



RESEARCH PROTOCOL

1. Project Details

Project Title:	Exploring outcomes in adults following major abdominal surgery – a pilot study		
Protocol Number (Version and Date):	Version 4, 17/12/2021		
Project Start Date:	November 2021	Project Finish Date:	November 2022
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Project Summary

There is limited research on the medium-term recovery and outcomes of patients three months following major upper abdominal surgery. The aim of this study is to explore the functional outcomes and lived experiences in adults three months after major upper abdominal surgery at Royal Perth hospital in Perth, Western Australia. Data collected from the participants prior to their surgery will be compared with data collected from them three months after they have been discharged from hospital. The measures will include clinical frailty and functional independence. At three months post discharge, information regarding abdominal pain, post-surgical fatigue and cognition will also be gathered in order to explore the association between these variables and the participants level of functional recovery three months following the surgery. Qualitative interviews will also be conducted at this time to explore the participants lived experiences and those of their primary carer.

2. Rationale / Background

2.0 Background

2.1. Major upper abdominal surgery

Upper abdominal surgery (UAS) is defined as any surgical procedure performed to the abdomen through an incision that is superior to or extends superior to level of the umbilicus^{1,2}. Upper abdominal surgery involves opening the abdomen in order for a surgeon to examine the contents and, where possible, remedy any pathology³. Major upper abdominal surgery (MUAS) is defined as an upper abdominal procedure requiring general anaesthetic for more than one hour and a post-operative hospital length of stay more than 24 hours⁴. Common pathologies addressed via MUAS include viscus organ perforation, mesenteric ischemia, haemorrhage, cancer related pathologies and bowel obstructions^{2,5}. The risk of internal trauma and associated bleeding is high following MUAS, potentially involving organs such as the liver, gallbladder, stomach, pancreas, kidneys, intestines and spleen⁶.

2.2. Upper abdominal surgery in Australia

Within Australia, it is estimated that approximately 300 to 500 procedures of abdominal surgeries per 100,000 head of population are performed in developed countries per year⁴. Hence it can be extrapolated to predict that approximately 77,080 to 128,466 abdominal surgeries are performed

in Australia per year based of the Australian Bureau of Statistics population statement as of September 2020⁷. The number of patients undergoing MUAS is rising with a reported increase of 2-5% per year⁵. Information on the average age of patients undergoing MUAS is limited, however a study done by Boden in Australia between 2013 and 2015 identified the average age of patients undergoing MUAS as being approximately 65 years of age.²

2.3. Serious adverse events following MUAS

Following MUAS, adults are at risk of serious adverse events, which require medical intervention or result in post-operative mortality. Recent research pertaining to the development of serious adverse events has focused on post-operative mortality following emergency MUAS⁷⁻⁹. In Australia, mortality rates following elective MUAS have not been well documented. However, in other first world countries such as Norway and the USA, recent studies have reported mortality rates of 3.5% and 3.8% respectively following elective abdominal surgery^{10, 11}. Risk factors for post-operative mortality include clinical frailty, older age, comorbidities, emergency procedures and reoperations^{5, 12-15}.

A recent study carried out in Australia reported a 30-day mortality rate ranging from 5.2-10.5% following emergency MUAS⁸. The risk of in-hospital mortality increases significantly if a reoperation is required, with a recent German study reporting an in-hospital mortality rate of 57% following emergency major abdominal reoperations⁵. This is more than double the in-hospital mortality rate following initial emergency MUAS reported in this same study (23.8%)⁵.

Comorbidities such as coagulopathy, fluid and electrolyte disorders and weight loss have been found to have the highest impact on in-hospital mortality rates, with reported rates of 17.2%, 9.4% and 11.9% associated with each respectively¹². In the UK, the association between frailty and post-operative mortality following MUAS has been extensively researched, with some of these studies concluding that high clinical frailty is the strongest predictive factor of post-operative mortality following MUAS¹³⁻¹⁵.

Other post-operative adverse events such as delirium, post-operative pulmonary complications (PPC), wound infection, incisional hernias and bowel obstructions are of high prevalence following abdominal procedures, prolonging hospital length of stay, increasing health-care costs and potentially putting the patient at risk of post-operative mortality^{1, 16-21}.

With such a high prevalence of adverse events during the acute in-hospital period following MUAS, more data on functional recovery post-discharge following MUAS is needed to better understand the trajectory of recovery following such procedures.

2.4 Recovery following MUAS

To date, details regarding the post-operative recovery of a person following MUAS are largely confined to the acute care stay, with follow-up data beyond the point of discharge from acute care rarely reported.

In the few days following MUAS, people report being limited by moderate to severe pain and also post-surgical fatigue^{22, 23}. Acute management focuses on symptom relief via pain medication and progressive mobilisation on the ward to minimise complications (i.e. post-operative respiratory infections) and return to functional independence to facilitate early discharge²⁴.

Hospital length of stay following MUAS can vary greatly depending on the presence of pre-operative comorbidities or frailty as well as post-operative complications. Some Australian studies have reported average hospital length of stays between 2-6 days following abdominal procedures, while others exploring outcomes following more major abdominal procedures report an average stay of 13-16 days^{9, 25-27}. Functionally, most patients are discharged once they achieve their baseline function, which in most cases is independent ambulation.

Research data on longer-term recovery following MUAS is also limited, however, a recent study reported that 36% of adults who were six months following MUAS continued to describe chronic postoperative abdominal pain²⁸. Those at greatest risk of persistent pain were characterised by greater feelings of anxiety and depression. In addition to persistent pain and fatigue, at six-months following surgery, 24% of adults also reported faecal incontinence as an important factor that impaired their social functioning²⁸. Pre-operative frailty has not been investigated as a predictor of long-term outcomes after MUAS.

2.5 Care Giver Burden

The effect of upper abdominal surgery not only influences the patient but also the care giver. As described by Lawrence,²⁰ independence of activities of daily living (ADL's) was significantly decreased after MUAS until 3 months.²⁰ Tasks such as dressing, eating and bathing are just some examples of ADL's in which require larger muscle group recruitment, hence the individual is unable to complete these tasks individually and the onus falls to the care giver.²⁰ Numerous studies look at care giver burden in the context of cancer with 'caregiver burden' being categorised as the physical, physiological, social and/or financial reactions which can be experienced during care.²⁷ Recovery after MUAS impacts the daily routine of both the patient and the care giver which puts them in a position where they have to adapt to a new situation.²⁸ Care givers are all unique hence the burden of care on the individual is influenced by various factors including but not limited to; age of the caregiver, his/her present illnesses, severity of symptoms experienced by the patient and relatedness to the patient.²⁸ In the study by Dundar²⁸ which looks at caregiver burden of patients with cancer, the topics brought up include duties such as physical, emotional and social support, setting up outpatient appointments, helping with ADL's and indicates that the care givers report difficulties in daily life due to the demand on them physically, emotionally, physiologically, socially and professionally.²⁸ If identification of the extent and nature of care giver burden researched in relation to patients post MUAS would help to identify areas in which the care givers may need extra support.

3. Project Aims / Objectives / Hypotheses

3.1 Project aim:

In patients who are three months post major upper abdominal surgery (MUAS) at Royal Perth Hospital in Perth Western Australia, to 1) explore functional outcomes and 2) explore the lived experience, expectations and beliefs of patients who have undergone MUAS as well as people identifying as the caregivers of patients who have undergone MUAS will be explored.

3.2 Research questions

Primary research question 1

In adults who are three months following MUAS (at RPH), is there a decrement in clinical frailty and functional independence when compared with measures collected pre-operatively?

Primary research question 2

In adults who are three months following MUAS (at RPH), do factors such as the magnitude of pain, fatigue or cognition influence functional recovery?

Primary research question 3

In adults who are three months following MUAS (at RPH), what are the lived experiences of their post-operative recovery, regarding symptoms (pain, fatigue), mood (feelings of anxiety and depression) and return to activities of daily living?

Secondary research question

In people who identify as the primary caregiver for adults who underwent MUAS, what are their lived experiences regarding care-giver burden three months following surgery?

4. Project Design

4.1 Study design

This is a pilot, mixed methods study. The quantitative aspect of the study will involve using validated questionnaires to measure frailty, independence in activities of daily living, pain, fatigue and cognition. The qualitative aspect of the study will involve explorative interviews of patients who have undergone MUAS as well as their carers to identify their lived experiences.

4.2 Participants

4.2.1 Number of participants (sample size)

Recruitment for this study will take place between November 2021 and April 2022. A convenience sample of greater than 30 participants is expected to be recruited for the quantitative aspect of the study. For the qualitative aspect of the study, patient interviews will be conducted until thematic saturation is reached. This number is likely to be much lower than the 30 recruited for the quantitative aspect.

4.2.2 Inclusion criteria

- ≥ 18 years of age.
- Fluent in written and spoken English.
- Attending RPH for MUAS, defined as an incision 5cm or longer that extends above the umbilicus and the requirement for general anaesthesia ≥ 1 hour
- Anticipated post-operative hospital length of stay ≥ 24 hours.
- The medical team deem the patient to be suitable to provide consent

4.2.3 Exclusion criteria

- Documented evidence of a cognitive impairment.
- Scheduled for an isolated hernia repair.
- From supported residential care or high-level care.
- Prior to surgery, inability to ambulate without physical assistance.
- Unable to be contacted by telephone following hospital discharge

4.3 Data Sources

- Medical records and surgical notes

4.4 Data to be Collected

With regard to the first primary research question the outcome measures that will be collected are level of functional independence and clinical frailty. The second primary research question will involve measuring outcomes related to cognition, and pain and fatigue levels. The measures are as follows:

4.4.1 Clinical frailty

Clinical frailty will be measured using the CFS (Appendix 1), a validated scale used to assess frailty and fitness in individuals²⁹. It is a 9-point scale, where a score is derived based on clinical judgement, with 1 being very fit, and 9 being terminally ill. A person with a score of 5 or above is considered frail²⁹. This will be collected at the time of consent as well as at the three month follow up call.

4.4.2 Level of functional independence with instrumental ADL

Level of functional independence will be measured using the Lawton's IADL scale (Appendix 2). The Lawton's IADL scale is a reliable and validated self-rating instrument that assesses independent living skills such as food preparation, house-keeping, and the ability to handle finances, medications and laundry^{30, 31}. The scale is a useful tool to measure deterioration/improvement in function over time³⁰. This will be collected at the time of consent as well as at the three month follow up call.

4.4.3 Pain levels

Pain levels will be measured using the NPRS (Appendix 3) post-operatively. The NPRS is an 11-point ordinal scale that measures the intensity of pain in adults³². The scale ranges from 0 to 10, with 0 representing no pain, and 10 representing the worst pain imaginable. The test-retest reliability of the NPRS has been reported to be between 0.67 and 0.96, making it a reliable tool for measuring post-operative pain in the study's participants³². This will be collected at the three month follow up call.

4.4.4 Fatigue levels

Fatigue levels will be measured using the FSS (Appendix 4). The FSS consists of 9 items, measuring fatigue severity and interference with functioning.³³ Each item is scored using a Likert-type scale ranging from 1 ("strongly disagree") to 7 ("strongly agree"). FSS total scores range from 9 to 63, with scores greater than or equal to 36 suggesting clinically elevated fatigue³³. This will be collected at the three month follow up call.

4.4.5 Cognitive state

Cognitive state will be measured using the Montreal cognitive assessment via telephone (MoCA blind) (Appendix 5). The MoCA blind is a modified version of the original MoCA with removal of the two visually presented items³⁴. This allows it to be implemented over the telephone making it feasible for this study. It is a valid and reliable instrument used to assess orientation, attention, immediate and delayed recall (memory), language and abstraction³⁵. A total score of $\geq 18 / 22$ is considered normal, and a score below $18 / 22$ is

suggestive of a cognitive impairment^{36,37}. This will be collected at the three month follow up call.

4.4.6 Patient interviews

Participants will be interviewed, and data will be collected on their experiences. Interviews will be conducted approximately three months after surgery. Interviews will be recorded and transcribed verbatim. The number of participants interviewed is dependent on when no new themes or codes emerge from the data. At this point data collection will stop and data analysis will commence.

4.4.7 Care giver interview

Caregivers will be interviewed, and data will be collected on their experiences. Interviews of carers will be conducted approximately three months after surgery. Interviews will be recorded and transcribed verbatim.

In addition to these outcome measures, patients contact details will be recorded at the time of consent. At patient discharge, the following data will be collected from the medical records: indication for why the surgery is being carried out, pathologies associated with the surgery, emergency or elective status, pre-operative haemoglobin, pre-operative pH level, pre-operative base excess, pre-operative lactate level, P-POSSOM risk score, ANZELA risk score, surgical procedure name, length of surgery, complications during hospital stay and length of hospital stay.

4.5 Method

Participants

Once written informed consent of the participant has been obtained, the physiotherapist will complete the data collection form (see Appendix 6). Details on this form include two methods of contacting the patient, the patient's Clinical Frailty Score (this is already calculated as part of routine clinical care) and the Lawton's instrumental activities of daily living (IADL) scale (see Appendix 2). Data collection forms will be stored in a secure, locked cupboard within the Physiotherapy Department of RPH. At patient discharge the remaining details of the data collection form will be completed (length of surgery, surgery procedure, complications during hospital stay, length of hospital stay) by a member of the study team.

Participants will be allocated a unique study number. The participant's name and study number will be recorded in a master log. The master log linking the participant details with the unique study number will be securely stored at WA Health (W:\ Drive) and will not be made available to Curtin University. Data will be entered into REDCap (central database) in coded format by the (site) study coordinator.

At two and a half months post discharge participants will be contacted by telephone to arrange an appropriate date and time to have their follow up interview. Participants will be offered the choice of completing the remaining questionnaires at the three month appointment (either face to face or via video call) or having paper copies of the questionnaires sent to their house along with a reply-paid self-addressed envelope.

The three month follow up appointment will collect the following data: CFS, MoCA Blind test and for participants who have chosen to carry out questionnaires via video call or in person, the Lawton's IADLs, NPRS and FSS. For participants who are willing to complete the interview as well, a

series of open-ended questions regarding their experience during recovery after MUAS will be asked. The interview is aimed to take less than 30 minutes.

The data gathered from the questionnaires that were filled in via video call will be entered directly into the REDCap system. The data from the completed questionnaires that were mailed back will be transferred into the REDCap system within 1 week to allow time for necessary follow-up where there might be missing/incomplete data. Interviews will be recorded and transcribed verbatim.

Data integrity and completeness will be optimised by making a maximum of 2 follow-up phone calls within a 2 week-period to participants with missing or incomplete data after the post-operative questionnaires have been mailed. Remaining participants with missing or incomplete data after these 2-weeks will be considered non-responders.

Caregivers

At the two and a half month phone call to the study participant, the study investigator will ask if the primary caregiver of the participant would be willing to partake in a shorter interview. Verbal consent will be recorded at this time and a written consent form will be mailed with a reply-paid envelope attached to the caregiver to obtain formal written consent. Only when written consent is obtained will any information obtained be used. If the interview is conducted face to face, a consent form can be signed in person. The interview can take place either via video call or in a face to face interview and will take approximately 15 minutes. The interview will ask caregivers about their experiences caring for someone who has undergone MUAS and any burden this placed upon them. The patient will not be present during the interview.

Guiding principles for the interviews

The interviews will focus on broad categories, informed by the literature, and comprise open-ended questions exploring functional recovery following surgery. Activities will be grouped as basic activities of daily living (e.g. eating, bathing dressing toileting, mobility and grooming) and activities that require more complex planning such as more complex activities such as meal preparation, domestic chores, paying bills and taking medication. Both perceived barriers and enablers to these tasks will be sought. A discussion will be facilitated on points of disagreement between the participants and caregiver, with clarification sought to understand the nature of these areas of discord in lived experiences. Responses from the participants and caregivers interview transcripts will be entered into NVivo10 (QSR International Pty Ltd, version 10, 2012) to facilitate data organisation, coding, and management. Data collection and analyses will be performed concurrently to monitor the emergence of new themes. Inductive thematic analysis will be used to identify codes and themes that reflected participants' perceptions and experiences. To enhance the trustworthiness of the analysis, individual data and interpretations will be independently reviewed by a second investigator experienced with thematic analysis.

4.6 Duration of Project

This project is anticipated to last one year

5. Treatment of Participants

5.1 Recruitment

Potential participants will be identified by a physiotherapist who is a member of the treating team at Royal Perth Hospital, either at the Pre-admission anaesthetic clinic or on Ward 6G (abdominal

surgery ward) prior to or following their surgery. A physiotherapist will screen for patients meeting inclusion criteria daily and consult with the medical team to ensure the potential participants are deemed capable of consent.

Participants will be approached by a physiotherapist to consent to participate in the study. Two forms of contact will be obtained at this point in order to arrange for the three month follow up interview.

At two and a half months post MUAS, the study investigator will call the participant to arrange a time to complete the questionnaires and interview. During this phone call, the study investigator will ask if the primary caregiver of the participant would be willing to partake in a shorter interview. Verbal consent of the caregiver will be recorded at this time and a written consent form will be mailed with a reply-paid envelope attached to the caregiver to obtain formal written consent. Only when written consent is obtained will any information obtained be used. If the interview is conducted face to face, a consent form can be signed in person.

6. Assessment of Safety

6.0 Safety

The risk of emotional discomfort or distress during the interviews due to re-examining feelings of pain and fatigue after surgery will be mitigated by having an established participant distress protocol (Appendix 7) with relevant contact numbers. Training the interviewers in management of situations where a participant may become distressed will also be provided by experienced researchers. If participants raise concerns relating to the surgery itself, the researcher will ask permission to contact the surgeon and arrange appropriate follow up care.

Confidentiality of data will be managed in a number of steps. Participants will be allocated a unique study number. The participant's name and study number will be recorded in a master log. All data will be 'coded' before it is entered into REDCap. This means identifiers will have been removed and replaced with a code. The master log linking the participant details with the unique study number will be securely stored at WA Health (W:\ Drive) and will not be made available to Curtin University. Data will be entered into REDCap (central database) in coded format by the (site) study coordinator. No identifiable data will leave Royal Perth Hospital.

There is minimal benefit to the participant as their experiences are being used to identify the typical challenges and experiences in the recovery following major upper abdominal surgery. However the participant will be contributing their data and experiences which will be used in the future to improve the recovery of patients recovering from major upper abdominal surgery. Participants of this study may also have positive feelings towards participating in this study as they are having their story heard and are making an impact.

7. Data Management, Statistical Analysis and Record Keeping

7.1 Statistical methods (including sample size / any planned interim analysis)

Recruitment for this study will take place between November 2021 and April, 2022. A convenience sample of greater than 30 participants is expected to be recruited for the quantitative aspect of the study. For the qualitative aspect of the study, patient interviews will be conducted until thematic saturation is reached. This number is likely to be much lower than the 30 recruited for the quantitative aspect.

7.2 Data Analysis

Descriptive statistics will be used to analyse quantitative data. Parametric data will be expressed using mean and standard deviation and non-parametric data will be expressed using median and interquartile range. Associations will be explored between measures if adequate participant numbers allow. Where there is an adequate sample size, subgroup differences will be examined. These subgroups will be based on the patient's presenting category and will likely include elective/booked admissions, trauma admissions and emergency admissions. Statistical analysis of these groups will be descriptive only due to small sample size.

Responses from the participants and caregiver's interview transcripts will be entered into NVivo10 (QSR International Pty Ltd, version 10, 2012) to facilitate data organisation, coding, and management. Data collection and analyses will be performed concurrently to monitor the emergence of new themes. Inductive thematic analysis will be used to identify codes and themes that reflect participants' perceptions and experiences. To enhance the trustworthiness of the analysis, individual data and interpretations will be independently reviewed by a second investigator experienced with thematic analysis.

7.3 Data Management

Confidentiality of data will be managed by allocating participants with a unique study number. The participant's name and study number will be recorded in a master log. All data will be 'coded' before it is released to Curtin University. This means identifiers will have been removed and replaced with a code. The master log linking the participant details with the unique study number will be securely stored at WA Health (W:\ Drive) and will not be made available to Curtin University.

Data will be entered into REDCap (central database) in coded format by the site coordinator. The Master List with participant details stored against the study ID will be kept separately at Royal Perth Hospital.

7.4 Data storage and transfer

The master log linking the participant details with the unique study number will be securely stored at WA Health (W:\ Drive). De-identified data will be entered and stored on the secure RedCap program (approved for secure data storage by both Curtin University and Royal Perth Hospital).

7.5 Data retention

All data including participant information and identifying study number will be kept securely for up to 7 years at Royal Perth Hospital before being destroyed.

8. Quality Control and Quality Assurance

8.1 Quality

Trained researchers will assist study investigators in interview techniques and will assist and monitor interviews of patients and their carers

9. Ethics

9.1 Ethics

This project focusses on interviewing patients and their caregivers three months after MUAS. Ethical considerations for this study include the time the participants will spend undertaking the questionnaires and interviews. The process has been practiced and timed and is likely to take

approximately 15 minutes for the questionnaires and less than 30 minutes for the patient interview or 15 minutes for the caregiver interview. This will be explained up front to participants.

The risk of emotional discomfort or distress during the interviews due to re-examining feelings of pain and fatigue after surgery will be mitigated by having an established patient distress protocol with relevant contact numbers (see Appendix 7). Training the interviewers in management of situations where a participant may become distressed will also be provided by experienced researchers.

Participant recruitment has the potential for the patient to feel pressured into participating in the study due to perceived feelings that the decision will influence the level of care they receive. It will be explained that their decision to partake in this study will have no impact on the level of care they receive at the hospital and partaking is completely voluntary.

Confidentiality of data will be managed in a number of steps. Participants will be allocated a unique study number. The participant's name and study number will be recorded in a master log. All data will be 'coded' before it is released to Curtin University. This means identifiers will have been removed and replaced with a code. The master log linking the participant details with the unique study number will be securely stored at WA Health (W:\ Drive) and will not be made available to Curtin University.

Data will be entered into REDCap (central database) in coded format by the (site) study coordinator. The Master List with participant details stored against the study ID will be kept separately at site. No identifiable data will leave Royal Perth Hospital.

10. Budget

	Estimated cost	Source of Funding
Questionnaire printing and posting	\$100	Curtin University School of Allied Health
Recruiting physiotherapist time	\$1050 0.5 hours x 30 participants at \$70/hour (wage plus 20% on costs)	In kind support from Physiotherapy Department, Royal Perth Bentley Group
Cost of Ethics Review	\$3500	In kind support from East Metropolitan Health Service Executive
Cost of Site Processing and Review Fee (Governance)	\$3500	In kind support from East Metropolitan Health Service Executive
Total	\$8150.00	

11. Publication

11.1 Dissemination of results

Findings of this study will be presented as a report for two Honours' theses. The findings will also be written up for publication in a scientific journal.

12. References

1. Colucci DBB, Fiore Jr JF, Paisani DM, Risso TT, Colucci M, Chiavegato LD, et al. Cough Impairment and Risk of Postoperative Pulmonary Complications After Open Upper Abdominal Surgery. *Respiratory Care*. 2015;60(5):673-678. doi:10.4187/respcare.03600
2. Boden I, Browning L, Skinner EH, Reeve J, El-Ansary D, Robertson IK, et al. The LIPPSMAck POP (Lung Infection Prevention Post Surgery - Major Abdominal - with Pre-Operative Physiotherapy) trial: study protocol for a multi-centre randomised controlled trial. *Trials*. 2015;16(1):573-573. doi:10.1186/s13063-015-1090-6
3. Toftlund SA, Gögenur I, Thygesen LC. Descriptive study of all Danish patients undergoing emergency exploratory laparotomies in the period 2003–2014. *Scandinavian Journal of Public Health*. 2020;48(3):243-249. doi:10.1177/1403494819875271
4. Boden I, Skinner EH, Browning L, Reeve J, Anderson L, Hill C, et al. Preoperative physiotherapy for the prevention of respiratory complications after upper abdominal surgery: pragmatic, double blinded, multicentre randomised controlled trial. *BMJ*. 2018;360:j5916. doi:10.1136/bmj.j5916
5. Kassahun WT, Mehdorn M, Wagner TC. The effects of reoperation on surgical outcomes following surgery for major abdominal emergencies. A retrospective cohort study. *International Journal of Surgery*. 2019;72:235-240. doi:10.1016/j.ijsu.2019.11.024
6. Moore KL, Dalley AF, Agur AMR, Taylor C, Vosburgh A, Scogna K, Ferran A, editors. *Clinically Oriented Anatomy*. 8th ed. Philadelphia, PA: Wolters Kluwer; 2018. p. 404-552.
7. Boden I, Sullivan K, Hackett C, Winzer B, Lane R, McKinnon M, et al. ICEAGE (Incidence of Complications following Emergency Abdominal surgery: Get Exercising): study protocol of a pragmatic, multicentre, randomised controlled trial testing physiotherapy for the prevention of complications and improved physical recovery after emergency abdominal surgery. *World Journal of Emergency Surgery*. 2018;13(1):1-17.
8. Fagan G, Barazanichi A, Coulter G, Leeman M, Hill AG, Eglinton TW. New Zealand and Australia emergency laparotomy mortality rates compare favourably to international outcomes: a

- systematic review. ANZ Journal of Surgery [<https://doi.org/10.1111/ans.16563>]. 2021 [cited 2021/05/08];n/a(n/a) doi:<https://doi.org/10.1111/ans.16563>
9. Tocaciu S, Thiagarajan J, Maddern GJ, Wichmann MW. Mortality after emergency abdominal surgery in a non-metropolitan Australian centre. *Aust J Rural Health*. 2018;26(6):408-415. doi:10.1111/ajr.12428
 10. Hicks CW, Canner JK, Arhuidese I, Obeid T, Black Iii JH, Malas MB, et al. Comprehensive Assessment of Factors Associated With In-Hospital Mortality After Elective Abdominal Aortic Aneurysm Repair. *JAMA Surgery*. 2016;151(9):838-845. doi:10.1001/jamasurg.2016.0782
 11. Furnes B, Storli K, Forsmo H, Karliczek A, Eide G, Pfeffer F. Risk factors for complications following introduction of radical surgery for colon cancer: a consecutive patient series. *Scandinavian Journal of Surgery*. 2019;108(2):144-151.
 12. Ho VP, Schiltz NK, Reimer AP, Madigan EA, Koroukian SM. High-Risk Comorbidity Combinations in Older Patients Undergoing Emergency General Surgery. *Journal of the American Geriatrics Society*. 2019;67(3):503-510. doi:10.1111/jgs.15682
 13. Vilches-Moraga A, Rowley M, Fox J, Khan H, Paracha A, Price A, et al. Emergency laparotomy in the older patient: factors predictive of 12-month mortality—Salford-POPS-GS. An observational study. *Aging Clinical & Experimental Research*. 2020;32(11):2367-2373. doi:10.1007/s40520-020-01578-0
 14. Parmar KL, Law J, Carter B, Hewitt J, Boyle JM, Casey P, et al. Frailty in Older Patients Undergoing Emergency Laparotomy: Results From the UK Observational Emergency Laparotomy and Frailty (ELF) Study. *Ann Surg*. 2021;273(4):709-718. doi:10.1097/sla.0000000000003402
 15. Lin H-S, Watts JN, Peel NM, Hubbard RE. Frailty and post-operative outcomes in older surgical patients: a systematic review. *BMC Geriatrics*. 2016;16(1):157. doi:10.1186/s12877-016-0329-8
 16. Bowie JM, Badiee J, Calvo RY, Sise MJ, Wessels LE, Butler WJ, et al. Outcomes after single-look trauma laparotomy: A large population-based study. *Journal of Trauma and Acute Care Surgery*. 2019;86(4) Available from: https://journals.lww.com/jtrauma/Fulltext/2019/04000/Outcomes_after_single_look_trauma_laparotomy__A.2.aspx
 17. Janssen TL, Steyerberg EW, Faes MC, Wijsman JH, Gobardhan PD, Ho GH, et al. Risk factors for postoperative delirium after elective major abdominal surgery in elderly patients: A cohort study. *International Journal of Surgery*. 2019;71:29-35. doi:10.1016/j.ijso.2019.09.011
 18. Boden I, Robertson IK, Neil A, Reeve J, Palmer AJ, Skinner EH, et al. Preoperative physiotherapy is cost-effective for preventing pulmonary complications after major abdominal surgery: a health economic analysis of a multicentre randomised trial. *Journal of Physiotherapy*. 2020;66(3):180-187.
 19. Soares SMDTP, Nucci LB. Association between early pulmonary complications after abdominal surgery and preoperative physical capacity. *Physiotherapy Theory and Practice*. 2019;1-9. doi:10.1080/09593985.2019.1650404
 20. Parry S, Denehy L, Berney S, Browning L. Clinical application of the Melbourne risk prediction tool in a high-risk upper abdominal surgical population: an observational cohort study. *Physiotherapy*. 2014;100(1):47-53. doi:10.1016/j.physio.2013.05.002
 21. Goussous N, Kemp KM, Bannon MP, Kendrick ML, Srivastyan B, Khasawneh MA, et al. Early postoperative small bowel obstruction: open vs laparoscopic. *American Journal of Surgery*. 2015;209(2):385-390. doi:10.1016/j.amjsurg.2014.07.012
 22. Mattson J, Thayer M, Mott SL, Lyons YA, Hardy-Fairbanks A, Hill EK. Multimodal perioperative pain protocol for gynecologic laparotomy is associated with reduced hospital length of stay. *Journal of Obstetrics & Gynaecology Research*. 2021;47(3):1082-1089. doi:10.1111/jog.14640
 23. Kahokehr A, Broadbent E, Wheeler BR, Sammour T, Hill AG, Kahokehr A, et al. The effect of perioperative psychological intervention on fatigue after laparoscopic cholecystectomy: a

- randomized controlled trial. *Surgical Endoscopy*. 2012;26(6):1730-1736. doi:10.1007/s00464-011-2101-7
24. Corke P. Postoperative pain management. *Australian Prescriber*. 2013;36(6):202-205.
 25. Wong C, Goh A, Merkur H. Comparison of surgical outcomes using Gyrus PKS™ vs LigaSure™ in total laparoscopic hysterectomy: A randomised controlled trial. *Australian & New Zealand Journal of Obstetrics & Gynaecology*. 2020;60(5):790-796. doi:10.1111/ajo.13217
 26. Wilkie B, Summers Z, Hiscock R, Wickramasinghe N, Warriar S, Smart P. Robotic colorectal surgery in Australia: a cohort study examining clinical outcomes and cost. *Australian Health Review*. 2019;43(5):526-530. doi:10.1071/AH18093
 27. Haines KJ, Skinner EH, Berney S. Association of postoperative pulmonary complications with delayed mobilisation following major abdominal surgery: an observational cohort study. *Physiotherapy*. 2013;99(2):119-125. doi:10.1016/j.physio.2012.05.013
 28. Strik C, van den Beukel B, van Rijckevorsel D, Stommel MWJ, ten Broek RPG, van Goor H. Risk of Pain and Gastrointestinal Complaints at 6Months After Elective Abdominal Surgery. *Journal of Pain*. 2019;20(1):38-46. doi:10.1016/j.jpain.2018.07.010
 29. Rockwood K, Theou O. Using the Clinical Frailty Scale in Allocating Scarce Health Care Resources. *Canadian Geriatrics Journal*. 2020;23(3):254-259. doi:10.5770/cgj.23.463
 30. Harper KJ, Riley V, Jacques A, MacDonald K, Spendier N. Australian modified Lawton's Instrumental Activities of Daily Living Scale contributes to diagnosing older adults with cognitive impairment. *Australasian Journal on Ageing*. 2019;38(3):199-205. doi:10.1111/ajag.12629
 31. Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. *The gerontologist*. 1969;9(3_Part_1):179-186.
 32. Riley SP, Tafuto V, Cote M, Brismée J-M, Wright A, Cook C. Reliability and relationship of the fear-avoidance beliefs questionnaire with the shoulder pain and disability index and numeric pain rating scale in patients with shoulder pain. *Physiotherapy Theory & Practice*. 2019;35(5):464-470. doi:10.1080/09593985.2018.1453004
 33. Wilson N, Wynter K, Fisher J, Bei B. Postpartum fatigue: assessing and improving the psychometric properties of the Fatigue Severity Scale. *Archives of Women's Mental Health*. 2018;21(4):471-474. doi:10.1007/s00737-018-0818-1
 34. Mace RA, Mansbach WE. Validity of Brief Cognitive Assessment Tool modifications for older adults with visual and motor limitations. *Journal of Clinical and Experimental Neuropsychology*. 2018;40(7):715-721. doi:10.1080/13803395.2017.1423041
 35. Pendlebury ST, Welch SJV, Cuthbertson FC, Mariz J, Mehta Z, Rothwell PM. Telephone assessment of cognition after transient ischemic attack and stroke: modified telephone interview of cognitive status and telephone Montreal Cognitive Assessment versus face-to-face Montreal Cognitive Assessment and neuropsychological battery. *Stroke*. 2013;44(1):227-229. doi:10.1161/STROKEAHA.112.673384
 36. Wittich W, Phillips N, Nasreddine ZS, Chertkow H. Sensitivity and Specificity of the Montreal Cognitive Assessment Modified for Individuals who are Visually Impaired. *Journal of Visual Impairment & Blindness*. 2010 [cited 2021/07/16];104(6):360-368. doi:10.1177/0145482X1010400606
 37. Effendi-Tenang I, Tan MP, Khaliddin N, Jamaluddin Ahmad M, Amir NN, Kamaruzzaman SB, et al. Vision impairment and cognitive function among urban-dwelling malaysians aged 55 years and over from the Malaysian Elders Longitudinal Research (MELoR) study. *Archives of Gerontology and Geriatrics*. 2020;90:104165. doi:https://doi.org/10.1016/j.archger.2020.104165
 38. Rockwood K, Song X, MacKnight C, Bergman H, Hogan DB, McDowell I, et al. A global clinical measure of fitness and frailty in elderly people. *Canadian Medical Association Journal*. 2005;173(5):489. doi:10.1503/cmaj.050051

39. Kahl C, Cleland JA. Visual analogue scale, numeric pain rating scale and the McGill pain Questionnaire: an overview of psychometric properties. *Physical Therapy Reviews*. 2005;10(2):123-128. doi:10.1179/108331905X55776

40. Krupp LB, LaRocca NG, Muir-Nash J, Steinberg AD. The Fatigue Severity Scale: Application to Patients With Multiple Sclerosis and Systemic Lupus Erythematosus. *Archives of Neurology*. 1989 [cited 5/21/2021];46(10):1121-1123. doi:10.1001/archneur.1989.00520460115022

Appendix 1: Clinical frailty scale: Canadian study on health and aging, revised 2008³⁸.

Clinical Frailty Scale*



1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.



2 Well – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.



3 Managing Well – People whose **medical problems are well controlled**, but are **not regularly active** beyond routine walking.



4 Vulnerable – While **not dependent** on others for daily help, often **symptoms limit activities**. A common complaint is being “slowed up”, and/or being tired during the day.



5 Mildly Frail – These people often have **more evident slowing**, and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.



6 Moderately Frail – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.



7 Severely Frail – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).



8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.



9. Terminally Ill - Approaching the end of life. This category applies to people with a **life expectancy <6 months**, who are **not otherwise evidently frail**.

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

* 1. Canadian Study on Health & Aging, Revised 2008.
2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

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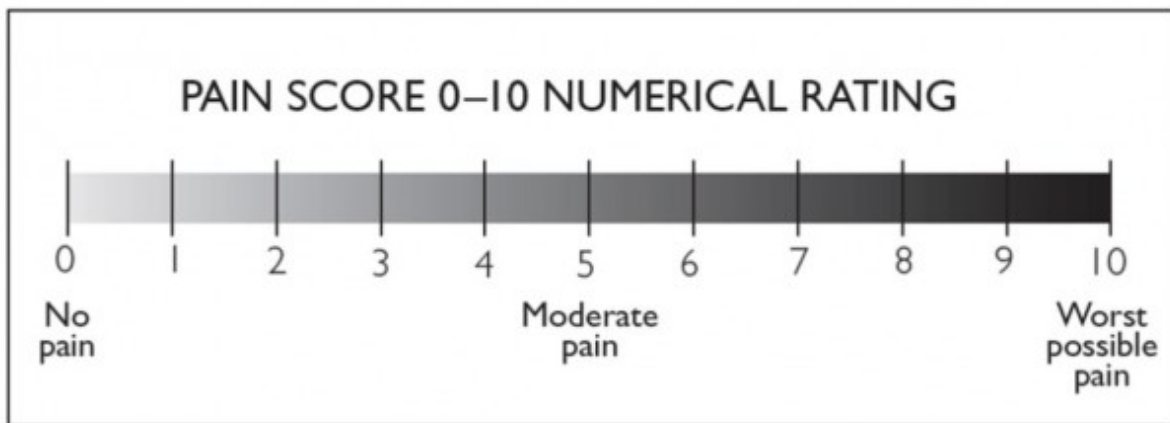
Appendix 2: The Lawton Instrumental Activities of Daily Living (IADL) Scale³¹.

Patient Name: _____ **Date:** _____

Patient ID # _____

LAWTON - BRODY INSTRUMENTAL ACTIVITIES OF DAILY LIVING SCALE (I.A.D.L.)			
Scoring: For each category, circle the item description that most closely resembles the client's highest functional level (either 0 or 1).			
A. Ability to Use Telephone		E. Laundry	
1. Operates telephone on own initiative-looks up and dials numbers, etc.	1	1. Does personal laundry completely	1
2. Dials a few well-known numbers	1	2. Launders small items-rinses stockings, etc.	1
3. Answers telephone but does not dial	1	3. All laundry must be done by others	0
4. Does not use telephone at all	0		
B. Shopping		F. Mode of Transportation	
1. Takes care of all shopping needs independently	1	1. Travels independently on public transportation or drives own car	1
2. Shops independently for small purchases	0	2. Arranges own travel via taxi, but does not otherwise use public transportation	1
3. Needs to be accompanied on any shopping trip	0	3. Travels on public transportation when accompanied by another	1
4. Completely unable to shop	0	4. Travel limited to taxi or automobile with assistance of another	0
		5. Does not travel at all	0
C. Food Preparation		G. Responsibility for Own Medications	
1. Plans, prepares and serves adequate meals independently	1	1. Is responsible for taking medication in correct dosages at correct time	1
2. Prepares adequate meals if supplied with ingredients	0	2. Takes responsibility if medication is prepared in advance in separate dosage	0
3. Heats, serves and prepares meals, or prepares meals, or prepares meals but does not maintain adequate diet	0	3. Is not capable of dispensing own medication	0
4. Needs to have meals prepared and served	0		
D. Housekeeping		H. Ability to Handle Finances	
1. Maintains house alone or with occasional assistance (e.g. "heavy work domestic help")	1	1. Manages financial matters independently (budgets, writes checks, pays rent, bills, goes to bank), collects and keeps track of income	1
2. Performs light daily tasks such as dish washing, bed making	1	2. Manages day-to-day purchases, but needs help with banking, major purchases, etc.	1
3. Performs light daily tasks but cannot maintain acceptable level of cleanliness	1	3. Incapable of handling money	0
4. Needs help with all home maintenance tasks	1		
5. Does not participate in any housekeeping tasks	0		
Score		Score	
Total score			
A summary score ranges from 0 (low function, dependent) to 8 (high function, independent) for women and 0 through 5 for men to avoid potential gender bias.			

Appendix 3: Numerical pain rating scale³⁹.



Appendix 4: Fatigue Severity Scale and the Visual Analogue Fatigue Scale⁴⁰.

FATIGUE SEVERITY SCALE (FSS)

Date _____ Name _____

Please circle the number between 1 and 7 which you feel best fits the following statements. This refers to your usual way of life within the last week. 1 indicates “strongly disagree” and 7 indicates “strongly agree.”

Read and circle a number.	Strongly Disagree	→	Strongly Agree
1. My motivation is lower when I am fatigued.	1	2	3 4 5 6 7
2. Exercise brings on my fatigue.	1	2	3 4 5 6 7
3. I am easily fatigued.	1	2	3 4 5 6 7
4. Fatigue interferes with my physical functioning.	1	2	3 4 5 6 7
5. Fatigue causes frequent problems for me.	1	2	3 4 5 6 7
6. My fatigue prevents sustained physical functioning.	1	2	3 4 5 6 7
7. Fatigue interferes with carrying out certain duties and responsibilities.	1	2	3 4 5 6 7
8. Fatigue is among my most disabling symptoms.	1	2	3 4 5 6 7
9. Fatigue interferes with my work, family, or social life.	1	2	3 4 5 6 7

VISUAL ANALOGUE FATIGUE SCALE (VAFS)

Please mark an “X” on the number line which describes your global fatigue with 0 being worst and 10 being normal.

0	1	2	3	4	5	6	7	8	9	10

Appendix 5: Montreal Cognitive Assessment/MoCA-Blind³⁵.

MONTREAL COGNITIVE ASSESSMENT / MoCA-BLIND
Version 7.1 Original Version

Name:
Education:
Sex:
Date of birth:
Date:

MEMORY		FACE	VELVET	CHURCH	DAISY	RED	POINTS
Read list of words, subject must repeat them. Do 2 trials even if 1st trial is successful. Do a recall after 5 minutes.	1st trial						No points
	2nd trial						
ATTENTION							
Read list of digits (1 digit/sec.) Subject has to repeat them in the forward order [] 2 1 8 5 4 Subject has to repeat them in the backward order [] 7 4 2							___ / 2
Read list of letters. The subject must tap with his hand at each letter A. No point if ≥ 2 errors [] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B							___ / 1
Serial 7 subtraction starting at 100 [] 93 [] 86 [] 79 [] 72 [] 65 4 or 5 correct subtractions: 3 pts, 2 or 3 correct: 2 pts, 1 correct: 1 pt, 0 correct: 0 pt							___ / 3
LANGUAGE							
Repeat: I only know that John is the one to help today. [] The cat always hid under the couch when dogs were in the room. []							___ / 2
Fluency / Name maximum number of words in one minute that begin with the letter F. [] _____ (N \geq 11 words)							___ / 1
ABSTRACTION							
Similarity between e.g. banana - orange = fruit [] train - bicycle [] watch - ruler							___ / 2
DELAYED RECALL		Has to recall words	FACE	VELVET	CHURCH	DAISY	Points for UNCUED recall only
		With no cue	[]	[]	[]	[]	
Optional		Category cue					
		Multiple choice cue					___ / 5
ORIENTATION							
[] Date [] Month [] Year [] Day [] Place [] City							___ / 6
© Z. Nasreddine MD		www.mocatest.org		Normal $\geq 18 / 22$		TOTAL	
Administered by: _____						___ / 22 Add 1 point if ≤ 12 yr edu	

Appendix 6: Data collection form

DATA COLLECTION FORM Functional outcomes in adults after major upper abdominal surgery.	Please place patient sticker here
Does the patient meet the following study criteria? Please tick the boxes that apply.	
1 Are they eighteen years of age or older?	<input type="checkbox"/>
2 Are they fluent in written and spoken English?	<input type="checkbox"/>
3 Are they attending Royal Perth Hospital for major upper abdominal surgery, defined <u>as</u> :	
- an incision \geq 5cm long that extends above the umbilicus and	<input type="checkbox"/>
- the requirement for general anaesthesia for \geq 1 hour?	<input type="checkbox"/>
- Do they have an anticipated post-operative length of stay of \geq 24 hours?	<input type="checkbox"/>
Patients with the following characteristics cannot be recruited for the study:	
<ul style="list-style-type: none">• Documented evidence of a cognitive impairment.• Scheduled for an isolated hernia repair.• From supported residential care or high-level care.• Unable to ambulate without physical assistance prior to surgery.	
Consent form signed by <u>patient</u>	<input type="checkbox"/>
Patient contact details:	
1 st mobile/phone number: _____	
2 nd mobile/phone number: _____	
Residential address: _____	
Patient clinical frailty score: _____	
Lawton IADL score: _____	

Appendix 7: Distressed participant protocol

DISTRESSED PARTICIPANT PROTOCOL

Should the participant become distressed at any time during the interview, the following protocol will be followed:

1. Terminate all questions being asked.
2. Assess the need for contacting additional services immediately:
Call **000** in an emergency if you feel someone is at risk of harm
OR for mental health emergency assessment, support and referral contact

- [Mental Health Emergency Response Line](#) (MERL)
 - Metro callers **1300 555 788**
 - Peel **1800 676 822**
 - Rural and remote areas **1800 552 002**
- Call after hours **GP Helpline (health direct)** on **1800 022 222**
- Find a **GP after hours** clinic near the patient
- Find the patients nearest [public hospital emergency department](#)

3. Ask if someone is at home or accessible to talk to the participant **or** offer to contact the participant's GP, treating specialist, or nominated person on their behalf **or** provide the participant with a number of services they can contact. Alternatively the interviewer can offer to contact the relevant services on behalf of the participant, including organising an appointment or a follow-up call from the services listed above or below.

- **Lifeline:** **13 11 14**
- **Beyond Blue:** **1300 224 636**
- **Veterans counselling service:** **1800 011 046**
- [Men's Line:](#) Dedicated service for men with relationship and family concerns:
1300 789 978

If the participant ceases the interview and is distressed, the interviewer will attempt further contact with the participant to ensure their welfare and to confirm that they have the relevant contact details for support services.

4. Document any advice given, and action taken in the comments section of the interview.