A Pilot Study Examining Feasibility of Perioperative Rehabilitation for Inguinal Hernia Repair Surgery

by

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ABSTRACT

Introduction: Despite the relative simplicity and high frequency of inguinal hernia repair (IHR) surgery, there is little research investigating pre- or post-operative exercise and education in this population. Recommendations regarding perioperative physical activity are inconsistent and largely based upon clinical opinion. We examined feasibility of recruitment and assessment methods for studying perioperative rehabilitation for IHR surgery. Baseline results allow us to better describe the pre-surgical population.

Methods: A pilot randomized controlled trial (RCT) was conducted. Patients being considered for IHR were referred from a general surgeon in Edmonton, Alberta between February to October 2022. Eligible participants completed online consent forms and surveys regarding demographics, work status, and level of pain and disability. Following this, a baseline performance-based functional assessment was completed by a masked observer, which included a Short Form Functional Capacity Evaluation (FCE) of the trunk and lower extremities.

Results: From 60 referrals we enrolled 31 participants (recruitment rate 51.67%) with a mean age of 49.4 years awaiting IHR. The primary reason for referrals opting out of the study was inability to take time from work to attend the in person assessment. One participant opted out of the study due to scheduling conflicts after expressing interest but prior to completing the consent form. Two participants did not undergo functional testing after completing the online surveys due to COVID-19 infection and new musculoskeletal injuries experienced before testing. Of those attending the performance-based functional assessment 20 out of 28 participants finished the assessment with no hernia related symptoms. Mean performance on floor-to-waist lifting was 34.5 kg (±10.5), with only 2 participants reporting hernia-related pain. Eleven participants lifted

to within 4.5kg of the test ceiling (45kg). The most problematic test for participants was an abdominal muscle endurance test, with 8 participants reporting hernia pain during this activity.

Conclusion: Adequate number of participants were recruited to our pilot study with a relatively high recruitment rate (51.7%). Most patients awaiting IHR demonstrated excellent functional ability, lifting to maximum capacity with no exacerbation of hernia symptoms. Our pilot RCT methods appear feasible however, changes to the assessment protocol are needed to avoid a potential ceiling effect with performance-based functional testing.

PREFACE

This thesis is an original work by Anna Shologan. The research project, of which this thesis is a part, received research ethics approval from the University of Alberta Health Research Ethics Board, Study Title: "A Study Evaluating the Feasibility of a Peri-Operative Rehabilitation Program for Inguinal Hernia Repair Surgery to Reduce Risk of Post-Surgical Pain"; Study ID: Pro00106451; Approval Date: March 3, 2021.

Some of the research in the Methods and Appendices sections of this thesis forms part of a collaborative effort led by Dr. Douglas Gross at the University of Alberta, with contributions from Dr. Luciana Macedo of McMaster University, Dr. Geoff Bostick and Dr. Quentin Durand-Moreau of the University of Alberta, and Dr. Omar Farooq of MH Surgery.

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INTRODUCTION

Background

Inguinal hernia repair (IHR) surgery is one of the most common surgeries performed around the globe, with an estimated 20 million procedures annually. (1) Despite the frequent occurrence of this condition and consequent surgical repair, patient outcomes for IHR need improvement; the rate of hernia recurrence following surgical repair is approximately 15% and an estimated 10-12% of patients undergoing this surgery have chronic post-surgical pain that lasts months or years. (2) Poor surgical outcomes negatively affect the individual patient who experiences pain, activity limitation, and decreased quality of life. In addition, it also results in significant socioeconomic burden on employers, insurance companies, and healthcare systems through decreased productivity, lost time at work and an increased number of appointments. The lack of quality literature investigating the effects and safety of physical activity surrounding inguinal hernia results in recommendations given to patients being variable, inconsistent, and widely based upon clinical opinion. Evidence from related procedures suggests that pre-operative exercise and education followed by post-operative rehabilitation results in better outcomes following surgery. While technologies and techniques for the procedure continue to evolve and improve there is limited research that investigates whether better surgical preparation through pre-operative exercise and education (ie. prehabilitation) followed by post-surgical rehabilitation results in improved outcomes following IHR surgery. This thesis presents preliminary results from a feasibility study to better describe the pre-surgical population and provide meaningful information to guide further research.

LITERATURE REVIEW

Defining Inguinal Hernia

Inguinal hernia (also known as groin hernia) is described as a protrusion of viscera or adipose tissue through the inguinal or femoral canal. (1) These hernias may be indirect (congenital) or direct (acquired) and may occur unilaterally or bilaterally. Occurrence of inguinal hernia is higher among men (27-43%) than women (3-6%) and most common risk factors include inheritance, gender, age, collagen metabolism, history of prostatectomy, and obesity. (2) Upon physical examination inguinal hernia is classified as reducible or non-reducible; individuals with symptomatic reducible hernia are usually encouraged to undergo an elective surgical repair where the surgeon pushes the contents back into the abdominal cavity to prevent possible strangulation of herniated tissue. (3,4) Irreducible hernia can be described as obstructed, incarcerated, gangrenous or non-gangrenous change of intestine (3) and requires emergent surgical intervention. Inguinal hernias are typically symptomatic, creating pain and discomfort for the patient and limiting them in certain activities, and the only solution is surgical treatment. (5) See Table 1 below briefly defining several common types of hernia.

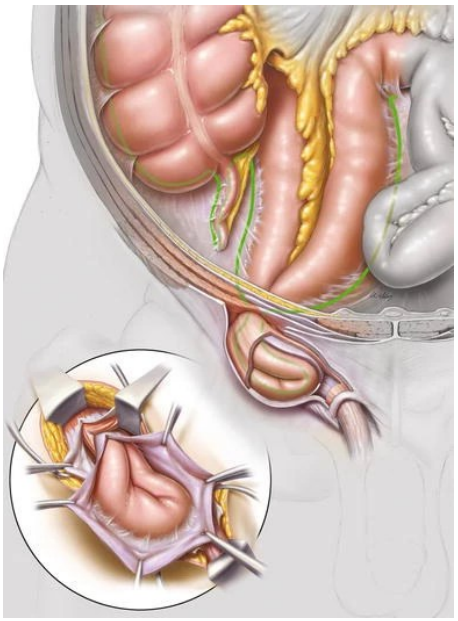

Figure 1. Superior view of an incarcerated right inguinal hernia. With permission from Springer-Verlag.(6)

Type of hernia	Definition
Inguinal	Protrusion of abdominal contents through a weak point in the fascia of the abdominal wall. More common in men and are often bilateral.
Femoral	Presents as a lump in groin in inner upper part of thigh, beneath the inguinal ligament and medially to femoral vessels. Extremely rare before

	the age of 20. More common in females than males. Much less common than inguinal hernia.
Epigastric	(Ventral hernia) Hernia of the linea alba between umbilicus and xiphoid. Incidence: 1.6-3.6% of all abdominal wall hernia. (7)
Umbilical	(Ventral hernia) Asymptomatic and presents as a bulge at umbilicus. Occurs in 10% of all infants, infantile types less than 1cm in diameter close spontaneously by 5 years of age.
Incisional	(Ventral hernia). Development of hernia at incision following abdominal surgery.
Hiatus	(Internal hernia) Abdominal contents are through the esophageal hiatus of the diaphragm.

Table 1. Briefly defining common types of hernia. (3)

Surgical techniques for repair vary widely and are largely dependent on the setting and resources available. (2) Advances in technology such as the use of synthetic mesh as a barrier to strengthen the abdominal wall and techniques like minimally invasive laparo-endoscopic surgery has greatly improved IHR surgery (8); patients do not require long hospital stays, are typically treated via day surgery, and surgeons can perform multiple repairs in one day. Despite the relative simplicity of the procedure, significant implications are present for patients and the healthcare systems that support them. Along with the discomfort of symptoms associated with inguinal hernia, undergoing a surgical procedure may cause anxiety and stress, which are contributing risk factors in predicting chronic post-surgical pain. (9) Patients also must often account for lost time from work which may in turn create considerable costs for employers and insurance companies. Because IHR surgery is so common, even modest improvements in clinical outcomes could hold significant impact for a large number of people. (10)

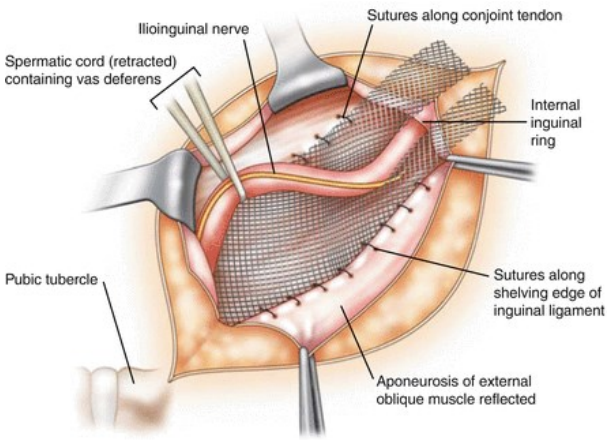

Figure 2. Simplified surgical anatomy during open mesh repair of inguinal herniorrhaphy. With permission from SpringerNature. (4)

There are multiple studies that examine the risk factors and occurrence of chronic pain following IHR surgery. (10-14) The International Association for the Study of Pain describes chronic pain as pain that persists beyond 3 months after the initiating event and is not uncommon following a variety of surgical procedures including spinal surgery, hysterectomy, arthroplasty, thoracotomy, amputation, breast surgery, and herniotomy. (11) Evidence shows that occurrence of chronic pain following IHR is more common after open mesh repair compared to laparoscopic repair. (12) Risk factors for chronic post-surgical pain following IHR include but are not limited to younger age, female gender, bilateral IHR, higher rated pre-operative pain, pre-operative anxiety, prior IHR, and high intensity of acute pain reported at 1 week post-operatively. (12, 13)

Prehabilitation and Rehabilitation

Evidence from related procedures indicates that better surgical preparation through pre-operative exercise and education (prehabilitation) followed by ongoing post-surgical rehabilitation leads to more rapid recovery, return to activity, and lower likelihood of persistent post-surgical pain. This combination of prehabilitation and post-operative rehabilitation is termed perioperative rehabilitation. Reddy et al. (15) showed that patients awaiting abdominal surgery who were able to complete a task of stair climbing faster experienced less perioperative complications, demonstrating that improved physical conditioning

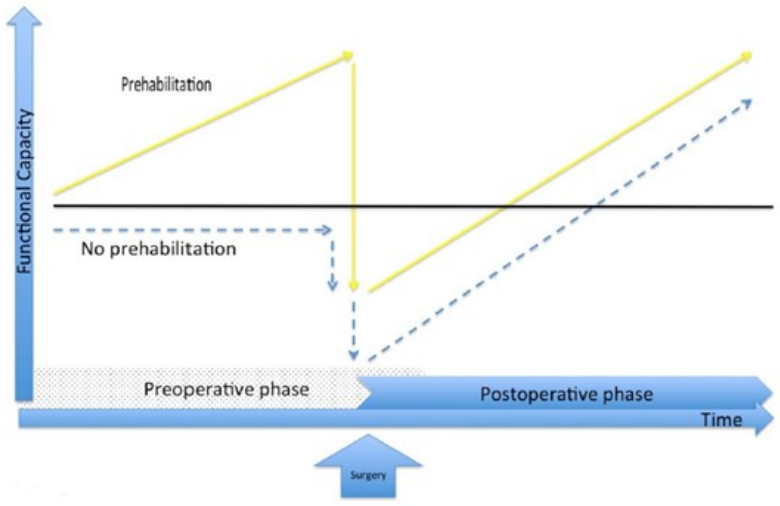

Figure 3. A modified version of the underlying theoretical model of prehabilitation, as suggested by Topp et al. (16) and Ditmyer et al. (17)

prior to surgery resulted in better surgical outcomes. Figure 3 illustrates the theoretical model of prehabilitation promoted by Topp et al. (16) and Ditmyer et al. (17) that proposes patients who participate in presurgical exercise with the goal of improving functional capacity may experience more rapid postoperative recovery than patients who are physically inactive during the preoperative period. (18)

The positive effects of physical activity on the muscular and cardiovascular systems following periods of inactivity have been well researched; exercise and education is commonly recommended for patients undergoing surgeries such as orthopedic and cardiovascular procedures so they may safely return to regular activity. (17) Current clinical guidelines for return to work and activity after inguinal hernia repair are inconsistently informed by evidence, highly variable, and outdated, with typical practice guidelines often recommending limiting activity for at least 3 months to avoid re-rupture. (19) However, these guidelines are based on clinical opinion due to lack of quality research and can pose a risk in building unhelpful beliefs about pain, fear of movement, and poor coping strategies. (20) This raises the question of whether perioperative rehabilitation would improve physical capacity prior to undergoing surgical intervention and as a result improve outcomes following IHR.

Recent Literature

There is little research investigating how IHR surgery may benefit from perioperative rehabilitation, and what few studies exist have limitations.

Liang et al. (21) was the first randomized controlled trial (RCT) examining the effects of prehabilitation in 118 patients undergoing ventral hernia repair. They found that patients who underwent pre-operative physical conditioning and weight loss programs were more likely to be hernia free and complication free following surgery (69.5% vs 47.5%). Prehabilitation however

was also associated with risks such as higher rate of dropout and higher need for emergent repair. The possible increased risk of pre-operative patients requiring emergent care requires further investigation, as the four patients (out of 118) who required emergent repair all belonged to the intervention group (though it should also be noted that these four individuals also all had recurrent ventral hernias). This safety concern must be examined for further development of clear guidelines for safe exercise prior to hernia repair surgery. A major limitation of this study was that the sample consisted of patients with obesity and weight loss was the primary presurgical goal for the intervention group. As such, the length of prehabilitation was non-standardized, ranging between 1 to 6 months, making it difficult to extrapolate specific protocol recommendations.

A case study by Pesanelli et al. (22) outlined the process of an individual participating in a post-operative occupational rehabilitation program following IHR surgery. The individual chosen for this study was meant to be non-exceptional and to typify many patients commonly seen for this procedure. Using an occupational rehabilitation approach the patient was able to return to his job as a baggage service attendant for a major airline only 22 days post-operatively, carrying up to 70lbs with no symptoms. This return to activity is far sooner than current guidelines typically recommend, with common recommendations having patients lift no more than 10lbs for 6 weeks following surgery. (20) However, as this was a case study done on one patient, the predominant question remains whether the results seen are applicable to a wider population of patients undergoing IHR. This study does well to outline the economic implications that improving outcomes could yield but was completed nearly twenty years ago and replication and expansion on a larger scale has yet to be completed.

There is limited good quality research investigating the effects of pre- and post-operative exercise and education on IHR outcomes. Santilli et al. (23) claimed that non-athlete patients who underwent a sports rehabilitation program following laparoscopic IHR were able to return to activity sooner than patients who did not undergo rehabilitation. This study has several shortcomings which makes the validity of results questionable. A description of the included population, intervention, control, outcome measures, randomization, and level of blinding were all inadequate, if included at all. No information was presented regarding what type of facility the procedures were performed in, or where the interventions were completed, and no information was provided regarding the control group and what the intervention was compared to. While return to work status was a key outcome listed, there was no indication of employment status of the patients, and although patients were listed as being followed for up to 2 years post-operatively, there is reporting bias with results only presented for up to 10 days post-operatively. No mention is made of patient drop-out and the few post-operative complications that are recorded were not specified as belonging to the control or intervention group. While it is encouraging to see the use of a structured rehabilitation program being used post-operatively following IHR, the study quality was poor so accurate conclusions are hard to draw.

Reviews investigating the use of perioperative rehabilitation for individuals undergoing IHR are also limited. A recent review by Perez et al. (24) compared similarities between ventral hernia repair and more common musculoskeletal tendon repair. It reported how the concepts of prehabilitation and rehabilitation used commonly for tendon repairs can be applied to ventral hernia repair. This theoretical article outlines the similarities in composition of structures affected during surgical intervention, as well as key concepts in physical therapy following common orthopedic repairs and how they have evolved over time. Very few other reviews look

this closely at the use of prehabilitation and rehabilitation for IHR surgery, however the Perez review remains conceptual and based largely on analogy. Mercier et al. (25) retrospectively studied the rates of readmission within 30 days following groin hernia repair and found that post-operative rehabilitation may be a protective factor against readmission. However little information is available as to what type of rehabilitation was performed, and only a small percentage of patients (1.4%) were reported to have received post-operative rehabilitation. A review led by Knapp et al. (26) described the modifiable factors that can be optimized prior to abdominal wall reconstruction to improve surgical outcomes. Improving physical stamina was one of the top factors identified. This review identified many modifiable factors that when improved upon not only keep patients safer during surgery but also improve outcomes afterwards. However, despite a promising title, conditioning and prehabilitation programs were not described in detail and the review focused more closely on weight loss counselling, glycemic control, and dietary factors.

There is some evidence from related procedures that investigated the effect of perioperative rehabilitation following abdominal surgeries. A retrospective analysis run over five years from 275 patients of one surgeon in Texas investigated the value of a post-operative rehabilitation program following complex abdominal wall reconstruction. Results indicated that 137 patients who received abdominal wall rehabilitation showed decreased rates of hernia recurrence compared to the 138 patients who did not receive rehabilitation. (27) It should be noted however that these patients had all undergone previous intra-abdominal operations and herniorrhaphies and were now having complex reconstruction. (27) The protocol for exercises and rehabilitation following surgery focused primarily on strengthening and was well outlined and replicable. Similarly, a randomized blinded controlled trial by Barberan-Garcia et al. (28)

examined the use of personalized prehabilitation in 125 high-risk patients undergoing elective major abdominal surgery. They found that the 62 patients in the intervention group experienced fewer post-operative complications than the 63 patients in the control group who received usual care. Interestingly, the goal for the intervention group in this study was to increase aerobic capacity prior to surgery and when comparing these two studies from related procedures it can be inferred that a general increase in physical capacity and resilience likely improves outcomes during and following abdominal surgery.

Problem Statement

Recommendations regarding physical activity surrounding IHR surgery are inconsistent and largely based upon clinical opinion. This is due to an overall lack of literature examining activity surrounding inguinal hernia, and whether exercise and education through perioperative rehabilitation for IHR surgery would be beneficial in improving patient outcomes. The little evidence available is promising, however the overarching recommendation is clear: further study is needed. Given the high frequency of this surgery around the globe, improving outcomes could not only benefit millions of patients but also hold significant socioeconomic implications through earlier return to work. Evidence from our pilot study will be used to justify further investigation on a larger scale, better inform clinical recommendations given to patients regarding physical activity and improve outcomes following IHR surgery.

Research Purpose

The purpose of this pilot project is to determine the feasibility of study methods and protocols providing perioperative rehabilitation to patients undergoing IHR surgery, to inform a larger RCT in the future. This master's thesis examines the initial pre-surgical stages of the pilot

project including feasibility and clinical utility of participant recruitment and baseline data collection protocols.

RESEARCH QUESTION

Research Question: Is a study evaluating a perioperative rehabilitation program for patients undergoing IHR surgery feasible in terms of recruitment rate, assessment, and protocol implementation?

Research Hypotheses: We hypothesize that we will: 1) enrol adequate numbers and meet 50% recruitment rate to meet criteria to proceed with the study's outlined protocol, and 2) that our assessment and exercise protocols will be safe, provide meaningful information to guide further research, and help inform clinical recommendations given to patients undergoing IHR. See Appendix A: "Feasibility and Acceptability Criteria".

RESEARCH METHODS

Research methods for the entire pilot study are outlined to provide an accurate representation of the pilot study, however the timeline of this feasibility study was influenced by external factors including the COVID-19 pandemic and resulting surgical delays through Alberta Health Services. Due to the time constraints of a master's degree program, this thesis presents the preliminary results of baseline data collection and clinical testing to better describe the pre-surgical population.

Design: We conducted a pilot randomized controlled trial (RCT). This pilot project included the development and testing of a specific exercise and education program, tailored to each patient's individual needs, and conducted before and after the IHR surgery, to reduce likelihood of chronic post-surgical pain while doing minimal harm. This master's thesis examines the recruitment, baseline data collection, and assessment phase of the pilot study.

Sample: We enrolled patients referred to general surgery for elective IHR within Alberta Health Services. Patients were directed to our study by one surgeon who is a participating member of the research team. Patients meeting the inclusion criteria were randomized via Research Electronic Data Capture (REDCap) to either undergo 6 weeks of prehabilitation exercises + post-surgical follow-up or else usual care with education provided by the research team.

Inclusion criteria included:

1) Scheduled to undergo first-time IHR surgery after a physical examination identified signs and symptoms consistent with inguinal hernia (direct or indirect hernia).
2) Willingness to participate in a 6-week targeted exercise program.
3) 18+ years of age.
4) No medical contraindications to participation in exercise: this included uncontrolled medical conditions such as diabetes, hypertension, vertigo, congestive heart failure, chronic obstructive pulmonary disease, intra-abdominal ascites, or pre-existing malnutrition.
5) Employed full-time and required to lift at least 10kg (22lb) at work.

Exclusion criteria included:

1) Recurrent hernia.

2) Body Mass Index >35.0 since morbidly obese patients experience more surgical complications. (26)
3) Use of narcotics.
4) Poorly controlled bone and joint conditions of the spine or extremities.
5) History of other abdominal surgeries that have resulted in a permanent lifting restriction.

Sample Size: Since this is a pilot study evaluating feasibility of our intervention and evaluation protocols, we aimed to enrol 30 patients and randomize 15 to both the intervention and control groups. This sample size has been found to often provide adequate feedback for feasibility criteria to determine whether it is advisable to pursue ongoing study. (29)

Data Collection Procedures: See Appendix B for activities and timing of data collection as outlined in "Perioperative Rehabilitation Activity and Data Collection Protocol for Inguinal Hernia". We enrolled patients undergoing first time IHR surgery. Participation was voluntary, and patients were informed of the study at least 8 weeks before their surgery. Once scheduled and enrolled (i.e. consent obtained), patients were randomized by a research team member using a random sequence generator within REDCap. Baseline testing included an assessment done by a physical therapist and modified Short Form Functional Capacity Evaluation for trunk and lower extremities. An abdominal endurance test (horizontal plank test) and 30 second sit to stand test were added to the protocol to evaluate possible symptoms during abdominal muscle activation and repetitive standing. See Appendix C for Functional Testing form used. Following baseline assessment participants in the intervention group then received perioperative exercise instruction from a clinical exercise physiologist (CEP). Participants in both groups received educational videos regarding pain self-management and expectations surrounding the surgical and recovery

process, while those in the intervention group received additional education regarding pre- and post-operative exercise guidelines; see Appendix D for web links to educational videos. Three weeks after surgery, participants in the intervention group are gradually progressed through post-operative exercises and modifications are made as needed. The exercises avoid all contraindications in the acute post-surgical period, including no lifting >10kg for the first 4 weeks. The study has not impacted scheduling of surgery or typical procedures.

COVID-19 Implications: Since IHR operations continued to be conducted despite the pandemic and physiotherapy clinics were operative following public health recommendations, this study was conducted within the typical clinical care pathway. All interventions have been conducted in accordance with the current COVID-19 specific requirements from Public Health and University of Alberta authorities. In person interactions were kept to a minimum, during which masks were worn and all exercise and testing equipment sterilized after every use. All surveys and follow-up visits between evaluations were conducted online and education was delivered through online videos.

Blinding: To minimize observer bias the physical therapist conducting performance-based functional testing was blinded to which group participants were randomized into. Participants were not informed which treatment group they were randomized into until baseline functional testing was complete. Blinding participants to which treatment group they are in is not possible in this study, with the primary intervention obviously being exercise. This results in risk of performance bias being a factor in this study.

Protocol Design: Performance-based functional testing was developed primarily from a Short Form Functional Capacity Evaluation (FCE) for testing trunk injuries which has been shown to

provide effective information for injuries of these areas compared to a full FCE. (30) Items chosen included a 15-minute stand, floor-to-waist lift, 1-minute crouch, 2-minute sustained forward flexion, and 5-minute repetitive trunk rotation. An abdominal endurance test (horizontal plank test) and 30 second sit-to-stand test were added to the assessment protocol to evaluate possible hernia symptoms during abdominal muscle activation and repetitive standing. The abdominal endurance test has been shown to be a reliable tool to evaluate abdominal muscle fatigue (31), and the 30 second sit-to-stand test is commonly used by rehabilitation professionals as a valid indicator of lower extremity strength. (32)

The exercise protocol was developed with consideration for what exercises would be safe for this patient population while providing maximum benefit for their condition, while being simple to implement and easy for patients to learn. Exercises chosen included diaphragmatic breathing, abdominal bracing (transverse abdominis activation), bridging, dead-bugs, bird-dogs, push-ups, chair squats, and floor-to-waist lifting. These exercises were all easily modifiable to make them more challenging for participants if needed, or less challenging for following surgery. See Appendix E: “Perioperative Rehabilitation Protocol for Inguinal Hernia Repair” for a detailed outline of exercise protocol implementation.

Emphasis was placed during instruction on proper breathing techniques to use while performing the exercises to avoid Valsalva maneuver and maintain safe intrathoracic pressure. (19) Goals for prehabilitation were primarily improving neuromuscular control as morphological changes are not typically seen within a six-week period. (33) Neuromuscular adaptations within this early training period often result in improved physical performance due to changes in coordination and improved muscle recruitment and activation during specific tasks. (33)

Intervention Description: The perioperative rehabilitation protocol was developed by our research team after reviewing available literature. The protocol included an established set of structured exercises aimed at core strengthening in pre- and post-operative stages. We followed a traditional occupational rehabilitation approach, focusing exercise training on activities that the patient was expected to experience difficulty with due to the hernia. The program was delivered in person by an experienced CEP and follow-ups were conducted virtually.

Education was provided in person by the surgeon and the study team, as well as through YouTube videos that provide more standardized information. Educational videos were created by study team members based on available best practice guidelines related to IHR surgery as well as pain education. Education provided includes basic information about inguinal hernia and the surgical repair technique, what to expect in the days and weeks following surgery, advice for post-operative recovery, importance of activity and exercise to recovery, pain coping strategies and techniques for reducing risk of hernia recurrence. (See Appendix D for web links to educational videos).

Measures: Following initial contact, enrollment, and consent, baseline descriptive data were collected. Descriptive data regarding demographics, work status, pain levels, and quality of life were collected via online surveys delivered through REDCap. Baseline surveys administered included Demographics and Work Status Questionnaires, Numerical Pain Scales, the Pain Disability Index, and the Short Form-12 (SF-12) Health Survey. See Appendix E: Perioperative Rehabilitation Activity and Data Collection Protocol for Inguinal Hernia Repair.

Descriptive characteristics of particular interest were age, sex, ethnicity, BMI, regular exerciser, active smoker, and job demands. Regular exercise was defined as ≥ 150 minutes per week of moderate to vigorous physical activity as outlined by the Canadian Society for Exercise

Physiology guidelines. (34) Questionnaires such as the Pain Disability Index and SF-12 Health Survey are easy to administer and comprehend, and provide reliable data that corresponds before and after surgery (35, 36), while the Carolina's Comfort Scale was added post-operatively to measure symptoms related directly to IHR. (8)

In addition to demographic and occupational information, we collected feasibility and clinical outcomes. Feasibility outcomes are:

1) Recruitment rate expressed as the average number of patients referred to the study and the number of participants enrolled in the program was greater than 50%.
2) Acceptability and compliance with study questionnaires.
3) Acceptability of functional testing protocol.

See Appendix A: "Feasibility and Acceptability Criteria" for full study feasibility outcomes outlined in detail for ethics and funding.

Clinical outcomes were collected at baseline, following six weeks of exercise and/or education, and 12-weeks post-surgical IHR by a researcher not involved in the delivery of the intervention. See Appendix C for the functional testing protocol, "Inguinal Hernia Perioperative Study Work-Related Functional Testing".

Ethics, Safety, and Adverse Effects: Ethics approval was obtained through the University of Alberta's Health Research Ethics Board on March 3, 2021, Study ID: Pro00106451. See Appendix F for Ethics approval form. Consent to contact was required prior to initial contact by the research team (see Appendix G), and full consent was required prior to participants being randomized (see Appendix H). During in-person clinical assessment, floor to waist lifting was given a ceiling of 45kg, heart rate was monitored to remain below 80% of estimated Heart Rate

max, biomechanics monitored for breakdown, and patients recommended to terminate the task if their hernia pain rating exceeded a 6/10.

At the virtual weekly sessions for participants in the intervention group, participants were asked about both exercise completion as well as any symptoms or adverse events experienced; these are documented. Severe complications (i.e. new severe pain, unexplained symptoms, etc.) were referred to the surgeon and any complications severe enough to warrant referral to the surgeon or ultrasound imaging were tracked.

Since the prehabilitation program involves physical exercise by the participants, there is an inherent element of physical risk. This was explained to participants to possibly involve fatigue, tiredness, physical stress or injury, or other related complications. The prehabilitation program was in addition to individual's usual activity. With exercise, possible complications could arise before the operation is performed or after surgery. Prior to surgery, the patient may experience more pain in the hernia site as well as normal pain associated with exercise, they may notice worsening of the size of the hernia, and there is a very small chance of hernia incarceration (i.e. typically occurs in less than 1% (0.18% to 0.79%) of hernia cases). Increased symptoms were monitored, and exercises modified if the symptoms become intolerable to the participant. Exercise prior to surgery requires mental concentration and participants may feel psychologically or emotionally stressed or fatigued. Since participants are in a research study, there is always some risk of social risk through loss of privacy. To minimize risk and mitigate harm, the exercise program was monitored by an experienced CEP who tracked patient progress. Since the exercise program is overall low intensity exercise, we did not anticipate many injuries or adverse events. However, if patients began to experience adverse events (AE) such as symptoms or minor injury, the therapist provided advice on alterations to make the exercises less

intensive or recommended that the program be stopped. The therapist was also available should more serious adverse events (SAE) have occurred such as suspected hernia incarceration requiring emergent surgical repair. If this was to occur, the therapist would initiate follow-up with the surgeon or advise the patient on when to seek immediate medical attention.

Statistical Analysis: We used REDCap to administer consent, collect descriptive data, and collect baseline data regarding pain and quality of life. Raw data were stored in REDCap and then exported to MS Excel. Basic descriptive statistics from surveys and questionnaires are also generated by REDCap.

Data for this thesis was analyzed once recruitment and baseline assessment were complete. Data from functional assessments were entered into REDCap by a member of the research team, however extra information recorded by the assessor on testing forms was also included in the MS Excel database. Descriptive statistics (mean, standard deviations or number, proportion) from baseline functional testing were generated by MS Excel using the Analysis ToolPak Add-in to summarize characteristics of this patient population. No statistical testing was completed as this was a pilot study of feasibility only.

RESULTS

Feasibility Data

Inclusion criteria were expanded to allow for 4 referrals who were not necessarily employed full time, but were otherwise active, healthy, and willing to participate in the study. Exclusion criteria also required modification during the recruitment process, as during the early phases of the study the participating surgeon pointed out that excluding individuals who had any

previous abdominal surgeries would have had a significant effect on the referrals. Referrals were then screened for any previous surgeries that resulted in a permanent lifting restriction.

We received 60 referrals of patients referred to a surgeon to undergo elective IHR surgery. Of these 60 individuals, 31 were enrolled in the study (recruitment rate: 51.7%). Reasons for declining enrollment in the study included scheduling conflicts due to work and the inability to take time off to attend baseline assessment (18.3%), no response (15.0%), incomplete consent to contact forms (6.7%), had already had the surgery (3.3%), were having the surgery too soon (1.7%), were having the surgery too far in the future (1.7%), and personal emergency (1.7%).

Cancellations and rescheduling of baseline assessments was not uncommon. Of 30 participants who agreed and were scheduled to come for assessment 8 appointments were cancelled and rescheduled due to reasons including inclement weather and road conditions, no shows, work, new musculoskeletal injury, and COVID-19 infection.

Consent and baseline information regarding demographics, work status, pain levels, and quality of life were collected for 30 participants. One participant dropped out of the study due to work commitments after being enrolled in REDCap and prior to completing informed consent and baseline surveys. Twenty-eight participants completed baseline assessment and functional testing. Two participants were unable to complete the baseline assessment, 1 due to COVID-19 infection and 1 due to new musculoskeletal injury.

Participants were randomly assigned to either the control or intervention group by REDCap: 14 participants (46.7%) were assigned to the intervention group and 16 (53.3%) were assigned to the control group. The 2 participants who dropped out prior to baseline assessment

had both been randomized to the control group. See Figure 4 below for a flowchart illustrating participant recruitment.

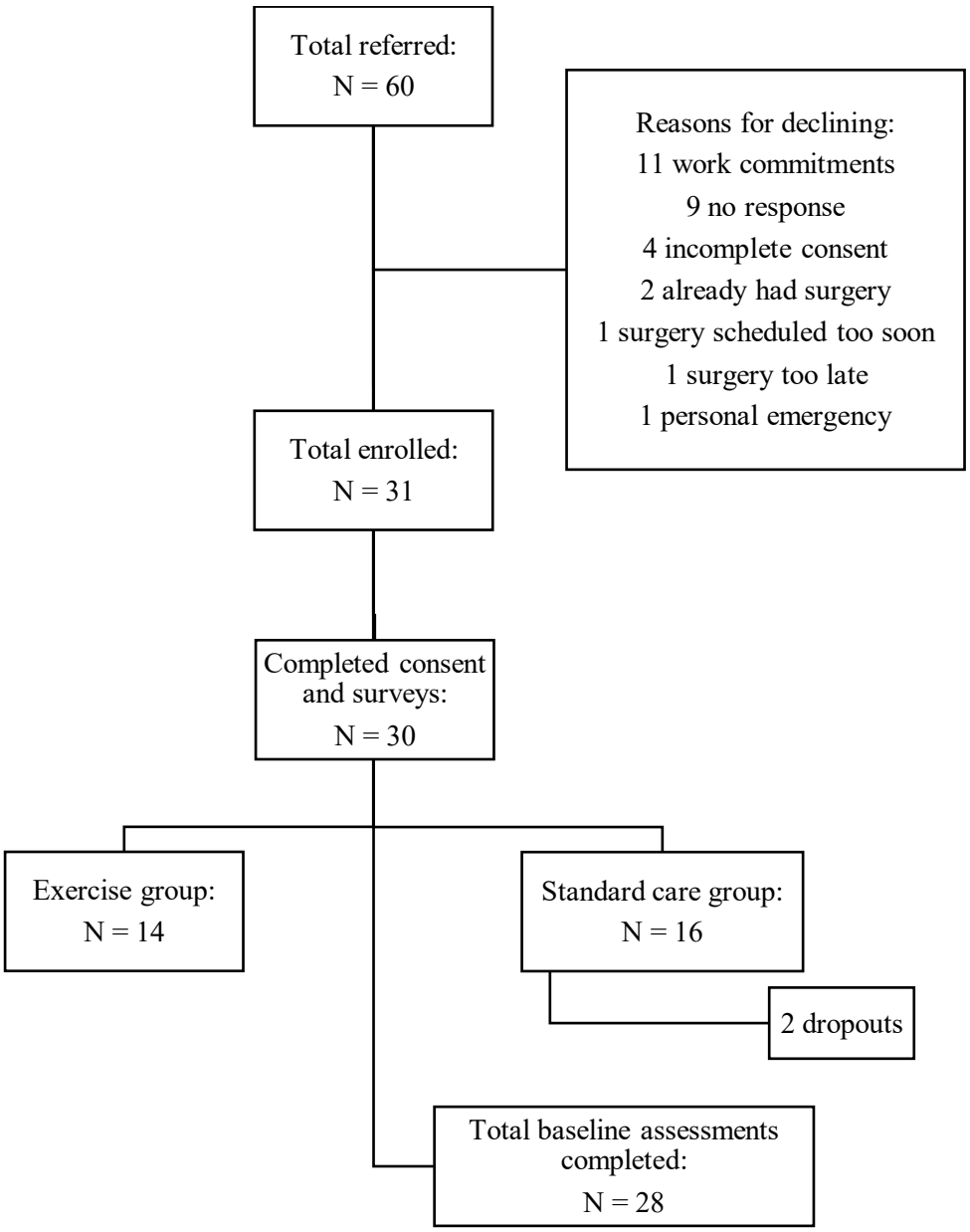

Figure 4. Flowchart illustrating participant recruitment.

Descriptive Data

Mean age was 49.4 years (SD ± 11.6), mean duration of hernia was 72.8 weeks (SD ± 141.8), and 44.3% described themselves as regular exercisers. Participants were generally healthy with minimal co-existing medical conditions; any co-existing conditions were well-controlled. Inclusion criteria were expanded to accommodate 4 referrals who were seasonally employed, employed part time, or currently seeking employment; these individuals were otherwise active and healthy. See Table 2 below for descriptive statistics regarding baseline information.

Table 2: Baseline Information

Characteristic	**Total N = 30**	**Median, Range**
Age* (years)	49.4 (±11.6)	51.0, 47.0
Sex, no. (%)		
Male	25 (83.3%)	
Female	5 (16.7%)	
BMI*	26.1(±3.7)	26.0, 16.0
Ethnicity‡, no. (%)		
Canadian	19 (67.9%)	
Indigenous	2 (7.1%)	
American	2 (7.1%)	
European - western	2 (7.1%)	
European - southern	1 (3.6%)	
Asian - south	1 (3.6%)	

South and central American	1 (3.6%)	
Duration of hernia‡* (weeks)	72.8 (±141.8)	30.0, 729.0
Regular exerciser, no. (%)	13 (43.3%)	
Active smoker, no. (%)	9 (30.0%)	
Job demands‡, no. (%)		
Light/Sedentary	10 (35.7%)	
Medium	10 (35.2%)	
Heavy	5 (17.9%)	
Very Heavy	3 (10.7%)	
Avg. pain in past week* (/10)	2.4 (±1.8)	1.5, 5.0
Avg. pain in past 24hr* (/10)	1.8 (±1.6)	1.0, 6.0
Worst pain in past 24hr* (/10)	2.3 (±2.0)	2.0, 7.0
Pain Disability Index rating* (/70)	15.6 (±11.8)	15.5, 44.0
SF-12 Health Survey[a]*		
PCS-12 (Physical Score)	43.2 (±9.3)	41.8, 32.0
MCS-12 (Mental Score)	53.0 (±9.9)	55.1, 41.3

***Mean [± standard deviation (SD)].**

‡ Missing: N = 2.

[a]Missing: N=1.

Table 2. Baseline information.

Clinical Data

Of the 31 individuals enrolled in the study, 28 completed baseline assessment and functional testing. Three participants wore a hernia belt during baseline testing. One participant had an active claim with the Workers' Compensation Board of Alberta as a result of his hernia that assigned him a lifting restriction of no greater than 30 lbs prior to surgery, which was respected by the research team. Mean weight lifted during the floor to waist lift was 34.5kg (±10.5); 11 participants (39.3% of baseline assessments) reached at or within 4.5kg of the study-implemented test ceiling (45kg). Only 2 participants reported mild hernia symptoms during the floor-to-waist lift. Mean pain rating of all participants' pain during the floor to waist lift was 0.2 (± 0.7) on a 0-10 numerical pain scale. One participant was unable to complete the 5-minute rotation task due to hernia pain. The most problematic task was the abdominal endurance test, with 8 participants reporting hernia pain during this task. Twenty participants (71.4%) completed baseline functional testing with no hernia pain. See Table 3 below for results of baseline functional testing.

Table 3: Results of Baseline Testing

Task	**Total N = 28**	**Median, Range**
Floor to waist weight lifted* (kg)	34.5 (±10.5)	35.5, 75.0
Pain rated on floor to waist lift* (/10)	0.2 (±0.7)	0.0, 3.0
15 minute stand* (minutes)	15.0 (±0.0)	15.0, 0.0
1 minute crouch* (seconds)	60.0 (±0.0)	60.0, 0.0
5 minute rotation* (seconds)	292.2 (±41.2)	300.0, 218.0
2 minute forward bend* (seconds)	120.0 (±0.0)	120.0, 0.0

Abdominal endurance test* (seconds)	93.6 (±61.9)	83.0, 292.0
Pain rated during abdominal endurance test* (/10)	0.9 (±1.6)	0.0, 5.0
Sit to stand* (# of repetitions)	14.1 (±3.1)	13.0, 0.0
Pain following testing* (/10)	0.9 (±1.7)	0.0, 6.0

***Mean [± standard deviation (SD)]**

Table 3. Results of baseline testing.

DISCUSSION

When asked "how does one assess the functional capacity of a patient with inguinal hernia?" our research team had little to work from when designing the assessment protocol for this pilot study. The baseline data presented shows that while adequate numbers were enrolled and assessed in this pilot study, our assessment protocol likely did not adequately capture functional capacity of enrolled participants and may require amendment in further study.

Recruitment Feasibility

With a recruitment rate of 51.7% this study met criteria to proceed with the full study as outlined in Appendix A. Feasibility was complicated by the COVID-19 pandemic, with health and safety guidelines fluctuating and cancellations due to illness. With the pandemic also affecting many people's workplaces, we experienced some difficulty with recruitment due to individual's inability to take time off to attend assessments in-person. Including full time work as part of inclusion criteria became challenging as individuals were unable to commit to assessment due to work commitments, only working seasonally or part time, or recent retirements of the age group assessed.

Feasibility of Assessment Protocol

Minimal hernia pain was reported during baseline testing. Interestingly, the floor-to-waist lift – a common activity that many patients with inguinal hernia are advised by their primary care providers to avoid loading – produced minimal symptoms. Only 2 participants reported mild discomfort during floor to waist lifting. Both participants who reported hernia pain during floor-to-waist lifting were female and lifted less than most of the other participants in the study, aligning with known risk factors for chronic pain that include female gender. (12, 13) None of the 11 participants that reached within 4.5kg of the floor-to-waist lift ceiling reported hernia symptoms during the task, suggesting that overall strength and practice of safe lifting techniques may even be protective against pain for these patients. The test that was most likely to produce hernia symptoms was the abdominal endurance test. This indicates that a traditional Functional Capacity Evaluation used in many traditional workplace rehabilitative settings may not be a valid measurement of this patient population's physical work limitations. Twenty participants (71.4% of baseline assessments) completed baseline functional testing with no hernia related pain. Average pain rating following testing was 0.9/10 (±1.7) compared to patients' average pain in the past week being reported at 2.4/10 (±1.8), showing that in a symptomatic population our testing did not recreate acute hernia symptoms. This generates the question of what tasks is it that this patient population struggles with and how do we best measure limitations?

While a more accurate conclusion will be drawn once the study has completed, from examining the results of baseline clinical data we must ask if the functional assessment portion of this study is a valid reflection of physical limitations experienced by this patient population. With most participants completing baseline assessment and functional testing with no exacerbation of hernia symptoms one can argue that a ceiling effect may be seen in this

assessment and adjustments should be made to the assessment protocol when going forward to a larger study.

Risk of Bias

The possibility of selection bias was high due to working with one surgeon who was involved in the study design and responsible for all patient referrals to the study. It is possible that rather than telling every patient with hernia seen by the surgeon about the study, that only patients who the surgeon saw as a good fit for the study were referred. Some of this bias could be eliminated in a larger study by opening recruitment to a wider population, finding numerous surgeons' clinics, and using posters and self referral of interested patients. However, working with only one surgeon for patients in this pilot study provided some benefit as it ensured that all patients undergo a similar surgical process with skill level remaining a constant. This decreases the variability that comes with multiple surgeons of various skill levels using differing procedures to complete the IHR. Using one surgeon, one assessing physical therapist, and one CEP to administer the exercise intervention keeps inter-examiner/practitioner variability low.

Some bias is unavoidable in a study such as this due to the inability to fully blind the research participants and assessors. Efforts have been made to keep observer bias low by blinding the assessing physical therapist to which group participants are randomized into. Yet despite attempts to minimize interaction with the assessor that would risk revealing participant's randomization, it is possible with the intervention being exercise instruction that it will be apparent during reassessment which group the participant belongs to due to improvement in biomechanics during reassessment. However, it can also be counter-argued that improvement in

biomechanics during assessment could also be partially due to repetition bias and participants knowing what to expect during the reassessment.

Considerations for Further Study:

Our research team lacked information regarding what physical limitations individuals with inguinal hernia experience, and as such the baseline assessment protocol did not effectively recreate hernia symptoms. One way to gather further information to improve assessment for inguinal hernia would be to conduct a qualitative study asking for patient feedback on what activities they are most limited in due to hernia pain; this would be an excellent opportunity to include patient participation in patient orientated research. That knowledge could then be taken along with the information gained from this pilot study to create a more reliable assessment for a larger RCT. It could be considered that a performance-based functional assessment may not even be a useful component in a larger study and rather work predominantly from self-reports of patients. This may also increase recruitment rate as delivery could be done virtually and not require patients to schedule time away from work, which was the most common reason that individuals referred to this pilot study opted out. A study with remote delivery would be easier to distribute, reach a higher number and variety of patients, and eliminate some of the bias that our pilot study is subject to.

CONCLUSION

The goal of our pilot study was to determine the feasibility of a perioperative rehabilitation program for patients undergoing IHR, and to provide meaningful information to take forward into a larger study. In examining the recruitment and baseline data collection we

present meaningful considerations to take forward to a larger study. Considerations such as expanding inclusion criteria to increase recruitment, and the benefit from collecting qualitative data and including patient involvement in designing more accurate questions to ask regarding what activities are made difficult by inguinal hernia. Collecting qualitative information could help in designing an objective assessment that better reflects physical limitations experienced by inguinal hernia patients. On the contrary, we must consider if objective assessment is even useful in this patient population and whether more accurate information could be gathered subjectively. If our exercise protocol is deemed safe by the next stages of this study, a larger study could be conducted that accesses more patients and is easier to distribute, while generating meaningful, relevant information that can help guide clinical recommendations and improve outcomes for individuals undergoing IHR.

REFERENCES

1. Kingsnorth A, LeBlanc K. Hernias: inguinal and incisional. Lancet. 2003;362(9395):1561-71. doi:10.1016/S0140-6736(03)14746-0.
2. Group H. International guidelines for groin hernia management. Hernia. 2018;22(1):1-165. doi:10.1007/s10029-017-1668-x.
3. Wagner JH. Hernias: Types, Symptoms and Treatment. New York: Nova Science Publishers, Inc; 2011. p. 57-80.
4. Sarpel U. Inguinal Hernia Repair. Surgery: An Introductory Guide. New York, NY: Springer New York; 2014. p. 257-68.
5. Fitzgibbons RJ, Ramanan B, Arya S, Turner SA, Li X, Gibbs JO, et al. Long-term results of a randomized controlled trial of a nonoperative strategy (watchful waiting) for men with minimally symptomatic inguinal hernias. Ann Surg. 2013;258(3):508-15. doi:10.1097/SLA.0b013e3182a19725.
6. Freundlich RE, Hawes LT, Weldon SA, Brunicardi FC. Laparoscopic repair of an incarcerated right indirect sliding inguinal hernia involving a retroperitoneal ileum. Hernia. 2011;15(2):225-7. doi:10.1007/s10029-010-0638-3.
7. Lang B, Lau H, Lee F. Epigastric hernia and its etiology. Hernia. 2002;6(3):148-50. doi:10.1007/s10029-002-0074-0.
8. Heniford BT, Lincourt AE, Walters AL, Colavita PD, Belyansky I, Kercher KW, et al. Carolinas Comfort Scale as a Measure of Hernia Repair Quality of Life: A Reappraisal Utilizing 3788 International Patients. Ann Surg. 2018;267(1):171-6. doi:10.1097/SLA.0000000000002027

9. Nienhuijs SW, Rosman C, Strobbe LJ, Wolff A, Bleichrodt RP. An overview of the features influencing pain after inguinal hernia repair. Int J Surg. 2008;6(4):351-6. doi:10.1016/j.ijsu.2008.02.005.
10. van Hanswijck de Jonge P, Lloyd A, Horsfall L, Tan R, O'Dwyer PJ. The measurement of chronic pain and health-related quality of life following inguinal hernia repair: a review of the literature. Hernia. 2008;12(6):561-9. doi:10.1007/s10029-008-0412-y.
11. Schug SA, Lavand'homme P, Barke A, Korwisi B, Rief W, Treede RD, et al. The IASP classification of chronic pain for ICD-11: chronic postsurgical or posttraumatic pain. Pain. 2019;160(1):45-52. doi:10.1097/j.pain.0000000000001413.
12. Forester B, Attaar M, Chirayil S, Kuchta K, Denham W, Linn JG, et al. Predictors of chronic pain after laparoscopic inguinal hernia repair. Surgery. 2021;169(3):586-94. doi:10.1016/j.surg.2020.07.049.
13. Liu Y, Zhou M, Zhu X, Gu X, Ma Z, Zhang W. Risk and protective factors for chronic pain following inguinal hernia repair: a retrospective study. J Anesth. 2020;34(3):330-7. doi:10.1007/s00540-020-02743-5.
14. Poobalan AS, Bruce J, Smith WC, King PM, Krukowski ZH, Chambers WA. A review of chronic pain after inguinal herniorrhaphy. Clin J Pain. 2003;19(1):48-54. doi:10.1097/00002508-200301000-00006.
15. Reddy S, Contreras CM, Singletary B, Bradford TM, Waldrop MG, Mims AH, et al. Timed Stair Climbing Is the Single Strongest Predictor of Perioperative Complications in Patients Undergoing Abdominal Surgery. J Am Coll Surg. 2016;222(4):559-66. doi:10.1016/j.jamcollsurg.2016.01.010.

16. Topp R, Ditmyer M, King K, Doherty K, Hornyak J. The effect of bed rest and potential of prehabilitation on patients in the intensive care unit. AACN Clin Issues. 2002;13(2):263-76. doi:10.1097/00044067-200205000-00011.
17. Ditmyer MM, Topp R, Pifer M. Prehabilitation in preparation for orthopaedic surgery. Orthop Nurs. 2002;21(5):43-51; quiz 2-4. doi:10.1097/00006416-200209000-00008.
18. Lundberg M, Archer KR, Larsson C, Rydwik E. Prehabilitation: The emperor's new clothes or a new arena for physical therapists? Vol. 99, Physical Therapy. 2019. doi:10.1093/ptj/pzy133.
19. Forbes J, Fry N, Hwang H, Karimuddin AA. Timing of return to work after hernia repair: Recommendations based on a literature review. BC Medical Journal. 2012;54(7):341-5.
20. Sobol-Kwapinska M, Bąbel P, Plotek W, Stelcer B. Psychological correlates of acute postsurgical pain: A systematic review and meta-analysis. Eur J Pain. 2016;20(10):1573-86. doi:10.1002/ejp.886.
21. Liang MK, Bernardi K, Holihan JL, Cherla DV, Escamilla R, Lew DF, et al. Modifying Risks in Ventral Hernia Patients With Prehabilitation: A Randomized Controlled Trial. Ann Surg. 2018;268(4):674-80. doi:10.1097/SLA.0000000000002961.
22. Pesanelli KE, Cigna JA, Basu SG, Morin AR. Occupational rehabilitation following open mesh surgical repair of an inguinal hernia. Phys Ther. 2003;83(1):58-66.
23. Santilli O, Santilli H, Nardelli N, Tripoloni D, Etchepare H. Sports rehabilitation after laparoscopic hernioplasty. Int J Abdom Wall Hernia Surg. 2020;3(4). doi:10.4103/ijawhs.ijawhs_28_20.

24. Perez JE, Schmidt MA, Narvaez A, Welsh LK, Diaz R, Castro M, et al. Evolving concepts in ventral hernia repair and physical therapy: prehabilitation, rehabilitation, and analogies to tendon reconstruction. Hernia. 2020. doi:10.1007/s10029-020-02304-5.
25. Mercier G, Spence J, Ferreira C, Delay JM, Meunier C, Millat B, et al. Postoperative Rehabilitation May Reduce the Risk of Readmission After Groin Hernia Repair. Sci Rep. 2018;8(1):6759. doi:10.1038/s41598-018-25276-0.
26. Knapp N, Jedrzejewski B, Martindale R. Abdominal wall procedures: the benefits of prehabilitation. Plast Aesthetic Res. 2020;2020. doi: 10.20517/2347-9264.2019.69.
27. Pezeshk RA, Pulikkottil BJ, Mapula S, Schaffer NE, Yap L, Scott K, et al. Complex Abdominal Wall Reconstruction: A Novel Approach to Postoperative Care Using Physical Medicine and Rehabilitation. Plast Reconstr Surg. 2015;136(3):362e-9e. doi:10.1097/PRS.0000000000001532.
28. Barberan-Garcia A, Ubré M, Roca J, Lacy AM, Burgos F, Risco R, et al. Personalised Prehabilitation in High-risk Patients Undergoing Elective Major Abdominal Surgery: A Randomized Blinded Controlled Trial. Ann Surg. 2018;267(1):50-6. doi:10.1097/SLA.0000000000002293.
29. Lewis M, Bromley K, Sutton CJ, McCray G, Myers HL, Lancaster GA. Determining sample size for progression criteria for pragmatic pilot RCTs: the hypothesis test strikes back! Pilot and Feasibility Studies. 2021;7(1). doi:10.1186/s40814-021-00770-x.
30. Gross DP, Battié MC, Asante AK. Evaluation of a short-form functional capacity evaluation: Less may be best. Journal of Occupational Rehabilitation. 2007;17(3). doi:10.1007/s10926-007-9087-y.

31. de Blaiser C, de Ridder R, Willems T, Danneels L, vanden Bossche L, Palmans T, Roosen P (2018). Evaluating abdominal core muscle fatigue: Assessment of the validity and reliability of the prone bridging test. Scandinavian Journal of Medicine and Science in Sports. 2018:28(2). https://doi.org/10.1111/sms.12919.
32. Jones CJ, Rikli RE, Beam WC. A 30-s chair-stand test as a measure of lower body strength in community-residing older adults. Research Quarterly for Exercise and Sport. 1999;70(2). https://doi.org/10.1080/02701367.1999.10608028.
33. Folland JP, Williams AG. The adaptations to strength training: Morphological and neurological contributions to increased strength. Sports Medicine. 2007;37(2). https://doi.org/10.2165/00007256-200737020-00004.
34. Ross R, Chaput JP, Giangregorio LM, Janssen I, Saunders TJ, Kho ME, Poitras VJ, Tomasone JR, El-Kotob R, McLaughlin EC, Duggan M, Carrier J, Carson V, Chastin SF, Latimer-Cheung AE, Chulak-Bozzer T, Faulkner G, Flood SM, Gazendam MK, Healy GN, Katzmarzyk PT, Kennedy W, Lane KN, Lorbergs A, Maclaren K, Marr S, Powell KE, Rhodes RE, Ross-White A, Welsh F, Willumsen J, Tremblay MS. Canadian 24-Hour Movement Guidelines for Adults aged 18-64 years and Adults aged 65 years or older: an integration of physical activity, sedentary behaviour, and sleep. Applied Physiology, Nutrition, and Metabolism. 2020;45(10 (Suppl. 2)):S57-S102. doi: 10.1139/apnm-2020-0467.
35. Crighton AH, Wygant DB, Applegate KC, Umlauf RL, Granacher RP. Can brief measures effectively screen for pain and somatic malingering? Examination of the Modified Somatic Perception Questionnaire and Pain Disability Index. Spine Journal. 2014;14(9). https://doi.org/10.1016/j.spinee.2014.04.012

36. Melville MR, Lari MA, Brown N, Young T, Gray D. Quality of life assessment using the short form 12 questionnaire is as reliable and sensitive as the short form 36 in distinguishing symptom severity in myocardial infarction survivors. Heart. 2003;89(12). https://doi.org/10.1136/heart.89.12.1445.

APPENDICES

Appendix A:

FEASIBILITY AND ACCEPTABILITY CRITERIA		
Proceed	**Proceed with Protocol Amendments**	**Significant Amendments Required**
Recruitment		
n=30 within 4 months	n ≥ 15 within 8 months	n < 10 within 8 months
50% of eligible participants consent to participate	40% of eligible participants consent to participate	25% of eligible participants consent to participate
Exercise program		
60% of participants report exercise at least 3 times a week	40% of participants report exercise at least 3 times a week	25% of participants report exercise at least 3 times a week
Content Acceptability		
50% found treatment useful (Likert ≥ 4/5)	25% found treatment useful (Likert ≥ 4/5)	< 25% found treatment useful (Likert ≥ 4/5)
50% found treatment helpful (Likert ≥ 4/5)	25% found treatment helpful (Likert ≥ 4/5)	< 25% found treatment helpful (Likert ≥ 4/5)
Format Acceptability		
50% found treatment delivery (in-person and home) acceptable (Likert ≥ 4/5)	25% found treatment delivery acceptable (Likert ≥ 4/5)	< 25% found treatment delivery acceptable (Likert ≥ 4/5)
50% reported being likely to recommend this treatment	25% reported being likely to recommend this treatment	< 25% reported being likely to recommend this treatment
50% reported being likely to use this treatment again	25% reported being likely to use this treatment again	< 25% reported being likely to use this treatment again

Follow Up		
90% of participants followed up at the end of Prehab	50% of participants followed up at the end of Prehab	25% of participants followed up at the end of Prehab
80% of participants followed up at 3 months	50% of participants followed up at 3 months	25% of participants followed up at 3 months
Treatment		
70% of participants attended all treatment sessions	50% of participants attended all treatment sessions	25% of participants attended all treatment sessions
70% of sessions were compatible with participant's work/activity schedule	50% of sessions were compatible with participant's work/activity schedule	25% of sessions were compatible with participant's work/activity schedule
Burden		
75% of participants found the burden of completing questionnaires Likert <3/10 (0 = no burden, 10 = most burden)	50% of participants found the burden of completing questionnaires Likert <3/10 (0 = no burden, 10 = most burden)	25% of participants found the burden of completing questionnaires Likert <3/10 (0 = no burden, 10 = most burden)
Adverse Events		
No adverse event	1 adverse event related to re-injury	2 or more adverse events

Appendix B:

Perioperative Rehabilitation Activity and Data Collection Protocol for Inguinal Hernia Repair

(Intervention group)

Before the operation – Approximately 12 hour commitment

Timing	*Activity*	*Measures Collected*
8 weeks pre-op	Recruitment and consent process. In-person meeting: baseline data collection (partially done online using REDCAP if possible) and physical assessment (1 hour) Deliver Prehab for Hernia video to intervention group	Demographic and Work Status Questionnaire Numerical Pain Scales Pain Disability Index SF-12 Health Survey Work-Related Functional Testing
6 weeks pre-op	In-person meeting: start 6 week pre-op exercise protocol (1 hour)	Adherence Adverse Events
Weekly between weeks 6 until operation	Patient to do exercises and education sessions on their own at home 5x/week in 15-20 minute sessions (1.5 hours per week x 6 weeks = 9 hours) Virtual follow-ups 1x/week to progress as needed, monitor adherence and provide guidance and motivation (included in exercise time above)	Adherence Adverse Events
1 week pre-op	In-person meeting: Last visit before surgery, interim data collection and physical assessment (1 hour)	Work Status Questionnaire Numerical Pain Scales Pain Disability Index

	Deliver pain management video and surgery information video to both control and intervention groups Deliver post surgery activity video to intervention group	SF-12 Health Survey Work-Related Functional Testing

After the operation - Approximately 18 hour commitment

Timing	*Activity*	*Measures Collected*
1 week post-op	Electronic survey using REDCAP for pain/complications (Done online, 15 minutes)	Numerical Pain Scales Pain Disability Index Carolinas Comfort Scale questionnaire
2 weeks post-op	In-person follow-up with surgeon	
3 weeks post-op	In-person meeting: Start 6 week post-op exercise protocol (1 hour)	Adherence Adverse Events
Weekly between weeks 3 to 12	Patient to do exercises on their own at home 5x/week in 15-20 minute sessions (1.5 hours per week x 10 weeks = 15 hours) Virtual follow-ups 1x/week to progress as needed, monitor adherence and provide guidance and motivation Weekly monitoring for adverse effects included in virtual follow-ups	Adherence Adverse Events
4 weeks post-op	In-person surgeon follow-up (as part of usual clinical practice)	Ultrasound if needed

9 weeks post-op	Virtual check-in, return to work/activity advice (30 minutes)	Adherence Adverse Events
12 weeks post-op	Final in-person assessment (1 hour)	Numerical Pain Scales Pain Disability Index Work Status Questionnaire SF-12 Health Survey Carolinas Comfort Scale questionnaire Work-Related Functional Testing Feedback and Satisfaction Survey

Appendix C:

Inguinal Hernia Perioperative Study Work-Related Functional Testing

Unique ID#:_____ Date:_____

Heart Rate – Resting:_____ Maximum:_____ 80% max: _____

FLOOR TO WAIST LIFT:

Workplace requirements:

Attempt	1	2	3	4	5	6	End of test
Lbs							Pain:
HR							Reason:
Pass?							

Other Tests:

Test	Workplace Req	Benchmark	Completed	Reason for stopping
Standing		15 minutes		
Crouching		1 minute		
Trunk rotation		5 minutes		
Forward bend		2 minutes		
Plank	N/A	N/A		
30 sec Sit-to-stand		N/A		

OTHER WORK-RELATED FUNCTIONAL TESTING:

_____

_____

_____

_____

_____

Hernia related pain at end of assessment/testing: _____

Recommended modifications to exercises/functional limitations to be aware of:

_____

_____

_____

_____

_____

Appendix D:

Hernia Educational Videos

Pain Management Video: https://www.youtube.com/watch?v=M1Yri-RCtYw

Hernia Surgery Video: https://youtu.be/JQA2RjyJ19c

Prehabilitation Video: https://www.youtube.com/watch?v=gpiLpNJIPh0

Post-surgery RehabilitationVideo: https://www.youtube.com/watch?v=bCoHXe7R-4U

Appendix E:

Perioperative Rehabilitation Protocol for Inguinal Hernia Repair

Exercise protocol (Intervention group)

General goals for having the intervention group complete exercise prior to and following inguinal hernia repair surgery is to strengthen the abdominal wall and improve general physical resilience in this population. It is assumed that many of the individuals in this population have a low physical fitness level to begin with and that any exercise would bring them benefit, however for the purpose of this study exercises have been chosen that have components of abdominal strengthening, functional strength, and ergonomic conditioning.

Exercises will be initially introduced and taught by a physical therapist or other qualified exercise professional 6 weeks before the operation, and gradually reintroduced after the operation starting at three weeks post-op after being cleared by the surgeon. Initial introduction of exercise following surgery will begin with gentler activities such as diaphragmatic breathing, transverse abdominis activation, and simple bridging, and over six weeks of supervision progress weekly to more complicated and functional exercises.

Instruction will include attention to breath coordination during strengthening activities in order to avoid valsalva maneuver and increasing intrathoracic pressure. Participants will be encouraged to spend approximately 15-20 minutes daily completing their exercise routine with the goal to see exercises completed at least 5x/week. Exercise intensity will be adapted according to individual ability and presence of pain and will be delivered and tracked online using physitrack.com.

See following tables for example exercise outline.

6 weeks before the operation – full program instruction

Exercise	*Basic/Starting*	*Progression*
Diaphragmatic breathing	Instruction for breathing into three sections of the lungs: collar bones, ribs, belly. 3 cycles of 3 breaths.	
Transverse abdominis (TA) activations	Instruct activation of the transverse abdominis muscle using breath cueing.	Add pelvic floor activation. Add knee lifts or heel slides. Add 90° leg hold.
Bridging	Raise hips off the mat, squeeze glutes.	Incline bride. One-leg bridge
Bird-dogs (4-point progression)	May begin by using only one limb at a time.	Opposite arm and leg extend.
Dead-bugs	May begin by using only one limb at a time, having knees bent.	Opposite arm and leg extend; straight legs.
Chair squat	Weight-bearing. May begin with sit to stand if necessary.	Add theraband to increase glute med. firing. Add weight
Push up progression	Begin with wall push ups	Progress to counter/knee/floor push ups
Floor to waist lift	Weight-bearing. Begin with no weight - 10 lbs	Increase weight according to job demands.

After the operation – gradual program implementation

Timing	*Exercise*	*Progression (as tolerated)*
3 weeks post-op	Diaphragmatic breathing TA activations Bridging	
4 weeks post op	Diaphragmatic breathing TA activations Bridging +Bird-dogs (one limb) +Dead-bugs (one limb) +Sit to stands	Add: -knee lift to TA activations -increase lift and hold on bridging
5 weeks post-op	Diaphragmatic breathing TA activations	Add: -body weight chair squats

	Bridging Bird-dogs (one limb) Dead-bugs (one limb) (Chair) squats +Wall push ups +Floor to waist lifts (10lbs)	-catch up on progressions as appropriate
6 weeks post-op	Diaphragmatic breathing TA activations Bridging Bird-dogs Dead-bugs Chair squats (with band) Push up progression Floor to waist lifts (15 lbs)	Add: -opposite arm/leg to bird dogs and dead bugs -band to squat -add weight to floor to waist lift
7 weeks post-op	Diaphragmatic breathing TA activations (One leg) Bridging Bird-dogs Dead-bugs Chair squats Push up progression Floor to waist lifts (20 lbs)	Add: -one-leg bridge -increase weight on floor to waist lift
8 weeks post-op	Diaphragmatic breathing TA activations (one leg) Bridging Bird-dogs Dead-bugs Squats Push ups Floor to waist lifts (20 lbs)	Add: -increase weight on floor to waist lift -progress push ups as tolerable
9 weeks post-op	Diaphragmatic breathing TA activations (one leg) Bridging Bird-dogs Dead-bugs Squats Push ups Floor to waist lifts (30 lbs)	Add: -increase weight on floor to waist lift

Appendix F: Ethics Approval Form

Health Research Ethics Board

308 Campus Tower
University of Alberta, Edmonton, AB T6G 1K8
p. 780.492.9724 (Biomedical Panel)
p. 780.492.0302 (Health Panel)
p. 780.492.0459

Approval Form

Date:	March 3, 2021
Study ID:	Pro00106451
Principal Investigator:	Douglas Gross
Study Title:	**A Study Evaluating the Feasibility of a Peri-Operative Rehabilitation Program for Inguinal Hernia Repair Surgery to Reduce Risk of Post-Surgical Pain**
Approval Expiry Date:	Wednesday, March 2, 2022
Approved Consent Form:	Approval Date: 3/3/2021 — Approved Document: CLEAN Letter of Information and Consent V2
Sponsor/Funding Agency:	Alberta Spine Foundation
RSO-Managed Funding:	Project ID: View RES0052621 — Title — Grant Status — Program — Project Start Date — Project End Date — Purpose — Other Information

Thank you for submitting the above study to the Health Research Ethics Board - Health Panel. Your application, including the following, has been reviewed and approved on behalf of the committee;

- CLEAN Consent to Contact Form V2 (3/3/2021)
- CLEAN Assessment Booklet V4 (3/3/2021)
- Feedback Survey (3/2/2021)
- Functional Testing Form (3/2/2021)
- Adherence and Adverse Events Form (3/2/2021)
- Full Proposal (1/13/2021)
- Data Collection Timeline and Protocol (3/2/2021)
- Exercise Protocol (3/2/2021)
- Appendix with Feasibilty Criteria (1/13/2021)

The Health Research Ethics Board assessed all matters required by section 50(1)(a) of the Health Information Act. Subject consent for access to identifiable health information is required for the research described in the ethics application, and appropriate procedures for such consent have been approved by the HREB Health Panel. In order to comply with the Health Information Act, a copy of the approval form is being sent to the Office of the Information and Privacy Commissioner.

Any proposed changes to the study must be submitted to the REB for approval prior to implementation. A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date (Wednesday, March 2, 2022), you will have to re-submit an ethics application.

Enquiries regarding Alberta Health approval should be directed to (780) 407-6041. Enquiries regarding Covenant Health approvals should be directed to (780) 735-2274.

Approval by the Research Ethics Board does not encompass authorization to recruit and/or interact with human participants at this time. Researchers still require operational approval as applicable (eg AHS, Covenant Health, ECSD etc) and where in-person interactions are proposed, institutional and operational requirements outlined in the *Resumption of Human Participant Research - June 24, 2020* ***must be met.***

Sincerely,

Anthony S. Joyce, PhD.
Chair, Health Research Ethics Board - Health Panel

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Appendix G: **CONSENT TO CONTACT FOR RESEARCH PURPOSES**

TITLE: A Study Evaluating the Feasibility of a Peri-Operative Rehabilitation Program for Inguinal Hernia Repair Surgery to Reduce Risk of Post-Surgical Pain

SPONSOR: University of Alberta Faculty of Rehabilitation Medicine

INVESTIGATORS: Douglas Gross, Omar Farooq, Luciana Macedo, Geoff Bostick, Quentin Durand-Moreau, Anna Shologan, Chad Piper

PRIMARY STUDY CONTACT: Dr. Douglas Gross Email: doug.gross@ualberta.ca

Phone number: 780-492-2690

You are being asked to give consent for Dr. Douglas Gross, or a qualified member of his study team to contact you at some time in the future to tell you more information about a research study.

Are you willing to learn more about *A Study Evaluating the Feasibility of a Peri-Operative Rehabilitation Program for Inguinal Hernia Repair Surgery to Reduce Risk of Post-Surgical Pain*?

(Circle one) YES NO

If yes, you will be contacted at a later date. Please include your contact information below.

☐ Name: _____

☐ Telephone: _____

☐ Email: _____

What is your preferred contact method and time? _____

_____

By signing this form you authorize the disclosure of your name, telephone number, and/or email to the research team for the purpose of being contacted to learn more about the research study *A Study Evaluating the Feasibility of a Peri-Operative Rehabilitation Program for Inguinal Hernia Repair Surgery to Reduce Risk of Post-Surgical Pain.*

Every effort will be made to safeguard your contact information. Although access to this information will be limited, there is a small chance that this information could be inadvertently disclosed or inappropriately accessed.

You have been made aware of the reasons why the contact information is needed and the risks and benefits of consenting or refusing to consent.

This consent is effective immediately. Your consent to be contacted can be revoked by you at any time.

Patient's Signature: _____

Date: _____

Data Custodian/Clinician's Name: _____

Appendix H:

LETTER OF INFORMATION / CONSENT

Title of Study: A Study Evaluating the Feasibility of a Peri-Operative Rehabilitation Program for Inguinal Hernia Repair Surgery to Reduce Risk of Post-Surgical Pain

INVESTIGATORS: Douglas Gross, Omar Farooq, Luciana Macedo, Geoff Bostick, Quentin Durand-Moreau, Anna Shologan

PRIMARY STUDY CONTACT: Dr. Douglas Gross Email: doug.gross@ualberta.ca

Phone number: 780-492-2690

Funding Source: Medtronic External Research Grant

Why are you being asked to be part of this research study?

You are being invited to participate in a research study because you are scheduled for inguinal repair surgery.

To decide whether or not you want to be a part of this study, you should understand what is involved and the potential risks and benefits. This letter gives detailed information about the study that will be discussed with you. Once you understand the study, we will ask you to sign a consent form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family, or your family physician.

What are we trying to discover?

You are invited to take part in this study on the feasibility of a program to help people undergoing inguinal hernia repair surgery. The program includes exercise and education to help people prepare for their surgery and recover faster after the operation. We hope the program will improve your chance of a successful surgery and lead to faster recovery. We will study levels of pain, disability, work status, and quality of life before and after our program. We will also test things like whether you are satisfied with the program and how long it takes to complete study questionnaires. We will use results to make changes to the program. We will then test if the program works in a larger study.

What will happen during the study?

During this study you will be asked to participate in a program to help you get ready for your surgery. The program will take place over 6 weeks before your surgery and 12 weeks after the operation.

Before Surgery *(Approximately 12-hour commitment over 6 weeks)*

You will have one in-person assessment session at the beginning for testing. If you feel comfortable, we will ask you to disclose some personal information like your age, mailing address and education. You will also fill out questionnaires related to your job and levels of pain, disability, and quality of life. These questions should last 15 to 20 minutes.

You will then undergo work ability testing. We will ask you to do activities you usually perform at work (lifting, standing, crouching, bending and twisting). At the end of the assessment and after you formally agree to participate in the study, the therapists will use an automated computer service to randomize you into a treatment group.

You will then either be taught exercises and receive pain-related education or else only receive pain-related education. The sessions will be in person for the first session and then over videoconference for weekly follow-ups. The exercises (strengthening and stretching) and education will be delivered by a physiotherapist and a trained exercise therapist. You will be asked to exercise at home 15-20 minutes per day before the operation. The therapists will also teach you about inguinal hernia and how best to prepare for your surgery. You will also watch educational videos prepared by a surgeon.

After Surgery *(Approximately 18-hour commitment over 12 weeks)*

After your operation you will recuperate for 3 weeks. One week after the operation we will ask you to complete surveys related to pain and disability. After being cleared by the surgeon to participate in exercise you will again begin exercising under the supervision of an exercise therapist. You will have 1 in-person session with the therapist and then exercise on your own for 6 weeks. You will have weekly virtual check-ins with the therapist.

There will be one last in-person assessment session with a therapist about 12 weeks after your operation. We will repeat the same surveys and tests you did on the first day.

All the activities in this study should take about 30 hours in total including assessments and therapy sessions. Two hours will be for testing and completing surveys while the treatment activities will take approximately 28 hours in total.

Are there any risks to doing this study?

Before surgery - You may experience temporary muscle soreness following exercise. This is a normal response to exercise if you're not used to it. It should feel better within a day or two. People also sometimes have a temporary increase in their inguinal hernia symptoms following exercise. If this happens, you should tell the therapist. They will help you decide whether to modify or stop your exercises. There is also a very small risk that the hernia tissue will become trapped and cannot be easily moved back into place. The risk is not much greater than during your usual activity. But if this happens you will immediately visit the surgeon.

After surgery - There is a small risk of hernia re-rupture but not much higher than during your usual activity. You will be in regular contact with the surgeon. If the surgeon thinks a re-rupture

has occurred, you will be sent for an ultrasound scan. If the scan shows a repeat hernia you will have repeat surgery.

You do not need to answer questions that you do not want to answer or that make you feel uncomfortable. You can withdraw (stop taking part) at any time during the study. We will describe below the steps we are taking to protect your privacy.

What are the possible benefits for me and/or for society?

If you decide to participate in this study, you may benefit from the exercise and education sessions. You will receive two $50 gift cards to reimburse your time spent in the study. You will receive one at the time of baseline testing and another at pre-surgical testing. You will still be entitled to the gift card if you withdraw from a testing session early. We also hope that what is learned will help us improve the pre-surgical program for people with inguinal hernia. The end goal is to help people have successful surgeries. This includes lower pain, higher function, and shorter length of hospital stay after surgery. However, we cannot guarantee that you will experience these potential benefits.

Who will know what I said or did in the study?

Every effort will be made to protect your confidentiality and privacy. A member of the research team will contact you to discuss participating in the study. We will not use your name or any information that would allow you to be identified. The information you provide will be kept in a secure computer where only we will have access to it. Information kept on a computer will be protected by a password. The research data will be kept for at least 5 years to allow for the publication of findings. De-identified data from this study will be shared in a public archive, but people will not be able to identify you.

What information will be kept private?

The health information collected in this study will be kept confidential unless release is required by law. All information will be used only for the research study. The researchers and the University of Alberta Health Research Ethics Board may access your study records to monitor the research and verify the accuracy of study information.

In Canada, study information is required to be kept on file for five years. Even if you withdraw from the study, the information and data that is obtained for study purposes will not be destroyed. You have the right to check your health records and request changes if personal information is incorrect.

What if I change my mind about being in the study?

If you volunteer to be in this study, you may withdraw at any time. You have the option of removing your data from the study. You may also refuse to answer any questions you don't want to answer and remain in the study. Not following the study protocol will not be a reason for excluding you from the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so. This could include things like cancellation of your surgery or major delays due to COVID-19.

How do I find out what was learned in this study?

We expect to have this study completed by approximately December 2022. If you would like a brief summary of the results, please let us know how you would like it sent to you.

What do I do if I have questions about the study?

If you have questions or need more information about the study itself, please contact **Dr. Doug Gross at email: doug.gross@ualberta.ca or phone: 780-492-2690.**

This study has been reviewed by the University of Alberta Research Ethics Board (REB). The REB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the REB at (780) 492-2615.

Part 2		
Title of Project: A Study Evaluating the Feasibility of a Peri-Operative Rehabilitation Program for Inguinal Hernia Repair Surgery to Reduce Risk of Post-Surgical Pain **INVESTIGATORS:** Douglas Gross, Omar Farooq, Luciana Macedo, Geoff Bostick, Quentin Durand-Moreau, Anna Shologan **PRIMARY STUDY CONTACT:** Dr. Douglas Gross Email: doug.gross@ualberta.ca Phone number: 780-492-2690		
	Yes	No
Do you understand that you have been asked to participate in a research study?	☐	☐
Have you read and received a copy of the Information Letter?	☐	☐
Do you understand the benefits and risks of being involved in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study with a representative thereof?	☐	☐

Do you understand that you are free to withdraw from the study at any time without having to give a reason and without affecting your future medical care?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to the information you provide?	☐	☐
I agree to take part in this study:	☐	☐

Participant's Name_____ Date_____

Contact Information for Future Follow-up

Phone Number:

Address:

Email: