THE UNIVERSITY OF WESTERN AUSTRALIA
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ST JOHN OF GOD Health Care

Exercise rehabilitation and functional recovery following reverse shoulder arthroplasty: A prospective randomised control trial.

Participant Information Sheet

You are being invited to take part in this study. Before you decide it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with your surgeon, GP and family before making your decision. Please ask the doctor or study staff to explain anything that you do not clearly understand or if you want more information about the study.

Investigators: Mr Allan Wang, Mr Peter Honey, Dr Jay Ebert, Mr Peter Edwards, Prof Tim Ackland

Background

Reverse total shoulder arthroplasty (RSA) is an end-stage surgical treatment option for patients with rotator cuff arthropathy and/or massive rotator cuff tears, who have significant difficulty in moving their shoulder and undertaking daily activities. RSA has demonstrated good success at relieving pain, improving range of motion, functional capacity and overall patient satisfaction and now, on the back of expanding indications and successful midterm outcomes, it is now being performed in a wider patient demographic, including younger patients. Return to sports and physical activity is increasingly being evaluated as a factor in judging orthopaedic surgical outcomes. Patient satisfaction is closely correlated with resumption of regular activities, and in the case of RSA, it has been shown that those who return to their pre-surgery physical activity and recreational sports after RSA, report greater levels of satisfaction post-surgery. Furthermore, patients with greater shoulder strength are more likely to participate in higher demand recreational or sports activity and also report fewer difficulties with activities of daily living after RSA. Conversely, patients with lower shoulder strength are more likely to have a reduced range of motion, and potentially inferior clinical outcomes following RSA.

One factor that influences function and patient satisfaction is the postoperative rehabilitation protocol. As with other joint arthroplasties such hip, knee and traditional shoulder arthroplasties, patients receiving RSA rely on postoperative exercise rehabilitation to regain range of motion and strength after surgery. To our knowledge, no studies to date have evaluated the effect of structured post-operative exercise programs that can improve muscular strength and accelerate functional recovery of patients after RSA, compared with patients who receive the normal course of care. Therefore, this study will investigate the benefit of a structured, post-operative exercise rehabilitation program designed to safely restore patients' ability to actively elevate their arms, externally rotate their shoulder and ultimately return them to work, physical activity and recreation faster, with improved patient based outcome scores and without risk to the prosthesis.

Nature and Purpose of this study

This is a prospective randomised control trial (RCT) investigating the benefit of a structured post-operative exercise rehabilitation program in patients undergoing RSA. This will be evaluated via validated questionnaires about your pain and function, clinical scores looking at your strength, mobility and function, as well as the time taken to return to work/sport, and overall satisfaction. Furthermore, this study will evaluate your shoulder function using body-worn activity monitors ("wearables") to assess your upper extremity function, and physical activity level throughout the post-surgery timeline. This information will be of benefit to you in your return to full function, as well as other patients who require such treatment in the future.

What this study will involve - What will happen in this clinical trial?

This trial will investigate two different post-operative management pathways for patients scheduled for RSA. If you meet the inclusion criteria and consent to participate in this RCT, you will be randomised to either one of two groups: Ususal Management (UM) or Exercise Management (EM). You will be required to undergo a comprehensive education session and pre-operative functional assessment to record baseline data with an Exercise Physiologist, at a rehabilitation facility convenient for you. You will be asked a series of standardised, introductory questions about any previous injuries and medical history, and you will also be required to participate in a series of musculoskeletal capacity tests including measurement of height, body mass, and active range of motion of both of your shoulders. You will also be asked to wear four wearable monitors secured bilaterally to the upper arms at the mid-biceps, and on the lower arms at the wrist, whereby activity data will be collected over three consecutive days in your natural living environment.

Usual Management Group (UM)

If you are randomised to the UM group, you will be provided with standard instructions and guidelines on managing your shoulder post-surgery, and are free to contact the study investigator (PE) for any advice during your postoperative management course. By agreeing to the study, you will be required to undertake post-operative evaluations at 2 weeks, 6 weeks, as well as 3-, 5-, and 12 months' post-surgery. This will include validated self-reported questionnaires, wearable activity data assessment over three consecutive days, and a series of strength/functional tests relevant to the specific time point. These are all measures that are employed routinely in the follow up evaluation of reverse shoulder replacement.

Exercise Management Group (EM)

If you are assigned to the EM group, following surgery, you will receive the same standard instructions and guidelines on managing your shoulder post-surgery as the UM group. At the first follow-up (2 weeks) you will be referred to the Exercise Physiologist to advance your home exercise program and to review your immobilisation sling, as well as education on how to manage your shoulder. At the second follow-up (6 weeks), the Exercise Physiologist will advance your home exercise program, which will focus on progressing the current passive range of motion exercises to more active exercises including some light strengthening of the shoulder muscles. You will be required to complete these home exercises daily for a further 6 weeks with ongoing surveillance monitored via weekly phone

calls to follow up on the exercises and progress further if needed. You will be asked to refer to a “post-surgery home exercise guide” as well as being provided with a “home exercise kit” for instruction and guidelines, and strictly and accurately record all your rehabilitation in an exercise diary, daily.

At 3 months, you will again be required to meet with an Exercise Physiologist for education as well as undertake your first supervised exercise session at a rehabilitation facility (HFRC). From 3 months, you will be required to undertake strength and conditioning aimed at advancing your shoulder strength and mobility, under the supervision of an Exercise Physiologist twice per week for 8 weeks. Again, you will also be required to complete daily home exercises, which will again be referenced in the “post-surgery home exercise guide.” Again, you will be required to strictly and accurately record all your rehabilitation in an exercise diary, daily.

As above, by agreeing to participate in the study, you will be required to undertake post-operative evaluations at 6 weeks, as well as 3-, 5-, and 12 months’ post-surgery. This will include validated self-reported questionnaires, wearable activity data assessment over three consecutive days at each time point, and a series of strength/functional tests relevant to the specific time point. These are all measures that are employed routinely in the follow up evaluation of reverse shoulder replacement.

Potential Benefits

- As a participant in this study, you will be provided with a comprehensive post-operative rehabilitation program, that will assist in restoring function post-surgery. Patients are often unaware on when they can resume activities of daily living safely, and what activities they can undertake without detriment to their joint post-surgery. You will be guided by an Accredited Exercise Physiologist for the first four months following surgery, and followed up routinely, where you will be continuously assessed, progressed and educated on how to safely get your shoulder back to full function.
- This study will also benefit patients, such as you, who require such treatment in the future.

Risks and Discomforts

- There are no expected risks/discomforts expected through participation in this study. The postoperative shoulder is at a risk of dislocation early post-surgery. However, agreeing to participate in this study will in no way increase this risk of dislocation. In fact, the investigators believe that greater patient education, instruction and compliance as a result of being involved in this study, will **LOWER** this risk.
- You may experience some joint and/or muscular soreness as a result of the rehabilitation sessions or functional evaluation tests employed, though this will be temporary and remains part of normal care.
- You will be required to perform a part of your exercise rehabilitation program at home independently, without supervision. While unlikely, there is a risk that these exercises may be performed incorrectly resulting in more soreness than normal and putting the joint in positions vulnerable to dislocation. However, you will be fully educated and instructed on safe performance of these exercises, and equipped with a home exercise manual, with detailed descriptions of each exercise to be performed.

- Those patients randomised to the "Usual Management" group, will be undertaking a post-operative rehabilitation program that is routine, considered very conservative. Those patients randomised to the "Exercise Management" group will undertake rehabilitation which is more advanced, but still considered conservative. Although this protocol is currently clinically untested, it has been prescribed previously, based upon clinical experience and opinion, and as such we anticipate no harmful complications as a result of this rehabilitation approach.

What happens if there is an adverse medical event?

Should there be any problems encountered throughout either post-operative protocol, the rehabilitation approach shall be modified accordingly, and you may be referred to your General Practitioner or Orthopaedic Surgeon for consultation. Your usual rights under Australian law in relation to an adverse medical event or injury will not be affected by your agreeing to participate in this research study or by signing the consent form.

Voluntary Participation and Withdrawal from the study

You will not be paid to take part in this study, nor will you be reimbursed for travel expenses incurred for taking part in the study. It is up to you to decide whether to take part in this study. If you do decide to take part, you will be asked to sign a consent form and will be given a copy of this signed information and consent form to keep. You will still be free to withdraw from the study at any time. Before withdrawing you should discuss this with your surgeon or GP. If you decide to withdraw or decide not to take part in this study, there will be no penalty. Your decision will not affect your continuing medical care including your relationship with your surgeon, doctor or other clinical staff. No reason or justification for withdrawing is needed. If you decide to withdraw, the records of your participation will be destroyed.

What happens when the research is completed?

After the study is completed, you will be given appropriate education and advice regarding ongoing treatment. Further rehabilitation and therapy will be offered to you, but whether you accept is at your own discretion. The results of the research will be made available through medical journals, conference meetings and a thesis, but all patient information will be de-identified and no private information will be identified outside the investigator office.

Confidentiality – who will see my records?

During study, staff from St John of God Subiaco Clinic will be granted direct access to your medical records so that they can confirm that the information collected about you during the study is accurate. Paper records will be kept under lock and key in a metal filing cabinet in the St John of God Subiaco Clinic. Computer records will be stored in the assessor database and will be password protected. The chief investigator will only have access to hand written and electronic records. Records will be kept for 15 years after which paper records will be shredded and computer records will be permanently deleted including back-up copies. The results of this research will be made available through journal publications and meetings, but all patient information will be de-identified and no private information will be identified outside the investigator office.

Study Costs

There are no additional costs to you, outside of the normal standard of care. All post-operative clinical assessments undertaken as part of the study will not be paid by you. However, your cost of travel to and from the venue for the assessments will not be reimbursed.

Ethical Approval

The University of Western Australia HREC and St John of God Health Care HREC have given ethical approval for the conduct of this study. If you have any concerns or complaints about the study please contact the Executive Officer on (08) 9382 6940 on a confidential basis. Your concerns will be drawn to the attention of the Committee who is monitoring the study.

Questions?

If you have any questions or concerns now or at any time throughout the study, regarding your safety or your rights, please ask your surgeon or the research coordinator. If you would like to participate in this study, or like to discuss any aspect of this study, please feel free to contact Peter Edwards on 0422 370 913 or via email, peter.edwards@uwa.edu.au or Dr Jay Ebert 9386 9961 or jay.ebert@uwa.edu.au.

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Participant Consent Form

I confirm that I have read and understand the Participant Information and Consent Form for the above study and have had the opportunity to ask questions and all of these have been answered in a way I understand.

I understand that my participation is voluntary. I may refuse to take part in this study and I am free to withdraw from the study at any time, without my medical care or legal rights being affected. There is no penalty. My decisions do not affect my continuing medical care including my relationship with my doctor or other clinical staff.

I understand that sections of any of my medical record may be looked at by responsible individuals from St John of God Hospital or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

_____	_____	_____
Name of Participant	Date	Signature

I, the undersigned have discussed the nature and purpose of the study and the possible risks and benefits of participation with the participant and/or legally authorised representative.

I believe that the participant and/or his/her representative has been fully informed, using language which is understandable and appropriate, and has understood this explanation.

_____	_____	_____
Person obtaining consent	Date	Signature

Revocation of Consent

I hereby WITHDRAW my consent to participate in the research project described above and understand that such withdrawal will not make any difference to my medical care or my relationship with my doctor or other clinic staff.

_____	_____	_____
Name of Participant	Date	Signature

CONTACT: **Peter Edwards – PhD Candidate – UWA – peter.edwards@uwa.edu.au / 0422 370 913**