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Online Yoga-Based and Standard Exercises for Patients with a Rotator Cuff Injury Awaiting Surgery: A Feasibility Study

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A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Health and Rehabilitation Sciences

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Abstract

This study investigates the feasibility of conducting a 6-week intervention program comparing online yoga-based and standard exercises among 10 injured pre-surgery rotator cuff patients. Case reports on two patients are presented to demonstrate implementation and potential consequences of both interventions. A feasibility study was conducted after recruiting 10 patients from surgical wait list of 51 patients. Patients in both studies were assessed for shoulder flexion, abduction and external rotation range of motion and strength at baseline and 6-weeks. The SPADI questionnaire was used to assess pain/function. Most (8/10) patients in the feasibility study did not complete the full protocol. One case worsened (yoga), while another (standard exercise) improved in strength. This does not indicate relative efficacy. SPADI results were changed by less than 10% indicating no clinically important change. Qualitative feedback suggested that patients might be open to online exercises. Developmental work is needed to define a feasible intervention/study design.

Keywords: rotator cuff, yoga, online exercises, pre-operative, rehabilitation

Co-Authorship Statement

This paper contains a case study co-authored by Professor Joy MacDermid, Professor Jackie Sadi and Dr. Ken Faber.

This paper also contains a feasibility study, for which the co-authors are the aforementioned and Dr. George Athwal.

Dolly Mehta is the first author on both manuscripts and was responsible for completing ethics, collecting study data, editing the intervention videos, drafting manuscripts and revising them with feedback. Joy MacDermid and Jackie Sadi led development of the clinical content of the videos, contributed to study design and revised manuscripts. Ken Faber consulted on the clinical content, research design and revised manuscripts.

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To all the patients who were a part of this study: thank you for your time and feedback. I truly hope your recovery is a quick and smooth journey.

Thank you to my fellow Graduate students who provided their support. Special thank you to Katrina Munro and Joshua Vincent as well for their help with patient recruitment and testing.

To my wonderful family who has taught me the deeper lessons of life: I love you, thank you for being mine.

Above all, thank you Lord for my blessings. I sought You and You gave me miracles. OM.

Western's Graduate Research Scholarship supported this research.

Dedication

I would like to dedicate this work to the following:

Students: who at one point or another may have felt utterly lost—keep going.

“Difficulties in your life don’t come to destroy you, but to help you realize your hidden potential.”

~ Dr. APG Abdul Kalam

Enjoy the journey.

Teachers: who have a profound influence in nurturing their students’ minds and shaping lives.

“A teacher gives knowledge to his students and enlightens him.”

~Yajur Veda

I fold my hands in deep gratitude to all my teachers, including Life itself—the greatest teacher of all.

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List of Abbreviations

ER	External Rotation
HHD	Handheld Dynamometer
PT	Physiotherapy
RC	Rotator Cuff
RCIs	Rotator Cuff Injuries
ROM	Range of Motion
SA	Shoulder Abduction
SF	Shoulder Flexion
SPADI	Shoulder Pain and Disability Index
STD	Standard (Standard exercises = std. ex.)

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CHAPTER 1

Statement of Problem and Literature Review

Statement of Problem

Rotator cuff injuries (RCIs) are the most common shoulder injuries seen in primary care practices (Lin, Weintraub & Aragaki, 2008). In fact, in the United States approximately 3 million patients a year seek medical help for shoulder pain. Individuals over the age of 60 years are particularly susceptible (Reilly, Macleod, Macfarlane, & Emery, 2006). Unfortunately, rotator cuff (RC) prevalence is only expected to grow, considering that the general population is aging (Gomoll, Katz, Warner & Millett, 2004) and RC pathology increases with age (Ainsworth & Lewis, 2007).

The shoulder is the most mobile joint in the body (Quillen, Wuchner & Hatch, 2004), and any injury to it invariably causes much distress by limiting self-care and functional independence (Lin, Weintraub & Aragaki, 2008). Daily routine activities such as reaching, washing, dressing and carrying everyday objects are difficult (Lowe, Moser & Barker, 2014). Unfortunately, tendon healing is poor (and thus slow) because blood flow to the cuff is reduced (Karthikeyan et al., 2015).

With the rate of recovery being a time-consuming process, it follows that healthcare costs are significant. A study by Yeranorian, Terrell, Wang, McAllister & Petrigliano (2013) examined pre-operative costs associated with RC tears prior to surgery and found surprising results. The 90-day pre-operative period cost \$161,933,100 for the 92,688 patients that were enrolled (average of \$1748 per patient). Diagnostic imaging costs were the highest, representing 65% of the total charges with outpatient visits representing 18% and physical therapy representing 8.5%. Pre-operative and laboratory studies comprised 4.2% of the total, with 1% being miscellaneous costs. Recognizing that healthcare costs associated with RCIs are likely to increase in the future since there is an aging population, it will be necessary to reduce healthcare expenditure by preventing injuries and/or focusing on rehabilitation techniques that facilitate quicker recovery.

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What is Rotator Cuff Disease?

Rotator cuff injuries (RCIs) are one of the most common shoulder disorders (Ciccotti, 2005). Abnormalities increase with age and the prevalence has been found to be 9.7% in patients 20 years and younger to 62% in patients 80 years and older (Teunis, Lubberts, Reilly & Ring, 2014). The rotator cuff (RC) is comprised of four muscles and associated tendons, which together form a “cuff” at the top of the arm. This cuff helps to lift and rotate the arm, allowing individuals to do a range of activities (Armstrong, 2011).

There are a number of causes that can result in an individual experiencing an RCI. Natural degeneration due to age or overtime “wear and tear” (Matsen, 2008) is *micro-traumatic*, which stems from repeated overuse. A *macro-traumatic* cause, on the other hand, is a sudden onset. Overusing the arm (Cofield & Minnesota, 1985) is an example of micro-trauma (Muscolino, 2015) whereas falling or carrying a heavy load are examples of macro-trauma (Muscolino, 2015). Older patients (>40 years) typically suffer an RCI that is due to degeneration and compared to younger patients, older patients often experience asymptomatic tears that become symptomatic without any distressing event (Lazarides et al., 2015).

There are three forms of RC pathology. *Tendinitis*, which occurs when there is tendon inflammation and irritation. *Tendinosus*, which occurs when the inflammation diminishes but due to chronic physical stress, tendinosus tissue degeneration occurs. This leads to weakness in the tendon’s structure and if the RC continues to undergo physical stress, *tearing* – the third form of RC pathology – can occur (Muscolino, 2015).

In addition, individuals belonging to the following occupations are particularly susceptible: swimmers, pitchers, volleyball players (athletic professions), mill workers, carpenters, operators and welders (Pribicevic & Pollard, 2004) because of repetitive shoulder joint overuse (Muscolino, 2015). Other risk factors that can contribute to an RCI include: age [the older one is, the greater the chance of injury] and family history [genes might play a role in how likely one is in sustaining such an injury] (Mayo Clinic, 2015). Family history, smoking status, occupation and limb dominance can also play a role (Sambandam, Khanna, Gul, & Mounasamy, 2015). Thus, RC pathology is likely to be multifactorial (Ainsworth & Lewis, 2007).

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Treatment for an RCI depends on its severity. For mild injuries applying hot/cold packs and/or exercising might suffice. For more severe injuries medications like ibuprofen might be required; for cuff tears, surgery often becomes a necessity (Nall, 2014). Furthermore, it is important to correctly differentiate RCIs from a number of other similar ailments, such as: early glenohumeral arthritis and calcific tendonitis (Vollans & Ali, 2016). A patient's history of shoulder condition; a physical examination of the shoulder via palpation (to assess stiffness, pain, restricted arm movements, etc.); radiographs; and/or MRI tests should be done (Matsen, 2008). Ultrasonography and computed tomography imaging tests can also be done; however, MRIs, allow for a far more comprehensive evaluation of the shoulder than other imaging tests since a clinician can observe soft tissues, determine if the tear is full or partial, and determine a tear's size and location (Makhni et al., 2015).

Rotator Cuff Muscles and Function

There are four specific muscles that form the RC: subscapularis, supraspinatus, infraspinatus and teres minor. These muscles and their distal tendons combine to form a cuff-shape over the head of the humerus, which primarily stabilize the glenohumeral joint through isometric contractions. The glenohumeral joint is a ball-and-socket joint of the shoulder that allows for three-axis movements (Ihashi, Matsushita, Yagi & Handa, 1998). Each muscle, however, does have a specific role (Muscolino, 2015).

The subscapularis is the largest (Bartl, Scheibel, Magosch, Lichtenberg, Habermeyer, 2011) and strongest RC muscle, as well as the most important active shoulder stabilizer (Paladini, Merolla, Santis, Campi & Porcellini, 2012). It is primarily an internal rotator (Millett, Wilcox, O'Halleran & Warner, 2006), but can also serve as a shoulder abductor, stabilizer and humeral head depressor (Decker, Tokish, Ellis, Torry, & Hawkins, 2003). The superior subscapularis fibers support shoulder abduction and the inferior subscapularis fibers support shoulder adduction. Furthermore, this muscle helps to resist anterior dislocation (Morag, Jamadar & Miller, 2011).

The supraspinatus, the most commonly affected RC muscle (Jobe & Moynes, 1982), allows for shoulder abduction (SA) (Post, Silver, & Singh, 1982) of the glenohumeral joint (Vollans & Ali, 2016). It has stabilizing effects (Ihashi, Matsushita,

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Yagi & Handa, 1998) and according to Smith & Smith (2010), it also aids in forward flexion (the first 30 degrees) and external rotation of the humerus.

The infraspinatus and teres minor muscles primarily guide external rotation (Jobe & Moynes, 1982; Matsen, 2008). The infraspinatus muscle provides dynamic stability (Ha et al., 2013) and the teres minor muscle depresses the humeral head (Melis, DeFranco, Ladermann, Barthelemy & Walch, 2011).

It is important to note that despite performing a minor role in motion, each RC muscle works together as a single unit to aid in stability (Whittle & Buchbinder, 2015).

Prevalence of Rotator Cuff Disease

Rotator cuff disease is one of the most commonly seen orthopedic conditions and thus, surgical repairs are a common operation (Cofield et al., 2001). In the United States alone, over 4.5 million physician visits are due to rotator cuff tendon failures (Matsen, 2008) and the incidence of full-thickness tears varies from 5% and 40% (Monica, Vredenburgh, Korsh, & Gatt, 2016).

In a study conducted by Fehringer and colleagues (2008), it was found that in one hundred and four patients aged 65 years and up, 22% had full-thickness rotator cuff tears (Fehringer, Sun, VanOeveren, Keller, & Matsen, 2008). Unfortunately, the number of individuals with RCIs is only expected to increase because of our aging population (Meister & Andrews, 1993).

Assessment Outcomes for RCIs

There are a number of assessments one can take when evaluating RCIs, including: ROM, strength, tendon imaging, patient satisfaction and functional scoring (Makhni et al., 2015). Subjectively speaking, patients should provide as much detail as possible about their pain and how it affects their daily living. Some questions clinicians can ask are: have there been any traumatic events to the shoulder? How long have you had the pain? What ignites/soothes the pain? (Smith & Smith, 2010). Rotator cuff (RC) specific Patient Reported Outcomes (PROs) such as Disabilities of the Arm, Shoulder and Hand (DASH) as well as other RC specific and general shoulder PROs are both responsive and reliable in this population (MacDermid & Silbernagel, 2015). During physical

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examinations, RC's functional status and strength can be assessed via the following tests: lateral jobe test (for evaluating supraspinatus tendon); belly press (for evaluating the subscapularis tendon); lift off (for evaluating subscapularis tendon) and external rotation (for evaluating infraspinatus and teres minor tendons) (Smith & Smith, 2010).

Unfortunately, there is much variability in reporting RCI-related outcomes such as ROM and strength because a lack of standardization exists in the literature, making it difficult to compare findings between clinical studies (Makhni et al., 2015).

Functional Perspective

Patients that have full-thickness RCIs suffer from pain and limited functional ability (Ainsworth & Lewis, 2007). Shoulder/arm pain is the number one RC symptom reported, particularly when doing overhead activities. A dull pain abruptly becomes "sharp and stabbing" when doing overhead activities (Hermans et al., 2013). Furthermore, depending on the degree of impairment getting dressed, eating with utensils, attending to hygiene and sleeping can be seriously affected. While some individuals experience the aforementioned concerns, there are others who are asymptomatic (Ainsworth & Lewis, 2007). In addition, RCIs can negatively affect quality of life because not only can they cause disabling pain but also progressively weaken muscle strength and shoulder mobility (Razmjou, Bean, Osnabrugge, MacDermid & Holtby, 2006), inhibiting the ability of a patient to lift loads or do overhead activities (Wolff et al., 2006).

Nonsurgical Management

The nonsurgical management of RCIs includes: exercise therapy, electrotherapy, acupuncture, manual therapy, injection therapy and taping (Ainsworth & Lewis, 2007). The goals are to reduce pain and help restore function (Millett, Wilcox, O'Halleran & Warner, 2006).

Injecting non-steroidal and prescribing anti-inflammatory drugs is also considered as nonsurgical management of RC tears (Pegreff, Paladini, Campi, & Porcellini, 2011). Corticosteroid injections may also be administered, however there is disagreement in regards to their improvement (Dalton, 1994).

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Smith & Smith state that nonsurgical management should be the first treatment plan in caring for partial-thickness tears (2010). Typically, partial-thickness RC tears undergo manual physical therapy techniques such as joint mobilization with supervised exercise, which has been shown to be more effective than doing just strengthening muscle exercises, reducing pain and improving function (Millett, Wilcox, O'Halloran & Warner, 2006).

For full-thickness RC tears, nonsurgical management should only be considered after assessing the risk of irrevocable change to the risk of surgery. Interestingly, however, non-surgical treatment for full-thickness RC tears has been shown to be successful. In a prospective cohort study examining physical therapy in treating atraumatic full-thickness RC tears, physical therapists were given a rehabilitation book and asked to perform manual mobilization exercises on patients. Patients were then referred to an independent, at-home exercise program, which they practiced by following a rehabilitation book and DVD. Their program consisted of daily ROM, daily flexibility and strengthening exercises three times a week. It was found that patients opted for surgery less than 25% of the time, 75% demonstrating effectiveness of treatment. Those who opted for surgery tended to do so between 6 and 12 weeks (Kuhn et al., 2013).

This follows in accordance with Schmidt, Jarrett, & Brown's (2015) reporting that typically patients respond to treatment within 6 to 12 weeks of non-surgical practice. Generally after 6 months if symptoms do not improve, operative treatment is considered (Lädemann, Denard, & Collin, 2015).

Why Surgery is Performed and Potential Post-Operative Complications

Surgery for RCIs is performed when nonsurgical methods fail. A key symptom in knowing when one needs surgery is continued pain. Other factors include symptoms have persisted for more than 6 months, tear is larger than 3cm, severe weakness/loss of function and the injury is acute in nature (Armstrong, 2011). Furthermore, surgery is often considered if 6 months of nonsurgical therapy fails (Tytherleigh-Strong, Hirahara, & Miniaci, 2001).

Once surgeries do occur, potential post-operative complications for RC tears include the possibility of a re-tear and ongoing shoulder pain/stiffness. Fortunately, good

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to excellent outcomes can be expected in nearly 90% of cases. However, the success rate decreases depending on the following: large RC tears, patient age, poor quality of tendon, and muscle atrophy. Furthermore, because it can take up to 1 year for a patient's shoulder to normalize, post-operative rehabilitation is necessary although demanding. Following surgery, the first 4 weeks are geared toward maintaining passive ROM via physiotherapy, gradually moving on to increasing a patient's active ROM and strength (Vollans & Ali, 2016).

Types of Surgeries

There are three techniques for surgical repairs of RC tears: open, mini-open and arthroscopic (Parada, Dilisio & Kennedy, 2014), with the aim to restore the shoulder to its pain-free, normal functioning state (Millar, Wu, Tantau, Silverstone & Murrell, 2009).

In an open RC repair (typically used for large tears) a 3 to 6-cm incision is made over the shoulder. The deltoid muscle is removed from the acromion, dead/damaged tissue is removed from the cortical bone (*debridement*) and the deltoid is reattached in the end.

In a mini-open RC repair, a much smaller incision is made but unlike in the open repair, most of the procedure in mini-open is done arthroscopically. The benefit of this is that the removal of the deltoid muscle is avoided, which potentially reduces deltoid injury.

The last type, the arthroscopic RC repair, offers minimal risk of complications. Here, the deltoid muscle only experiences an insertion of a thin tube (*cannula*) and instruments are inserted into the shoulder via portals. No tissues are retracted, making this procedure the least surgically invasive compared to open and mini-open (Ghodadra, Provencher, Verma, Wilk & Romeo, 2009).

Clinical Practice Guidelines for RC Management

A conditioning exercise program is available online (<http://orthoinfo.aaos.org/topic.cfm?topic=A00663>) that offers step-by-step directions for eighteen different RC exercises (“Rotator Cuff and Shoulder Conditioning Program”, 2012). Approved by the American Academy of Orthopaedic Surgeons

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(AAOS) in 2010, (Pedowitz et al., 2011), this guideline—*Optimizing the Management of Rotator Cuff Problems* (Tashjian, 2011)—provides the best current evidence available for the management of RC problems, based on published studies. It offers clinical practice recommendations according to current literature and highlights research gaps along with potential areas for future research (Pedowitz et al., 2011).

Importance of Exercise for Rotator Cuff Treatment

Physiotherapy (PT) is typically the primary mode of management for RCIs. It aims to improve the biomechanics of the shoulder and thereby help reduce pain and disability. PT techniques include mobilization, tissue massage, exercise instructions and education (Bennell, et al., 2007). “ROM, stretching, flexibility, strengthening, manual therapy (joint/tissue mobilization) and modalities” are involved (Kuhn, 2009).

In a systematic review conducted by Fleming, Seitz and Ebaugh (2010), the role of exercise on RC impingement syndrome was investigated. They found that exercise improves pain, strength, ROM and function outcomes. They also state that such benefits might be amplified if manual therapy is performed in conjunction. Despite a number of studies examining exercise effects on RC patients, no single or gold standard exercise protocol for RCIs exists (Kuhn, 2009), because there is no agreement on the dosage, frequency, delivery method and acceptable pain levels (Lewis, 2016).

A study conducted by Bennell and colleagues (2010) investigated a daily physiotherapist-delivered, manual therapy, home exercise program on adults with chronic RC disease compared to a placebo group, on shoulder pain and function. Both groups had 10 sessions with a physiotherapist. In the intervention group (30-45 minutes), “soft-tissue massage, passive mobilization of the glenohumeral joint, scapular retraining and postural taping, spinal mobilization and daily home exercises” were administered. Educational and motivational strategies were also provided. The placebo group, on the other hand, underwent mock ultrasound therapy and light gel application on their shoulder regions. They were asked not to exercise. Results showed that at 11 weeks from baseline, the intervention group was no better than placebo. However, better functional improvement was seen at week 22 for the intervention group. Interestingly, McCaffrey and Park (2016)

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stated that a particular form of exercise, yoga, is likely to be as beneficial if not superior to exercise in terms of pain reduction and lowered medication use.

Brief Introduction to Yoga

Yoga is approximately a 5000 year-old ancient practice from India that benefits mental and physical wellbeing. It is a mind-body therapy that has become rather popular in the West. However, it is not just about bending oneself in specific poses (asanas) and breathing; it is a “lifestyle, health and spirituality”. Yoga combines physical exercise with mental concentration through breathing and meditation (Sorosky, Stilp & Akuthota, 2008). Breathing is believed to affect the sympathetic nervous system and metabolic activity while meditation often includes mantras (repeated phrases) to quiet the mind. Furthermore, there are different branches of yoga ranging from the very quiet/meditation only (Yoga-Nidra) to intense and powerful movements (Ashtanga yoga), which means yoga varies depending on the school of yoga is taught (Fouladbakhsh, 2011).

There are four key principles that underlie yoga. One: the human body is an interconnected entity and an illness in one dimension affects the others. Two: everyone has unique needs and thus, yoga practice must be tailored according to one’s individuality. Three: yoga is self-empowering because each one who practices yoga is his/her own healer. And four: the mind plays a crucial role in one’s health and wellbeing. A positive mind state promotes greater health at a faster rate than a negative mind state (Woodyard, 2011).

Yoga and Flexibility (ROM)

Yoga can help increase flexibility and increase ROM because stretching of muscles causes lactic acid to be released into the bloodstream, which allows muscular contractions to not be hindered (Ghoncheh and Smith, 2004; Williams et al., 2005).

In a study conducted by Amin and Goodman (2014), sixteen females ages 44 to 60 years participated in a 90-minute Iyengar yoga session once a week for 6 weeks. Lumbar and hamstring flexibility were assessed pre and post using sit-and-reach tests. Results showed that post-intervention tests were significantly greater than pre-

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intervention tests, meaning that flexibility increased substantially. In fact, subjects' scores went from "above average" to "excellent" in classification.

Yoga and Strength

In a study conducted by Schmid, Miller, Puymbroeck and DeBaun-Sprague (2014), 8 weeks of therapeutic yoga on stroke patients was investigated. They measured strength, ROM, pain and endurance of forty-seven chronic stroke patients (compared to ten in control) and found that all measures significantly improved. In the control group, however, no such changes occurred. Thus, using yoga to improve physical functioning was found to be highly beneficial; and such an intervention could be used in conjunction with mainstream rehabilitation practice.

Another study conducted by Srivastava, Avasthi, Srivastava and Raj (2015) analyzed yoga improvements on pain, stiffness and physical disability in knee osteoarthritis patients (KOA). One hundred and twenty KOA patients were randomized to either receive conventional treatment with yoga (group A) or conventional treatment alone (group B). Baseline and 6-month interval measurements were taken. Results showed that Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores significantly decreased in group A. In group B, however, WOMAC scores decreased, but with no statistical significance. Similar to Schmid and colleagues (2014) recommendation, yoga in conjunction with conventional KOA treatment can help increase physical function and quality of life.

Yoga and Pain

In a meta-analysis for 27 clinical studies conducted by Bussing, Ostermann, Ludtke and Michalsen (2012), it was found that the yoga intervention was favorable in all studies. They suggest yoga can be beneficial for a multitude of pain-related disabilities.

In a randomized pilot study conducted by Galantino and colleagues (2004), the effect of modified Hatha yoga on twenty-two participants with chronic low back pain, over a 6-week time period was investigated. Functional outcome measures were forward reach (FR) and sit-and-reach (SR) tests. Participants were randomized to the yoga-based treatment, which occurred biweekly for an hour or to the control group. They found

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increased balance and flexibility for participants in the yoga group, but because the study was not powered for statistical significance and had a high dropout rate, the findings should be taken with caution.

Yoga and Rotator Cuff

To the author's knowledge, only one study has examined the relationship between yoga and RCIs. Fisherman and colleagues (2011) examined a yoga-based maneuver in patients with partial or full-thickness RC tears through nonsurgical management. A triangular forearm support (TFS) position using either a chair or wall was performed during physical therapy sessions for an average of five times. It was found that painless active abduction and active flexion significantly increased. Moreover, pain rating immediately after the yoga pose and 2.5 years post significantly decreased. The TFS position combined with physical therapy thus appeared to substantially benefit the RCI patients.

Technologically Based Rehabilitation

Emerging technologies like the Wii have been created to allow users to combine fitness and fun in optimizing their health and fitness (McCarthy, Brazil, Greene, Rendell, & Rohr, 2013). McCarthy and colleagues (2013) studied flexibility and heart rate after a 4-week long Wii yoga fit session. Fourteen healthy participants were randomized to the training group and eighteen healthy participants were randomized to control. Upper and lower body flexibility was assessed both before and after the intervention. Results showed the participants in the Wii group had significant improvements in upper and lower body flexibility, while the control did not show any changes in flexibility.

What is a Pilot and Feasibility Study?

A pilot study is a methodological prelude to a bigger study. Typically, such studies are used to assess the methodical feasibility for randomized controlled trials and can be appropriate for either quantitative or qualitative study designs. Pilot studies allow researchers to sample different methods before moving onto larger, more intensive studies. They can assess elements such as: patient recruitment, patient feedback to

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interventions/willingness to participate, possible downfalls in the study and more (Foster, 2013). It is necessary to recognize that pilot studies are *not* pivotal trials and can neither accept nor reject null hypotheses because they are underpowered (Shader, 2015).

Essentially, they are a smaller version of the main study that assess if individual components can all function together for the main study (Arain, Campbell, Cooper & Lancaster, 2010) and determine if a larger study is reasonable (Shader, 2015).

A feasibility study, on the other hand, often precedes a large clinical trial and is intended to answer the fundamental question of “*can this study be done?*” Factors assessed are number of eligible participants; follow-up rates; data availability needed; amount of time required to collect and analyze data, etc. (Evaluation, Trials and Studies, 2016). Moreover, feasibility studies need not be randomized for randomized controlled trials and they do not assess outcomes – that is left to the main study (Arain, Campbell, Cooper, & Lancaster, 2010).

In practice, the definitions for the two terms are not clear and the definitions differ depending on health research funding bodies. It is suggested that authors report their requirements openly (Arain, Campbell, Cooper, & Lancaster, 2010).

Purpose of the Thesis

Despite the significant societal cost and patient burdens of RCIs and their contribution to millions of dollars spent on healthcare (RJ, JW, & TP, 2005), research on pre-rehabilitation home programs for patients waiting for rotator cuff tears, has not been studied. The purpose of this research was to lay down a foundation for future research on pre-rehabilitation in people with rotator cuff tears by conducting a case report and feasibility study that evaluates changes in shoulder ROM, strength and pain/function for RCI patients who participate in an online yoga-based or standard exercise program for 6 weeks. This research was designed to inform the design of the interventions and test procedures for future fully powered clinical trials.

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Research Questions

The research questions this study aims to investigate include:

- Is a 6-week pre-operative rehabilitation program consisting of an at-home, online, video-based exercise program feasible for RCI patients awaiting surgery?
- Is a future clinical trial comparing online yoga-based and standard exercises for RCI patients awaiting surgery potentially beneficial in terms of ROM, strength and function?
- Are yoga-based and standard exercises feasible and well received by patient?

CHAPTER 2

Case Study for Two Patients

INTRODUCTION

Pre-rehabilitation approaches have been shown to be beneficial by facilitating function and allowing patients to return to their daily living activities sooner than those who do not undergo pre-rehabilitation (Pechman, 2014). The concept behind pre-rehabilitation or “*prehabilitation*” is to improve one’s capacity before a stressful procedure such as surgery, so one can endure the stress better than someone who is inactive (Ditmyer, Topp & Pifer, 2002).

Patients who fail 6 months of nonsurgical management of rotator cuff disorders typically proceed to surgery (Tytherleigh-Strong, Hirahara, & Miniaci, 2001). Whether due to health system factors or personal factors there is often a waiting period between when a person has failed nonsurgical management and when a surgical procedure is conducted. It is during this wait time that patients may further deteriorate in muscle strength and function due to disuse. Although pre-rehabilitation has been investigated in other musculoskeletal disorders, there are no specific studies addressing the role of pre-rehabilitation prior to rotator cuff surgery.

There is evidence of the positive effects of exercise on rotator cuff injuries such as reduced pain and disability (Littlewood, Ashton, Chance-Larsen, May & Sturrock, 2012). Yoga has been shown to be beneficial in improving pain and functional outcomes for a number of musculoskeletal conditions (Ward, Stebbings, Cherkin & Baxter, 2013). Clinical practice guidelines have established specific therapeutic exercises that should be used to rehabilitate patients with rotator cuff pathology (“Rotator Cuff and Shoulder Conditioning Program”, 2012). Different types of exercise can potentially affect adherence, exercise fidelity, adverse effects and clinical outcomes. While therapeutic exercises that specifically target the rotator cuff have been traditionally used, there is a possibility that more activity-based exercises would be beneficial. Therefore the purposes of this study were to conduct a case report of two patients who completed an independent video-based exercise program while waiting for rotator cuff surgery. One who performed standard or traditional therapeutic exercises and one who performed yoga-based exercises

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METHODS

INCLUSION/EXCLUSION CRITERIA

To be included in the study, patients had to be on a surgery wait list for their rotator cuff injury and be 18 years or older. Patients were excluded if their surgery was booked within 6 weeks or they had co-morbidities that precluded participation in an exercise program.

ETHICS and CONSENT

A letter of information, a patient information/consent form, a Diary form and a telephone script were created for this study. Ethical approval was obtained from Western University's Research Ethics Board.

CASE STUDY FOR PARTICIPANTS

A 68 year-old Caucasian female, RC2, suffered a right RCI "several" years ago while in an aquatic class. During pre-assessments, she stated that she stays active by exercising at the YMCA, using weights, playing badminton and continuing with her aquatic classes. She was using pain medication for her shoulder pain.

RC6, a 62 year-old Caucasian male, suffered a left RCI from a work-related incident. (He worked in transportation). He has not been working since incurring his RCI, which has been for a minimum of 5 months. During pre-assessment testing he stated that he did physiotherapy (PT) for 3 months but did not find this to be particularly helpful. The only aspect he stated that he found helpful was the massages. RC6 has been regularly taking medications (Tylenol three for pain, adrentol for sleep and more).

INTERVENTIONS

Yoga

RC2 was provided a yoga video, which consisted of three exercises chosen by the second and third co-authors based on recommendations from the American Academy of Orthopedic Surgeons (AAOS) practice guidelines ("Rotator Cuff and Shoulder Conditioning Program", 2012). The third co-author, a physical therapist, had experience

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with yoga and recommended three specific yoga poses that might recruit rotator cuff muscles: isometric prayer, half cobra and sphinx pose.

The isometric prayer pose required the patient to press their palms firmly together while drawing the shoulder blades inward. The half cobra pose required the patient lie prone on the floor with their hands under the shoulders and lift themselves upward halfway – pressing out through the forearms. The last exercise, sphinx pose, required the patient to do the same as in half cobra, but go up all the way instead of half way. (See Figure 1). Each pose had to be performed for 3 sets, 10 repetitions, for a total of 30. (If 30 repetitions provoked symptoms, the patient was advised to limit repetitions within symptom tolerance). A key point stressed in all of these poses was having proper posture. This meant having ears over top of the shoulders, shoulder blades retracted and thinking of drawing the shoulder blades in. It was clearly stated in the video that if the patient performing the poses experienced pain that lasted for more than one-hour post-exercise, they should discontinue (a little discomfort was normal). The duration of the yoga video was 4 minutes and 7 seconds.

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Figure 1: demonstration of the three yoga poses shown in the video. [Top to bottom: isometric prayer pose, half cobra pose and sphinx pose].

Standard/Traditional Therapeutic Exercises

A patient (RC6) was provided the standard exercises video, which contained three exercises selected from the AAOS clinical practice guidelines (link:

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<<<http://orthoinfo.aaos.org/topic.cfm?topic=A00663>>>). All three exercises used a resistive exercise band. The first exercise—*standing row*—required the patient wrap their band around a doorknob and holding the two ends, pull their arms in and out. The second exercise—*internal rotation*—required the patient to tie a knot on one end of the band and place it in the crease of a door. Using a roll (i.e. towel) tucked under their arm close to their chest, the patient had to pull the other end of the band toward their stomach with their thumb pointing upward. The third exercise was *external rotation*, where the patient was required to keep the band in the crease of a door and pull the other end away from their body. (See Figure 2). Each exercise had to be performed for 10 repetitions, 3 sets, for a total of 30. (If 30 repetitions provoked symptoms, the patient was advised to limit repetitions within symptom tolerance). The standard exercise video was 3 minutes and 41 seconds in length.

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Figure 2: demonstration of the three standard exercises shown in the video. [Top to bottom: standing row, internal rotation and external rotation].

STUDY PROCEDURE

Testing took place at the Roth|McFarlane Hand and Upper Limb Centre (HULC), a specialized upper extremity unit, which has four shoulder surgeons, other surgeon

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specialists, multiple therapists and Western University Graduate students. Shoulder flexion (SF), shoulder abduction (SA) and external rotation (ER) movements were performed on both arms in a seated position. One co-author (DM) performed testing and recorded goniometric readings in the presence of an additional examiner, a trained physiotherapist, to confirm accuracy.

TESTS and MEASURES

ROM

For ROM testing, a double-armed plastic goniometer (Stryker Physiotherapy Associates) was used. During shoulder flexion SF and SA movements, the fulcrum or pin of the goniometer was closely aligned with the patient's glenohumeral joint axis (Sabari, Maltzev, Lubarsky & Homel, 1998), with one arm perpendicular to the floor and the other aligned according to the angle of the proximal humerus (Millett & Warth, 2015). For ER, the patient had their elbow flexed at 90 degrees with their humerus on the side (Millett & Warth, 2015). The goniometer was positioned with the fulcrum at the olecranon (or under the elbow), with one arm parallel to the patient's thigh and the moving along according to the forearm (Cools et al., 2014).

Strength

Strength measures were provided by the handheld dynamometer (HHD) (JTECH Medical). For SF the patient had their elbow extended and at zero degrees flexion. The HHD was placed above the patient's elbow (Ciesla et al., 2011) or middle of the humerus. For SA, the patient had their elbow fully extended and their arm at zero degrees abduction. The HHD was placed in the same position as stated in SF. For ER the patient had their elbow flexed to 90 degrees, arm at 0 degrees and forearm in neutral. Instructions to keep their elbow close to their body were given so arm abduction was avoided. The examiner placed the device on the "dorsal aspect of the distal forearm" and in each movement, the examiner stood to the patient's testing side holding the HHD firmly in both hands (Beshay, Lam, & Murrell, 2011).

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Self-Reported Pain and Function

Pain and function were assessed by the Shoulder Pain and Disability Index (SPADI) questionnaire during pre and post-assessments. SPADI is a reliable questionnaire to assess rotator cuff pathology (Ekeberg et al., 2008) and shows good construct validity, acceptable for clinical practice (Roy, MacDermid & Woodhouse, 2009). The MDC (95%) for SPADI is 18 points (Breckenridge & McAuley, 2011). The patient in the yoga-based video (RC2) did not answer one question on the disability subscale in either pre or post assessment testing, which reduced her total possible score maximum to 70 instead of 80.

Qualitative Feedback: Post-assessment Interview

During RC2 and RC6's post-assessment interview, key questions regarding their experience with the intervention were asked and all answers were jotted down by hand. Below are the questions and their answers.

Table 1. *Post-assessment interview responses for patients RC2 and RC6.*

	RC2	RC6
How did you find the video exercises?	<i>"They're ok; fine, fairly easy"</i>	<i>"No problem"</i>
Did you do them everyday for 5 minutes?	<i>More than 5 minutes</i>	<i>10 minutes</i>
Would you say your condition improved?	<i>"Hard to say"</i>	<i>Yeah</i>
What did you like about the study?	<i>"It was good because it kept you regular; not time consuming"</i>	<i>"Independent" but accuracy should have been supervised</i>
Is there anything you disliked about the study?	<i>"Well explained"</i>	<i>"No"</i>
Would you recommend these exercises to someone with an RCI?	<i>"Sure"</i>	<i>Yeah as long as they qualify</i>

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Is there any feedback you would like us to know?	<i>“The videos were very good; seeing the visual really helped; I like them”</i>	<i>(Should be) Supervised, easy to follow</i>
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RESULTS

RC2 participated in the yoga-based exercises daily for 43 days, missing only one day during the 6-week period, as stated in her Diary form. It was prescribed that the patient practice the exercises for approximately 5 minutes each day, but looking at her Diary form it is evident she spent more than 5 minutes (approximately double the prescribed time) because she provided her start and end timings for each day of exercise.

During her pre and post-assessment testing, a majority of her outcome indicators worsened. RC ROM values were: -18% for SF; +35% for SA; and -21% for ER. RC strength values were: -27% for SF; -26% for SA; and -23% for ER. SPADI results showed pain worsened by 8% while disability improved by 3%. However, these SPADI results do not reflect a MDC (95%) because they are less than 18 (Breckenridge & McAuley, 2011; Roy, MacDermid & Woodhouse, 2009).

According to RC6's Diary form, he participated in the exercises daily for a total of 42 days. In his first week of the intervention, he used a yellow resistive exercise band but progressed to using a red band for subsequent weeks.

RC ROM scores for RC6 were: 50% improvement for SF; 12% improvement for SA; and a 13% worsening for ER. His strength results demonstrated a 53% improvement for SF; 35% improvement for SA; and 43% improvement for ER. All three strength measures reflect a minimally detectable change (MDC) because all are over 15% (McLaine, Ginn, Kitic, Fell, & Bird, 2016), which means these results are unlikely to be due to measurement error. SPADI pain score decreased by 6% and the disability score decreased by 5%, meaning that both pain and disability improved. This, however, does not reflect a MDC since his values are less than 18 (Breckenridge & McAuley, 2011; Roy, MacDermid & Woodhouse, 2009). Table 2 below illustrates ROM and strength scores for RC2 and RC6 while table 2 illustrates their SPADI results.

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Table 2. ROM and Strength (kg) during pre/post for RC2 and RC6.

(RC2 affected shoulder = right; RC6 affected shoulder = left).

	ROM PRE		ROM POST		ROM % Change	
ROM RC2	Affected	Unaffected	Affected	Unaffected	Affected	Unaffected
FLEXION	164°	145°	134°	144°	-18	-0.7
ABDUCTION	104°	105°	140°	160°	+35	+52
EXTERNAL ROTATION	89°	92°	70°	84°	-21	-9
ROM RC6	Affected	Unaffected	Affected	Unaffected	Affected	Unaffected
FLEXION	100°	152°	150°	173°	+50%	+14%
ABDUCTION	110°	160°	123°	140°	+12%	-13%
EXTERNAL ROTATION	63°	78°	55°	75°	-13%	-4%
	STRENGTH PRE		STRENGTH POST		STRENGTH % Change	
Strength RC2 (Kg)	Affected	Unaffected	Affected	Unaffected	Affected	Unaffected
FLEXION	10.8	15.2	7.9	9.9	-27	-35
ABDUCTION	9.8	12.5	7.3	9.5	-26	-24
EXTERNAL ROTATION	8.9	10.4	6.9	7.9	-23	-24
Strength RC6 (Kg)	Affected	Unaffected	Affected	Unaffected	Affected	Unaffected
FLEXION	7.6	12.5	11.6	12.2	+53%	-2%
ABDUCTION	6.9	12.2	9.3	18.2	+35%	+49%
EXTERNAL ROTATION	4.7	8.4	6.7	10.8	+43%	+29%

Table 3. SPADI questionnaire results for RC2 and RC6 during pre/post.

SPADI RC2	PAIN SCORE (%)		DIS-ABILITY SCORE (%)		TOTAL SCORE (%)		% Change	
	PRE	POST	PRE	POST	PRE	POST	PAIN	DISABILITY
	32% (16/50)	24% (12/50)	21% (15/70)	24% (17/70)	26% (31/120)	24% (29/120)	-8%	+3%
SPADI RC6	PAIN SCORE (%)		DIS-ABILITY SCORE (%)		TOTAL SCORE (%)		% Change	
	PRE	POST	PRE	POST	PRE	POST	PAIN	DISABILITY
	56% (28/50)	50% (25/50)	58% (46/80)	53% (42/80)	57% (74/130)	52% (67/130)	-6%	-5%

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DISCUSSION

We know that isolated cases cannot be used to determine the effectiveness of treatment; nonetheless, the differences between these two cases are useful to consider. Although both cases demonstrated positive attitudes about the exercise program and reported a high level of adherence the outcomes of the two cases were quite different. The case where the patient performed traditional therapeutic exercises (RC6) had positive changes in physical impairment and small changes in pain function that were of questionable importance. Conversely, the patient who performed yoga exercises (RC2) demonstrated worsening in many of her impairment measures and no clinically important improvement in pain or function.

A number of possible reasons could explain the differences in the two cases. One possible reason for RC6's improvement could be due to the fact that the standard exercises better targeted the rotator cuff muscles and allowed the patient to better gauge the amount of force the muscles were producing. This possibility is reinforced by the fact that the patient increased the resistance band over the course of the intervention and improved in strength and motion. Conversely, yoga may have emphasized the whole/upper body and not specifically recruited the cuff muscles or perhaps the weight-bearing position may have placed greater stress on the cuff muscles and limited the extent to which the patient was able to control recruitment. Another possible explanation is that the yoga exercises were too vigorous for the patient and without supervision, worsened the glenohumeral alignment, which further irritated her symptoms rather than improve it. It could also be that the patient felt inhibited to perform the movements due to pain/discomfort. This may explain the worsened scores (ROM: -18% SF; -21% ER; strength: -27% SF; -26% SA; -23% ER; and pain -8%), although one would expect pain to be elevated if the problem was irritated. Worsening of pain with exercise should be considered an adverse event. Whether this irritated muscle or tendon tissue, or worsened the size of the tear itself cannot be determined from these case studies as no pre-post imaging was available.

Moreover, it may be that patients see the therapeutic benefit of cuff exercises and not yoga, but this was not reflected in the adherence logs. The standard exercises may have just been simpler for patients to perform than yoga poses since very specific and

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direct movements were shown. The instructions in the yoga video, while clear, may have been ineffective for patients to perform because of greater complexity.

It is unlikely that measurement error was a major concern because two examiners were present during testing to ensure accuracy. One examiner, a trained physiotherapist, was well experienced with upper extremity measurements and ensured accurate reading and performance of tests. Interestingly, despite the counterproductive results, the patient stated that she would continue with the online exercises until her surgery date.

From the case of RC2, it is clear that a need for close supervision when prescribing yoga-based exercises is needed. The importance of supervision was reinforced by RC6 who performed therapeutic exercises as he specifically mentioned that greater supervision would have been beneficial.

The primary conclusion of these two cases is that the therapist must be diligent in prescribing exercises to ensure that they are appropriately targeted, can be performed correctly by patients and that they actually recruit the muscles intended. While much enthusiasm has been created for independent home programs, these cases illustrate why supervision can be important to avoid adverse outcomes and achieve positive outcomes.

(Link to the yoga video: https://youtu.be/K_23286tXKk).

(Link to the standard exercise video: <https://youtu.be/wyGHjcChwsg>).

CHAPTER 3

Feasibility of an at Home, Online, Yoga-Based and Standard Exercise Intervention for Rotator Cuff Injuries

INTRODUCTION

BACKGROUND

Rotator cuff (RC) tears are a very common orthopedic condition. Reports claim that 25% of people in their 60s and 50% of people in their 80s suffer a RC tear, making it the most common shoulder surgery performed (Killian & Cavanaugh, 2014). Also, it is reported that the annual cost of RC repairs is approximately \$3 billion in the United States alone (Colvin, Egorova, Harrison, Moskowitz & Flatow, 2012).

Exercise has been shown to benefit RC patients in terms of reducing pain, improving strength, ROM and function (Fleming, Seitz & Ebaugh, 2010). However, clinical studies have primarily examined the role of traditional exercise for RC rehabilitation. The effects of yoga as exercise through an online home based setting have been scarcely investigated. This chapter will discuss the feasibility of a 6-week long exercise intervention. The purposes of this feasibility study were to:

1. Determine the logistics of implementing a 6-week, online exercises program for patients with rotator cuff (RC) tears awaiting surgical repair.
2. Identify potential positive and negative patient responses to the exercise programs (treatment effects and harms).
3. Identify recruitment issues and retention of participants for a future clinical trial.
4. Identify the feasibility of implementing outcome measures.
5. Identify potential improvements in the research protocol that might be needed to move forward with the future clinical trial.

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PARTICIPANTS

Sample Recruitment

Patients were recruited by telephone from the surgical wait lists of two orthopedic surgeons (fourth and fifth co-authors) at the Roth|McFarlane Hand and Upper Limb Centre (HULC), located in St. Joseph's Hospital. Patients provided informed consent as approved by their signatures on consent forms.

The initial intention was to recruit a sample of up to 30 participants, assuming a 50% response rate and a potential pool of 60 participants that would be contacted within a three-month interval. Over the course of the 3-month recruitment period, 51 patient files were obtained from two surgical wait lists. Each file was analyzed to see if patients were eligible; if their surgery was scheduled within 6 weeks from the time the file was received, that patient was excluded. A total of 49 calls were made during those 3 months. (Two files did not have patient contact information so calls could not be made). Of 49 calls, seven were excluded because the patient informed the examiner he/she would either be having their surgery within 6 weeks or had already undergone their surgery. Thus, 42 patients were eligible; however, 32 declined the invitation to participate and only 10 consented. Of these 10 patients, three were randomized to the standard exercise group and seven to the yoga group via envelopes. By the end of the 6 weeks, only two patients completed the entire intervention. (One patient discontinued with the exercises because of her upcoming RC surgery while another patient opted out due to vacation. Three patients elected out due to pain. Finally, three patients only provided qualitative feedback in response to predetermined interview questions over the telephone to inform understanding on their perceptions and adherence to the assigned exercise program, since they did not undergo pre/post). In the end, two patients completed the program and the full pre/post testing.

Figure 3 below illustrates the inclusion and exclusion flow of patients over a 3-month time period.

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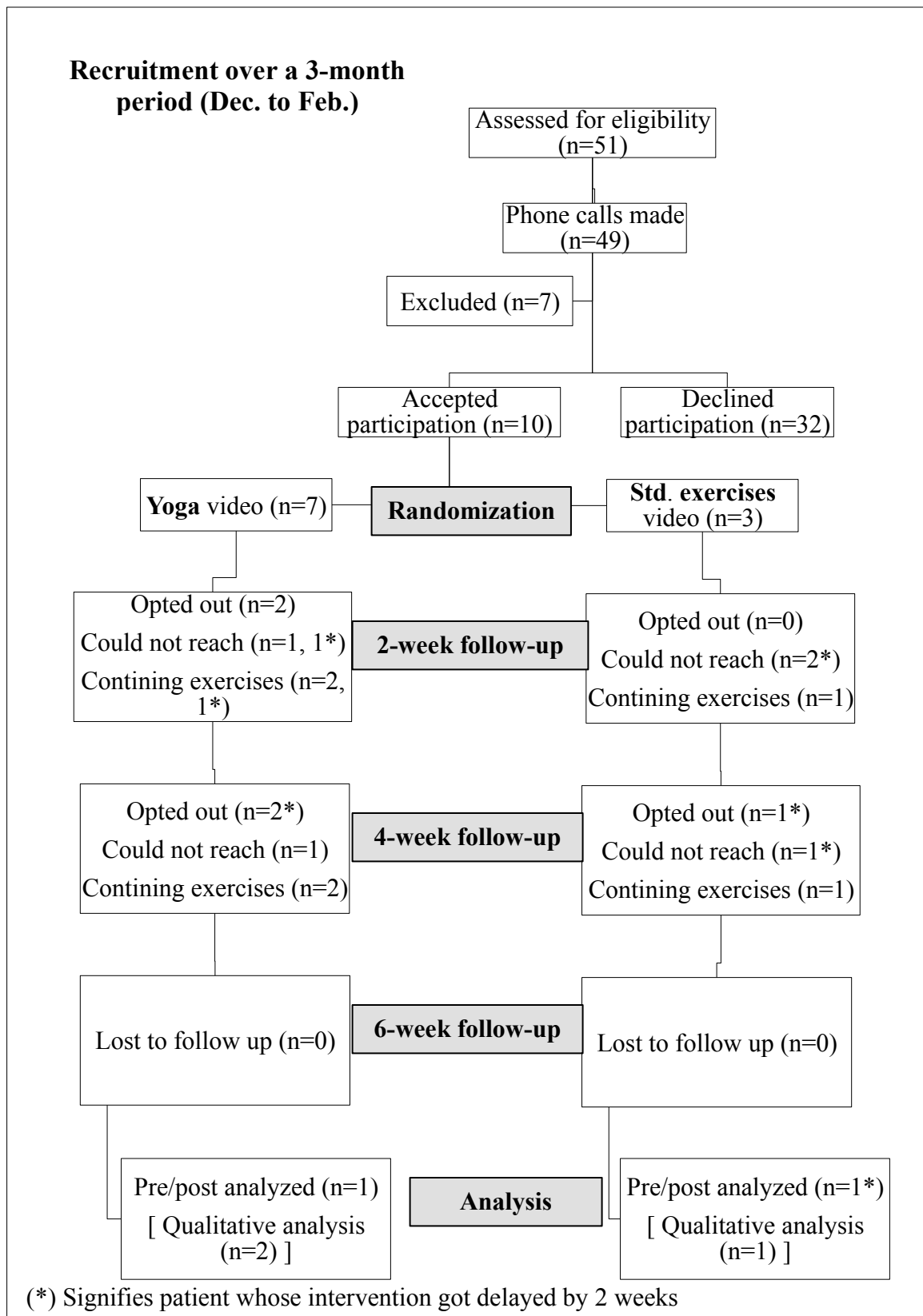


Figure 3: Flowchart demonstrating patient inclusion/exclusion.

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METHODS

INCLUSION/EXCLUSION CRITERIA

To be included in the study, patients had to be on a surgery wait list for their rotator cuff injury and be 18 years or older. Patients were excluded if their surgery was booked within 6 weeks or they had co-morbidities that precluded participation in an exercise program.

ETHICS and CONSENT

A letter of information, a patient information/consent form, a Diary form and a telephone script were created for this study. Ethical approval was obtained from Western University's Research Ethics Board.

DEVELOPMENT of INTERVENTIONS

Standard exercise for rotator cuff is therapeutic exercise that recruits specific rotator cuff muscle groups. The comparison was a yoga-based exercise also intended to recruit rotator cuff muscles. It was decided to only focus on three exercises to optimize adherence and understanding given that this was an independent home program. Further, we purposively kept the number of exercises (3), repetitions (3 sets, 10 repetitions) and length of instruction (under 5 minutes) the same in both exercise options.

The second and third co-authors reviewed AAOS practice guidelines for home programs for patients with rotator cuff disorders, integrated that with their own clinical expertise and identified three key therapeutic exercises: standing row, internal rotation and external rotation. The physical therapist had experience with yoga and identified three yoga poses that might recruit rotator cuff muscles: isometric prayer pose, half cobra pose and sphinx pose.

Once the exercises were selected, a video script was created, reviewed and edited by all authors. During filming the third co-author served as the instructor in the standard exercises video while a certified yoga teacher (KN) served as the instructor for the yoga video.

Both videos were shot using a Nikon point-and-shoot camera and edited on iMovie by one co-author (DM) and reviewed by all coauthors. Revisions of the video

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were made based on co-author feedback. Both videos were kept under 5 minutes each so patients did not have to spend a long time following the video.

Next videos were uploaded to YouTube as unlisted and patients were sent a link to their e-mail addresses (which they provided during pre-assessments or through phone), for individual viewing. Only patients with the link could access the content. The unlisted option (compared to private) allowed participants to have access to the video without having a YouTube account and also remain closed so only the individuals who had the video link could access the content.

STUDY MEASURES

The SPADI is a 13-item questionnaire that is used to measure pain and disability; five questions evaluate pain and eight questions evaluate disability (Breckenridge & McAuley, 2011). SPADI is a reliable shoulder questionnaire for measuring RC disease (Ekeberg et al., 2008), acceptable for clinical practice and shows good construct validity (Roy, MacDermid & Woodhouse, 2009). The minimally detectable change (MDC), which is the smallest real change outside of measurement error (deVet et al., 2006), is 18 points (95%) for patients assessed twice in SPADI (Breckenridge & McAuley, 2011).

ROM was measured using a double-armed, clear plastic goniometer (Stryker Physiotherapy Associates) and strength using a HHD (JTECH Medical), a portable (Thorborg, Petersen, Magnusson, & Holmich, 2010), non-invasive, light-weight and efficient device that is capable of detecting minor increases or decreases in muscle strength (Kolber & Cleland, 2005). Compared to Manual Muscle Testing (MMT), the HHD is better because it provides a more objective evaluation in determining muscle strength (Celik, Dirican, & Baltaci, 2012).

STUDY PROCEDURES

Participants were invited to HULC where ROM and strength testing were assessed. SPADI questionnaires were also completed during both pre and post. Consent forms were signed (one copy was given to the patient while another was kept in the clinic) and the study was explained in detail. Personal information including: name, age, sex, rotator cuff history and location of injury (right or left shoulder) were noted by

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hand. Patients were then randomized via envelopes to receive either an online yoga or a standard exercises video. They were informed to which group they belonged immediately after randomization.

Clear instructions were given that patients had to do the movements to the best of their ability; if it was too painful, they could stop. Patients sat on a chair with their back against the frame. Strength levels were generally assessed first by the examiner using a HHD. The examiner demonstrated SF, SA and ER before having the patient perform the movements (Roy, MacDermid & Woodhouse, 2009). The same testing protocol was used in both pre and post assessments.

Strength Assessment

Strength was measured using a HHD. All patients were assessed while seated. Calibration of the HHD and an explanation of the testing procedure were completed prior to commencing the test.

For SF the patient had their elbow extended and at 90 degrees flexion (Andrews, Thomas, & Bohannon, 1996). In our case, the patient had their elbow flexed at 0 degrees because it is likely that patients would have had difficulty starting at 90 degrees, seeing as how their injury affected their ROM and strength. The HHD was placed above the patient's elbow (Ciesla et al., 2011) or middle of the humerus. The examiner stood to the patient's testing side and held the HHD firmly in both hands (Beshay, Lam, & Murrell, 2011).

For SA the patient had their elbow fully extended and their arm at 90 degrees abduction (Beshay, Lam, & Murrell, 2011). Again, however, in our case the patient had their arm at 0 degrees for the aforementioned reason. The HHD was placed in the same position as stated in SF.

For ER the patient had their elbow flexed to 90 degrees, arm at 0 degrees and forearm in neutral. Instructions to keep their elbow close to their body were given so arm abduction was avoided. The examiner placed the HHD on the "dorsal aspect of the distal forearm" and stood to the testing side, clasping the device firmly in hand (Beshay, Lam, & Murrell, 2011).

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Patients were instructed to exert maximum effort to move their arm in the required position while the examiner applied increasing resistance (May, Burnham, & Steadward, 1997). They were also asked to sustain the effort for approximately 6 seconds until the examiner said to relax (Wikholm & Bohannon, 1991).

Unfortunately, the isometric testing performed was compromised because patient's testing positions were not accurately controlled. They were asked to perform each movement to whichever degree they could before it began to hurt and they could not go any further. Each movement's range ended on a different arc. To illustrate: SF, SA and ER all started at 0 degrees but there was no fixed point the patient was told to end their movement (i.e. stop at 90 degrees), which weakened the comparison of pre/post results. Unfortunately, with strength testing even minor changes in body positions significantly affected results (Kelly, Kadrmas, & Speer, 1996), so accuracy was compromised.

ROM Assessment

All patients were tested while seated. (Both strength and ROM testing used the same chair). SF, SA and ER movements were measured using a goniometer. The advantages of goniometry allow for: effortless use, direct measurement of [shoulder] joint angles; cost effective/economic benefit; and portability. Unfortunately, despite the advantages, a major disadvantage is the manual inspection of goniometric reading. Results could only be visually estimated, which made it difficult to assess ROM when measuring joints with thick layers of soft tissue (Nussbaumer et al., 2010).

Typically, ROM testing occurred after strength testing; however, there was no fixed rule.

For SF and SA, the fulcrum or pin of the goniometer was closely aligned with the patient's glenohumeral joint axis (Sabari, Maltzev, Lubarsky & Homel, 1998). The center of the goniometer was placed on the posterior glenohumeral joint ("Normal ROM", 2012), with one arm perpendicular to the floor and the other aligned according to the angle of the proximal humerus (Millett & Warth, 2015).

For ER, the patient had their elbow flexed at 90 degrees with their humerus on the side (Millett & Warth, 2015). The goniometer was positioned with the fulcrum at the

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olecranon (under the elbow), with one arm parallel to the patient's thigh and the other moving along according to the forearm (Cools et al., 2014).

Goniometric readings of maximum ROM were recorded for the affected and unaffected arm. ROM measures were taken only once for a total of six scores.

A single examiner (DM) performed all testing. It is important to note that the examiner is not a physiotherapist; however, testing was performed in the presence of an experienced physiotherapist, who verified the accuracy of the readings and provided suggestions for improvement. Finally, t-tests were not performed because this is a feasibility study and it did not have enough power. Descriptive analysis was performed from both ROM and strength assessment.

Follow-up Calls

Patients enrolled in the study were informed they would receive follow-up calls approximately every 2 weeks to determine how the study was progressing. The primary question asked was: how are you finding the exercises?

During the first follow-up call (2-week mark) four out of 10 patients (RC1/3/4/6) stated that they never received the video; three patients (RC1/7/8) did not answer the call so a brief voicemail message was left. (One patient (RC2) out of these three soon after returned the message and stated everything was going well [yoga group]). One patient (RC5) opted out due to pain with the (yoga) exercises; and the remaining two patients (RC9/10) stated the exercises were "good" and "pretty good".

It is unknown why some patients did not receive the video link while others did. Nevertheless, video links were re-sent using HULC's e-mail address instead of the examiner's Western's e-mail account, which was used initially.

The four patients who did not receive the video links initially were called to see how they were progressing 2 weeks after video links were re-sent. (One out of these four patients (RC3) had informed the examiner of her hesitation with performing the (yoga) exercises due to limited mobility/strength and opted out). One patient (RC1) did not answer the call so a voicemail message was left; another (RC4) stated he probably would not be continuing with the (yoga) exercises for much longer due to pain but would

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continue for a bit; and the last patient (RC6) was waiting for a resistive band in the mail (which was required for the std. ex. video) and therefore had not begun the exercises.

During the 4 week follow-up call for the patients who received the video when it was first sent, one patient's (RC2) family member answered the call and took down the examiner's contact information saying the patient would return our call; another patient (RC7) stated the (yoga) exercises aggravated his shoulder and caused pain (he had three cracked vertebrae in the lower back); another (RC9) stated the (std. ex.) exercises were going "fine" but did not feel there was an improvement in her condition; another (RC10) stated he had "fallen off a little bit" and it was "more work than he was getting out of it" (yoga).

For the patients whose schedule was pushed back by 2 weeks, one patient (RC1) stated that she discontinued with the (std. ex.) exercises because of her upcoming surgery; another (RC4) was recommended to stop the (yoga) exercises by his clinician because of pain; another (RC6) did not answer the call; and finally the last patient (RC8, yoga group) stated that she was not a part of the study because of vacation.

During the final or 6-week follow-up call, post-assessment testing was scheduled through e-mail for one patient (RC2) since follow-up phone calls were ineffective and another patient (RC6) contacted HULC to schedule post-assessment testing. The three patients who did not undergo pre/post testing (RC7/9/10) were asked specific questions regarding their perceptions of the video.

Post-Intervention Interview

A semi-structured interview developed by DM and approved by the second co-author for the purpose of this study was used to interview patients (RC2 and RC6) one-on-one regarding their experiences of using the online exercise program. Interviews took place at HULC and patient answers were jotted by hand as well as audio recorded (using an application called 'Audio Recorder') on a cellular phone. Diary forms were collected and kept on file.

The three patients who did not undergo pre or post testing (RC7/9/10) were asked the same questions that were asked of RC2 and RC6 – except for one: *would you say your condition improved?* Again, answers given were jotted down by hand. However, patient

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answers were not recorded. Patients who opted out of the study were asked for their general views about the online exercise program either during follow-up calls or through e-mail but no concrete set of questions was created.

RESULTS

PATIENT DEMOGRAPHICS

There were five female and five male patients in the study, the youngest being 49 years old and the oldest being 68. Among the females, the average age was 61 years and 59 among the males. Patient's group allocation (yoga or std. ex.); priority (level of urgency for surgery); age; sex; affected shoulder (left or right); RC history (number of RCI occurrences); and any co-interventions are provided below.

Table 4. *Key Information of Patients in Study.*

Name	Group Allocation	Priority	Age	Sex	Affected Shoulder	Pre/Post Tests Done?	RC History (RCI cause)	Co* or Prior Interventions
RC 1	Std. Ex.	4 (Least urgent)	66	F	Right	Yes/No	2 nd occurrence	<ul style="list-style-type: none"> ▪ Did PT for 12 weeks- 2 years ago
RC 2	Yoga	4 (Least urgent)	68	F	Right	Yes/Yes	1 st occurrence (accident in aquatic class)	<ul style="list-style-type: none"> ▪ Exercises at YMCA* ▪ Uses weights, plays badminton* ▪ Aquatic class*
RC 3	Yoga	4 (Least urgent)	49	F	Left	Yes/No	2 nd occurrence	<ul style="list-style-type: none"> ▪ Gym ▪ Exercises/ stretches
RC 4	Yoga	Not stated	66	M	Left	Yes/No	1 st occurrence	<ul style="list-style-type: none"> ▪ Tried PT but could not do it on RC arm
RC 5	Yoga	Not stated	64	M	Left	Yes/No	1 st occurrence	<ul style="list-style-type: none"> ▪ 12 weeks of PT – 3 months prior (before Christmas)

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RC 6	Std. Ex.	3 (Least urgent)	62	M	Left	Yes/Yes	1 st occurrence	▪ Did PT for 3 months
RC 7	Yoga	3 (Least urgent)	53	M	Left	No/No	N/A (tripped on a curb)	▪ Doing PT since Aug.*
RC 8	Yoga	3 (Least urgent)	60	F	Right	Yes/No	1 st occurrence (work related)	▪ Did PT and acupuncture
RC 9	Std. Ex.	4 (Least urgent)	62	F	Right	No/No	1 st occurrence (riding a bike)	▪ None listed
RC 10	Yoga	3 (Least urgent)	50	M	Right	No/No	N/A (overhead presses)	▪ Does PT, massage, strength training*

Note: "Priority": 1,2=most urgent; 3,4=least urgent

FEASIBILITY ISSUES

Recruitment

Recruitment was a major concern in this study as from a total of 51 potentially eligible only 10 were recruited. Even if retention were high, this would mean that a study requiring 200 participants would need to be drawn from a sample of about 1000 patients. A variety of barriers to recruitment were identified including incomplete information and the patient files, issues with patient concerns about the travel associated with the study, and the fact that surgery was imminent. Patients declined to participate for other reasons, such as: lack of availability (patients did not answer calls); general lack of interest; and/or busy with other commitments.

Potential solutions to these recruitment issues are possible. There are multiple sources within the hospital to verify patient contacts; and a site-specific study coordinator present when referrals were received could contact referral sources for contact information. The major barrier was the burden of interim assessments.

Options for future studies include measuring ROM using video motion technology like Dartfish (Khadilkar et al., 2014) or photographs (Craato, Sayari, Gray & Askari, 2015), Since the benefits of independent web/video exercise programs are aimed

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at reducing patient burden in travel, it appears that reducing visits for assessment for study outcomes is also important. Highlighting the potential convenience then may be important for recruitment since a number of potential participants were “not interested”.

Retention

Retention was equally problematic, with only 2 out of 10 completing the entire protocol (thus 80% drop out rate). While we asked non-completers to provide feedback, only three provided qualitative feedback, and five opted out at various points throughout the study primarily due to pain. This may need to factor in the issue that greater supervision and feedback may be needed to avoid increasing pain or poor targeting of the exercise program. In three cases we offered non-attenders the option to perform the video-based exercises and provide qualitative feedback at the end, and so better understand feasibility given our recruitment challenges. Regardless of this alternative option, certain patients still opted out. Potential ways to increase recruitment in future trials could be to offer an incentive and/or conduct in-house visits for assessment.

Future Sample Size Considerations

Knowing that the clinically important difference (CID) or the smallest change that is meaningful for a patient (Roy, MacDermid & Woodhouse, 2009) for our group is smaller than the CID estimated for individuals, we can assume that a potentially relevant CID for a future clinical trial might be a minimum four points on the SPADI (50% of the CID for individuals, which ranges from 8 to 13) (Roy, MacDermid & Woodhouse, 2009). Calculating the sample size requirements for 80% power, $\alpha=0.05$ for patients with moderate disability (SPADI 59 vs. 50) (<https://www.stat.ubc.ca/~rollin/stats/ssize/n2.html>), suggests that 63 patients would be needed per group. Without improvements in recruitment and retention the sample size for one group would be achieved by screening 315 patients and enrolling 63 patients. Clearly, the study is not feasible unless both improvements in recruitment and retention are attained.

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Outcome Measures

There is a possibility that some lack of standardization was introduced into the study protocol in terms of how strength and range of motion were measured since a consistent joint position was not used for all muscle testing. Better standardization of procedures might improve consistency across raters and overtime. Use of a single evaluator would reduce measurement errors but may not be possible if the sample size requirements necessitate a multicenter study. Standardized isometric testing that provides reliable results has been previously shown using a HHD for rotator cuff muscles (Kolber, Beekhuizen, Cheng & Fiebert, 2007). Lack of standardization weakens reliability and heightens random error, by making it difficult to determine a true change in patients over time (Roy, Ma, MacDermid, Woodhouse, 2011).

Exercise Fidelity and Adherence

The fidelity, or ability of the patients to reproduce the intended exercises, is unknown the program was designed to be delivered remotely and executed independently. While every intention to provide clear instructions was made, the extent to which these were understood and executed is unknown. Given the observations in this study and our previous case reports stating that exercises may have adverse consequences, the need for greater supervision in future interventions is indicated. A potential solution to this would be to provide in-person training at the beginning of the program and ensure that patients can reproduce the intended exercises prior to continuing on independently. A teach back approach to instruct patients on exercises and a check of the initial understanding could have avoided lack of exercise fidelity, may have enhanced satisfaction and in turn adherence (Tamura-Lis, 2013); but this would require more resources for an independent self-management approach.

Our results suggest that for the two patients who completed the intervention adherence was very high. This is inconsistent with the number of people who dropped out of the study. Since this study used self-reported measures (SPADI and Diary form) it is possible a bias is present. Patients were asked to be completely honest in their Diary and SPADI forms, but it is possible patients may have felt the need to present a certain image, thereby providing exaggerated/inaccurate information. Future studies should consider

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standardized adherence measures that are self-reported, can potentially wearable sensors that could objectively measure performance.

In designing future trials, it will be necessary to alter any shortcomings that were apparent in this study design. Table 5 illustrates the errors from this study and their potential rectifications.

Table 5. *Concerns in Study and their Rectification.*

Error/Concern	Potential Rectification
<ul style="list-style-type: none"> • Video link not received by some patients. 	<ul style="list-style-type: none"> • Call to verify if patients received the video soon after it is first sent by the examiner. • Use of a hospital-based website and email to deliver interventions
<ul style="list-style-type: none"> • Patients may not be doing the exercises correctly. 	<ul style="list-style-type: none"> • Consider using a teach back approach at the initiation of the program that would be delivered in person, or a virtual one on one consultation with the therapist • Institute an adverse event reporting procedure to immediately contact patients who experience worsening of symptoms • Provide online tools for how patients can assess their own exercise fidelity
<ul style="list-style-type: none"> • Randomization. Too many patients were randomized to the yoga group 	<ul style="list-style-type: none"> • Block randomization. I.e. using block of six, so three patients get yoga and three patients get standard exercise treatment.
<ul style="list-style-type: none"> • Yoga video does not stress the importance of engaging cuff muscles. 	<ul style="list-style-type: none"> • Stress the importance of cuff muscles in video by demonstrating the poses. (Perhaps show a right and wrong approach so patients have better understanding). • Consider other alternatives that might be more important than yoga for future clinical trials such as different formats for providing standardized exercise • Basic science studies investigating whether yoga poses do engage rotator cuff muscles
<ul style="list-style-type: none"> • Patients could not attend pre/post testing due to location 	<ul style="list-style-type: none"> • Have a virtual pre/post testing environment or do in-house assessments
<ul style="list-style-type: none"> • Discordance between high reported adherence and low participation in the 	<ul style="list-style-type: none"> • Consider alternate forms of measuring adherence including self-report and

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study	sensor-based
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ANALYSES

The feasibility of running a 6-week, online exercise, at home intervention in this study was weak, given the high attrition rate and the counter productive results for one patient. Adherence to the intervention was assessed through a paper diary, which were closely observed to assess the days and times of when patients participated in the intervention. However, only two such forms were available for analysis and both showed excellent adherence.

Responses to the exercise programs were assessed through patient feedback, which was given by e-mail, over-the-phone or in-person. Table 6 below demonstrates responses from the three patients who did not under go pre/post testing. “Q.1, Q. 2” etc. correspond with the questions below.

1. How did you find the video exercises?
2. Did you do them everyday for 5 minutes?
3. Would you say your condition improved?
4. What did you like about the study?
5. Is there anything you disliked about the study?
6. Is there any feedback you would like us to know?

Table 6. *Feedback from patients who did not undergo pre/post testing.
(Answers given over the phone).*

Patient	Q. 1	Q. 2	Q. 3	Q. 4	Q. 5	Q. 6
RC7	<ul style="list-style-type: none"> ▪ “Didn’t find them too bad” ▪ “They would definitely be a benefit” 	<ul style="list-style-type: none"> ▪ Everyday for 6 weeks 	<ul style="list-style-type: none"> ▪ “I think so, yes” ▪ “Definitely” 	<ul style="list-style-type: none"> ▪ “They were easy to follow” ▪ “Very well put together and clear” 	<ul style="list-style-type: none"> ▪ First time using it, nothing to compare the program to 	<ul style="list-style-type: none"> ▪ Not at this point
RC9	<ul style="list-style-type: none"> ▪ “Helpful” ▪ Videos were clear 	<ul style="list-style-type: none"> ▪ N/A 	<ul style="list-style-type: none"> ▪ “Yes I would” 	<ul style="list-style-type: none"> ▪ “Independent” ▪ “Didn’t have to 	<ul style="list-style-type: none"> ▪ Validity concern ▪ No one checked 	<ul style="list-style-type: none"> ▪ “Too loosey goosey” ▪ ROM

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				report to any clinic/ person”	in ▪ No pre/ post	and strength was not measured
RC10	▪ “I found them pretty basic” (He did a lot more)	<ul style="list-style-type: none"> ▪ Did exercises 2 or 3x a week for the first 2 weeks ▪ Week 3 = everyday ▪ Weeks 4-6 = 2x/ day ▪ At the start he had a harder time due to injured wrist 	▪ “I don’t think it would hurt”	<ul style="list-style-type: none"> ▪ “Pretty simple basic program” ▪ Felt good for my back 	▪ Not really	▪ “Hard to tell if the exercises did anything for the shoulder”

Two of the patients who dropped out of the study informed the examiner via e-mail that the video was clear and the instructions were easy to follow. However, they discontinued because of pain.

Potential improvements in treatment implementation were assessed by patient feedback and analyzing the reasons why patients declined to be in the study assessed recruitment issues. The feasibility of implementing the outcome measures (ROM, strength and function) was attainable. Results were collected from a goniometer, HHD and SPADI, and analyzed via percent change calculations. A simple mathematical formula was used:

$$[(post\ result - pre\ result) / (pre\ result)] * 100.$$

Moreover, SPADI forms specifically were analyzed by summing each subscale (pain and disability) as a percentage. The total SPADI score was calculated by summing questions from both subscales and dividing by the total. Note: SPADI is out of 130, but if a question was left unanswered then the total became 120 (Breckenridge & McAuley, 2011). Basic arithmetic (addition and subtraction) was done to determine if a change occurred from pre to post assessments.

CHAPTER 4 Discussion

This study examined the feasibility of a 6-week, online shoulder program for patients with RCI patients and awaiting shoulder reconstructive surgery. This study will contribute to the literature by exploring how an online exercise program can be implemented in the RCI population to optimize pre-operative rehabilitation. Areas needing attention will be considered preliminary and tailored accordingly for future studies.

The feasibility study was conducted on 10 participants with RCIs: five male, mean age 59 years and five female, mean age 61 years. Two orthopedic surgeons made diagnoses of an RCI.

Five patients failed to complete the intervention (three opted out due to pain; one due to vacation; and another because of an upcoming RCI surgery, which conflicted with the 6-week time frame). Three patients did not undergo pre/post assessments due to location and only completed the online video, providing qualitative data at the end via phone. Two patients completed the entire intervention.

Since only two patients – RC2 and RC6 – returned for follow-up, summary statistics cannot be performed. In the case of RC2, ROM results for the affected shoulder increased by 35% but only for SA. SF and ER worsened by 18% and 21%, respectively. The affected shoulder for RC6, on the other hand, improved for SF and SA by 50% and 12%, respectively. ER, however, worsened by 13%. Strength scores measured by the HHD revealed RC2 surprisingly worsened across all movements: SF, SA and ER by 27%, 26%, 23%, respectively. RC6 however, improved by 53% for SF; 35% for SA; and 43% for ER. Both RC2 and RC6 measures reflect a minimally detectable change (MDC), because strength changes of 15% or more (in any position) can be considered significant (McLaine, Ginn, Kitic, Fell, & Bird, 2016). Since all six values fall above 15%, it can be inferred that the results are clinically relevant and exceed random error.

Unfortunately, the results from RC2 demonstrate a meaningful improvement but only for SA. Results across all the other variables show a negative change. Thus, it might be necessary for a therapist to be involved because doing the yoga exercises without

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supervision did not appear to be feasible. The fact that 3/5 pre-tested patients opted out due to hesitation with performing the poses or increased pain testifies to this. One explanation for this could be because the feasibility of the yoga intervention compared to the standard exercises is more complex. The yoga video does not recruit any one specific muscle and patients may have found the technique to be difficult. The standard exercise video, on the other hand, recruits specific muscle(s) and it is likely that patients found the movements to be much simpler. In cases where yoga is administered, additional supervision while performing the exercises may be required, or perhaps in certain cases, the exercise may not be appropriate at all, especially if there is no supervision.

To the researcher's awareness this is a completely novel study. Pre-operative rehabilitation using online yoga-based exercises among RCI patients awaiting surgery has never been studied, making it a first in the literature.

Furthermore, because patients had the flexibility of doing exercises in the convenience of their personal comfort, interventions such as this may be a sound way for patients to exercise without having to go in-person. The online nature of the study allowed patients to perform the exercises whenever and wherever they deemed convenient.

Potential benefits for treatment are: increased ROM, strength and better shoulder functioning. It appears that these benefits apply well for the standard exercise video compared to the yoga video. However, because we only have one patient who experienced exercise benefit, more trials need to be conducted before one can claim reliability.

Finally, to optimize feasibility certain criteria were established. Table 7 shows the outcome for six feasibility factors.

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Table 7. *Criteria for feasibility and their outcome*

Feasibility	Criterion	Outcome
Produce a clinically feasible video?	Video should be within 5 minutes in length.	Yes.
Can video be delivered to remote locations?	All patients receive the video.	No. 4/10 patients had to have the video links re-sent (reasons why some patients received the link while others did not is unknown).
Can patients accurately perform the exercises?	Self-reported.	Unknown accuracy of performing exercises as patients were not asked to perform them.
Can patients adhere to the exercise program?	70% report consistent use in Diary form.	Yes. (Diary forms of both patients showed adherence of well over 70% to the 6-week intervention).
Were there any unwanted or adverse effects?	Patient feedback during follow-up calls and post-assessment testing.	Yes: increased pain.
Was a potential therapeutic effect observed?	ROM, strength and SPADI scores	A stronger therapeutic effect seen in standard exercise patient than yoga patient; however, as these findings are solely based on two patients, conclusions cannot be drawn.

Future trials may wish to implement these and other criteria to make the study more feasible. Any shortcomings in this design can be modified to ensure future studies run smoothly.

COMPETING INTERESTS

The authors have no competing interests.

AUTHOR'S CONTRIBUTIONS

Dolly Mehta drafted the thesis. Prof. Joy MacDermid, Prof. Jackie Sadi and Dr. Kenneth Faber carefully read, modified and approved the final version.

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Appendix A Ethics Approval Form



**Western
Research**

Research Ethics

**Western University Health Science Research Ethics Board
HSREB Full Board Initial Approval Notice**

Principal Investigator: Dr. Joy MacDermid
Department & Institution: Schulich School of Medicine and Dentistry\Surgery, Western University

Review Type: Full Board
HSREB File Number: 106668
Study Title: The effects of yoga on patients with rotator cuff injuries.
Sponsor:

HSREB Initial Approval Date: October 20, 2015
HSREB Expiry Date: October 20, 2016

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Instruments	Diary (Received 19Oct15)	
Instruments	SPADI (Received 21Apr15)	
Other	Telephone script	2015/05/29
Other	Final evaluation (Received 4Jun15)	
Letter of Information & Consent	Revised LOI clean copy	2015/09/28
Instruments	Revised telephone script - clean copy	2015/09/28
Recruitment Items	Revised poster - clean copy	2015/09/28
Western University Protocol	Protocol clean copy	2015/09/28

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration



Ethics Officer to Contact for Further Information: Erika Basile ___ Nicole Kaniki ___ Grace Kelly ___ Mina Mekhail ___ Vikki Tran ___

This is an official document. Please retain the original in your files

Appendix B
Letter of Information

Project Title: The effects of yoga on patients with rotator cuff injuries

Principal Investigator: Joy MacDermid, PhD, Health and Rehabilitation Sciences,
UWO

Graduate student: Dolly Mehta

Letter of Information

1. Invitation to Participate

You are being invited to participate in the research study entitled '*The effects of yoga on patients with rotator cuff injuries*' because you have a rotator cuff injury and are on a surgery waiting list.

2. Purpose of the Letter

The purpose of this letter is to provide you with information required for you to make an informed decision regarding participation in this research.

3. Purpose of this Study

The purpose of this study is to determine if doing specific yoga exercises has any effect on patients with rotator cuff injuries. Specifically, on pain level, strength and range of motion.

4. Inclusion Criteria

Individuals who are 18 years and older; have access to YouTube/Internet; have a rotator cuff injury and are on a surgery waiting list are eligible to participate in this study.

5. Exclusion Criteria

Individuals who are not on a surgery waiting list, are younger than 18 years of age and/or do not have access to YouTube/Internet are not eligible to participate in this study.

6. Study Procedures

If you agree to participate, you will be randomly placed in one of three groups: yoga, standard exercises or control. Depending on which group you are assigned to, you will be asked to do follow along an online yoga video, an online standard exercises video or undergo no intervention at all. (Patients will be randomly assigned to one of the three groups via envelopes).

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If you are in the yoga group or the standard exercises group, you will be asked to follow an online video, which will be privately available on YouTube, everyday for 6 weeks, 5 minutes each time. You will be asked to do the exercises exactly as the video shows, to the best of your ability. The exercises will be conducted in the comfort of your homes and after each exercise bout, you will be required to fill out a diary form, indicating the day/time you did the exercise. For individual assessments (where range of motion and strength will be taken) you will be asked to come in to the research lab – once at the beginning of the study and the other at the end of the study.

Please note: in the middle of the study (3-week mark) you will receive a phone call by Dolly Mehta, the researcher, asking questions regarding your pain/disability level. The questions will come from the SPADI questionnaire and will be asked via telephone.

7. Possible Risks and Harms

The possible risk and harm to you include some discomfort.

8. Possible Benefits

{Outline any possible benefits to the participants and to society as per your protocol submission here. You may indicate there are no benefits to the participant but there should always be societal benefits}

The possible benefits to participants may be reduced pain, increased flexibility/range of motion and increased strength. The possible benefits to society may be increasing shoulder mobility through an all-natural approach and understanding ways to help a significant number of individuals who have a rotator cuff injury. Please note: participation in the study will **not** delay your surgery.

9. Compensation

You will be compensated for your parking space each time you visit the hospital for measurement purposes in this study.

10. Voluntary Participation

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with **no** effect on your future care. If you choose to withdraw your consent, your data will also be removed as well.

11. Confidentiality

All data collected will remain confidential and accessible only to the investigators of this study. If the results are published, your name will not be used. If you choose to withdraw from this study, your data will be removed and destroyed from our database. (If you withdraw consent, you can choose to withdraw data). Upon completion of the study, data will be kept for 15 years. Finally, if new information becomes available that could affect your participation, you will be informed.

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12. Contacts for Further Information

If you require any further information regarding this research project or your participation in the study you may contact the Principal Investigator, Dr. Joy MacDermid.

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Research Ethics.

13. Publication

If the results of the study are published, your name will not be used. If you would like to receive a copy of any potential study results, please contact Dolly Mehta or Dr. Joy MacDermid.

14. Consent

Completion of the survey is indication of your consent to participate.

This letter is yours to keep for future reference.

Consent Form

Project Title: The effects of yoga on patients with rotator cuff injuries.

Study Investigator's Name: Dolly Mehta

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Participant's Name (please print): _____

Participant's Signature: _____

Date: _____

Person Obtaining Informed Consent (please print): _____

Signature: _____

Date: _____

Appendix C
Patient Information and Consent Form

Project Title: The effects of yoga on patients with rotator cuff injuries

Investigators:

Dr. Joy MacDermid, BScPT, MSc, PhD
Dr. Kenneth Faber MD
Dr. Jackie Sadi PhD
Dolly Mehta, M.Sc. candidate

What is the purpose?

You are being invited to enroll in a research study looking at how yoga affects patients with rotator cuff injuries, who are waiting for a surgery. The purpose of the research study is to look at the effects of yoga exercises when compared to standard treatment option such as physical therapy or no exercises at all based on pain intensity, range of motion and quality of life. We would like to understand more about the effects yoga has on patients with rotator cuff injuries, so that we can provide more information as well as better care to future patients who suffer from rotator cuff injuries. Any individual who experienced a rotator cuff injury and has not yet received surgery is eligible to participate in the study. Conversely, any individual who has this injury and has been treated with surgery would not be eligible for enrolment.

What is involved?

We are looking for participants who are currently not receiving treatment that can be randomized to either yoga, physical therapy or to no treatment at all. If you agree to participate, you will be asked to complete a 6-week intervention that will look at how your shoulder feels. You will also be asked about your age, sex, and any other significant medical conditions. A research team member will measure how well your shoulder moves prior to starting the intervention and again after the intervention period. Your arm strength will also be measured using special equipment that will require you to do some brief resistance-type exercises. Overall, it is estimated that these tasks will take less than

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45 minutes each. Everything will be conducted at the Hand and Upper Limb Centre (HULC) at St. Joseph's hospital.

What are the benefits of having my data in the database?

You may not benefit directly for participating in the research study, but as mentioned before, the information that you provide will be invaluable to society because we can understand more about this injury and the expected treatment outcomes without surgery providing better care for people who experience similar injuries in the future.

Is there any compensation?

You will not be compensated for your participation in this research. Enrolment is completely voluntary. You may refuse to participate, refuse to answer any questions, or withdraw from the study at **any** time with **no** effect on your future orthopedic care.

Are there any risks of discomfort associated with this study?

We do not anticipate that there will be any significant risks associated with participating in this study. Some participants may experience minor discomfort because of the unfamiliarity with the study. Our research team seeks to minimize stress by answering any questions that you may have prior to beginning the study.

Other than questionnaires, will there be any additional requirements?

No additional testing for research purposes other than that stated above will be performed.

Will your results be kept confidential?

The overall results of the study will be available to you upon request. Your individual results will be held in strict confidence. No person, other than your doctor or therapist and the study co-investigators will have access to your records without your permission. Your data that is sent into the study database will have your personal identifying information removed or coded so that the study database will be anonymous. Information collected during the study may be presented to other doctors in a presentation or paper. Your results would be part of a group of anonymous data, and would not identify you in any way. Representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

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Alternatives to Study Participation:

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. You will receive a copy of the letter of information and consent form for your records. You do not waive any of your legal rights by signing the consent form.

Whom may you contact to find out more about this study?

You will be given a copy of this letter and the signed consent form. If you have questions about taking part in this study, you can directly contact:

Dr. Joy MacDermid, BScPT, MSc, PhD. Hand and Upper Limb Centre, St. Joseph's Health Centre.

Kate Kelly M.Sc., MPH/Gero

The Hand and Upper Limb Clinical Research Lab St. Joseph's Health Centre

Consent To Participate In: The effects of yoga on patients with rotator cuff injuries

I have read the letter of information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Signature of Participant

Print Name

Date

Signature of person
obtaining consent

Print Name of person
obtaining consent

Date

Appendix D

Shoulder Pain and Disability Questionnaire

SPADI (SHOULDER)

Name _____ Date _____

PAIN SCALE	
How severe is your pain:	
1. At its worst.	No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain Imaginable
2. When lying on involved side.	No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain Imaginable
3. Reaching for something on a high shelf.	No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain Imaginable
4. Touching the back of your neck.	No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain Imaginable
5. Pushing with the involved arm.	No pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain Imaginable
DISABILITY SCALE	
How much difficulty did you have:	
1. Washing your hair.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
2. Washing your back.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
3. Putting on an undershirt or pullover sweater.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
4. Putting on a shirt that buttons down the front.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
5. Putting on your pants.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
6. Placing an object on a high shelf.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
7. Carrying a heavy object of 10 pounds.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help
8. Removing something from your back pocket.	No difficulty 0 1 2 3 4 5 6 7 8 9 10 So difficult required help

DEVELOPED BY Roach 1991 [1];

Reference List

1. Roach KE, Budiman-Mak E, Songsiridej N, Lertratanakul Y. Development of a shoulder pain and disability index. *Arthritis Care Res.* 4[4], 143-149. 1991.

(MacDermid, Solomon, & Prkachin, 2006).

Appendix E
Telephone Script

Hi,

May I speak with [patient's name] please?

Hi [patient's name],

My name is Dolly Mehta and I am calling on behalf of Dr. Ken Faber.

Do you have a minute to talk?

You are receiving this call because you are on a surgery wait list for your rotator cuff. I am a Graduate student at Western University and I would like to ask if you would be interested in being a part of a research study that is looking at how patients feel after doing specific exercises for their rotator cuff.

If you agree to be a part of this study, you will be asked to follow a YouTube video demonstrating 3 different exercises every day for 5 minutes, for a total of 6 weeks.

Would you be interested in being a part of this study?

IF YES → invite them in for assessments.

I would like to invite you to the HULC clinic for initial assessments. I would be taking your range of motion and strength levels for the study.

IF NO → thank them for their time.

Do you have any questions?

YES → answer them.

NO → continue below:

Thank you for your time,

Have a great day.

Bye.

ROTATOR CUFF INJURIES AND ONLINE EXERCISES

Appendix F
Diary Form

Please record the date & duration of each intervention session. Notes can be made, too.

	Date	Time	Notes
WEEK 1			
WEEK 2			
WEEK 3			

ROTATOR CUFF INJURIES AND ONLINE EXERCISES

WEEK 3			
WEEK 4			
WEEK 5			

ROTATOR CUFF INJURIES AND ONLINE EXERCISES

WEEK 6			

Curriculum Vitae

Name: Dolly Mehta

Post Secondary Education and Degrees: M.Sc. Western University
2014-2016

B.Sc. York University
2010-2014

Work Related Experience: Teaching Assistant Western University (Prof. Ravenek and Prof. Spaulding)
2015-2016

Teaching Assistant Western University (Prof. Spaulding)
2015

Certifications: Teaching Assistant Training Program (TATP)
2014

Academic Presentations: Health and Rehabilitation Sciences Conference
2015

Health and Rehabilitation Sciences Conference
2016