

ELIGIBILITY

1. **Can I be in the study if I have already had physical therapy for my shoulder?** Yes, you can still participate in this study even if you have already had physical therapy for your shoulder.
2. **Can I participate in this study if I am currently part of another study?** It depends on what kind of study you are already participating in. If it is not related to your shoulder treatment, then the answer is most likely yes. Be sure to mention it to our research staff to make sure before enrolling in the ARC trial.

STUDY TREATMENT DETAILS

1. **Can I choose which treatment I receive?** This is a randomized controlled trial, which means that if you choose to participate in the study, you will NOT choose which treatment you receive. You will be randomly assigned to either operative (surgery + physical therapy) or non-operative (physical therapy without surgery). There is a 50-50 chance of being in either group, regardless of whether you have previously had physical therapy for your shoulder.
2. **How soon do I need to start treatment for my shoulder?** We ask that you begin treatment within 8 weeks of enrolling in the trial. If there is too much difference between when people start treatment, it makes it difficult to accurately compare treatment results among participants. However, if for some reason you are unable to begin treatment within 8 weeks (2 months), you will still be part of the study.
3. **How long do I need to stick with my assigned treatment?** It takes 6 months for either treatment to be fully effective. Therefore, we ask participants to stick with their assigned treatment for at least 6 months.
4. **Can I pursue a different treatment after 6 months?** Yes. For example, if you are assigned to the non-operative (physical therapy) treatment group and later wish to have surgery on your shoulder, you can. We just ask that you wait 6 months before doing so, so we can accurately measure the effectiveness of your initial assigned treatment.
5. **Will I be withdrawn from the study if I do not have my assigned treatment?** No, we will continue to follow you as planned even if you switch treatment groups or do not pursue treatment at all.

PHYSICAL THERAPY

1. **How often will I need to attend physical therapy?** The usual recommended physical therapy program is 1-2 times a week on average for 3 months (for non-operative treatment) or for 4 months (following surgery).

- 2. Can I tailor the number of physical therapy visits based on my needs and insurance coverage?**
Yes, you and your physical therapist can determine how many physical therapy sessions you need to attend over the course of your treatment and how frequently.
- 3. Can I use my own physical therapist or do I need to go to a study physical therapist?** You can go to the certified physical therapist of your choice. If you do not already have a preferred physical therapist, our research staff can help refer you to one near you.
- 4. How will my physical therapist know that I am participating in this study?** A physical therapist with the ARC trial will contact your treating physical therapist to make sure they know about the study and receive the appropriate treatment instructions. You will also be given a packet with information about the study to take with you to your first physical therapy visit.

COSTS

- 1. Will the study pay for treatment of my shoulder?** No, the ARC study will not pay for the cost of your shoulder treatment. Your insurance company will be billed as it normally would for any surgery or physical therapy as well as follow-up doctor visits related to treatment. However, you will NOT have to pay for any tests or treatments done only for research purposes.

PATIENT PRIVACY

- 1. Who will have access to my information during the study?** Your information will only be accessed by authorized personnel for study purposes, including study staff, research monitors, auditors, and federal regulatory agencies, as needed.
- 2. How will my privacy be protected?** We take protecting your confidentiality very seriously. You will be assigned a study ID which will be used instead of your name during the course of the study. Participant information will be stored in locked cabinets and secure, password-protected research servers, accessible only to authorized study personnel.

MY ROLE AT HOME

- 1. What exercises will I need to do at home?** Your physical therapist will assign specific exercises for you to do at home each week. Bring your ARC Rotator Cuff Home Exercise Program booklet with you to each visit, so your exercise assignments can be updated each time.
- 2. How often will I need to do exercises at home?** You should perform home exercises 2-4 times a week, as instructed by your physical therapist. Your home exercise program should take approximately 30 minutes a day to complete.
- 3. How long to I need to keep track of my physical therapy visits and home exercises?** Complete your diary each day any time that you are attending formal physical therapy for your enrolled

shoulder during the first year of the study. This means you should complete the diary daily for each course of shoulder PT - from the first physical therapy visit until the last - even if you switch treatment arms or go back to physical therapy a second time later on.

- 4. Where can I get another copy of the physical therapy home exercise program booklet or physical therapy diary, if I lose mine?** Copies of these documents can be found on our website in the patient section for the ARC Trial (www.shoulderstudy.org/studies/arc-trial/participants/).
- 5. Is there a way to complete my Physical Therapy Diary electronically?** Yes, there is a special MyCap app that will allow you to complete your Physical Therapy Diary using your smartphone. Our research staff will help you install and set up this app before you leave the clinic. The MyCap app is currently available for both iPhones and Androids.
- 6. Can I complete my study questionnaires electronically?** Yes, you can choose whether you prefer to complete your questionnaires on paper or electronically (via computer or tablet). If you choose to complete them electronically, a unique link to your questionnaire will be sent to you via email at each follow up.

OTHER TREATMENTS

- 1. Can I pursue other treatments in conjunction with my assigned treatment?** Yes, other non-surgical treatments, such as cortisone injections, pain medications, acupuncture, etc., can be utilized while undergoing your assigned treatment for the study.
- 2. Do these additional treatments need to be reported?** Yes. There will be questions that ask about these treatments on each follow up questionnaire.

STUDY FOLLOW UP AND CONTACT

- 1. How will I know the results of the study?** A summary of the study results will be made available on our website: www.shoulderstudy.org. Information about the trial can also be found at www.clinicaltrials.gov.
- 2. Whom should I contact if I have a question about the study or no longer want to be part of the study?** Please contact the ARC Trial research team at Vanderbilt: arcstudy@vumc.org / (629) 777-8022.