Baylor Scott & White Protocol

Title: Rotator cuff Evaluation Across Care settings for Home telehealth vs. hospital-based physical therapy: REACH Trial

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Background & Significance

Shoulder symptoms led to 12.6 million ambulatory physician visits in 2015 in the United States and is one of the top 15 reasons for patients to seek healthcare in ambulatory outpatient settings[1]. Rotator cuff tears are a leading causes of shoulder pain and disability[2,3]. Most cuff tears are degenerative or atraumatic and therefore are the focus of our investigation. Physical therapy is often the first line of treatment for patients with rotator cuff tears[4,5]. Patients undergoing physical therapy have good outcomes[6-9]. Over 80% of patients receiving supervised physical therapy treatment reported improved pain and function at 6 months to 1 year of follow-up[8]. This relief was also persistent in longer-term follow-up. Smaller studies have also shown good outcomes in patients with cuff tears receiving a home exercise program[10-12]. However, there is preliminary evidence to suggest that the natural history of rotator cuff disease is favorable and that patients may spontaneously become asymptomatic over time[13,14]. A small, randomized trial on physical therapy versus placebo in patients with shoulder impingement (not cuff tears) showed no significant benefit for pain and functional improvement in the exercise group compared with placebo[6]. Hence, it is questionable whether improvements from non-operative rehabilitation treatment in patients with rotator cuff tears are due to the active components of physical therapy (such as strengthening, stretching, and real-time adjustments from a physical therapist), or from a combination of a favorable natural history and a placebo effect from hands-0n interaction with a physical therapist. Telehealth-delivered physical therapy offers a strategy to isolate the effect of hands-on, in-person delivery from the active components of a physical therapy program, and is feasible for a range of musculoskeletal conditions,[15-17] including shoulder pain.[18,19] Despite this, perceived limitations in effectiveness compared to in-person care, from both patients and therapists, likely explain why only 2.5% of physical and occupational therapy visits were delivered via telehealth between 2020-2021,[20] even after policy changes expanded access.[21] It remains unknown whether a physical therapy program for rotator cuff tears needs to be delivered in-person, or whether a physical therapist-guided telehealth program produces comparable outcomes. Establishing equivalence would offer significant cost- and time savings for patients and payers and expand access to physical therapy for patients in rural and underserved communities.

Study Question/Hypothesis & Specific Aims

Study Purpose/Question

This trial will determine whether standard in-person physical therapy produces superior pain and functional outcomes, as measured by the Shoulder Pain and Disability Index (SPADI), compared with a therapist-guided telehealth exercise program in patients with atraumatic rotator cuff tears,

and will examine the trajectory of recovery and patient-level characteristics associated with treatment response within each arm.

Study Hypothesis

Patients undergoing standard in-person physical therapy will show significantly greater improvement in pain and function, as measured by the Shoulder Pain and Disability Index (SPADI), and a faster rate of recovery across the treatment course, compared with patients undergoing a therapist-guided telehealth exercise program for atraumatic rotator cuff tears.

Specific Aims

Trial Aim 1: To compare pain and function in patients undergoing standard in-person physical therapy with a telehealth guided exercise program for atraumatic rotator cuff tears at 12 months of follow-up

Hypothesis 1: Patients undergoing standard physical therapy will have significantly greater improvement in pain and function (measured by Shoulder Pain and Disability Index-SPADI)[26] at 12 months of follow-up.

Trial Aim 2: Compare the trajectory of pain and function recovery between the two arms across the treatment course (e.g., 3 months, 6 months, 12 months).

Hypothesis 2: Patients undergoing standard physical therapy will show a faster rate of improvement in SPADI scores across all time points than patients undergoing the telehealth exercise program.

Trial Aim 3: Explore patient-level characteristics associated with treatment response (e.g., tear size and location, baseline SPADI score, age, adherence to the assigned intervention) within each treatment arm.

Exploratory Question: Which patient-level characteristics are associated with greater improvement in SPADI scores at 12 months, within the standard physical therapy arm and the telehealth exercise program arm?

Study Design

Two-arm randomized clinical trial

Study Population/Subject Selection

Inclusion and Exclusion Criteria for the REACH Trial	
Inclusion criteria	**Exclusion criteria**
Age 40 years and older	Primary diagnosis of something other than a rotator cuff tear
Shoulder pain and/or loss of range of motion, strength or function	History (in last 2 years) of shoulder fracture involving the humeral head on affected side
MRI-confirmed partial- or full-thickness supraspinatus and/or infraspinatus tear of 4 centimeters or less in the longitudinal dimension	Contraindication to MRI *(claustrophobia, pacemaker, pregnancy, shoulder implant, etc.)*
Ability and willingness to provide informed consent	Receiving Worker's Compensation

Absence of glenohumeral osteoarthritis on x-rays	Acute rotator cuff tear caused by severe trauma (details in Table 7)
No isolated subscapularis and/or teres minor tear	Grade 4 fatty infiltration (any tendon)
	Surgical candidates on presentation or prior rotator cuff surgery

The primary outcome of this study will be the Shoulder Pain and Disability Index and American Shoulder and Elbow Surgeons (ASES) score at 3, 6, and 12 months with 12 months serving as the end point for statistical analysis.

Sample size projections are based on SPADI change scores at 12 months (see Figure 1). This approach is equivalent to our linear model approach (above) without adjustment for covariates. For reference, preliminary data taken from our ROW non-randomized cohort[85] of patients with degenerative rotator cuff tears receiving either non-operative or operative intervention showed an overall mean $\Delta SPADI_{12}$ of -32.38 (SD=26.40; n=135). Estimates for non-operative and operative therapy were -22.04 (SD=24.58; n=76) and -45.70 (SD=22.54; n=59). A total analyzable sample of 84 participants (42 per treatment group) provides 80% power to detect a mean difference of 0.50 between the two treatment groups, assuming a standard deviation of 1.10, an intraclass correlation coefficient of 0.45, and a two-sided significance level of 0.05, using a mixed-effects model without a treatment-by-center interaction. To account for attrition and ensure at least 42 evaluable participants per group, we will enroll 96 participants, with 48 randomized to each treatment group.

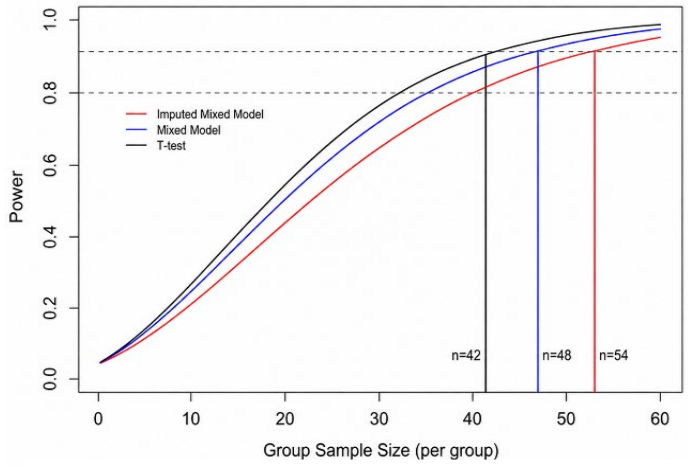


Figure 1: Power curves for pairwise treatment comparisons. Solid black and solid red lines reflect conservative power estimates for a two-sample t-test and mixed model for two-sided type I error of 0.05. Solid black line shows (anti-conservative) effects of not adjusting for multiple comparisons.

Study Procedures

Study procedures for individual visits/interventions and/or interactions

All study-related data are considered standard of care and are routinely collected within Dr. Khazzam's clinical practice.

- Baseline data will be collected following informed consent and after the patient has met all inclusion/exclusion criteria and been enrolled into the study.

- Participants will be randomized in a 1:1 ratio to either (1) a standard, in-person physical therapy program delivered by a physical therapist or (2) a physical therapist-led telehealth home exercise program.
- Randomization will be stratified by site, tear size, and age, with permuted blocks of randomly varying sizes of 4 and 6 used within strata to maintain treatment balance while minimizing predictability of subsequent assignments.
- Patients will be sent questionnaires at 0, 3, 6, and 12 months. The follow-up will be consolidated at TWU. A research assistant will send follow-up questionnaires either electronically or via mail (with a pre-paid return envelope).
    - Baseline
        - Patient Demographics
        - Patient Medical History
        - Previous/Current Treatment for Shoulder
        - Imaging data (tear size, fat, and atrophy) – from clinical MRI
        - Questionnaires (SPADI, ASES, MHI, SF12)
    - 3-Month:
        - Recent/Current Treatment for Shoulder
        - Questionnaires (SPADI, ASES, MHI, SF12)
        - Physical Therapist Report Form
    - 6-Month:
        - Recent/Current Treatment for Shoulder
        - Questionnaires (SPADI, ASES, MHI, SF12)
        - Physical Therapist Report Form
    - 12-month:
        - Recent/Current Treatment for Shoulder
        - Questionnaires (SPADI, ASES, MHI, SF12)

Informed Consent Process
Waiver of Informed Consent

Justification for Waiver of Informed Consent

1. The research involves no more than minimal risk to participants.
2. The waiver will not adversely affect the rights or welfare of participants.
3. The research could not practicably be carried out without the waiver.
4. The data will be handled with strict confidentiality safeguards.

Data Collection Details
The following data points will be collected:
- Anthropometric and Demographic Data (height, weight, BMI, waist circumference, age, sex, ethnicity, race, marital status, and education level)
- Social History (Smoking and drinking status)
- Medical History (Co-morbidities, Medication use (hypertension, hyperlipidemia, etc., supplement use (Calcium & Vitamin D)
- History of Shoulder Injury (Traumatic, non-traumatic, chronic, etc.)

- MRI shoulder characteristics (Baseline MRI is the standard of care for patients with a suspected rotator cuff tear)
- Standard of care shoulder-specific and general health questionnaires (SPADI, ASES, MHI, SF12)
- EMR for any missing data

Data Protection & Confidentiality

All study-related data will be collected and stored in a secured REDCap data collection tool. Only IRB approved BSWH/ BSWRI personnel will be able to access medical records for data extraction and have access to the data collected. All study staff will be trained, IRB approved and will comply with all HIPAA and confidentiality guidelines and laws to maintain confidentiality of patients and their PHI.

Records retention will follow BSWRI policy. All study data will be kept on secure drives after completion of the study for 7 years. After this 7 year period, an assigned study personnel will delete the stored excel files containing participant information.

Investigators on this study are currently at three institutions, TWU, Baylor Scott and White and the University of Michigan. Data will be securely shared with TWU for data analysis through a HIPAA compliant platform approved by Baylor Scott and White Research Institute. A Data Use and Sharing Agreement will be fully executed before data is shared.

Data Analysis

Data will be analyzed in collaboration with statisticians at TWU. The following statistical methods will be used:

Patient accrual, randomization, and dropout will be summarized as per CONSORT guidelines. The distribution of 12-month SPADI will be summarized graphically with histograms, boxplots, and plots of cumulative distribution functions (CDFs). We will not perform comparative statistical tests of the distribution of baseline characteristics by treatment groups since statistically significant differences in these features between groups in a randomized trial are reasonably attributable to chance. Further, balance is not the principal reason to adjust for covariates in a randomized trial but to absorb patient outcome heterogeneity and improve power and precision. Hence, we will have a pre-specified covariate set. A descriptive report of covariates distributions by treatment will be included in the final analysis report. The primary comparison between the two treatment arms will be conducted in the context of the following mixed model,

$$y_{ij} = \beta_0 + \beta_1 I_{\{TRT_i=SPT\}} + \beta_2 t_{ij} + \beta_3 I_{\{TRT_i=SPT\}} t_{ij} + \gamma Z_i + u_i + e_{ij}$$

where Y_{ij} represents the SPADI for participant $i = 1, \dots, n$ at time j= 3, 6, 12 months who was assigned to treatment arm TRT_i ($I_{\{TRT_i=HEP\}} = 1$ if participant i is on the standardized physical therapy arm and 0 standardized home exercise program without a physical therapist; $I_{\{TRT_i=SPT\}} = 1$ if participant i is on the standardized physical therapy arm and 0 if on the home exercise arm, which serves as the reference group). Z_i is a k-dimensional vector of covariates for

participant i (*a priori covariates example*: age, sex, tear size, baseline SPADI, MHI-5, and fatty infiltration). β_0 is the intercept for the home exercise arm, β_2 is change in SPADI score over time (i.e., the treatment effect over time; assumed linear here but it will be modeled flexibly as needed), and γ is the k-dimensional parameter vector of effects associated with covariates that potentially will help identify patients most likely to benefit from treatment (e.g., those with high baseline SPADI). The last 2 terms represent a patient specific random intercept and residual error, respectively. The estimate of interest from this longitudinal model is the predicted differential between baseline and 12-month SPADI, which is typically estimated as a model-based contrast.

Risks & Benefits

The risks to the subject include those inherent in the treatment and risks related to completing questionnaires. The questionnaires pose no risk other than potential breach of confidentiality. To minimize this risk, all data collected will be securely stored in a password-protected REDCap database &/or locked file cabinet. These will only be accessible to authorized study personnel. Paper forms will be labelled with the patient's assigned study ID only.

There are no known physical risks or lasting side effects to participating in physical therapy or prescribed home exercises. Participants may experience mild discomforts, such as temporary soreness or no improvement of symptoms. The physical therapy to be performed will be consistent with standard-of-care treatment the patient would receive regardless of participation in the study.

No direct benefit to study participants is expected as a result of participation in this feasibility study. However, knowledge gained from the REACH trial may help improve the scientific understanding of the treatment rotator cuff tears. This study presents minimal risk, and the risk of a confidentiality breach can be minimized by implementing sound data protection procedures.

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