted quite well, I don't recall any patients saying anything about them that troubled them. (HP2)

I think the fact that the monitor can seem quite big.... And I know on a monitor that we have there were some issues with the back strap not having the second loop...To hold the back of the longer part of the strap, so it was actually getting in people's way. And they couldn't, sort of, fold it under, so it wasn't very manipulative, so it was quite rigid....if they were slightly smaller...Then, you know, patients would probably think they were, you know, they would forget about them (HP1)

But from a physical point of view, no, apart from the inconvenience of wearing it for a long period of time, which might be uncomfortable (HP3)

An important issue was raised about the need to take off the WAM prior to swimming or going in the bath, and for the operation itself. This meant that some patients may not have worn the WAM continually:

Just reminding them after surgery to have them on. Because sometimes you go to the ward and they haven't got them on or it's, the anaesthetist put it in a bag, or something random like that (HP1)

I don't think the fact that they couldn't have a bath with them made such a big difference because they could leave it on the side, um I think the only problem patients did say was that when they came in they had the band taken off them when they had their operation. And when they got up they didn't know where the band was (HP2)

Another important practical aspect was the battery life of the WAM and how the data from the WAM was sent to other devices/monitors:

The battery life of a sensor, that then either WiFi or Bluetooth get straight onto sonar. That's, I guess, the difficulty of the batteries getting better and connectivity's getting better (HP4)

The ability to visualise the WAM data in real-time was thought to be important and beneficial for the patients:

And you can see it, because actually it's on the screen on your monitor rather than it's just a blank screen and they're just, like, well, do I, do I get any benefit from this, I can't see what I'm doing with this. So, is it actually doing anything? (HP1)

I suppose they haven't been able to see how many steps they're doing or see any results while they've been wearing the sensor. So, I think they've just been like, oh, I'm wearing a bracelet I'm not really... I don't know maybe they have thought more about it but I think if they could see their activity and maybe, I don't know, their heart rate, their pulse, their, um, steps whatever it would... it would be more of a benefit to them (HP2)

Using a monitoring device similar to that for regular observation checks, that could also show trends was thought to be beneficial to healthcare professionals:

So it's probably beneficial if it was on for the clinician type. Um, to be on sonar, a bit like, you know, when you're looking at a trend in say, like... I don't know, a tumour marking, eg... You can just click on it and then it will bring in the trend over the last however long (HP1)

The main extra functions that healthcare professionals wanted within the WAM were the normal nurse read observations:

I don't know. How much information do you actually want? Do you want things like, um, ECG type of reading? You know, you could do that along with the heart rate, so it actually shows. It... When they're doing something

(HP1)

So, steps is good.... having things like maybe if, um, perhaps their respiration or, you know, if somehow it was able to measure if they were taking in deep breaths or not (HP3)

Blood pressure, heart rate, respiratory rate and saturations (HP4)

Some of the healthcare professionals thought it would be useful to have an interface within the WAM to input other data manually, e.g. other activity that has been done:

Maybe cycle options so they can plumb it in that they've done a cycle or, you know. I know they won't be doing that initially post-op but if they wanted to continue to use it (HP3)

One idea was to have a prompt or indication that alerts the patient, and/or the clinicians, if activity levels were too low, or a message could be sent to encourage more movement:

Well, if their activity was particularly low, it would be nice if it could or people indicate to them, or at least some positive reinforcement as well, you know. And, kind of, let them know that (HP3)

But if there is something that's modifiable that you can have an interface that, um, tries to make them change whatever parameter it is then I think that could potentially be very useful (HP5)

A further concern was the reliability of the data, with a worry that it may not be accurate, or may have fluctuations that alter how a patient would be assessed:

Err, if it's unreliable, if it causes... if it has occasional fluctuations in the recordings. If it gives you aggregate results then it could increase the workload potentially of what would be hard to fund, err, support for patients being remotely monitored. So, I think it would... that's my main concern is the reliability (HP5)

There were different opinions on the way the data was presented, and the best form to present it to the patients and the healthcare professionals. Some liked numerical data more than the graphical representation:

Yeah, I... find this more helpful than the pie charts to actually see a number rather than just like a wedge cos it actually gives you the amount of data rather than just a size of a wedge if that makes sense (HP2)

I prefer looking at the actual numbers as opposed to the pie chart... for myself I would pick the actual physical numbers (HP3)

Whereas other thought the bar graphs were easier to read and understand:

I prefer the bar graphs (HP1)

I just think it's easier to see, you can see the levels going up so you can easily see that there's a trend going up with more activity. Whereas the other ones it was just a segment and it wasn't as... it wasn't as clear (HP2)

I prefer the bar chart in comparison to the pie chart, yes, because it's easier to, kind of, track it. You can draw lines

across it... It just makes more sense to me, I mean, you can still read it from the pie chart as well, but I think it could... This could be more patient friendly as well (HP3)

Most were of the opinion that the patients would prefer something more colourful and graphical rather than numerical:

Like lots of blue or a little bit of orange maybe that (HP2) The patient I would look at the bar graph (HP3) For the patients it's probably quite nice if they got something colourful? Because if they're just seeing something in black and white they don't always... Say, well, actually, that, that's really good, but if they've got colour, they'll probably take to it a bit more easily. (HP1)

Yes, I think that's probably the easiest to interpret, is the bar graph. for patients, easy for clinicians (HP4) And if it was colour coded green, red whatever I think that would probably assist more and just as be able to glance at it and work out what's going on (HP5)

Although one clinician thought that a simple percentage off baseline numerical data could be more helpful to the patients:

They will probably be more interested in this kind of data. So, I think the last one if you're giving them percentage relatively simple things to assess compared to, err, the baseline assuming they're interested which there will be some who are, some who aren't. Then I think this is probably what they'd be interested in I would guess (HP5)

Figure 7.10. and Table 7.2. show a summary of words and ideas expressed by the healthcare professionals during the interviews.

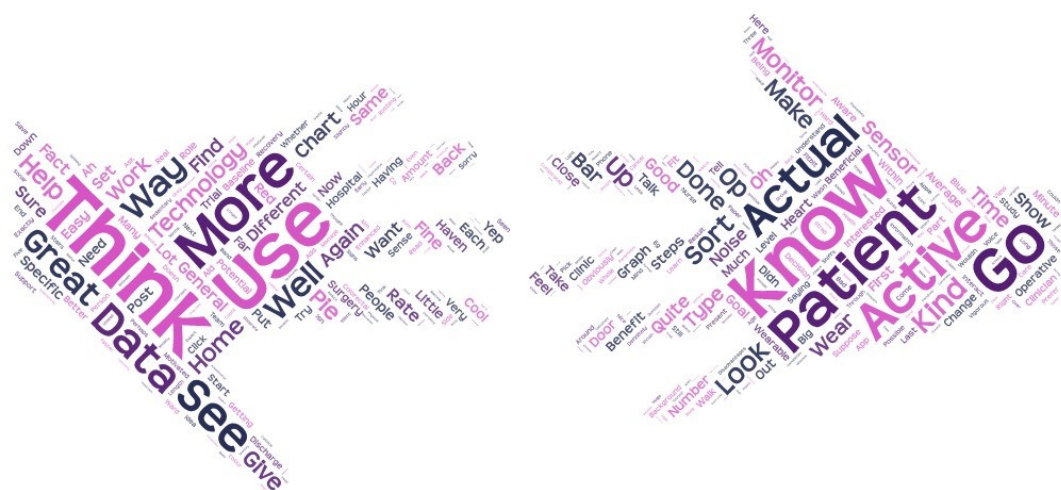


Figure 7.10. World cloud based on clinician feedback transcripts

Table 7.2. Top 20 most frequent words used within clinician feedback interviews

Think	More	Technology	Sort
Patient	Use	Way	Home
Know	Go	Well	Different
Active	Data	Kind	Great
Actual	See	Look	Monitor

7.4. Discussion

This study investigated patient and healthcare professional ideas, understanding and preferences in relation to wearable technology within the healthcare setting. Overall patients and healthcare professionals had insight into wearable technology, with opinions about the WAMs and their preferences for wearable technology in the peri-operative period. In general, the WAMs were acceptable and seen as valuable within the clinical setting, and as a useful adjunct for the ERAS paradigm. The majority of patients and healthcare professionals had some awareness of wearable technology prior to this study, with the most frequently identified being the *Fitbit* and the *Apple watch* as fitness products, and the most commonly used technology being applications on smartphones to track daily steps. Both the patients and healthcare professionals had a good understanding of the WAM technology itself, and insight into how it could be used in a positive manner within a healthcare setting as well as the potential to increase the focus of the patient as an integral team member, enabling their successful recovery.

The key overarching themes that came out from this study were sensor design and interface, objective data and information, and clinical impact and implementation. Table 7.3. shows the themes and subthemes that were extracted from interviews with the patients and the healthcare professionals. There was some overlap in themes including; decision making, teamwork, graphics and individualisation.

Table 7.3. Summary of themes and subthemes that were extracted from patient and healthcare professional feedback interviews. Subthemes highlighted in grey show concordance between patient and healthcare professionals

Patient		Healthcare Professional	
<i>Themes</i>	<i>Subthemes</i>	<i>Themes</i>	<i>Subthemes</i>
Practicality	Wearability	Value	ERAS tool
	Interaction with other devices		Objective evidence
	Comfort		Monitoring remotely
	Attractiveness		Motivation
	Discretion		Goal setting
Value	Utility of data	Multi-disciplinary relationships	Decision making
	Generalisability and accuracy		Detecting deterioration
	Reinforcement and incentive		Teamwork
Functionality	Data feedback		Communication
	Interpretation of data		Individualised
	Graphics		Resources
	Data privacy		Practical issues
Holistic tool	Peri-operative fitness	Functionality	Visualisation
	Teamwork		Graphics
	Decision making		Added extras
	Emotional impact		
	Individualised		
	Educational tool		

Certain design requirements were identified as necessary for a successful WAM by both the patients and healthcare professionals. Comfort was of the highest importance in addition to the sensor being small and lightweight. This is similar to the findings by Ozanne et al²⁴³ who looked at wearables in patients with epilepsy and Parkinson's disease and found that participants thought that a simplified and unobtrusive design was most important for wearable sensors.

One of the major design issues that was flagged up by this study was the WAM strap. Although the strap is lightweight (16g) and made from silicone material, some of the patients did develop an

irritation after wearing it. One study²⁴⁴ used the AX3 WAM and evaluated the acceptability of WAM use in patients with Parkinson's disease. Patients within that study also found the strap uncomfortable especially after wearing for long periods of time. Another practical issue that was highlighted in our study was that the WAM strap only had one retainer loop, meaning it became unwieldy and got caught on clothing, however, this could be easily remedied by adding a second loop onto the strap.

The WAM interface and its interaction with other data, healthcare systems and day to day clinical care was highlighted as further important aspects of the WAM design. Often patients had to take the device off, or move from one hand to another, when intravenous cannulas were inserted, and during the operation itself. This caused some inconvenience and became a little intrusive, furthermore the healthcare professionals highlighted that some patients forgot to put the WAM on after the operation, needing a reminder to wear it again. A study monitoring pregnant women during their pregnancy and one month after birth²⁴⁵ found that the women only occasionally wore the WAM, or not at all, after giving birth. This could be due to a shift in their priorities and thought processes, as they have a new born baby to look after and wearing a WAM was low on their priority list. Similarly, post-operative patients may have had other priorities or thought on their mind and remembering to wear the WAM was not high on their list, particularly as they could not necessarily see the benefits of it at the time. This could be because the WAM that was used in the study had no interface or interaction with the patient, this led to a further finding from the study, that it was considered absolutely vital that the WAM physical activity data could be viewed in real-time by both the patient and healthcare professionals.

There were differences in opinion as to whether numerical data, pie charts or bar graphs were the best way to portray the data, and which were best for the patients and the healthcare professionals. People in general assimilate and understand numbers and data in different ways and it would

therefore be necessary to show the physical activity data on the WAM in a number of ways, allowing patient choice. It is also important for the healthcare professional to be able to quickly assimilate the information and see any trends in order to make clinical decisions as necessary.

There were a number of ideas discussed about increasing the WAMs function over and above just recording physical activity. There were suggestions to record the regular observations that nursing and allied healthcare professionals perform, allowing an integrated system. It was thought that this could alleviate the lack of resources, saving time and a large amount of work, so that the nursing staff are able to use the extra time to help patients needing extra care. It may also provide observations with greater frequency. A further function that was deemed useful was the ability to input data into the WAM, for example other exercise performed like swimming, when the WAM isn't worn. Other ideas included a function that can be used to show the trends over the previous days or weeks. It was, however, postulated that there could be too much information on the WAM, and it may be necessary to filter out which functions the patient can view, and which the clinician can view. The ability for the WAM to prompt a patient to perform activity and to positively reinforce any activity performed was seen as a major benefit to future iterations of WAMs within the clinical environment. These functions are already in place on the commercial models e.g. *Fitbit* and *Apple watch* and could be added in to the design of research WAMs in the future. One study²⁵⁶ looked at female college students who had high levels of alcohol consumption. They wore a WAM that sent alerts to the participant when the WAM sensed they were heading into alcohol drinking behaviours due to specific stressors. The study found that the alerts provoked an increased awareness of their thoughts, feelings and behaviours in positive ways.

The benefit of obtaining information and data from the WAM was identified by both the patients and the healthcare professionals. Having objective proof of patients' current status and how their activity changes pre-operatively to post-operatively rather than subjective feelings from the patient

or estimates from other healthcare professionals was thought to be highly valuable to the healthcare professionals. The patients identified the added benefit of knowing what activity they had done each day, allowing them to keep track of their progress. Although there were no comparisons in the literature for colorectal or general surgical patients with WAMs, Papi et al²⁴⁷ investigated using a WAM in a patient population with osteoarthritis. They too found that patients saw a benefit of using the WAM to monitor their progress within the context of a chronic disease affecting mobility.

More specifically, the WAM and the data that it can relay, was seen as a tool to encourage and motivate patients to improve and increase the amount of physical activity they performed in the post-operative period. It incentivised the patients and gave them positive reinforcement to continue to be more active each day. It was seen more specifically by the patients as a tool that the healthcare professionals could use in order to encourage and motivate patients on the wards, with the idea of goal setting. Each day a specific activity goal could be set which would push the patients to increase their daily activity. Similar goal setting has been used in other studies^{59, 246} and been found to be useful to help patients not only learn to set their own goals but also to help them meet these aims. However, patients and healthcare professionals also identified possible disadvantages to this, some patients should not be performing certain activities post-operatively, e.g. lifting heavy weights, and other patients may become anxious or disappointed if they cannot reach their set target.

It is important to recognise that though the technology used in WAMs is similar to those in the fitness arena, our aim is more complex, to identify and improve recovery, as well as recognising complications, after surgery. It is not used just as a simple step counter or weight-loss tool and the monitoring of activity behaviours pre-operatively are the key to this. Instead the aim is to define levels and patterns of behaviour pre and post-operatively so that lifestyle changes can be

implemented if necessary, as well ensuring that the correct data is available to inform whether the patients have done too much activity, as well as too little. There is still some way to go in refining the use of the peri-operative activity data which will happen with time, further studies and more importantly using the feedback gained from this study.

The clinical impact of the WAM data was thought, by the patients, to be beneficial for inpatient management decisions, giving insight into patient recovery and leading to an alteration in management as necessary. However, the healthcare professionals themselves viewed it in a slightly different way and were of the opinion that the WAM could be more beneficial as a tool to help support discharge planning, monitoring patient remotely once they had been discharged home and aiding the detection of deteriorating patients in their home environment. This is similar to the findings of Papi et al²⁴⁹ who found that clinicians viewed a WAM as an adjunct that provided objective measures rather than the subjective account of patients, but that it would not change a diagnosis or change a management plan, rather evaluating the effectiveness of a current treatment or intervention.

Both patients and healthcare professionals thought using the WAM could help to individualise patient care, as well as empower patients to play a bigger role within the healthcare team leading to the patient being an active participant in their own recovery. The healthcare professionals expanded this further, linking it to enhanced recovery and how the WAM could be used as a tool within the ERAS paradigm. The WAM was seen as a tool that could provide a role in initial education and guidance for patient prior to surgery, facilitating conversations about enhanced recovery and the need to be active both prior to the surgery and post-operatively. As discussed previously, it allows objective evidence to be provided to the patient and clinicians as to the state of recovery and physical activity on the ward post-operatively. It was also identified that discharging patient within an enhanced recovery framework, often much earlier than those not on

the pathway, can lead to anxiety for the patients. The WAM has been recognised here as a tool to enable continued links with the hospital and healthcare team, once discharged, as the communication and monitoring would be ongoing, enabling deteriorations to be detected and facilitating an open link back to the hospital.

To date there has been minimal research analysing qualitative data from patients and healthcare professionals about wearable technology, especially within a general surgical or colorectal clinical setting and ERAS. It is, however, an important consideration for the future to ascertain feedback and patient participation within research studies, to ensure that the WAM is utilised correctly and that any issues and problems can be addressed and resolved prior to any further studies.

7.4.1. Limitations of study

There are limitations to this study, including the recruitment of patients only undergoing one specific type of surgery, from a single site. A more representative sample from patients undergoing surgery within different specialties at multiple centres would be helpful to offer insights into patients who may have different experiences of wearable technologies. A further limitation is that we only recruited consultant surgeons and colorectal nurse specialists for the healthcare professional feedback, this was because they were part of the patient journey from pre-op to post-op and were aware of the use of the WAM throughout this time. However, it would be helpful to have feedback from the ward nursing staff and physiotherapists, as they care for the patients on the ward and are integral members of the team to ensure safe discharge. Although we were able to show patients and healthcare professionals their activity data, it was not in real-time and so their views were based on seeing the data after their recovery, back in the outpatient clinic. It would be worthwhile setting up a further study where the activity data can be seen by the patients, and clinicians, in real-time and exploring their views following this. Specifically, the healthcare professionals did not see as much benefit in monitoring inpatients as much as on discharge.

However, given that they were not able to see the real-time activity data, their views may have been skewed. The data presented to them was from a patient who had a relatively straight forward recovery trajectory, who started off with low levels of activity post-operatively which then gradually increased to discharge and at home. Should clinicians have been presented with a sudden deterioration in activity, with or without any other clinical signs, nursing observations or bloods tests, their response may have been different and this needs to be explored further in complementary studies. The questionnaire for the study was based on the study by Papi et al²⁴⁷, however, ideally a focus group would have taken place to help ensure there was an appropriate topic guide, with some face to face validation of the questions and topics.

7.4.2. Potential clinical impact

In spite of these limitations this study is encouraging and shows that WAMs are seen as a beneficial adjunct within the peri-operative period by both patients and healthcare professionals. WAMs are seen as a tool to help implement and improve the ERAS principles, including peri-operative activity, thereby improving patient outcomes. Future studies could look into which specific elements of design and interface are more acceptable to the end users, especially the materials used and the data display. It is important to further investigate how surgeons and the healthcare team envisage implementing the WAM and how it can best be used to improve ERAS, whether this is on the ward/hospital setting or as a tool for early discharge or home follow-up. A further area that needs to be explored is the economic impact of WAMs, this is important as there are costs involved with the technology, but also potential cost and efficiency savings that can be made from their use. This is especially true if patients are discharged earlier to be monitored at home (Table 7.4.).

Overall our findings highlight the importance of patient participation and inclusion in clinical research. This is crucial as implementing any new technology into the clinical setting needs both the clinicians' and patients' support, and with these the potential for wearables to have a major

impact peri-operatively is greatly improved.

Table 7.4. Recommendations for future ideal WAM use

Recommendations	
<i>Design</i>	
Light	Non-allergic materials
Unobtrusive	Extra strap hoops
Waterproof materials	Display interface on sensor
<i>Function</i>	
Multiple data types available	Combined with observations
Real-time feedback	Ability to input own data
Personalised goals	
<i>Indications for clinical use</i>	
<i>Pre-operative</i>	Pre-op Baseline Pre-op conditioning/prehabilitation
<i>Inpatient</i>	Monitoring PA for ERAS compliance Monitoring PA to detect deterioration Monitoring PA for accelerated discharge
<i>Post-operative at home</i>	Home monitoring to detect deterioration Information and communication tool and patient support
<i>Other</i>	Money and efficiency savings Goal setting Larger population studies

Chapter 8

Conclusions and further work

The main body of work looked to utilise a wearable activity monitor (WAM) in order to measure physical activity as a marker of peri-operative wellbeing and recovery after surgery within an enhanced recovery framework. This took the form of clinical studies with significant patient and healthcare staff involvement. In total 65 participants (healthy cohort, patients and healthcare professionals) were recruited into the study.

Continuous, objective activity assessment using a wearable activity monitor is feasible in a normal healthy cohort, allowing refinement of the technology and specific data analysis techniques prior to use of the WAM in a patient cohort.

The WAM was trialled in a healthy normal cohort, in their own home environment. Data was collected and analysed and showed that it was feasible to monitor continuous physical activity in a healthy cohort in a free-living environment. Activity data were processed both at an individual level and as a group, this allowed analysis of participants within a cohort as well as identifying individual participant's activities and daily routines. The data set from this cohort of patients were then used as a baseline and comparator against the surgical patient cohort.

Wearable activity monitors can feasibly and objectively detect physical activity in the peri-operative period.

The feasibility of using the WAM in patients within the peri-operative period to objectively monitor, quantify and evaluate their physical activity was shown. The on-going monitoring and evaluation of physical activity data gave insight into patients' baseline function as well as their progression and recovery following their surgical procedure. More detailed analysis showed the WAM's ability to reflect the daily activities on the ward which has implications for ERAS and

revising the traditional post-operative recovery paradigm. To our knowledge, this was one of the first studies to monitor patients undergoing colorectal surgery, continuously and unobtrusively, with a WAM throughout the peri-operative period, including once home after discharge.

Physical activity is an objective surrogate outcome measure of recovery after general surgery.

The relationship between physical activity, monitored by the WAM, and post-operative outcomes was investigated. There was a statistically significant correlation between post-operative physical activity and length of hospital stay, as well as a significant correlation between pre-operative activity and length of hospital stay. Being active for ten minutes or more on the first post-operative day doubled the probability of LOS being less than seven days. This could indicate that both pre-operative and post-operative activity could predict length of hospital stay. A correlation was also found between physical activity and post-operative complication, levels of post-operative C-reactive protein and quality of life (as measured by the SF-36).

These findings allow the possibility that a prediction tool can be created with the ability to predict post-operative outcomes, including length of hospital stay, from peri-operative activity data. This could facilitate a more tailored enhanced recovery programme for each individual patient.

A systematic review was also undertaken to determine if there were any other studies that investigated the relationship between objectively measured physical activity in the in-patients surgical setting and hospital length of stay. It is the first systematic review that has explored this subject, and six studies were identified. The amount of physical activity performed whilst an inpatient on the ward following surgery negatively correlated with length of hospital stay. However, a meta-analysis could not be performed due to the heterogeneity of WAMs used and the outcomes reported.

Peri-operative physical activity monitoring is perceived as acceptable and beneficial by both patients and clinicians within the healthcare and ERAS setting.

A qualitative study was undertaken with semi-structured feedback interviews used to help understand how WAMs and wearable technology were viewed by patients and healthcare professionals. Overall patients and healthcare professionals had insight into wearable technology in the healthcare setting and viewed it as both acceptable and beneficial, seeing a WAM as a useful adjunct within the ERAS setting. Patient and healthcare professional opinions and preferences highlighted many of the important features of WAMs for both research and clinical use which can be used for future device development and implementation of WAMs in the healthcare setting.

8.1. Future work

This work addressed the significant clinical challenge of optimising post-operative recovery by assessing and utilising a WAM which objectively monitored physical activity in the peri-operative period. Physical activity was shown to be a measurable marker of peri-operative well-being and the objective physical activity data was shown to be a valid marker of recovery after surgery. The WAM assessed physical activity levels in the peri-operative setting and its use as an important component, with potential in improving ERAS, was shown. The benefits of the WAM in facilitating early hospital discharge, enabling home monitoring after discharge and predicting patients who need more care either before or after surgery was evident. However, given the paucity of current research, further study is necessary in this field prior to clinical implementation of this relatively new technology.

8.1.1. Initial further research

Subsequent studies should use a new WAM, updated to meet the specifications expected by patients and clinicians. It would be necessary to maintain the accuracy and reliability of the WAM used in our study, but to develop the hardware further, so that not only does the WAM measure activity, but also is able to feedback in real-time the data, both on the device itself, and potentially to be streamed and viewed via a computer at the nursing terminal, or even on a portable tablet. The data would need to be available to the patient and to all healthcare professionals who have clinical roles caring for the patient, both whilst they are at home pre-operatively, and post-operatively on discharge, and whilst they are in-patients on the ward. There is a potential to collaborate with industry partners to combine the clinical and research knowledge together with the slick designs and interfaces already used outside of the healthcare sphere. It would be necessary to then trial this new device and ensure that it is accurate, reliable and produces the data necessary. It would need to be tested against an already proven WAM, e.g. the AX3 Axivity used within our

study. Further feedback and opinions should then be sought from the patients and healthcare professionals that the device and its design were beneficial and compatible with use in the clinical setting.

Having designed and trialled the new device, the next step would be to set up a pilot study with this new device for usability analysis. This will ensure that the WAM is functioning to the correct standards, that patients understand the data they are shown from the WAM, and that any technical issues can be fully ironed out. Following this a single centre RCT would be set up to investigate and assess if using the WAM alters post-operative outcomes, length of hospital stay and patient satisfaction. The changes to these may be small, and it is important to remember that there are many ERAS factors that may lead to a bias in the results. Once this study has been completed a power calculation could be undertaken in order to power a large multi-centre RCT which would aim to assess whether peri-operative physical activity could predict post-operative outcomes.

A further study that could be implemented in the shorter term would be to use the WAMs to look at prehabilitation in colorectal patients. An initial prospective observational study would entail giving physiotherapy and mobilisation recommendations to patients prior to their colorectal surgery, in the pre-operative period, with WAMs being worn pre and post-operatively. This would both measure activity levels and monitor compliance with recommendations, the outcome measures would be post-operative outcomes, recovery time to baseline and functional recovery. Following this a single centre RCT would be run, with two arms, one arm would have patients having prehabilitation advice and using the WAM that can both monitor activity levels, but also has the function to be programmed with advice and motivation, the other arm would have patients having usual clinical care and a WAM that monitors physical activity only.

8.1.2. Longer term research for the future

In the longer-term, use of WAM technology could help to change the culture of in-patient hospital stays and the classic ward-based care model. As seen by the End PJ paralysis campaign, patients can be motivated to get up and out of bed, get dressed and mobilise around the ward. However, a campaign may work for a short time, but long-term changes to maintain and promote this type of behaviour need a more permanent change. The structure of the ward itself may need to change, with a communal dining and/or sitting room and spaces to walk, whether this is inside or outside. The WAM would help facilitate this change. The traditional model of patients lying in bed on a ward would often be to ensure that regular observations were carried out, or so that patients were ready in their bed-space whenever a clinician wanted to review them. The WAM would allow patients to mobilise freely about the hospital, ensuring their physical activity, and potentially nursing observations, were continually monitored. A function to alert the patient if a clinician wanted to review them could be enabled, ensuring that the patient does not miss any clinical review.

The first stage of implementing WAMs would be at a Hospital and Trust level, starting with a one or two hospitals within a trust being approached to take part. Initially WAMs would be used for all elective surgical patients, but once this has been rolled out successfully, emergency surgical patients and medical patients would also be included, with the eventual standard being all in-patients would be using a WAM. The implementation of this can fit in with the smart ward, sensors used for nursing observation and the idea of a 'digital approach' to optimise care, recovery and discharge in a more automated fashion. It will be important to include clinicians, patients and managers from the outset to ensure engagement with the implementation of the new WAM technology. Key leaders need to be identified and empowered to communicate and educate about the use and benefits of the WAM technology and all staff and patients will need training in the use of the WAM technology. On-going feedback will need to be sought from the patients, clinicians

and managers, and the process and data capture will need to be audited. Once the WAM technology has been successfully implemented and adopted into routine use the technology could then be extended to further hospitals and trusts. Larger multi-centre RCTs can then be undertaken and the evidence from these used to inform NICE guidelines and technology appraisals. Once there is NICE guidance about use of WAM within the hospital setting, the technology would become a standard of care for all patients and would be implemented on a national level to all patients admitted to any NHS trust and hospital.

8.2. Concluding remarks

WAMs have been shown, increasingly, to provide possible solutions to a wide range of clinical challenges. In some cases, the WAM facilitates the provision of objective information about a patient to help support in-hospital care, in other cases it enables care out of the hospital to be provided. In all cases the technology can be used to ensure greater patient to clinician and clinician to patient communication, confirming the patient as an active member of their healthcare team, with an essential role in aiding their own recovery. Further clinical trials, with robust study designs, must be planned to evaluate the use of WAMs to predict and improve post-operative patient outcomes, thereby refining the ERAS paradigm that began in the 1990s.



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04 September 2015

Ms Aliza Abeles
10th Floor, QEQM Building
St Mary's Hospital, Praed Street
Paddington, London
W2 1NY

Dear Ms Abeles

Study title: The Step Home Trial: Utilising Physical Activity Data in the Acute Post-operative Setting
REC reference: 15/LO/1038
IRAS project ID: 177761

Thank you for your letter of 21 August 2015, responding to the Committee's request for further information on the above research.

The further information has been considered on behalf of the Committee by the Acting Vice Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Miss Maeve Groot Bluemink, nrescommittee.london-cityroadandhampstead@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.



Health Research Authority

London - City Road & Hampstead Research Ethics Committee

Level 3, Block B
Whitefriars
Lewins Mead
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BS1 2NT

Tel: (0117) 3421339

22 October 2015

Ms Aliza Abeles
10th Floor, QEQM Building
St Mary's Hospital
Praed Street
Paddington
London W2 1NY

Dear Ms Abeles

Study title: The Step Home Trial: Utilising Physical Activity Data in the Acute Post-operative Setting
REC reference: 15/LO/1038
Amendment number: Minor amendment dated 19 October 2015
Amendment date: 19 October 2015
IRAS project ID: 177761

Thank you for your letter of 19 October 2015, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Notice of Minor Amendment [Change of wording from 18-85 years old to 18 years and older]		19 October 2015

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research

A Research Ethics Committee established by the Health Research Authority

Joint Research Compliance Office
Academic Health Science Centre
Imperial College London and
Imperial College Healthcare NHS Trust
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r.nicholson@imperial.ac.uk
www.ic.ac.uk/clinical/research/governanceoffice

Ruth Nicholson
Research Governance Manager

12/05/2015

Ms Aliza Abeles
Imperial College London
St Mary's Hospital
Praed Street
London
W2 1NY

Dear Ms Abeles

RE: The Step Home Trial: Utilising Physical Activity Data in the Acute Post-operative Setting.

Joint Research Compliance Office Reference number: 15SM2689

This is to confirm that the above named research project utilises human participants, their organs, tissue and/or data as defined under the sponsorship requirements of the Research Governance Framework for Health and Social Care 2005, incorporating the Medicines for Human Use (Clinical Trials) Regulations 2004.

On behalf of Imperial College of Science, Technology and Medicine, we undertake to act as the identified Research Sponsor for this project.

This letter confirms:

- The research proposal has been discussed, assessed and registered with the Joint Research Compliance Office, Imperial College Academic Health Science Centre, Imperial College London and provisional sponsor approval granted.
- The Chief Investigator has undergone a process of scientific critique commensurate with the scale of the project.
- Indemnity and insurance arrangements have been put in place to cover the project.
- Resources and support are available to the research team to aid delivery of the research as proposed.
- Management, monitoring and reporting responsibilities for the research have been approved.
- Imperial College will undertake and enforce those sponsor duties set out in the NHS Research Governance Framework for Health and Social Care.

Imperial College Sponsorship is conditional on the project receiving applicable ethical and regulatory approval for all research related aspects of its conduct. It is also conditional on successful contract and agreement negotiations and sign off via the Joint Research Office, where relevant, and before the study commences.

A copy of the ethics approval letter **must** be sent to the Research Governance Manager prior to the study commencing. Sponsorship is dependant on obtaining R&D Office approval for all NHS sites where the research is being conducted.

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r.nicholson@imperial.ac.uk
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Ruth Nicholson
Research Governance Manager

21/09/2015

Ms Aliza Abeles
Clinical Research Fellow
Imperial College London
St Mary's Hospital
Praed Street, Paddington
London W2 1NY

Dear Ms Abeles

RE: JRCO Study Approval

Project Title: The Step Home Trial: Utilising Physical Activity Data in the Acute Postoperative Setting

Short Title: The Step Home Trial: Utilising Physical Activity Data in the Acute Postoperative Setting

Joint Research Compliance Office Reference number: 15SM2688

Ethics reference number: 15/LO/1038 Principal Investigator: Ms Aliza Abeles

I confirm that this project has now been approved by the Joint Research Compliance Office. The project may now start at Imperial College Healthcare NHS Trust sites. Please note that the start date of the project is the date of this letter and the duration is the same as that provided in your application form.

The list of documents reviewed and approved by the Joint Research Compliance Office under requirements of the Research Governance Framework are as follows.

Document	Version	Date
HRA NRES Committee London – City Road & Hampstead favourable ethical opinion letter		04 September 2015
Evidence of Sponsor Insurance or indemnity (for NHS Sponsors only): [Clinical Trials Insurance]		21 July 2014
Letter from Sponsor (Sponsorship from Imperial College London):		12 May 2015
Other [RMKwasnicki CV, Research Associate]		
Other [Phase 1 – Patient feedback]	2.1	07 July 2015
Other [Phase 1 – Clinician feedback]	2.1	07 July 2015
Other [Phase 2 – Patient feedback]	2.1	07 July 2015
Other [Phase 2 – Clinician feedback]	2.1	07 July 2015
Other [PI3 phase 1 track changes]	2.1	08 July 2015
Other [CIS phase 1 track changes]	2.2	10 July 2015

Joint Research Compliance Office
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Ruth Nicholson
Research Governance Manager

22/10/2015

Ms Aliza Abeles
Clinical Research Fellow
Imperial College London
St. Mary's Hospital
Praed Street, Paddington
London W2 1NY

Dear Ms Abeles

RE: Non-Substantial Amendment

Project Title: The Step Home Trial: Utilising Physical Activity Data in the Acute Postoperative Setting

Joint Research Compliance Office Reference number: 15SM2689

Ethics reference number: 15/LO/1038 **Principal Investigator:** Ms Aliza Abeles

Thank you for forwarding the details for the non-substantial amendment to the original study documentation for the above study. The documents received were:

Document	Version	Date
Notification of Minor Amendment [Change of wording from 18-65 years old to 18 years and older]	Enrail	19 October 2015
HRA London - City Road & Hampstead Research Ethics Committee acknowledgement of minor amendment letter	Minor amendment dated 19 October 2015	22 October 2015

Before you commence your research, please note that you must be aware of your obligations to comply with the minimum requirements for compliance with the Research Governance indicators 17 (Data Protection), 25 (Health and Safety) and 22 (Financial Probity). Details of the requirements to be met can be found in the Research Governance Framework available on www.dh.gov.uk.

I wish you well in your research and look forward to seeing regular annual progress reports, funding details as well as information about any publications resulting from the study.

Yours sincerely



Ms Ruth Nicholson
Research Governance Manager

Chapter 4 information sheets and consent form

Healthy Cohort PARTICIPANT INFORMATION SHEET Phase 2

Version 1, Date 27/02/2017

Contact

Ms Aliza Abeles
10th Floor QEQM Building
St Mary's Hospital
Praed Street
London W2 1NY
United Kingdom
Email: a.abeles@imperial.ac.uk

PARTICIPANT INFORMATION SHEET

'You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.'

Thank you for reading this.'

1. What is the purpose of the study?

We are interested in seeing how patient's physical activity levels change following surgical procedures. The movements of study participants will be measured using a lightweight wrist-worn sensor.

This research will also be forming part of a PhD thesis at Imperial College.

2. Why have I been chosen?

You are invited to participate in this study as a healthy control to help us understand the differences between physical activity in patients who are undergoing surgical procedures.

3. Do I have to take part?

You decide whether or not to take part. Please contact Aliza Abeles (details above) if you are interested in doing so. If you decide to take part you will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason.

4. What will happen to me if I take part?

Please see the following timetable:

1	You have received this participant information sheet.
2	If you decide to take part you will sign a written consent form. Demographics will be noted down anonymously.

3	You will be given a wrist-worn sensor that you should wear continuously except if swimming or taking a bath.
4	Please wear the sensor for 5 -10 days and the sensor will be collected back by the researcher
5	You will then have finished taking part in the study and do not need to do anything further

The data captured will only be used by the researchers in this project and will be completely anonymised. This data will be securely stored in a database at Imperial College.

It is highly unlikely that you will lose mental capacity during the study. However, should you do so, you will be withdrawn from the study. If data has been collected before the loss of capacity, we may still use the data in the study to avoid introducing a scientific bias. Participant in the study does **NOT** increase changes of losing capacity. There are no risks associated with participation.

6. What happens to the data collected?

Data collected from the sensor will be stored on a secure encrypted database. The data will be completely anonymised and securely stored. The data will be processed to give the investigators a more manageable value of physical activity for each participant.

7. What are the possible disadvantages and risks of taking part?

The wrist-worn activity sensor is a CE approved device and is completely safe. The sensor does not affect any other electrical equipment that you might carry. We will not ask you to attend any extra clinics or meetings above normal standard care. We understand that one may become anxious about taking part in a research study, and as such we would like to invite you to call the support number on this information sheet should you have any concerns.

8. What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (see above). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Office.

9. Will my taking part in this study be kept confidential?

All information collected about you during the course of the research is strictly confidential. Any information about you which leaves the clinic will have your name and details removed.

10. What will happen to the results of the research study?

The results of the research will be analysed and published in scientific journals. We will happily provide you with a copy of the results after publication.

11. Who is organising and funding the research?

The research is being organised by Imperial College London University.

12. Who has reviewed the study?

This study has been reviewed and approved by the Research Ethics Committee – London City Road and Hampstead.

13. Contact Aliza Abeles (details above) for Further Information and support

OR for independent advice please contact:

Patient Advice and Liaison Service (PALS)

Ground floor of Queen Elizabeth the Queen Mother (QEQM) wing, St Mary's Hospital. Open Monday to Friday, from 10.00 to 16.00

PALS address: PALS manager, Ground floor, Clarence wing, St Mary's Hospital, London W2 1NY

Telephone: 020 3312 7777, Monday to Friday from 09.00 to 17.00 **Text phone:** 07962 985118 **Fax:** 020 3312 1753 **Email:** pals@imperial.nhs.uk

Participants will be given a copy of the consent form and information sheet to keep.

Subject Identification Number for this trial:

**Healthy Cohort
CONSENT FORM
Phase 2**

Version 1, Date 27/02/2017

Title of Project:

The Step Home Trial: Utilising Physical Activity Data in the Acute Post-operative Setting

Name of Researcher:

Ms Aliza Abeles
Department of Surgery and Cancer
10th Floor QEQM building
St Mary's Hospital
Praed Street
London W2 1NY United Kingdom

Email: a.abeles@imperial.ac.uk

Please initial box

1. I confirm that I have read and understand the information sheet dated 27/02/2017 version 1 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that if I was to lose capacity to consent during the study, although no further data would be collected, the data already collected may still be used in the study. ☐
4. I agree to take part in the above study. ☐

Name of Participant

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

(COPIES: 1 for participant, 1 for researcher, 1 for medical notes)

Chapter 5, 6 & 7 information sheets and consent forms

PARTICIPANT INFORMATION SHEET & CONSENT FORM

Phase 1

Version 2.2, 12/05/2016

Contact

Ms Aliza Abeles
10th Floor QEQM Building
St Mary's Hospital
Praed Street
London W2 1NY
United Kingdom
Email: a.abeles@imperial.ac.uk

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part.

Thank you

Summary

Why?

We are researching how peoples' activity levels change before and after surgical operations. This is important to help us understand how people recover from operations and to help doctors make decisions about these patients in the future.

What?

We are asking participants to wear a light wrist-worn activity monitor/sensor to measure how much movement and activity they undergo daily both before and after their operations. The activity monitor will be worn for two weeks at home before the operation, and in the hospital after the operation.

Who?

Anyone undergoing a surgical procedure that requires at least one overnight stay is eligible to take part in this study.

Where?

This study is being conducted at St Mary's Hospital.

How?

The study will last 6 months, or until 60 patients have been recruited.

1. **What is the purpose of the study?**

We are interested in seeing how patients' movement and activity levels change around the time of surgical procedures.

The movements of study participants will be measured using a light wrist-worn activity monitor/sensor. This will help doctors to understand how people recover from operations and will help us to make decisions in the future about patients after they have had surgical procedures.

This research will also be used as part of a PhD thesis at Imperial College London University.

2. **Why have I been chosen?**

You have been invited to take part in this study because you are undergoing a surgical procedure at St Mary's Hospital and will be staying in the hospital for at least one day after the operation.

3. **Do I have to take part?**

You can decide whether or not to take part. If you decide to take part you will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason.

Not participating or withdrawing from this study will not affect your current clinical care or any future clinical care.

4. **What will happen to me if I take part?**

Please see the following timetable:

1	You have received this participant information sheet and have time to ask any questions in the initial outpatient clinic appointment
2	You will come to the normal pre-admission clinic that all patients attend before their operation. At this point you will have the opportunity to ask any questions to the researcher before you decide whether or not to take part. If you are happy to participate you will be asked to read and sign a consent form.
3	Once you have signed the consent form you will be asked to complete a short health survey (SF-36) questionnaire.
4	You will be given a small and light wrist-worn activity monitor/sensor to wear. This should be worn continuously on your wrist (it is showerproof) except if you go swimming or take a bath. Please continue to go about your normal daily activity.
5	You will be admitted to the hospital on the day of surgery. Please continue to wear the sensor while you are in the hospital. The activity monitor/sensor will be collected from you just prior to discharge from hospital. It is essential that you return the activity monitor/sensor to the researchers at the end of the study. If the device is broken, lost or stolen please contact the researcher as soon as possible and we will try to replace it with a new device.
6	You will attend the usual follow-up clinic 2-3 weeks after the operation and at 3-6 months. At this time we will ask you to complete another short health survey (SF-36) questionnaire. You will also be asked to fill in a short feedback form to ensure any issues or concerns are addressed early on in the study. If you have concerns or worries at any other time please contact Aliza Abeles (as above).

The total amount of time that you will wear the activity monitor/sensor will be 3 weeks. You will be involved in the study for approximately 6 months, until you have been seen in the outpatient clinic for follow-up and have repeated the questionnaire forms. At this point you will no longer be involved in the research.

You will meet a researcher on 4 separate occasions. The first time will be at your regular outpatient clinic after you have seen the surgical team. You will then meet again at the pre-admission clinic for a formal consent form to be signed, as well as being given the wrist-worn activity monitor/sensor. Just before you are discharged from hospital the researcher will collect the activity monitor/sensor from you (please don't take it home with you). The final meeting with the researcher will be at your follow-up outpatient clinic appointment.

Taking part in this study in no way changes or affects the standard of clinical care you will receive now

or in the future.

It is highly unlikely that you will lose mental capacity during the study. However, should you do so, we will take you out of the study. If data has been collected before this, we may still use the data in the study to make sure that we present the actual data collected.

Participating in the study does **NOT** increase chances of losing capacity. There are no risks associated with participation.

6. What happens to the data collected?

The data collected from the activity monitor is the amount and type of activity done throughout the day. Other data we will collect in this study will include the operation you are having, other medical conditions you suffer from and how you recover both in hospital and at home after the operation. This information will be used only by the researchers in this project.

Data collected will be stored on a secure encrypted database. The data will be completely anonymised. The data will be processed to give the investigators a more manageable value of physical activity for each participant. **Important: none of the data collected from the study will be used to influence your clinical management.** You will receive the same care whether you participate or not.

7. What are the possible benefits and disadvantages/risks of taking part?

Benefits

There are no specific benefits to taking part in this study. However, participants may find some satisfaction knowing that they are participating in research that is likely to help improve decision making by doctors in the future.

Disadvantages/risks

The wrist-worn activity monitor/sensor is a CE approved device and is completely safe. The monitor/sensor does not affect any other electrical equipment that you might carry.

We will not ask you to attend any extra clinics or meetings above normal standard care.

We understand that taking part in a research study can lead to increased anxiety, and as such we would like to invite you to call the support number on this information sheet should you have any concerns.

Although there is no financial incentive to participate, you are entitled to reasonable travel expenses for any visits to the clinic over and above standard clinical care visits.

8. What will happen if I don't want to carry on with the study?

The decision to take part in this study is entirely voluntary and you can change your mind at any time. Any decision you take to withdraw from the study will not affect the care you receive now or in the future. If you do withdraw from the study information already collected may still be used.

9. **What if something goes wrong?**

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation, but you may have to pay your own legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Office.

10. **Will my participation in this study be kept confidential?**

All information collected about you during the course of the research is strictly confidential. Any information about you which leaves the clinic will have your name and details removed.

11. **What will happen to the results of the research study?**

The results of the research will be analysed and published in scientific journals. No individual participants will be identifiable from any report or publication. We will happily provide you with a copy of the results after publication.

12. **Who is organising and funding the research?**

The research is being organised and funded by Imperial College London.

13. **Who has reviewed the study?**

This study has been reviewed and approved by the Research Ethics Committee NRES committee London – City Road & Hampstead

14. **Contact Aliza Abeles (details above) for further information and support**

OR for independent advice please contact:

Patient Advice and Liaison Service (PALS)

Ground floor of Queen Elizabeth the Queen Mother (QEQM) wing, St Mary's Hospital. Open Monday to Friday, from 10.00 to 16.00

PALS address: PALS manager, Ground floor, Clarence wing, St Mary's Hospital, London W2 1NY
Telephone: 020 3312 7777, Monday to Friday from 09.00 to 17.00 **Text phone:** 07962 985118 **Fax:** 020 3312 1753 **Email:** pals@imperial.nhs.uk

Participants will be given a copy of the consent form and information sheet for their own records.

Site: St Mary's Hospital
Patient Hospital Number:
Subject Identification Number for this trial:

**CONSENT FORM - Patients
Phase 1**

Version 1.2, Date 12/05/2016

Title of Project:

The Step Home Trial: Utilising Physical Activity Data in the Acute Post-operative Setting

Name of Researcher:

Ms Aliza Abeles
Department of Surgery and Cancer
10th Floor QEQM building
St Mary's Hospital
Praed Street
London W2 1NY United Kingdom

Email: a.abeles@imperial.ac.uk

Please initial box

1. I confirm that I have read and understand the information sheet dated 12/05/2016 version 2.2 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from Imperial College, the NHS Trust or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to access my records that are relevant to this research. ☐
4. I understand that if I was to lose capacity to consent during the study, although no further data would be collected, the data already collected may still be used in the study. ☐
5. I agree to take part in the above study. ☐

Name of Participant

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

(COPIES: 1 for participant, 1 for researcher, 1 for medical notes)

PARTICIPANT INFORMATION SHEET
Phase 2

Version 1.3, Date 27/02/2017

Contact

Ms Aliza Abeles
10th Floor QEQM Building
St Mary's Hospital
Praed Street
London W2 1NY
United Kingdom
Email: a.abeles@imperial.ac.uk

PARTICIPANT INFORMATION SHEET

'You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.'

Thank you for reading this.'

1. What is the purpose of the study?

We are interested in seeing how patient's physical activity levels change following surgical procedures. The movements of study participants will be measured using a lightweight wrist-worn sensor.

This research will also be forming part of a PhD thesis at Imperial College.

2. Why have I been chosen?

You are invited to participate in this study as you are undergoing a surgical procedure in the department of general surgery.

3. Do I have to take part?

You decide whether or not to take part. Please contact Aliza Abeles (details above) if you are interested in doing so. If you decide to take part you will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason.

4. What will happen to me if I take part?

Please see the following timetable:

1	You have received this participant information sheet.
2	At the pre-admission clinic you will have the opportunity to ask any questions to the researcher before you decide whether or not to take part. If you are happy to participate, you will be asked to read and sign a consent form.

3	Following consent, you will be asked to complete a short health survey (SF-36), before being given a small lightweight wrist-worn sensor to wear. This should be worn continuously on your wrist (it is showerproof) except if you go swimming or take a bath. Please continue to go about your normal daily activity.
4	You will be admitted to the hospital on the day of surgery, please continue to wear the sensor as an inpatient. You will be given another fully charged sensor on discharge to wear at home. Again please wear this continuously except in the bath or swimming.
5	When you attend your usual follow-up clinic we will ask you to return the sensor back to us and to complete another short health survey (SF-36). We will tell you your physical activity level data and ask you to fill out a short feedback questionnaire and semi-structured interview at this time. If you have concerns or worries at any other time please contact Aliza Abeles – as above.

The data captured will only be used by the researchers in this project and will be completely anonymised. This data will be securely stored in a database at Imperial College.

It is highly unlikely that you will lose mental capacity during the study. However, should you do so, you will be withdrawn from the study. If data has been collected before the loss of capacity, we may still use the data in the study to avoid introducing a scientific bias. Participant in the study does **NOT** increase changes of losing capacity. There are no risks associated with participation.

6. What happens to the data collected?

Data collected from the sensor will be stored on a secure encrypted database. The data will be completely anonymised and securely stored. The data will be processed to give the investigators a more manageable value of physical activity for each participant. **Important: None of the data collected from the study will be used to influence your further management.** You will receive the same care whether you participate or not.

Once you have been discharged from hospital we will present the physical activity level data to the clinical team to try and understand how we can use this data for future care of patients. It will not affect your clinical management.

7. What are the possible disadvantages and risks of taking part?

The wrist-worn activity sensor is a CE approved device and is completely safe. The sensor does not affect any other electrical equipment that you might carry. We will not ask you to attend any extra clinics or meetings above normal standard care. We understand that one may become anxious about taking part in a research study, and as such we would like to invite you to call the support number on this information sheet should you have any concerns.

Although there is no financial incentive to participate, you are entitled to reasonable travel expenses for any visits to the clinic over and above standard clinical care visits.

8. What happens when the research study stops?

When you come back to clinic for your follow-up appointment we will ask you to complete a short health survey and feedback questionnaire, then your participation is complete.

9. What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal

action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (see above). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Office.

10. Will my taking part in this study be kept confidential?

All information collected about you during the course of the research is strictly confidential. Any information about you which leaves the clinic will have your name and details removed.

11. What will happen to the results of the research study?

The results of the research will be analysed and published in scientific journals. We will happily provide you with a copy of the results after publication.

12. Who is organising and funding the research?

The research is being organised by Imperial College London University.

13. Who has reviewed the study?

This study has been reviewed and approved by the Research Ethics Committee.

14. Contact Aliza Abeles (details above) for Further Information and support

OR for independent advice please contact:

Patient Advice and Liaison Service (PALS)

Ground floor of Queen Elizabeth the Queen Mother (QEQM) wing, St Mary's Hospital. Open Monday to Friday, from 10.00 to 16.00

PALS address: PALS manager, Ground floor, Clarence wing, St Mary's Hospital, London W2 1NY

Telephone: 020 3312 7777, Monday to Friday from 09.00 to 17.00 **Text phone:** 07962 985118 **Fax:** 020 3312 1753 **Email:** pals@imperial.nhs.uk

Participants will be given a copy of the consent form and information sheet to keep.

Site: St Mary's Hospital
Subject Identification Number for this trial:

CONSENT FORM
Phase 2

Version 1.3, Date 27/02/2017

Title of Project:

The Step Home Trial: Utilising Physical Activity Data in the Acute Post-operative Setting

Name of Researcher:

Ms Aliza Abeles
Department of Surgery and Cancer
10th Floor QEQM building
St Mary's Hospital
Praed Street
London W2 1NY United Kingdom

Email: a.abeles@imperial.ac.uk

Please initial box

1. I confirm that I have read and understand the information sheet dated 27/02/2017 version 1.3 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from Imperial College, the NHS Trust or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to access my records that are relevant to this research. ☐
4. I understand that if I was to lose capacity to consent during the study, although no further data would be collected, the data already collected may still be used in the study. ☐
5. I agree to take part in the above study. ☐

Name of Participant

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

(COPIES: 1 for participant, 1 for researcher, 1 for medical notes)

Subject Identification Number for this trial:

The Step Home Trial: Utilising Physical Activity Data in the Acute Post-operative Setting

Patient Feedback Phase 1: Version 2.1, Date 07/07/2015

There are no right or wrong answers in this questionnaire. We would just like your honest opinion.

How much do you agree with the following statements? Please circle the answer that applies to you.

General

1. I was **NOT** happy with the information given to me before entering into this trial.

Strongly agree **Agree** **Neither agree nor disagree** **Disagree** **Strongly disagree**

2. I was happy that all my questions were fully answered.

Strongly agree **Agree** **Neither agree nor disagree** **Disagree** **Strongly disagree**

3. I was happy with the contact details given to me in case I needed to contact someone involved in this trial with any further questions.

Strongly agree **Agree** **Neither agree nor disagree** **Disagree** **Strongly disagree**

Sensor

4. I wore the sensor at all times before going into hospital for my operation.

Always **Often** **Sometimes** **Rarely** **Never**

5. If you did take the sensor off before the operation when was this? Please circle all that apply

Whilst showering
In the bath
When swimming
In an exercise class
At the gym
Whilst cooking
Socialising
When at work
At night in bed
Other – please specify

6. I wore the sensor in hospital.

Always **Often** **Sometimes** **Rarely** **Never**

7. If you did take the sensor off whilst in hospital when was this? Please circle all that apply.

During the operation
 In the recovery room after the operation
 Whilst showering/washing
 At night whilst sleeping
 During the day when lying in bed
 Other – please specify

8. The sensor stopped me from going about my normal activities during the day.

Strongly agree disagree **Agree** **Neither agree nor disagree** **Disagree** **Strongly**

9. I found the sensor to be comfortable to wear.

Strongly agree disagree **Agree** **Neither agree nor disagree** **Disagree** **Strongly**

Physical Activity

10. When I was wearing the sensor at home before my operation it made me think more about my own physical activity levels.

Strongly agree disagree **Agree** **Neither agree nor disagree** **Disagree** **Strongly**

11. When I was wearing the sensor in the hospital after the operation it made me think more about my physical activity levels.

Strongly agree disagree **Agree** **Neither agree nor disagree** **Disagree** **Strongly**

12. I think that giving doctors (and other members of the team looking after me) information about my movement and activity levels will help them to better monitor my recovery and plan my discharge home.

Strongly agree disagree **Agree** **Neither agree nor disagree** **Disagree** **Strongly**

13. I would be **unhappy** for doctors (and other members of the team looking after me) to have information about my physical activity levels.

Strongly agree disagree **Agree** **Neither agree nor disagree** **Disagree** **Strongly**

Please use the space to leave any other comments or feedback.

Medical Outcomes Study: 36-Item Short Form Survey Instrument

RAND 36-Item Health Survey 1.0 Questionnaire Items

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago , how would you rate your health in general now ?	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

The following items are about activities you might do during a typical day. Does **your health now** **limit you** in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not limited at All
3. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	[1]	[2]	[3]
4. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	[1]	[2]	[3]
5. Lifting or carrying groceries	[1]	[2]	[3]
6. Climbing several flights of stairs	[1]	[2]	[3]
7. Climbing one flight of stairs	[1]	[2]	[3]
8. Bending, kneeling, or stooping	[1]	[2]	[3]
9. Walking more than a mile	[1]	[2]	[3]
10. Walking several blocks	[1]	[2]	[3]
11. Walking one block	[1]	[2]	[3]
12. Bathing or dressing yourself	[1]	[2]	[3]

During the **past 4 weeks**, have you had any of the following problems with your work or other regular

daily activities **as a result of your physical health?**

(Circle One Number on Each Line)

	Yes	No
13. Cut down the amount of time you spent on work or other activities	1	2
14. Accomplished less than you would like	1	2
15. Were limited in the kind of work or other activities	1	2
16. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)

	Yes	No
17. Cut down the amount of time you spent on work or other activities	1	2
18. Accomplished less than you would like	1	2
19. Didn't do work or other activities as carefully as usual	1	2

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(Circle One Number)

- Not at all 1
- Slightly 2
- Moderately 3
- Quite a bit 4
- Extremely 5

21. How much **bodily** pain have you had during the **past 4 weeks**?

(Circle One Number)

- None 1
- Very mild 2
- Mild 3
- Moderate 4
- Severe 5
- Very severe 6

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Circle One Number)

- Not at all 1
- A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks** . . .

(Circle One Number on Each Line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

How TRUE or FALSE is each of the following statements for you.

(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

CLINICIAN INFORMATION SHEET & CONSENT FORM

Phase 1

Version 2.2, Date 16/07/2015

Contact

Ms Aliza Abeles
10th Floor QEQM Building
St Mary's Hospital
Praed Street
London W2 1NY
United Kingdom
Email: a.abeles@imperial.ac.uk

Thank you for reading this information sheet. It is intended for clinicians who will be involved with the care of patients who are being/have been recruited to the above study.

Please see patient information leaflet for information given to patients about the study.

What is your role as part of the multidisciplinary team in this process?

Please give over any information from the patient information leaflet to the patient if they have questions but also put them in contact with the research team (Aliza Abeles - see details above) to ensure all queries are fully clarified.

Feedback From Clinicians

We would like to gain feedback early on in this trial from members of the multidisciplinary team. If you would be happy to give feedback we will ask you to sign a written consent form and fill out a short feedback questionnaire.

What is the purpose of this feedback questionnaire?

To allow us to find out if there are any problems encountered with running this trial early on in the process.

Why have I been chosen?

You have been invited to give feedback because you are caring for/have cared for a patient who is enrolled in this trial.

Do I have to take part?

You decide whether or not to take part. You do not have to take part. If you decide to take part you will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason.

What will happen if I take part?

You will be asked to fill out a short feedback questionnaire by one of the research team.

Will my taking part in providing feedback be kept confidential?

Yes, all information collected during the course of the research is strictly confidential.

What will happen to the data collected?

The will be used to change aspects of the trial if necessary and inform further studies in the future.

What are the benefits/disadvantages?

There are no specific benefits in taking part, but you will be adding to the understanding of how clinicians view this trial and help with any changes needed to implement a safe and reliable trial.

There are no risks to this as the only involvement is filling out a feedback questionnaire.

Who is organising and funding the research?

The research is being organised and funded by Imperial College London.

Who has reviewed the study?

This study has been reviewed and approved by the NRES Committee London – City Road & Hampstead Research Ethics Committee.

Contact Aliza Abeles (details above) for Further Information and support

If at any time you, as a member of the MDT, have any questions or worries about the trial please contact the research team (Aliza Abeles – see details above).

Site: St Mary's Hospital
Patient Hospital Number:
Subject Identification Number for this trial:

**CONSENT FORM - Clinicians
Phase 1**

Version 1.2, Date 11/05/2015

Title of Project:

The Step Home Trial: Utilising Physical Activity Data in the Acute Post-operative Setting

Name of Researcher:

Ms Aliza Abeles
Department of Surgery and Cancer
10th Floor QEQM building
St Mary's Hospital
Praed Street
London W2 1NY United Kingdom

Email: a.abeles@imperial.ac.uk

Please initial box

1. I have read and understand the clinician information sheet dated 16/07/2015 version 2.2 for the above study. ☐
2. I understand that my participation is voluntary. ☐
3. I agree to provide feedback for the above study and for this data to be used for research purposes. ☐
4. I agree to take part in this study. ☐

Name of Participant

Date

Signature

Researcher

Date

Signature

CLINICIAN INFORMATION SHEET

Phase 2

Version 1.2, Date 11/05/2015

Contact

Ms Aliza Abeles
10th Floor QEQM Building
St Mary's Hospital
Praed Street
London W2 1NY
United Kingdom
Email: a.abeles@imperial.ac.uk

Thank you for reading this information sheet. It is intended for clinicians who will be looking after patients who have been recruited to the above study.

What is the purpose of the study?

We are interested in seeing how patient's physical activity levels change following surgical procedures. And how this data can help clinicians in their management of patients in the post-operative setting. The movements of study participants will be measured using a lightweight wrist-worn sensor. We will collate the data and once the patient has been discharged home we will present the data to the clinical team to find out clinicians' thoughts on this data and its utility and usability. This research will also be forming part of a PhD thesis at Imperial College.

Do I have to take part?

You decide whether or not to take part. If you decide to take part you will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason.

What does participating in this study mean practically for you?

You are being asked to participate because you are a clinician/part of a multidisciplinary team that is looking after patients who have been recruited to the above study. We will give you this information sheet and also give you time to ask any questions. If you are happy to participate we will ask you to sign a written consent form. We will then present you with easily readable tables/graphs showing the data for the physical activity levels of the patients in this phase of the study. We will ask you to look at them and then fill in a short feedback questionnaire.

What happens to the data collected?

The data collected from the patients will be stored on a secure encrypted database. The data will be completely anonymised and securely stored. The data from the feedback questionnaire will be used to help plan the next stage in this clinical trial.

Important: None of the data collected from the study will be used to influence further management.

What are the possible disadvantages and risks of taking part?

Since participation involves completing a feedback questionnaire concerning patient physical activity levels there are no risks or disadvantages foreseen.

Will my taking part in this study be kept confidential?

All information collected during the course of the research is strictly confidential.

What will happen to the results of the research study?

The results of the research will be analysed and published in scientific journals. We will happily provide

you with a copy of the results after publication.

Who is organising and funding the research?

The research is being organised by Imperial College London University.

Who has reviewed the study?

This study has been reviewed and approved by the Research Ethics Committee.

Contact Aliza Abeles (details above) for Further Information and support

Site: St Mary's Hospital
Patient Hospital Number:
Subject Identification Number for this trial:

**CONSENT FORM - Clinicians
Phase 2**

Version 1.2, Date 11/05/2015

Title of Project:

The Step Home Trial: Utilising Physical Activity Data in the Acute Post-operative Setting

Name of Researcher:

Ms Aliza Abeles
Department of Surgery and Cancer
10th Floor QEQM building
St Mary's Hospital
Praed Street
London W2 1NY United Kingdom

Email: a.abeles@imperial.ac.uk

Please initial box

1. I have read and understand the clinician information sheet dated 11/05/2015 version 1.2 for the above study. ☐
2. I understand that my participation is voluntary. ☐
3. I agree to provide feedback for the above study and for this data to be used for research purposes. ☐
4. I agree to take part in this study ☐

Name of Participant

Date

Signature

Researcher

Date

Signature

MDT member identification number:

The Step Home Trial: Utilising Physical Activity Data in the Acute Post-operative Setting

Multidisciplinary Team Feedback
Phase 1: Version 2.1, Date 07/07/2015

There are no right or wrong answers in this questionnaire. We would just like your honest opinion.

How much do you agree with the following statements? Please circle the answer that applies to you.

General

1. Before this study I was aware of the availability of commercial wrist-worn physical activity sensors (e.g. Nike Fuel Band, Fitbit etc).

Yes
No

2. I own a wrist-worn physical activity sensor (e.g. Nike Fuel Band, Fitbit etc).

Yes
No

3. I wear a wrist-worn physical activity sensor (e.g. Nike Fuel Band, Fitbit etc).

Always **Often** **Sometimes** **Rarely** **Never**

Recruitment (Clinic/Pre-op Clinic)

Please only answer these questions if you work in the outpatient clinic area.

4. The clinic was an appropriate time to recruit patients.

Strongly agree **Agree** **Neither agree nor disagree** **Disagree** **Strongly disagree**

5. Recruitment of patients in the clinic was simple and easy to perform.

Strongly agree **Agree** **Neither agree nor disagree** **Disagree** **Strongly disagree**

6. There was too much disruption to clinic when recruiting patients for this trial.

Strongly agree **Agree** **Neither agree nor disagree** **Disagree** **Strongly disagree**

7. There was not enough time in clinic for information to be given and questions to be answered.

Strongly agree **Agree** **Neither agree nor disagree** **Disagree** **Strongly disagree**

Admission/Theatre

Please only answer these questions if you work in theatre admissions or in the operating theatres.

8. The sensor did not get in the way of any pre-operative preparation that was needed.

Strongly agree disagree Agree Neither agree nor disagree Disagree Strongly

9. There was no problems with the sensor being worn during operative procedures in theatre.

Strongly agree disagree Agree Neither agree nor disagree Disagree Strongly

Recovery Room

Please only answer these questions if you work in the recovery room.

10. The sensor did not get in the way during recovery for the patient.

Strongly agree disagree Agree Neither agree nor disagree Disagree Strongly

Ward

Please only answer these questions if you work on the clinical wards

11. The patient wore the sensor at all times on the ward.

Strongly agree disagree Agree Neither agree nor disagree Disagree Strongly

12. There were no difficulties associated with patient care due to the wearing of the sensor by the patient at all times.

Strongly agree disagree Agree Neither agree nor disagree Disagree Strongly

13. There was an extra burden on the multidisciplinary team due to the patient wearing the sensor.

Strongly agree disagree Agree Neither agree nor disagree Disagree Strongly

Please use the space below to leave any other comments or feedback.

Semi structured feedback interview – Patients

Introduction

- Clarify format
- Assurance of confidentiality

Wearable technology

- Did you know of any wearable technology prior to this?
- If so, what? Did you use any?

Specifically wearing the sensor around their hospital admission

- Why did you decide to take part?
- Did you feel more confident when you were discharged knowing what you did about your activity, and how it had changed from before you were admitted until the day you were discharged?
- How satisfied were you with this information?
- Thinking about the data presented to you about your physical activity
 - Was it easy to understand?
 - Did the sensor make you think about your activity levels and recovery?
 - Did you feel more motivated to be more active? ?
 - Is there any other information you would want to know from the sensor? If so How would you like this information to be presented?
 - Graphs, pictures, motivational messages etc
- What benefits do you see from this type of technology?
 - Would you be happy to wear this type of technology again? In hospital or at home pre or post op?
- What disadvantages do you see?
 - Did you have any problems whilst wearing it? Were you able to wear it all the time? If you took it off, in which situations did you do this? Did you always remember to put it back on afterwards? Is there anything that would make it easier to wear all the time?

Impact on relationship with clinical team

- Do you think using this technology would change the way you interact with the clinical team (doctors, nurses, physiotherapists)? If so how?
- Are you happy for this sort of data to be monitored regularly and be given to the clinical team?
- Do you think this data will be useful to the clinicians to help with your treatment and discharge?

Close

- Any other things you would like to say or discuss that haven't been covered?
- Thank you

Semi structured feedback interview – Clinicians

Introduction

- Clarify format
- Assurance of confidentiality
- What is your professional role?

General: Wearable technology

- Did you know of any wearable technology prior to this?
- If so, what? Did you use any personally?
- What is your view on wearable technologies?
- Do you think they could be beneficial in your work/with your patients?
 - In which aspects?
- Do you think it could in any way be disruptive?

Specific: Sensor monitoring activity in peri-operative period with watch sensor

- What benefits do you see from this type of technology?
 - Do you think this can aid your clinical management, decision making or discharge planning?
- What did you learn, if anything that you were not aware of otherwise?

Are there any decision that you made that may have been different if you did not have this information?

- What disadvantages do you see?
- Thinking about the data displayed to you
 - Were they easy to understand?
 - Did you like how they were displayed and what was displayed?
 - Any changes you would like to see?
- Do you think this sensor technology is beneficial for patients?
 - In what way?
 - Would you use them for all your patients? Do you think there could be a certain subsection of patients where it could be more useful to use this technology?
- Are there any other functions that you would want to see on this type of sensor device?
 - Monitoring something else specifically?
 - Other functionality within the sensor or app?
 - Is there another way/format? you would like this data to be available to you?

Impact on patient relationship with clinical team

- Do you think using this technology would change the way you interact with the patient or have an impact on the doctor patient relationship? In what way?

Close

- Any other things you would like to say or bring up that hasn't been covered?
- Thank you

Search Terms for databases for Systematic Review

Embase 5 Jan 2016 – 1616 articles

1. walking/ or locomotion/ or physical activity/ or gait/ or walking speed/
2. ((physical adj1 activit\$) or (activity adj1 cycl\$) or (functional adj1 mobility) or (activity adj1 level\$) or (motor adj1 activit\$) or mobility or (activity adj1 pattern\$) or (body adj1 posture\$) or gait or (ambulatory adj1 activit\$) or walk\$ or (body adj1 movement\$) or ambulation or (physical adj1 performance) or (body adj1 motion\$) or movement or locomotion).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
3. 1 or 2
4. actimetry/ or measurement/
5. (accelerometer or accelerometry or actigraphy or actigrpah or (objective adj1 measurement) or (wireless adj1 technology) or (activity adj1 count) or (Patient adj1 assessment) or (patient adj1 track\$) or (patient adj1 sensor\$) or (patient adj1 logger) or (patient adj1 measurement) or (patient adj1 monitor\$) or (personal adj1 track\$) or (personal adj1 sensor\$) or (personal adj1 logger) or (personal adj1 monitor) or (activity adj1 assessment) or (activity adj1 track\$) or (activity adj1 sensor\$) or (activity adj1 logger) or (activity adj1 measurement) or (activity adj1 monitor\$) or (ambulatory adj1 assessment) or (ambulatory adj1 track\$) or (ambulatory adj1 sensor\$) or (ambulatory adj1 logger) or (ambulatory adj1 measurement) or (ambulatory adj1 monitor\$) or (motion adj1 assessment) or (motion adj1 track\$) or (motion adj1 sensor\$) or (motion adj1 logger) or (motion adj1 monitor) or (mobility adj1 assessment) or (mobility adj1 track\$) or (mobility adj1 sensor\$) or (mobility adj1 logger) or (mobility adj1 monitor)).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
6. 4 or 5
7. endoscopic sinus surgery/ or refractive surgery/ or throat surgery/ or open heart surgery/ or middle ear surgery/ or vitreoretinal surgery/ or computer assisted surgery/ or colon surgery/ or glaucoma surgery/ or larynx surgery/ or spine surgery/ or ear nose throat surgery/ or ureter surgery/ or ligament surgery/ or cornea surgery/ or endoscopic endonasal surgery/ or thorax surgery/ or endocrine surgery/ or esophagus surgery/ or bladder surgery/ or prostate surgery/ or transsphenoidal surgery/ or cerebrovascular surgery/ or minor surgery/ or elective surgery/ or uterine tube surgery/ or joint surgery/ or liver surgery/ or cardiovascular surgery/ or urinary tract surgery/ or shoulder surgery/ or major surgery/ or pancreas surgery/ or video assisted thoracoscopic surgery/ or pelvis surgery/ or stomach surgery/ or maxillofacial surgery/ or natural orifice transluminal endoscopic surgery/ or retina surgery/ or aneurysm surgery/ or colorectal surgery/ or experimental surgery/ or skin surgery/ or thoracic aorta surgery/ or cancer surgery/ or foot surgery/ or nerve surgery/ or hip surgery/ or cytoreductive surgery/ or breast surgery/ or spinal cord surgery/ or off pump surgery/ or rectum surgery/ or abdominal surgery/ or craniofacial surgery/ or urethra surgery/ or plastic surgery implant/ or "head and neck surgery"/ or arthroscopic surgery/ or uterus surgery/ or eye surgery/ or microvascular surgery/ or geriatric surgery/ or aortic arch surgery/ or endoscopic surgery/ or coronary artery bypass surgery/ or minimally invasive cardiac surgery/ or artery surgery/ or dental surgery/ or robot assisted surgery/ or nose surgery/ or vascular surgery/ or orthopedic surgery/ or male genital system surgery/ or descending aorta surgery/ or knee ligament surgery/ or trachea surgery/ or ascending aorta surgery/ or biliary tract surgery/ or heart valve surgery/ or thyroid surgery/ or heart surgery/ or computer assisted surgery system/ or strabismus surgery/ or plastic surgery/ or stapes surgery/ or orthognathic surgery/ or intestine surgery/ or facial nerve surgery/ or minimally invasive surgery/ or urologic surgery/ or brain surgery/ or gastrointestinal surgery/ or knee surgery/ or laser surgery/ or gynecologic surgery/ or mitral valve surgery/ or conversion to open surgery/ or laparoscopic surgery/ or nephron sparing surgery/ or thymus surgery/ or surgery/ or meniscal surgery/ or emergency surgery/ or vein surgery/ or decompression surgery/ or retina detachment surgery/ or ear surgery/ or off pump coronary surgery/ or failed back surgery syndrome/ or skull surgery/ or tendon surgery/ or lung surgery/ or second look surgery/ or laparoendoscopic single site surgery/ or oral surgery/ or general surgery/ or coronary artery surgery/ or hand surgery/ or bypass surgery/ or carotid artery surgery/ or "aortic root surgery"/ or stereotaxic surgery/ or esthetic surgery/ or anus surgery/ or ultrasound surgery/ or kidney surgery/ or bariatric surgery/ or face surgery/ or aorta surgery/ or endovascular surgery/ or spleen surgery/
8. (postoperative or (post adj2 surgery) or (after adj2 surgery) or post-surgical or (after adj2 operation) or (post adj2 procedure)).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

9. 7 or 8
10. 3 and 6 and 9

Medline 5th Jan 2016 – 245 articles

1. movement/ or locomotion/ or walking/
2. actigraphy/ or remote sensing technology/
3. specialties, surgical/ or colorectal surgery/ or general surgery/ or gynecology/ or neurosurgery/ or obstetrics/ or ophthalmology/ or orthognathic surgery/ or orthopedics/ or otolaryngology/ or surgery, plastic/ or thoracic surgery/ or traumatology/ or urology/
4. (postoperative or (post adj2 surgery) or (after adj2 surgery) or post-surgical or (after adj2 operation) or (post adj2 procedure)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
5. 3 or 4
6. ((physical adj1 activit\$) or (activity adj1 cycl\$) or (functional adj1 mobility) or (activity adj1 level\$) or (motor adj1 activit\$) or mobility or (activity adj1 pattern\$) or (body adj1 posture\$) or gait or (ambulatory adj1 activit\$) or walk\$ or (body adj1 movement\$) or ambulation or (physical adj1 performance) or (body adj1 motion\$) or movement or locomotion).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
7. 1 or 6
8. (accelerometer or accelerometry or actigraphy or actigrpah or (objective adj1 measurement) or (wireless adj1 technology) or (activity adj1 count) or (Patient adj1 assessment) or (patient adj1 track\$) or (patient adj1 sensor\$) or (patient adj1 logger) or (patient adj1 measurement) or (patient adj1 monitor\$) or (personal adj1 track\$) or (personal adj1 sensor\$) or (personal adj1 logger) or (personal adj1 monitor) or (activity adj1 assessment) or (activity adj1 track\$) or (activity adj1 sensor\$) or (activity adj1 logger) or (activity adj1 measurement) or (activity adj1 monitor\$) or (ambulatory adj1 assessment) or (ambulatory adj1 track\$) or (ambulatory adj1 sensor\$) or (ambulatory adj1 logger) or (ambulatory adj1 measurement) or (ambulatory adj1 monitor\$) or (motion adj1 assessment) or (motion adj1 track\$) or (motion adj1 sensor\$) or (motion adj1 logger) or (motion adj1 monitor) or (mobility adj1 assessment) or (mobility adj1 track\$) or (mobility adj1 sensor\$) or (mobility adj1 logger) or (mobility adj1 monitor)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
9. 2 or 8
10. 5 and 7 and 9

Cochrane 5th Jan 2016 – 157 articles

- #1 (accelerometer or accelerometry or actigraphy or actigrpah or (objective adj1 measurement) or (wireless adj1 technology) or (activity adj1 count) or (Patient adj1 assessment) or (patient adj1 track\$) or (patient adj1 sensor\$) or (patient adj1 logger) or (patient adj1 measurement) or (patient adj1 monitor\$) or (personal adj1 track\$) or (personal adj1 sensor\$) or (personal adj1 logger) or (personal adj1 monitor) or (activity adj1 assessment) or (activity adj1 track\$) or (activity adj1 sensor\$) or (activity adj1 logger) or (activity adj1 measurement) or (activity adj1 monitor\$) or (ambulatory adj1 assessment) or (ambulatory adj1 track\$) or (ambulatory adj1 sensor\$) or (ambulatory adj1 logger) or (ambulatory adj1 measurement) or (ambulatory adj1 monitor\$) or (motion adj1 assessment) or (motion adj1 track\$) or (motion adj1 sensor\$) or (motion adj1 logger) or (motion adj1 monitor) or (mobility adj1 assessment) or (mobility adj1 track\$) or (mobility adj1 sensor\$) or (mobility adj1 logger) or (mobility adj1 monitor))
- #2 ((physical adj1 activit\$) or (activity adj1 cycl\$) or (functional adj1 mobility) or (activity adj1 level\$) or (motor adj1 activit\$) or mobility or (activity adj1 pattern\$) or (body adj1 posture\$) or gait or (ambulatory adj1 activit\$) or walk\$ or (body adj1 movement\$) or ambulation or (physical adj1 performance) or (body adj1 motion\$) or movement or locomotion)
- #3 (postoperative or (post adj2 surgery) or (after adj2 surgery) or post-surgical or (after adj2 operation) or (post adj2 procedure))
- #4 MeSH descriptor: [Exercise] explode all trees

#5 MeSH descriptor: [Actigraphy] explode all trees
#6 MeSH descriptor: [Specialties, Surgical] explode all trees
#7 #1 or #5
#8 #2 or #4
#9 #3 or #6
#10 #7 and #8 and #9

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