Randomized trial **E**valuating first time shoulder **D**islocation: s**U**rgery vs **C**onservative car**E**

(**REDUCE)**

PILOT TRIAL PROTOCOL

Version: 4.0

Date: 20-Sep-2024

Principal Investigator: Moin Khan, MD., MSc., FRCSC
Associate Professor, Division of Orthopaedic Surgery, Faculty of Health Sciences
Phone: 905.522.1155 ext. 32953 khanmm2@mcmaster.ca

Co-Investigators: Asheesh Bedi, MD, Mohit Bhandari, MD, PhD, FRCSC

Steering Committee:
George Athwal, MD, Asheesh Bedi, MD, FRCSC, Mohit Bhandari, MD, PhD, FRCSC, John M Tokish, MD

Reviewed and Approved by:		
Dr. Moin Khan *(Principal Investigator)*	***Signature:***	***Date:*** 20-Sep-2024

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LIST OF ABBREVIATIONS

Abbreviation	Explanation
AROM	Active Range of Motion
ASES	American Shoulder and Elbow Surgeons
CEO	Centre for Evidence-Based Orthopaedics
CRF	Case Report Form
CI	Confidence Internal
DSMC	Data and Safety Monitoring Committee
EDC	Electronic Data Capture
ER	External Rotation
FTD	First-Time Dislocation
HiREB	Hamilton Integrated Research Ethics Board
ICF	Informed Consent Form
IR	Internal Rotation
IRB	Institutional Review Board
ISIS	Instability Severity Index Score
MRI	Magnetic Resonance Imaging
NISIS	Non-Operative Instability Severity Index Score
PE	Physical Examination
PHI	Personal Health Information
PNF	Proprioceptive Neuromuscular Facilitation
PROM	Passive Range of Motion
PT	Physical Therapy
RCT	Randomized Controlled Trial
REB	Research Ethics Board
SAE	Serious Adverse Event
WOSI	Western Ontario Shoulder Instability
WSIB	Workplace Safety & Insurance Board

STUDY SUMMARY

Study Design	Randomized Controlled Trial with Embedded Non-randomized Cohort
Coordinating Centre	McMaster University, Department of Surgery Clinical Trials Unit, in collaboration with St. Joseph's Hospital, department of Surgery.
Background	The shoulder is the most commonly dislocated joint in the body with a global incidence that ranges from 15 to 25 per 100 000 people. The estimated annual societal cost in North America due to first-time shoulder dislocations exceeds $1.2 billion CAD. Anterior dislocations, the most common type of shoulder dislocation, are often complicated by subsequent instability and recurrent dislocation, with reported rates as high as 47%. Shoulder instability commonly results in pain and negatively impacts quality of life. Current standard of care suggests surgical stabilization of the shoulder after two or more dislocations, but the evidence is far from conclusive. Observational studies suggest that early surgical stabilization has strong biological rationale in limited risks of recurrent dislocation, improving quality of life, and potentially decreasing the future risk of shoulder arthritis. Also, some economic health studies suggests that surgery is less costly and more effective, even after recurrent dislocations.
Objective of the Pilot Study	The primary objective of the pilot study is to assess the feasibility of a definitive trial to determine the effect of arthroscopic soft tissue stabilization vs. non-surgical treatment on rates of recurrent anterior dislocation and functional outcomes in patients presenting with a first-time dislocation (FTD) over a 24-month period.
Diagnosis and Main Inclusion Criteria	1. Patients ages 14-40 years; 2. Diagnosis of post-traumatic first-time anterior shoulder dislocation having occurred within the past 3 months; 3. Provision of informed consent.
Treatment Groups	1. Arthroscopic stabilization (intervention group) 2. Non-operative management (control group)
Length of Follow-Up	Participants will be followed for 24 months post-treatment. Outcomes will be assessed at 6 weeks, (±7 days), 6 months (±30 days), 12 months (±30 days) and 24 months (±60 days) post-treatment.
Sample Size	50 participants

1.0. INTRODUCTION

1.1. An Unsolved Problem with Over $1 Billion in North American Health Care Costs

The shoulder is the most commonly dislocated joint in the body with a global incidence that ranges from 15 to 25 per 100 000 people [1–3] and is the most common reason for surgical referral in the young active patient[4]. It is estimated that over 85,000 dislocations occur in North America annually, with a maximum incidence rate (47.8 per 100,000 person-years [95% confidence interval (CI), 41.0 to 54.5]) occurring in those between the ages of 20 and 29 years[1,3]. Anterior dislocations, the most common type of shoulder dislocation, are often complicated by subsequent instability and recurrent dislocation, with reported rates as high as 42%[1]. The estimated annual societal cost in North America due to first-time shoulder dislocations (FTDs) exceeds $1.2 billion CAD[1,5].

1.2. The Anatomy of the Shoulder Dislocation

The shoulder joint, also called the glenohumeral joint, is a ball and socket joint stabilized by a number of structures including the capsule, ligaments, and a cartilaginous lining known as the labrum. Most commonly, shoulder dislocations happen anteriorly (>90%) and are due to a traumatic event (95%) from a violent external rotation of the arm in an abducted position. When the shoulder dislocates anteriorly, there is an injury to the anterior-inferior glenoid labrum, a critical stabilizing structure of the shoulder. This is known as a Bankart lesion [6,7]. Biomechanical data confirms that injury to the anterior-inferior labrum results in significantly decreased joint translation forces[8]. Despite relocation of a dislocation, recurrent instability (partial or complete dislocations) often persists and results in further damage to cartilage surfaces of the humerus and glenoid[9,10]. While the immediate focus in any dislocated joint is an expeditious re-location of the joint, definitive management varies among surgeons. Some prefer early surgical intervention to repair and stabilize the torn labrum, while others prefer non-operative care (short period of immobilization with early rehabilitation).

1.3. Recurrent Dislocations Have Devastating Impacts on Pain, Function and Quality of Life

By far, the most feared complication following a dislocation is a re-dislocation. Recurrent instability, experienced as a partial or complete dislocation of the humeral head from the glenoid socket post-initial dislocation, can reach upwards of 85%[11]. Re-dislocation and continued instability results in decreased quality of life, shoulder pain, kinesiophobia and decreased physical activity and sport, as well as substantially increased costs over initial dislocation [12–14]. Recurrence mainly occurs in the first 2 years after the first anterior shoulder dislocation event, and 83% of patients who develop recurrent instability by 5 years do so within the first 2 years of a dislocation event[11]. Surveys of patients demonstrate that 4 of 10 desire definitive treatment to limit further instability events and prefer surgery as their treatment of choice[12,13].

In addition to the health care costs of a dislocation, a prospective study of 257 patients followed for 25 years found that even if a patient does not sustain a subsequent complete re-dislocation, the presence of subtle instability can result in further labral tearing, cartilage injury, and glenoid and humeral bone erosion, which may increase the risk of developing arthritis. This is of critical concern to young active patients in whom this injury is most prevalent[14].

1.4. Rationales for Early Versus Delayed Surgical Intervention

Following the initial urgent management and relocation of a dislocated shoulder, the prevention of recurrent instability is the critical management consideration for health care providers and

surgeons. Two initial management options exist in patients with a FTD: non-operative care or surgical stabilization.

Non-Operative Care (Secondary Surgical Stabilization, if needed)

The current standard of care for the vast majority of FTDs is aggressive non-operative treatment with a brief period of immobilization (around 3 weeks) followed by a physiotherapy shoulder strengthening protocol[15]. Failure of non-operative management with a recurrent dislocation remains the indication for surgical stabilization or if there are further complaints of instability[16]. Proponents of this approach argue that approximately half of patients are adequately treated by non-operative methods alone without additional risks of surgery[17,18]. Additionally, physicians and patients involved in seasonal sports often prefer non-operative treatment to allow a quick return to play and avoid ending the sporting season with a surgical procedure, despite the potential risk of increased instability. A cohort study by Shanley et al. found that 85% of athletes treated non-operatively following a shoulder dislocation returned to pre-injury sport for an entire season without a recurrent instability event[19]. Utilizing available risk stratification tools, those advocating for this approach believe that patients at high risk of recurrent instability – younger, involved in contact sports, or with subtle bony injury - are identified appropriately and the remainder can be treated non-operatively[20].

Primary Surgical Stabilization

Surgeons who prefer primary surgical stabilization of a FTD argue the following:
1. Evidence for early non-operative treatment is inconclusive;
2. Recurrent instability rates are unacceptably high;
3. Outcomes (shoulder stability and functional scores) following primary stabilization are superior to those of stabilization with recurrent instability;
4. Delay in treatment results in further injury to the joint, and;
5. Early surgical intervention more cost effective than initial non-operative management.

Recent research and available evidence over the past 10 years have called into question the role of a delayed approach to managing FTDs for a number of reasons. Surgical management has been suggested as a more reliable option to prevent further dislocations and improve patient outcomes when compared with non-operative management. Arthroscopic soft tissue repair (Bankart repair) has become increasingly popular given advancements in surgical technique allowing for a minimally invasive and reliable improvement in shoulder stability with a low risk of complication. The high recurrence rate in younger patients may justify offering surgical treatment after the first dislocation episode. A recent systematic review by Hurley *et al.*[16] found arthroscopic Bankart repair resulted in a 7-fold lower recurrence rate and a higher rate of return to sport and activity than non-operative management[21]. While other surgical stabilization options exist, including non-anatomic bony transfer (Latarjet procedure), the Bankart repair is widespread as it is minimally invasive and restores native anatomy.

Recent data also suggests that patients who are surgically treated following a FTD have improved outcomes when compared to those who have recurrent instability events before undergoing surgery. Marshall *et al.*[22] found an increased rate of instability in patients initially treated non-operatively in comparison to those undergoing surgery immediately after a FTD (Odds Ratio (OR) = 4.14) as well as an increased odds of requiring further surgical procedures (OR=6.01). Fox *et al.*[23] similarly found rates of recurrent dislocations were 3-fold higher in those undergoing surgery after two dislocation events in comparison to a single dislocation (42.8% vs. 14.2%, p=0.03). Such

findings raise significant concern with current widespread practice of non-operative care after an initial dislocation event.

Delayed management of shoulder instability results in further injury to the shoulder joint. MRI evaluation of individuals who were assessed greater than 6 months from the time of initial dislocation had increased prevalence of not only recurrent shoulder instability events but a greater incidence and severity of intra-articular injury, including SLAP tears, labral tears, and glenoid cartilage damage[24].

2.0 STUDY AIMS AND OBJECTIVES

Prior to a large trial, we will conduct a pilot trial comparing arthroscopic soft tissue stabilization (intervention group) vs. non-operative management (control group) on recurrent dislocation rates and functional outcomes over a 24-month period.

2.1. Primary Questions

We aim to examine the feasibility of a larger trial comparing surgical intervention vs. non-operative management for a first-time shoulder dislocation. Feasibility objectives include:

1. Ability to recruit patients across multiple clinical sites;
2. Ability to follow patients for 24 months;
3. Ability to operate on patients within 3 months following enrollment; and
4. Assessment of crossovers.

2.2 Secondary Questions

The secondary objectives of the pilot trial will be the clinical objectives of the definitive trial:

1. Rates of recurrent shoulder dislocations up to 24 months' post-treatment;
2. Symptoms of instability without dislocation up to 24 months post treatment;
3. Clinical outcomes measured by Western Ontario Shoulder Instability (WOSI) Index, American Shoulder and Elbow Society (ASES) score, Shoulder Activity Scale, EQ-5D, Visual Analog Scale (VAS) Pain Score, and Patient Satisfaction questionnaire;
4. Physical examination: range of motion, strength, stability;
5. Return to previous level of activity and work, and;
6. Safety, shoulder-related complications and serious adverse events.

Hypothesis: We believe that that the pilot trial will be feasible in our ability to recruit participants rapidly and meet our feasibility objectives.

3.0. TRIAL DESIGN

We propose a multi-centre pilot RCT to compare the effect of arthroscopic soft tissue stabilization (Bankart procedure) and non-operative treatment (physical therapy) in patients with a post-traumatic anterior FTD. Eligible and consenting participants will be followed-up by the site for 24 months. Outcomes will be assessed at 6 weeks, 6 months, 12 months, and 24 months post-treatment. Since the decision between surgery and conservative management may be heavily influenced by patient preference, we will also embed a prospective non-randomized cohort within this RCT to capture all patients who would be eligible for the study but refuse to be randomized. These patients will choose to either undergo arthroscopic stabilization or non-operative management to treat their FTD and will be followed the same way as the randomized cohort (Figure 1). This study design not only ensures maximal participation but is also more generalizable to the real world where preferences might play a role in shared decision-making.

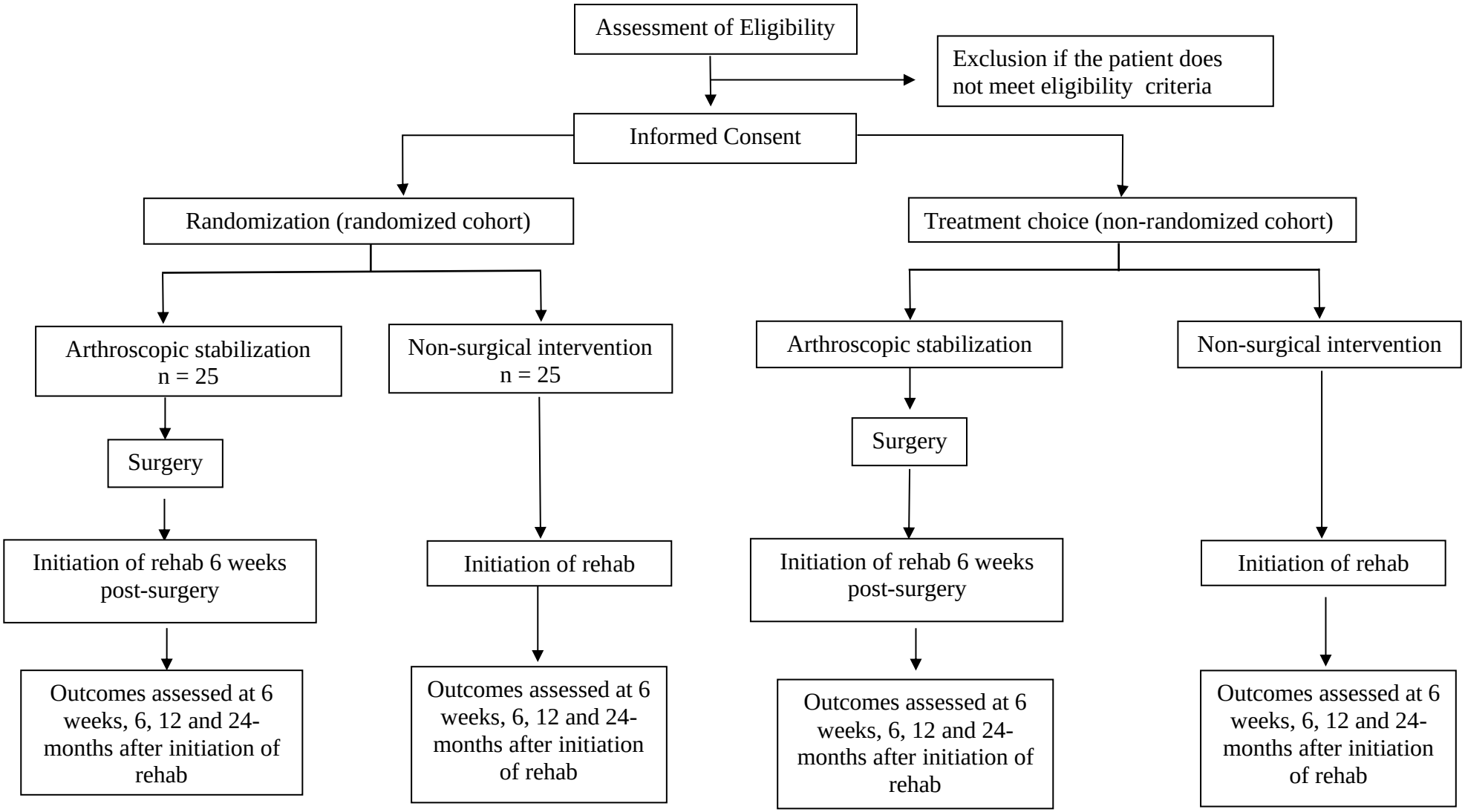

Figure 1. Trial Design Overview

4.0. METHODS

4.1. Study Setting
This pilot trial will be conducted at a number of clinical sites across Canada, USA, South America and Europe. This study will be coordinated at McMaster University by the Department of Surgery Clinical Trials Unit who will be responsible for trial oversight, clinical site management, data management, data analysis, and knowledge dissemination.

4.2. Eligibility Criteria
Patients who meet the eligibility criteria outlined below are to be included in the study.

The inclusion criteria are:

1. Patients ages 14-40 years;
2. Diagnosis of first-time anterior shoulder dislocation having occurred within the past 3 months, confirmed either by radiographic evidence or documented reduction of anterior shoulder dislocation as well as physical examination eliciting unwanted glenohumeral translation with reproduction of symptoms;
3. Provision of informed consent.

The exclusion criteria are:

1. Patients that cannot undergo surgery or anesthesia;
2. Patients with concomitant injuries (rotator cuff tear, fracture);
3. Previous shoulder surgery;
4. Patients that will likely have problems with maintaining follow-up or are incarcerated;
5. Epilepsy/seizure disorder
6. Pregnancy;
7. Diagnosis of multidirectional instability;
8. Bony glenoid defect (bony Bankart) >10% as measured on preop imaging;
9. Dislocation without trauma, in a context of hyper laxity or atraumatic instability;
10. Cases involving litigation or workplace insurance claims (e.g. WSIB).

4.3 Recruitment Strategy and Patient Screening
Participating centers will identify patients with a FTD through outpatient clinics. The surgeon, designated fellow, or resident will conduct a history and physical examination as per standard of care. Standard radiographs must be obtained as part of this assessment.

Patients who are potentially eligible based on history and examination will be invited to participate in the trial. If they agree, written informed consent will be obtained. To obtain informed consent, study personnel will adhere to the following procedures:

- Present study information in a manner that is understandable to the patient;
- Discuss the study with the patient and answer any questions they have;
- Allow the patient ample time to discuss participation with their family/significant others, and treatment team;
- Confirm that the patient understands the risks and benefits of participating in the study and that their participation is voluntary;
- Complete the consent process and obtain signatures from the patient and site investigator or delegate.

The process of obtaining and documenting informed consent forms will be completed in accordance with local Good Clinical Practice guidelines. Participants may withdraw their consent at any time. The pilot trial will exam the feasibility of recruitment and determine the proportion of patients who are eligible after screening, refusal rates, and reasons for declining participation.

Consenting minors: Sites that will be enrolling minors should follow their local REB guidelines for consenting minors.

4.4. Group Allocation

For participants who agree to be randomized, eligible and consenting patients will be randomized using an online web-based randomization system (REDCap electronic data capture (EDC)). Randomization will be stratified by centre and will employ randomly permutated block sizes. A statistician who is otherwise uninvolved in the trial will generate the randomization list and program the randomization system. Eligible participants will be randomized in 1:1 manner to one of two treatment groups:

- Arm 1: Arthroscopic stabilization
- Arm 2: Non-operative management

Participants who agree to participate in the non-randomized arm of the study will not be randomized. Their treatment preference will be noted at baseline.

4.4.1. Blinding

The patient and the study team including the treating surgeon and study coordinator cannot be blinded as they will be undergoing/performing the procedure and/or will have access to post-operative imaging and clinical notes. Outcome assessors and study statisticians, however, will be blinded.

4.5. Trial Intervention Procedures

Participants will undergo arthroscopic soft tissue stabilization (Bankart procedure) or non-surgical treatment as described below. All participants will follow the same standardized 3-phase rehabilitation protocol.

4.5.1 Arthroscopic Stabilization (Intervention)

Patients randomized to surgical intervention will be required to undergo surgery within 3 months of enrollment. The period of 3 months between enrolment and surgery was chosen to balance practicality in a public system while also seeking to acutely repair the pathology. A focus group of Canadian surgeons was brought together in 2023 and determined this to be reasonable and clinically important. Prior to surgery, advanced imaging will be obtained: MRI, MR arthrogram or preoperative CT scan. This imaging is done as standard care for surgical planning only and will not be used to assess prognosis. For arthroscopic Bankart repair, the participant will be placed in the lateral decubitus or beach chair position. Standard diagnostic arthroscopy will be performed. The capsulolabral complex will be freed from the anterior aspect of the scapular neck. The anterior aspect of the scapular neck will be decorticated using a motorized burr. A capsuloligamentous repair will be performed with the capsule shifted from inferior to superior and repaired on the glenoid face. The number of anchors used for the repair will be left to the discretion of the surgeon (a minimum of 3 anchors recommended). Remplissage procedure will be performed at the

discretion of the operating surgeon. Participants will wear a sling for 6 weeks after surgery. Type of sling will be left to discretion of the treating surgeon. All participants will follow the standardized 3-phase rehabilitation protocol detailed below, starting 6 weeks after surgery once the sling is removed.

4.5.2 Non-surgical treatment (Control Group)

All participants will follow the standardized 3-phase rehabilitation protocol detailed below immediately after the date of consent, unless the dislocation occurred less than two weeks prior to consent, in which case the patient will wear a sling until they reach two weeks post-dislocation. This is to allow for sufficient healing and pain management prior to initiating physical therapy. Type of sling will be left to discretion of the treating surgeon.

4.6. Rehabilitation Protocol

Standardized rehabilitation protocol for both groups: This protocol was adapted from the published consensus rehabilitation guideline developed by the American Society of Shoulder and Elbow Therapists for rehabilitation following arthroscopic anterior capsulolabral repair of the shoulder[25]. Handouts detailing the complete rehabilitation protocol will be provided to the participants to share with their physiotherapists. This protocol details certain criteria that must be met in order for participants to progress to the next phase. Progression through the phases is dependent on the successful completion of the listed criteria. The length of rehabilitation is estimated to be six weeks in both groups. Participants will be provided a document to bring to every physiotherapy visit to document progress and compliance. Physical therapists will confirm advancement criteria are met on the provided document in order for the study team to track participants' progression through the phases.

Phase I: Passive/active range of motion (ROM)

- *Stretching/PROM/AROM:* Pendulum exercises, Supine ER, Standing ER, Supine passive arm elevation, Seated-standing forward arm elevation, Behind the back internal rotation (IR).
- *Isometrics:* IR and ER at neutral, Prone row, Prone extension (do not extend past hip), Side lying ER, Rhythmic stabilization and proprioceptive exercises with therapist.

Criteria to be met to progress to phase II: 80% ROM with reference to contra-lateral shoulder, strength level 4/5 (movement against at least some resistance supplied by the examiner). ROM and strength measured in scaption.

Phase II: Strengthening

- *Stretching/PROM/AROM:* Pendulums, Standing ER / door / wall slide stretch, Hands behind the head stretch, Behind the back IR, Supine cross body stretch, Side lying IR;
- *Strengthening/Theraband:* ER, IR, Standing forward punch, Shoulder shrug, Seated row; Dynamic hug, Wall "W's", Side lying ER, Prone horizontal abduction "T's", Prone scaptation "Y's", Prone row, Prone extension, Standing scaptation "full can" exercises, Rhythmic stabilization and proprioception exercises with therapist.

Criteria to be met to progress to phase III: 100% ROM (within 5 degrees of the contra-lateral shoulder), strength level 5/5 (full strength, pain-free). ROM and strength measured in scaption.

Phase III: Advanced strengthening/functional therapy

- *Stretching/PROM/AROM:* Continue phase II exercises, ER at 90 degrees' abduction stretch;
- *Strengthening/Theraband:* Continue phase II exercises, ER at 90°, IR at 90°, Standing 'T's, Diagonal up, Diagonal down.
- *Strengthening/Dynamic:* Continue phase II exercises, Prone ER at 90 degrees' abduction, Biceps curls, resisted forearm supination/pronation, resisted wrist flexion/extension, proprioceptive neuromuscular facilitation (PNF) manual resistance with therapist, Push up progression

PT discharge criteria: no apprehension, SANE score >90%[26].

4.7. Assurance of Standardization of the Procedures

Differential expertise bias will be limited by ensuring that all participating surgeons will be fellowship trained in shoulder surgery and would have performed a sufficient number of cases to limit the potential for expertise bias. Based on the available literature, a minimum of 50 cases of arthroscopic Bankart repair would be required for surgeons to meet our participation requirements[27].

4.8. Primary Outcome

The success of the pilot study will be based upon the following *a priori* thresholds:

1. 50 patients recruited within 10 months;
2. 42 of 50 participants (85%) achieving complete follow-up at two years;
3. 85% of patients allocated to surgical intervention receiving surgery within 3 months of enrollment;
4. Less than 5 crossovers* between both groups.

*__Note__: Crossovers are defined as either: 1) participants randomized to non-operative management (control group) who choose to undergo surgery in the absence of any feelings of recurrent instability or re-dislocation; or 2) participants randomized to surgical intervention who opt out of surgery prior to surgical intervention and choose to undergo primary non-operative management.

We will confirm feasibility with a "traffic light" approach to determine if the definitive trial will be feasible, require modifications or will not be feasible.

4.9. Secondary Outcomes

Secondary objectives are to evaluate:

1. Number of recurrent shoulder dislocations up to 24 months post-treatment;
2. Symptoms of instability up to 24 months post-treatment;
3. Patient reported outcomes include the WOSI Index, ASES score, Shoulder Activity Scale, EQ-5D, VAS pain scale and Patient Satisfaction questionnaire.

- The WOSI is a self-administered quality of life outcome measure designed for clinical trials evaluating treatments for patients with shoulder instability. It has been shown to have high reliability, validity and responsiveness[11]. The WOSI score is commonly utilized and has been shown to provide excellent ability to detect variability in severity of post-operative instability symptoms including following shoulder stabilization procedures[28].

- The ASES score is designed to assess shoulder function including instability[29]. It allows for patient self-evaluation through 11 items that can be used to generate a score, divided into 2 areas: pain (1 item) and function (10 items).
- Shoulder Activity Scale is designed to assess patient's shoulder activity level. The activity rating is a numerical sum of scores for five activities rated on a five-point frequency scale from never performed (0 points) to daily (4 points).
- EQ-5D is a standardized measure of health-related quality of life and consists of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.
- VAS Pain Score is used to assess pain on a 100-point scale ranging from 0 to 100, with zero (0) representing no pain and 100 representing the worst pain imaginable.
- Patient Satisfaction will be documented on a visual analogue score of 0-100 "How satisfied are you with your medical care?" Rated by the subject with 0 is the least satisfied, 100 the most satisfied.

Functional outcome assessment will be patient-reported on paper using case report forms administered by the study coordinator or delegate at each site.

4. Physical examination (range of motion and stability): Physical examination following surgery will be performed by the operating surgeon or an assigned delegate and will consist of functional assessment important to patients. Range of motion and shoulder stability are commonly reported outcome measures in the literature when assessing success following shoulder instability surgery[30,31]. Range of motion will be assessed in forward flexion, abduction, ER and IR. Stability will be assessed primarily via the apprehension- relocation physical examination maneuver which has demonstrated the highest sensitivity in the literature for the diagnosis of anterior instability[32]. Presence of apprehension will be elicited by bringing the patient's shoulder into a position of 90° of abduction and 90° of external rotation in either the supine or upright position. A positive exam finding is the subjective feeling of impending subluxation or dislocation when in this provocative position. Relocation test is performed, positive test is resolution of feeling of impending subluxation.

5. Return to previous level of activity/sport and work: This outcome will be patient reported at each follow up visit. Time to return to sport will be based on when the patient is cleared by their treating surgeon to return. Time to return to work will reflect duration of work stoppage, if applicable. Specific dates of return to sport/work will be collected on study CRFs.

6. Safety: Rate of major and minor shoulder-related complications and serious adverse events.

Note: Feelings of recurrent instability or re-dislocation, regardless of group allocation and timing of onset, will be considered a treatment failure.

4.10. Data Collection and Participant Follow-up

The number of patients approached, who are potentially eligible, who agree to participate, and who decline participation (with their reason for refusal) will be recorded.

Once participants have provided informed consent, baseline demographics, relevant medical history, resilience status, and details regarding their diagnosis will be collected from the participant, the attending surgeon, their medical record and through physical examination. Participants will also complete the WOSI, Shoulder Activity Scale, EQ-5D, VAS pain score, Patient Satisfaction Scale and ASES questionnaires at the time of enrolment.

For the intervention group only, surgical and peri-operative details will be collected from the attending surgeon and the participant's medical records. Adverse events occurring during the surgical procedure or perioperative period will also be documented.

4.10.1. Follow-Up Visits

Participants will be followed for 24 months post-treatment. All outcome data will be collected at 6 weeks (±7 days), 6 months (±30 days), 12 months (±30 days) and 24 months (±60 days) post-treatment at regularly scheduled clinic visits. Of note, the first follow-up timepoint (6 weeks) is relative to the initiation of rehabilitation for both groups, i.e. 6 weeks from the date of the first physiotherapy visit. At each time point, participants will complete the WOSI, Shoulder Activity Scale, EQ-5D, VAS pain score, Patient Satisfaction Scale and ASES. Physical examination (PE) will be performed by the operating surgeon or assigned delegate. Shoulder-related adverse events and SAEs will also be documented. In cases where the participant does not return to the clinic or in-person visit is not viable, study personnel will contact the participant by telephone or email. The study questionnaires can be completed by the patient online, through REDCap EDC or by telephone. A missed follow-up form should be completed if the participant misses the follow up visit. An early withdrawal form should only be completed if the participant withdraws their consent. The Schedule of Events (Table 1) details the requirements and procedures for each visit.

4.10.2. Telephone Follow-Up

If a participant is unable or unwilling to return for follow-up in the confines of the allowable ranges of times for each follow-up period, then as much information as possible may be collected by telephone, text, email, or standard mail, per local REB/IRB guidelines for the specified follow-up period.

To maximize the integrity of the data, all possible attempts will be made to collect as much data as possible and to reduce loss to follow-up. If a participant wishes to withdraw their consent from the study, the following strategies will be used to reduce the demands of the study and help to retain the subject:

- Ask the participant if you can still collect clinical data from their medical and hospital charts; and
- Ask the participant if they may be contacted by telephone to ask about the primary and secondary outcomes.

Participant should not be deemed lost to follow-up until the 24-month visit is due and all attempts to contact the participant have been exhausted.

4.11. Early Withdrawal

Participants may decide to withdraw from this trial at any time. If a participant withdraws prior to completing the trial, the study personnel will document the reason for withdrawal and attempt to collect any available outcome data. Participants will not be withdrawn from the study due to lack

of adherence to the study protocol (e.g. participant received wrong treatment arm, missed follow-up visits, etc.).

4.12. Participant Retention

Once a patient is enrolled in the trial, the clinical site will make every reasonable effort to follow the participant for the entire duration of the study period. The expected follow-up rate for this study is greater than 90% based on similar fracture trials performed by the study investigators[33–35]. Based on this experience, we will implement similar procedures to maintain participant retention which include:

1. Individuals will be excluded if they are likely to present problems with follow-up (refer to exclusion criteria).
2. At the time of consent, each participant will provide the name and address of their primary care physician, and the name, address and phone number of one person at different addresses with whom the participant does not live with who are likely to be aware of the participant's whereabouts as well as their own address and phone number. This information, however, will not be stored in the EDC software and will be only collected on the paper CRFs, for internal use only. The research coordinator will confirm that these numbers are accurate prior to the participant's discharge from hospital.
3. The study coordinator will remind participants of upcoming clinic visits.
4. The study coordinator will contact participants no less than once every three months to maintain contact and obtain information about any planned change in residence.

4.13. Trial Committees

4.13.1 Steering Committee

The Steering Committee will provide guidance and direction; specific responsibilities include reviewing and approving the study protocol and working collaboratively to resolve any challenges that arise during the pilot study. The Steering committee will be comprised of national and international experts in shoulder and orthopaedic surgery and research methodology. The committee will be blinded throughout the trial.

4.13.2. Data and Safety Monitoring Committee

Data and Safety Monitoring Committee (DSMCs) are generally recommended for any controlled trial that will compare rates of mortality or major morbidity. Guidance from the Federal Drug Administration supports that a DSMC is not needed for clinical trials exploring interventions to promote symptom relief (http://www/fda.gov/RegulatoryInformation/Guidances/ucm12069.htm). As such, a DSMC will not be used in the pilot trial.

Table 1: Schedule of Events

Assessment/ Procedures	**Visit 1: Enrollment/ Screening**	**Visit 1A: Surgery****	**Visit 2: 6 weeks** (±7 days)	**Visit 3: 6 months** (±30 days)	**Visit 4: 12 months** (±30 days)	**Visit 5 24 months** (±60 days)
Screening	●					
Informed Consent	●					
Demographics	●					
Randomization*	●					
Operative Data**		●				
Reoperation**/Re-dislocation Instability			●	●	●	●
Rehab status			●	●	●	●
PROs	●		●	●	●	●
Physical Examination	●		●	●	●	●
Safety Assessment		●	●	●	●	●
Assessment of Crossovers and Treatment Failures		●	●	●	●	●

*For randomized cohort only
**For intervention group only

5.0. STATISTICAL PLAN

5.1. Sample Size Determination

Pilot Study: The feasibility objectives in our pilot study do not lend themselves to traditional power calculations. Sample size is based on the precision around the estimate of compliance of 90%. A sample size of 42 patients will yield a 95% CI of 78 to 96% which we feel is adequate precision. If we account for 15% drop-out / loss to follow-up we require a total of 50 patients. Therefore, we propose a sample size of at least 50 participants (25 participants per treatment arm). We have used similar pilot sample sizes to demonstrate feasibility in our previous multi-centre trials[33–36]. We will also aim to recruit an additional 50 participants in the non-randomized cohort.

5.2. Statistical Methods

Primary Analysis (RCT) – Feasibility: We will use descriptive statistics to analyze the primary objective of feasibility of this pilot RCT. The data will be presented as point estimates (proportions and 95% CIs) that define the components of the composite measure of feasibility: recruitment, follow-up, crossovers, and operation within 3 months of enrolment. We will use a "traffic light" approach for feasibility analysis to determine if the definitive trial can proceed or will require any modifications.

Secondary Analysis (RCT): Both intention-to-treat and per protocol analyses will be performed. We will use descriptive statistics to summarize the results. Mean between-group differences and corresponding 95% CIs will be reported for all secondary outcomes at each time point. No p-values will be provided given the trial is not powered for secondary outcomes. These outcomes will be exploratory in nature.

Non-randomized Cohort Analysis: Analysis for the non-randomized cohort will be done in a similar manner to the RCT whereby outcomes will be summarized descriptively by preference of treatment of the patient. Given the small sample size, no formal statistical testing will be performed. Data from the non-randomized cohort will be used to inform feasibility of incorporating a non-randomized cohort within this study design. The same data will be collected for both cohorts but will not be combined.

5.3. Frequency of Analyses

There will be only one analysis at the end of the trial.

6.0. DATA MANAGEMENT

6.1. Case Report Forms and Data Transmission

Clinical sites will be provided with the trial CRFs prior to initiation of enrollment. Research personnel at each clinical site will submit the required data, as detailed on the CRFs, to the Methods Centre using the REDCap electronic data capture system. Clinical site personnel will receive a unique login and password for the REDCap system and will be able to view and modify data for participants recruited at their clinical site.

6.2. Data Integrity

The REDCap system uses a variety of mechanisms for checking data at the time of entry including skip logic, range checks and data type checks. Upon receipt of new data, the personnel at the Methods Centre will query all missing, implausible, or inconsistent data. Clinical site personnel will be notified of open queries through regular reports and will be required to respond promptly.

7.0. ETHICS AND DISSEMINATION

7.1. Research Ethics Approval

This protocol will be reviewed and approved by the Hamilton Integrated Research Ethics Board (HiREB) prior to commencement of the trial, and by the local Institutional Review Board (IRB) or Research Ethics Board (REB) of each participating clinical site prior to initiation of trial activities at the clinical site.

7.2. Confidentiality

Information about study participants will be kept confidential and will be managed in accordance with the below rules:

- All study-related information will be stored securely.
- All study participant information will be stored in locked file cabinets and accessible only to authorized study personnel.
- All CRFs will be identified only by a coded participant number.
- All records that contain participant names, or other identifying information (e.g. consent forms and contact information forms), will be stored separately from the study records that are identified only by the coded participant number.
- All electronic databases will be password protected.

If a participant revokes authorization to collect or use personal health information (PHI), the clinical site retains the ability to use all information collected prior to the revocation of participant authorization. For participants who have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. primary outcome data) at the end of their scheduled study period.

7.3. Amendments

Any amendments to the study protocol which may affect the conduct of the study, or the potential safety of or benefits to participants (e.g. changes to the study objectives, study design, sample size, or study procedures) will require a formal amendment to the protocol. Any protocol amendments will be approved by the Principal Investigator and will require approval by the Hamilton Integrated REB and the local REB/IRB at each participating clinical site. Administrative changes (e.g. minor corrections or clarifications that have no effect on the way the study is conducted) will not need to undergo a formal amendment process.

7.4. Adverse Event Reporting and Definitions

7.4.1. Adverse Events

An adverse event is any untoward medical occurrence that may present during treatment, but which does not necessarily have a causal relationship with the treatment.

7.4.2. Serious Adverse Event

A serious adverse event (SAE) is any adverse event that is any of the following:

- Fatal
- Life threatening
- Requires or prolongs hospital stay
- Results in persistent or significant disability or incapacity
- A congenital anomaly or birth defect
- An important medical event

7.4.3. Unanticipated Problems Resulting in Risk to Participant or Others

Any incident, experience, or outcome that meets the following criteria:

- Unexpected in nature, severity, or frequency (e.g. not described in study-related documents such as the ethics-approved protocol or consent form, etc.).
- Related or possibility related to participation in the research (i.e. possibly related means there is reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research).
- Suggests that the research places participants or others at greater risk of harm (including physical, psychological, economic, or social harm).

7.4.4. Clinical Site Reporting: Notifying the Methods Centre

Clinical sites are responsible for reporting adverse events, including SAEs, to the Methods Centre via the REDCap system. Significant new information on ongoing adverse events should also be provided promptly to the Methods Centre via the REDCap system. Unanticipated problems resulting in risk to participants or others are also to be reported promptly to the Methods Centre.

7.4.5. Clinical Site: Institutional Review Board and Research Ethics Board Reporting

Clinical sites are responsible for reporting SAEs and unanticipated problems resulting in risk to participants or others to their local REB/IRB in accordance with local reporting requirements. Copies of each report and documentation of ethic board notification and receipt will be kept in the clinical site's study file.

7.5. Dissemination Policy

Results from the study will be submitted for publication regardless of whether or not there are statistically significant findings. Every attempt will be made to ensure that the amount of time between completion of data collection and release of study findings are minimized.

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