

Study Title: Feasibility and acceptability of a standardised shoulder exercise program for supraspinatus full thickness tears.

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ABSTRACT

Aim

To date, a standardised shoulder exercise program for full thickness supraspinatus tears has not been developed. The aim of this study is to examine the feasibility and acceptability of a standardised shoulder exercise program for supraspinatus full thickness tears and levels of compliance.

Methods

Six females and three males were recruited into a single cohort with ultrasound diagnostic confirmation of a full thickness supraspinatus tear. A standardised shoulder exercise program was the primary treatment. Outcome measures used were the SPADI questionnaire, active range of motion (AROM) for shoulder flexion and abduction, and external rotation and empty can strength. An End of study questionnaire was administered to analyse compliance.

Results

Average change in pain and disability for the SPADI questionnaire was -22% and -26% respectively, with a negative change representing improvement. Average increase for AROM in flexion and abduction was 13.4 ° and 14.2° respectively. Average increase in external rotation strength and empty can strength was 0.4 kg and 2.2 kg respectively. End of study questionnaire resulted in a self reported $\geq 90\%$ adherence to exercise in which all participants easily understood a verbal and written exercise program and found physiotherapy helpful.

Conclusion

A standardised shoulder exercise program for full thickness supraspinatus tears resulted in good feasibility and acceptability within this cohort. An overall improvement was observed in objective measures and SPADI scores. Good exercise adherence and physiotherapy experience expressed on the End of study questionnaire supports feasibility and acceptability to further examine the effectiveness of the shoulder exercise program.

INTRODUCTION

Full thickness rotator cuff tears affect an estimated 22.1% of the general population.[1] Rotator cuff tears occur within all age groups but are most commonly seen in individuals aged 60 and above and can be symptomatic or asymptomatic.[1, 2] Many factors can contribute to symptomatic and asymptomatic rotator cuff tears. In a study designed to establish the prevalence of such tears in the general population, researchers found that those with rotator cuff tears tended to be older, be male, have their dominant arm affected, be engaged in heavy labor, have a history of trauma, be positive for impingement sign, show less active forward elevation and have weaker muscle strength in abduction and external rotation.[2]

Rotator cuff tears have been treated surgically or conservatively, with both approaches yielding positive outcomes, leaving the superiority of surgical approaches in doubt.[3, 4] One group of researchers identified that an intact intramuscular supraspinatus tendon, less supraspinatus muscle atrophy, absence of an impingement sign, and a greater external rotation angle are

factors that correspond to patients who respond well to the conservative management of full thickness rotator cuff tears.[5] A recent study compared both surgical and conservative approaches and found significant improvements in shoulder pain and disability in patients who were randomized into the surgical group but a re-tear rate in this group of 73.4% at 1 year follow-up.[3] So the controversy remains on what specific indications can medical professionals obtain to appropriately allocate patients who benefit from surgical or conservative management. An appropriate use criteria has been developed to recommend referrals to conservative treatment, partial repair or debridement, repair, reconstruction, or arthroplasty in patients with full thickness rotator cuff tears.[6] The first line of factors that determine any route of approach is whether the patient responded positively or negatively to conservative management.[6] Despite the controversy, in regards to supraspinatus tears, a conservative approach should be considered as the primary line of treatment.[4]

In order to effectively establish a standardised shoulder exercise program for full thickness supraspinatus tears it's important to determine the feasibility and acceptability within this population. Although the benefits of exercise have been well documented the adherence to exercise is a problem physiotherapist encounter with some patients. A review of evidence on the factors associated with adherence to physiotherapy exercises found that although outcome expectations and self-efficacy correlated to exercise adherence, other external and internal barriers may affect these factors.[11] Time demands and convenience of exercise environment should be used strategically to motivate patients to exercises.[11] Amongst education of purpose and benefits of the exercise an incorporation of their lifestyle should be considered with each individual.

Exercise has been an integral component in the conservative management of rotator cuff tears with existing evidence of its benefits.[5-9] Patients will be concerned with the amount of time required to complete their exercises. Repetitions and sets are important to establish for adherence to exercise so that rehabilitation will result in effective outcomes. Researchers performed a study on determining what the most effective distribution of an hour of strength training exercise is for the neck and shoulders amongst office workers and found that longer exercise sessions have a lower adherence compared to sessions that were shorter in time but more frequent.[12] Shoulder exercises for shoulder pathologies have been found to receive high levels of compliance with short, frequent sessions a week.[9]

To date, a standardised shoulder exercise program for full thickness supraspinatus tears has not been developed. The aim of this study is to examine the feasibility and acceptability of a standardised shoulder exercise program for supraspinatus full thickness tears and levels of compliance.

METHODS

Research Design

A prospective feasibility study was performed in which data was obtained from a single small cohort of patients referred for physiotherapy. A cohort of patients performed a standardised shoulder exercise program and were monitored for a period of six weeks. To determine the effectiveness of the exercise program a pre-fatory assessment was performed to enable identification of changes in the selected outcome measures monitored over the duration of the exercise program.

Ethical approval

The study was granted ethical approval by the Bond University Human Research Ethics Committee (BUHREC), BUHREC Protocol number RO1897 and was amended for an extension to continue with the study and to add an additional co-author.

Participants

Recruitment of participants into the study employed the inclusion and exclusion criteria listed in Table 1. All participants were recruited from one of three Sports and Spinal Physiotherapy practices located on the Sunshine Coast in Queensland, Australia from January 2015 to April 2016. Each participant was identified to have a full thickness supraspinatus tear through a confirmed ultrasound diagnostic test which was recorded. All participants were informed about the background and purpose of the study verbally and through a patient information sheet. The participants were assured that their treatment plan discussed by their treating physiotherapist would in no way be affected by their decision to participate or not. Participant and clinician blinding were not performed in this study.

Table 1 Participant Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Full thickness, partial-width tear of the supraspinatus muscle confirmed by Ultrasound or MRI (+/- other rotator cuff tears)	Other substantial shoulder pathology (e.g. marked osteoarthritis)
Age over 18 years	Co-morbidities that prevented participation in the shoulder exercise program
The standardised shoulder exercise program already included as an agreed core part of physiotherapy treatment	

Procedures

At each patient's initial assessment with their treating physiotherapist they were informed of the type of treatment they were going to receive prior to being invited to participate in the current study, which involved the standardised exercise program. Demographic information and a history of their shoulder pain were obtained initially, in accordance with usual subjective examination procedures in physiotherapy clinics. The patient information sheet was distributed to advise them on the purpose and their involvement in the study. A decision to participate was confirmed by a signed consent form stating their awareness of the study implications. At the initial treatment preliminary assessment of outcome measures were conducted to enable assessment of the effectiveness of the program, with re-assessment at 3-6 weeks.

Exercise Program

The exercise program was designed by the primary investigator and colleagues. The selected exercises are explained below:

Patients were taken through each level of the program and progressed once they were able to perform the previous level with good technique as assessed by the physiotherapist, and with no pain. Table 2 shows the exercise goals and the stages progressed as follows.

Table 2 Shoulder exercise protocol description at each level

Level	Exercise goal / description
1	Involved humeral head control and scapula control in sitting
2	Increasing strength training in neutral position by increased load and range of motion
3	Involved strength in close range position with side lying external rotation, internal rotation, active/assisted flexion and standing wall push ups
4	Included strengthening in higher shoulder ranges of motion, such as standing external rotation with a therapy band and with increased forward shoulder flexion, standing shoulder press, and 45 degree push ups
5	Advanced strengthening, such as standing internal and external rotation with a therapy band with the shoulder at 70-90 degrees of abduction, and the “drawing the sword” exercise

*All exercises were performed at home and were reviewed and progressed by a physiotherapist (see Appendix A for full exercise program).

All exercises emphasized the importance of humeral head centering, control of the scapula, and ensuring the exercises were pain-free. Patients were asked to complete the exercises 2-3 times per day, with each session being between 5-10 repetitions, for 2-3 sets initially. This progressed to 2-3 times per week, with 20 repetitions for 3 sets as the exercise intensity increased and symptoms improved.

Outcome Measures

Outcome measures included the Shoulder Pain and Disability Index (SPADI) Questionnaire[13], shoulder range of motion, and shoulder strength. These outcomes were assessed at the initial assessment and after six weeks. The SPADI was used to evaluate levels of pain and disability of the shoulder. [13, 14]. The SPADI is found to have strong validity in out patient settings and a high degree of item reliability with high Cronbach’s alpha scores for the pain subscale, disability subscale, and total SPADI score.[15-17] The SPADI self-assessed questionnaire is composed of 13 questions divided into 2 sub-categories of pain and disability. The patient scores each question on a scale of 0 to 10 (0 = no pain/no difficulty , 10 = worst pain/most difficult) and the degree of shoulder pain and disability is expressed as a percentage. The higher the score the worse the pain and/or disability.[16] The SPADI is shown to have an excellent response rate (97.9%).[15] Active range of motion of the affected shoulder was performed in standing and measured in shoulder flexion and abduction through visual estimation of an experienced shoulder physiotherapist specialist. External rotation and empty can strength was measured using a dynamometer. Empty can test places a shoulder near 90° of elevation, 20° horizontal abduction, and full internal rotation to assess the supraspinatus strength when resistance is

placed.[23] Compliance levels and patient perceptions of the program were assessed through the exit questionnaire at the end of the patients program. It comprised of questions relating to the patients experience and perspectives of the program design, feasibility, and program compliance.

Data Collection

Data was collected at the initial assessment of consented participants on paper by the physiotherapist or physiotherapist student researcher. Relevant study Information was gathered using the demographics form, SPADI form, as well as an end of study questionnaire at 3-6 weeks. The data was transferred from paper to a Microsoft Excel spreadsheet by the physiotherapy student researcher. The data was reviewed by the physiotherapy student researcher to assure correct data entry.

Data Analysis

Participant demographics and objective examination results were analysed and reported as group means and averages. The response rate, completion of data, and total scores for the SPADI were calculated through means and averages. Response rate for the Exit Questionnaire was calculated. Exercise compliance data were analysed and reported thematically.

RESULTS

Data was collected from 9 participants during the period January 2015 to April 2016. Patient demographics are shown in Table 3.

Table 3 Patient Demographics

Participant	Age (years)	Sex	Occupation
1	78	F	House Wife
2	79	F	Retired
3	63	M	Truck Driver
4	67	F	Not working
5	75	M	Company Director
6	54	F	Office Admin
7	57	F	Metal Smith
8	71	M	Retired
9	73	F	House Wife

All participants had a full thickness tear of the supraspinatus muscle confirmed by ultrasound diagnostics. Tear size of the supraspinatus wasn't described for participants 1 and 2 but the tear size for the rest of the participants ranged from 10x10 mm to 24 mm. Four participants had

other cuff involvement and one with a subluxed biceps tendon. Ultrasound results are presented in Table 4.

Table 4 Ultrasound Results and Time in study

Participant	Tear size	Other Rotator Cuff involvement	Duration of symptoms	Time in study
1	Not specified	Full thickness tear infraspinatus	4 months	3 weeks
2	Not specified	Partial tear infraspinatus, intrasubstance tear of subscapularis	3 months	8.5 weeks
3	21x12 mm involving anterior and mid portion	Biceps tendon subluxed medially	6 weeks	3 weeks
4	10x10 mm	None	3 months	2.5 weeks
5	24 mm	Partial thickness tear infraspinatus and subscapularis	30 months	3 weeks
6	11x15 mm	None	6 weeks to 3 months	8 weeks
7	13x15 mm	None	6 weeks to 3 months	6 weeks
8	11x9 mm	None	3 months to 1 year	4 weeks
9	11x15 mm	Partial thickness tear long head biceps, subscapularis and infraspinatus	More than 1 year	3 weeks

Through chart analysis the final mean for AROM in flexion, abduction, external rotation, external rotation strength and empty can strength all increased from baseline in patients with recorded data. Table 5 shows the mean initial, mean final and mean change for each objective measure. For the Hand Behind Back objective measure only one participant increased range, one decreased in range, four had no change, and 3 had incomplete data.

Table 5 Mean initial, Mean final and change scores for Clinical Measures

Flexion (AROM, °) (n=6)	Abduction (AROM, °) (n=5)	External Rotation (AROM, °) (n=6)	External Rotation Strength (kg) (n=4)	Empty Can Strength (kg) (n=5)
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Initial Mean	143.6	125.8	66.3	4.1	1.3
Final Mean	157.5	140	72.1	4.5	3.5
Mean Change	13.4	14.2	5.8	0.4	2.2

*Due to clinical pressures during data collection, outcome measures were collected for most but not all participants

The responsiveness in this study was 89% with 8 out of 9 participants answering an initial and final SPADI questionnaire. Incomplete SPADI's were appropriately calculated to yield comparable results as instructed for score calculations.[13] Table 6 presents the mean initial, mean final and mean change in SPADI scores. Seven participants showed improvement in SPADI scores ranging from -3.1% to -63% change in scores. Participant 9 did not improve scores from the initial SPADI questionnaire with a 6% increase in pain scores, 11% increase in disability scores, and 9.1% change in total SPADI scores. Five participants significantly improved total SPADI scores, one participant improved their score by 4 points but was clinically insignificant, and 2 participants did not improve in total SPADI scores based on an MCD of 18 points.[13, 14]

Table 6 Mean initial, Mean final and change scores for SPADI Scores

	Mean Initial	Mean Final	Mean Change
Pain Score	56%	34%	-22%
Disability Score	45%	19%	-26%
SPADI Score	59%	29%	-30%

*A negative change represents improvement in average change

A 100% response rate of the End of Study Questionnaire showed an overall positive reaction to the application of a standardised shoulder protocol for a full thickness supraspinatus tear with an exercise compliance of $\geq 90\%$. All participants:

- Found the exercise instructions to be clear enough to perform at home
- Felt comfortable performing them at home
- Agreed that the program's level of difficulty was the right amount
- Thought the number of exercises were adequate
- Easily understood the physiotherapist's instructions on how to do the exercises
- Found Physiotherapy was helpful

DISCUSSION

This study of the feasibility and acceptability of a standardised shoulder exercise program for supraspinatus full thickness tears adds valuable evidence to the existing literature that supports a recommendation for the program's clinical use while it should be noted that further rigorous studies are required to confirm the apparent effectiveness of the program. Based on patient feedback and preliminary results of patient outcomes following the use of the standardised program, it appears that patients found the program to be a positive experience, that they managed to complete the program at home at the desired frequency with few problems, and that their levels of pain and disability improved substantially during the exercise period.

Self reported exercise adherence was shown to be $\geq 90\%$ in this prospective cohort. Minor adjustments can be made to improve the program in areas where patient feedback was not in agreement. Some patients found it difficult to fit the exercise plan into their routine due to time constraints and a busy lifestyle. Two participants expressed that the number of times they were asked to do the exercises each day was too much. Both recommended that twice a day would be the right amount. Lifestyle factors can affect an individuals compliance to exercise and should be tailored appropriately taking into account the composition of their activities of daily living.[18, 19]

Feasibility and acceptability of the selected exercises organised in a gradual progression resulted in a good response by both patient and practitioner within this shoulder population. An RCT that compared outcomes of rotator cuff tendon repair and a physiotherapy program with possibility of crossing over to tendon repair found better results in the surgical group on follow-up <5 years.[20] After five years, the surgical group had re-tears and between group differences evened out with the physiotherapy optional tendon repair cross over group[20]. Fifty-two different shoulder exercises, based on literature, were selected by the physiotherapist to individualise the program as they believed a defined protocol would not meet the therapeutic needs of the patient.[20] Although a more individualised shoulder exercise program was used for the RCT the design and central focus of their exercises coincided with our protocol. Our initial focus on patient education, unloading the supraspinatus tendon to decrease pain, and to correct positions through scapula setting and humeral head centering met with their primary treatment goals. This initial approach was found to have a positive effect following the participants next physiotherapy visit which gained patient compliance to continue with the exercise program.

One patient experienced pain during exercises and three experienced pain immediately after the exercises. The participant who experienced pain during the exercise had 2 specific exercises which caused pain: “Rotator cuff strengthening” (external rotation in side ly) and “Supine Active/Assisted Flexion progress to Active flexion”. These exercises did not negatively affect other participants which indicates factors influencing pain at an individual level. The three patients that experienced pain immediately after the exercises had relief immediately after to 15 min after exercise. Factors such as frequency, intensity, duration, speed, ROM, and muscle contraction type may have affected the stress put on the tissue.[18, 19] Under supervision, exercises were reviewed for technique correction and modified accordingly. These patients reported that physiotherapy was helpful and felt their shoulder had improved indicating that the feasibility and acceptability of the shoulder exercise program wasn’t affected.

Patient education on biomechanically safe movement patterns, shoulder position awareness, and activity modifications substantially influenced improvement on SPADI pain and disability scores. An immediate decrease in pain was expressed by most participants following one week post patient education previously mentioned. This increased adherence to the exercise program which allowed the strengthening aspect to be successful with patient compliance to exercise instructions. The development and use of this program in this private practice setting supports acceptability of the program by the physiotherapists.

The effectiveness of a standardised shoulder exercise protocol would follow this feasibility and acceptability study. Using feedback from this study will enhance the protocols structure and adherence.

LIMITATIONS

The research design initially aimed to recruit 20 participants but due to researcher time constraints the recruitment aim wasn't met. A limitation to be warranted was the change made in the participant criteria post data collection. Instead of including isolated supraspinatus full thickness tears the study accepted participants with supraspinatus full thickness tears with or without the involvement of other cuff tears. This change may have limited the sample size to 9 participants. A formal sample size calculation may not be important for feasibility studies.[22] Four participants (44%) had involvement of other cuff tears, three females and one male. Range of motion and strength did not greatly differ from the 5 participants with isolated supraspinatus tears at baseline and final assessments. All improved in outcome measures and SPADI scores, regardless except one. Participant 9 did not improve on SPADI scores and only improved in external rotation ROM. With a longer duration time in study the patient may see gradual improvements given compliance to practitioner advice. This study primarily examined feasibility and acceptability of the standardised exercise program and was not designed to rigorously examine its effectiveness. However, a preliminary assessment of changes in scores from baseline to post-exercise time points was conducted to ensure improvement did occur.

A definitive time frame was not used for follow-up preliminary measures, final SPADI questionnaire, and the End of study questionnaire. This is due to appointment inconsistency that varied time in the study duration. An established data collection time frame was difficult in private practice setting.

CONCLUSION

A standardised shoulder exercise program for full thickness supraspinatus tears resulted in good feasibility and acceptability within this cohort. An overall improvement was observed in preliminary measures and SPADI scores. Good exercise adherence and patient physiotherapy experience expressed on the End of study questionnaire supports the feasibility and acceptability to further examine the effectiveness of the shoulder exercise program.

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13 Koziol-McClain J, Brand D, Morgan D, et al. Measuring injury risk factors: question reliability in a statewide sample. *Inj Prev* 2000;6:148–50.

Chapter in book

14 Nagin D. General deterrence: a review of the empirical evidence. In: Blumstein A, Cohen J, Nagin D, eds. *Deterrence and Incapacitation: Estimating the Effects of Criminal Sanctions on Crime Rates*. Washington, DC: National Academy of Sciences 1978:95–139.

Book

15 Howland J. *Preventing Automobile Injury: New Findings From Evaluative Research*. Dover, MA: Auburn House Publishing Company 1988:163–96.

Abstract/supplement

16 Roxburgh J, Cooke RA, Deverall P, et al. Haemodynamic function of the carbomedics bileaflet prosthesis [abstract]. *Br Heart J* 1995;73(Suppl 2):P37.

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Electronic journal articles

Morse SS. Factors in the emergency of infectious diseases. *Emerg Infect Dis* 1995 Jan-Mar;1(1). www.cdc.gov/ncidod/EID/vol1no1/morse.htm (accessed 5 Jun 1998).

Electronic letters

Bloggs J. Title of letter. *Journal name* Online [eLetter] Date of publication. url eg: Krishnamoorthy KM, Dash PK. Novel approach to transseptal puncture. *Heart* Online [eLetter] 18 September 2001. <http://heart.bmj.com/cgi/eletters/86/5/e11#EL1>

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