Academy of Orthopaedic Physical Therapy, APTA, Inc.
Grant Program
Final Report Form

Date: March 15, 2024

Name of Investigators: Chad Cook PhD,PT,MBA,FAAOMPT & Heather Myers, PT, DPT, LAT, ATC

Name of Grant: "Can an intervention aimed at patient education, engagement, and cognitive restructuring improve functional outcomes and well-being for patients with rotator cuff related shoulder pain? A Pragmatic Randomized Clinical Trial"

Award Period: 3/22/2018 to 4/30/2020 (Initial award date – date on contract as start date)

The final report is due no later than 60 days after the end of the award date.

1. Briefly summarize major accomplishments of this project (2-4 pages)

Our study purpose was to test an innovative intervention to alter expectations about physical therapy that is informed by principles of cognitive-behavioral theory: Patient Engagement, Education, and Restructuring of Cognitions (PEERC). The cognitive-behavioral therapy (CBT) treatment techniques that form the core of our PEERC intervention are patient-centered and are designed not only to alter expectations about PT but also decisions to pursue surgical treatment. The primary aim of this randomized clinical trial was to examine the effect of PEERC on the patient report of having had shoulder surgery, or being scheduled for surgery (primary outcome) to address rotator cuff related shoulder pain. Our secondary aims were to evaluate the impact of PEERC on expectations of treatment outcome during the course of PT, satisfaction of outcome of PT, pain and function (secondary outcomes).

Project Overview:
In RTC related shoulder pain, pre-treatment expectations of the success of surgical and/or conservative approaches have demonstrated strong relationships with post-treatment outcomes1-3. Patient expectations are pre-existing thoughts, beliefs, and attitudes regarding the need for specific treatment methods that can influence an individual's treatment outcomes. Only a few rehabilitation-based studies have tested interventions designed to change patient expectations during the clinical care process and none of these studies have examined the effect of such interventions on the patient's decision to undergo surgery. We used a randomized pragmatic "add on" clinical trial to investigate the effect of our PEERC protocol on the decision to have surgery, and improve global well-being, pain catastrophizing, pain, functional outcomes, and follow up expectations. Our proposal is designed to assess the "add-on" value of the PEERC protocol that directly addresses patients' pre-treatment expectations in patients who are simultaneously, receiving an evidence based conservative intervention. This innovative "add-on" design is especially useful for the testing of experimental interventions that have a mechanism of action different from that of the established, effective treatment.

Patients in the PT + PEERC group received an evidence-based phased PT intervention plus a telephone-based intervention (designed by the authors), to challenge and change underlying thoughts, beliefs, and attitudes related to treatment expectations regarding PT care. PEERC, based on cognitive behavioral principles, was delivered by specifically trained physical therapists who conducted six 30-min telephone sessions with participants over a six-week period beginning the week after the initial evaluation. Treatment techniques used in PEERC were drawn from CBT to address issues related to thought distortions and irrational beliefs common in patients who have RCRSP.

Fifty-four (54) individuals, recruited from an outpatient hospital-based orthopedic clinic, were enrolled in the trial (25 randomized to PT, 29 randomized to PT + PEERC). Outcomes assessed at enrollment, 6 weeks, discharge, and six months after discharge included the patient report of having had surgery, or being scheduled for surgery (primary) and satisfaction with PT outcome, pain, and function (secondary outcomes).

At six months, one of the 29 (3.4%) in the PT + PEERC group and three (12%) of the PT only group reported having had surgery, or being scheduled for surgery, which was not different between groups ($p = 0.32$; $w = 0.09$). In our repeated linear mixed methods analyses, there were no significant differences between groups for pain ($p = 0.67$; $\eta 2 = 0.00$), SPADI total score ($p = 0.74$; $\eta 2 = 0.00$), SPADI pain score ($p = 0.32$; $\eta 2 = 0.02$), SPADI disability ($p = 0.97$; $\eta 2 = 0.00$), and the GRoC ($p = 0.96$; $\eta 2 = 0.00$). At six weeks, there were no between-group differences in expectations ($p = 0.97$; $d = 0.02$). At

discharge, there were no between group differences in satisfaction ($p = 0.08$; $d = 0.69$), discharge profile ($p = 0.37$; $w = 0.24$), Tegner score ($p = 0.89$; $d = 0.05$), or total visits ($p = 0.97$; $d = 0.01$). At six months (Table 2), there were no between group differences for SANE ($p = 0.71$; $d = 0.09$) or patient experience ratings ($p = 0.72$; $w = 0.03$).

The authors concluded that a novel six-week cognitive behaviorally-based intervention to alter expectations for PT provided no additional benefit when used as a routine adjunct to conventional PT alone for patients with rotator cuff related shoulder pain. Post-hoc power analyses suggest that a substantially larger sample size than projected, or substantially larger treatment effects than observed, would be necessary to show benefits. Therefore, it is difficult to advocate for PEERC adding value to PT alone in the management of rotator cuff related shoulder pain for individuals matching the characteristics of the patients enrolled in this trial (i.e. with high expectations of physical therapy). Future work in patient populations that are screened for high levels of surgical interest, with higher levels of pain associated distress, and/or poor expectations with physical therapy would be necessary to fully evaluate the potential value of PEERC.

Accomplishments:
Our efforts have led to a series of significant accomplishments. First and foremost, the development and subsequent implementation of the PEERC intervention was a pivotal step forward to work toward changing patients expectations. Additionally, the publication of our pragmatic trial protocol and the subsequent dissemination of results in *BMC Musculoskeletal Disorders* have underscored the rigor and relevance of our research. Furthermore, our findings were showcased through a platform presentations at *Combined Sections Meeting 2024.* Amidst the challenges posed by the Covid-19 pandemic, we demonstrated resilience and adaptability, successfully navigating interruptions in patient care and enrollment, ensuring the continuity and integrity of our research efforts.

Impact and Benefits:
Future work in patient populations that are screened for high levels of surgical interest, with higher levels of pain associated distress, and/or poor expectations with physical therapy may benefit from an intervention modeled after PEERC. Patient expectations are known to influence treatment outcomes for cervical, low back and lower extremity disorders and they commonly drive the decision to have surgeries and are one of many reasons for the increase of surgeries over the last decade. The PEERC approach may provide the appropriate foundations that could be applied to other musculoskeletal disorders. The approach to be tested and strategies used in the PEERC protocol (patient engagement, education, and cognitive restructuring/behavioral activation) may be scalable to a variety of other conditions and settings.

Partnerships and Collaboration:
Collaborating with multidisciplinary groups to develop the PEERC protocol has been integral to the success and effectiveness of our project. By bringing together individuals with diverse expertise and perspectives, notably Frank Keefe in psychology, physical therapists versed in pain management and cognitive behavioral therapy (Chad Cook and Steven George) were able to create a comprehensive protocol to implement as an add-on intervention. This collaborative approach has facilitated integration of best practices from different disciplines. We leveraged the strengths of each team member to develop a protocol that is evidence-based, culturally sensitive, and tailored to the unique requirements of our population but scalable to other diagnoses.

Additionally, this project engaged staff physical therapists at Duke Sports Sciences Institute as well as referring providers who routinely treat patients with rotator cuff related shoulder pain. This fostered continued partnership with respect to both research endeavors and patient care.

Within our institution, we've had support from various entities, the Duke Office of Clinical Research, Duke Clinical Research Institute, Institutional Review Board, and Grant Office, each contributing resources and expertise. The research department has provided essential administrative guidance and oversight, ensuring compliance with regulatory standards.

Lessons Learned:
Similar to many studies performed in the 2020 to 2022 timeframe, enrollment was challenging, especially for studies that involved patients seeking elective surgeries. Because of a lengthy COVID lock-down, and continued inaccessibility to see patients "live", we were unable to enroll the projected sample size estimate ($N = 94$) for our study. The lack of full enrollment suggests that our trial was likely underpowered. Further, our study was an "add on trial" (A versus A + B design), which generally requires a larger number of patients to see differences when analyzed.

Traditional, physical impairment based physical therapy care for RCRSP (which both groups received) involves strengthening and range of motion exercises, as well as a home exercise program. Our trial incorporated best recommended physical therapy treatment practices and accordingly this may be another reason PT alone and PT + PEERC had similar rates for patient report of having had surgery, or being scheduled for surgery and all secondary outcomes. Compared to baseline values for pain, and the SPADI scores associated with pain, disability, and total scores, both groups markedly improved.

Further, nearly every patient enrolled reported very favorable expectations (4.36; SD = 0.68 / 5.0) about their assigned conservative care, lessening the likelihood that the patient expectation modifications were necessary. At baseline, only

three of our 54 enrollees (5.5%) had expectations scores of 3/5 or lower, which we originally projected would be necessary to optimize the PEERC effect. Up to 20% of individuals had received physical therapy before, which may have also influenced expectations. Considered as a whole, the baseline characteristics of our study population suggest there may have been a "mismatch" between the patients we recruited and the goals of PEERC. That is, a majority of the study sample (70%) told us at baseline that they were not interested in having surgery and already had reasonably high expectations of PT care delivered by physical therapists. Simply stated, there is chance that the PEERC intervention is potentially beneficial, but the study was conducted with a population who is not as likely to need or benefit from it.

Although PEERC included six visits, over a six-week timeframe, with phone calls serving as the medium, it was clear that in multiple occasions, patients did not participate in the PEERC health visits at the level that we had hoped. Despite requests to dedicate time to the full session, there were several times in which PEERC calls occurred during inopportune times; 1) while the patient was driving a car, 2) attending or coaching their youth's sporting events, 3) while at work, 4) while cooking dinner, or 5) during other activities in which they multi-tasked the cognitive behavioral strategies of the PEERC with other daily activities. There were multiple occasions where a lack of preparedness from the patient was evidenced in the PEERC homework activities. This may be related to our selection of a phone to interact with the PEERC group. Although the use of phone allows broader accessibility, in situations such as cognitive behavioral based approaches, where non-verbal cues relationship building between patient and provider are known to enhance treatment, video may be a better alternative. We would certainly recommend this moving forward beyond this study along with strategies to oblige better compliance with homework preparedness.

Conclusion:
A novel six-week cognitive behaviorally-based intervention to alter expectations for PT provided no additional benefit when used as a routine adjunct to conventional PT alone for patients with rotator cuff related shoulder pain. Although planned sample size estimates were not met, post-hoc power analyses suggest that a substantially larger sample size than projected, or substantially larger treatment effects than observed, would be necessary to show benefits of PEERC on our primary outcome (patient reports of having had surgery or being scheduled for surgery). Therefore, it is difficult to advocate for PEERC adding value to PT alone in the management of RCRSP for individuals matching the characteristics of the patients enrolled in this trial (i.e. with high expectations of physical therapy). Future work in patient populations that are screened for high levels of surgical interest, with higher levels of pain associated distress, and/or poor expectations with physical therapy would be necessary to fully evaluate the potential value of PEERC.

The study team would like to thank the Academy of Orthopaedic Physical Therapy for funding this project.

2. Provide a one-paragraph summary of results or abstract suitable for posting on the Academy website.

Abstract
Background: Despite similar outcomes for surgery and physical therapy (PT), the number of surgeries to treat rotator cuff related shoulder pain (RCRSP) is increasing. Interventions designed to enhance treatment expectations for PT have been shown to improve patient expectations, but no studies have explored whether such interventions influence patient reports of having had surgery, or being scheduled for surgery. The purpose of this randomized clinical trial was to examine the effect of a cognitive behavioral intervention aimed at changing expectations for PT on patient-report of having had or being scheduled for surgery and on the outcomes of PT.

Methods: The Patient Engagement, Education, and Restructuring of Cognitions (PEERC) intervention, was designed to change expectations regarding PT. PEERC was evaluated in a randomized, pragmatic "add-on" trial in by randomizing patients with RCRSP to receive either PT intervention alone (PT) or PT + PEERC. Fifty-four (54) individuals, recruited from an outpatient hospital-based orthopedic clinic, were enrolled in the trial (25 randomized to PT, 29 randomized to PT + PEERC). Outcomes assessed at enrollment, 6 weeks, discharge, and six months after discharge included the patient report of having had surgery, or being scheduled for surgery (primary) and satisfaction with PT outcome, pain, and function (secondary outcomes).

Results: The average age of the 54 participants was 51.81; SD = 12.54, and 63% were female. Chronicity of shoulder pain averaged 174.61 days; SD = 179.58. Study results showed that at the time of six months follow up, three (12%) of the participants in the PT alone group and one (3.4%) in the PT + PEERC group reported have had surgery or being scheduled for surgery ($p = .32$). There were no significant differences between groups on measures of satisfaction with the outcome of PT ($p = .08$), pain ($p = .58$) or function ($p = .82$).

Conclusions: In patients with RCRSP, PT plus the cognitive behavioral intervention aimed at changing expectations for PT provided no additional benefit compared to PT alone with regard to patient report of having had surgery, or being scheduled to have surgery, patient reported treatment satisfaction with the outcome of PT, or improvements in pain, or function.

Trial registration: The trial is registered on ClinicalTrials.gov: NCT03353272 (27/11/2017).

Keywords: Cognitive behavioral therapy; Expectations; Patient reported outcome measures; Rotator cuff; Shoulder.

3. Attach a list of your publications published or accepted during the past year, or currently being written. Send reprints when available. List presentations made and abstracts accepted for presentation based on this work. Indicate with an asterisk (*) those publications supported by Academy of Orthopaedic Physical Therapy funding.

1. Myers, H., Keefe, F., George, S.Z., Kennedy, J., Lake, AD., Martinez, C., Cook, C. The Influence of a Cognitive Behavioral Approach on Changing Patient Expectations in for Conservative Care in Shoulder Pain Treatment: The PEERC trial. 2023. *BMC Musculoskeletal Disorders*. 24(1):930

2. Myers, H., Keefe, F., George, S.Z., Kennedy, J., Lake, AD., Martinez, C., Cook, C. The Influence of a Cognitive Behavioral Approach on Changing Patient Expectations in for Conservative Care in Shoulder Pain Treatment: a pragmatic randomized controlled trial. *Musculoskeletal Disorders – BMJ.* 2021 Aug 24;22(1):727.

3. *Myers, H., Keefe, F., George, S.Z., Kennedy, J., Lake, AD., Martinez, C., Cook, C. The Influence of a Cognitive Behavioral Approach on Changing Patient Expectations in for Conservative Care in Shoulder Pain Treatment: A Randomized Control Trial. Platform Presentation APTA Combined Sections Meeting 2024.

Budget:

4. Provide a budget, using the original approved budget. Indicate total funds spent to date per major categories. If there was ≥ 25% deviation (greater or less spent) of use of funds for any of the budget category, please BRIEFLY indicate the rationale.

5. Budget: please send out a final print-out from your institution indicating monies spent per major categories.

Your Signature

3/18/2024
Date

Return to:

Tara Fredrickson, Assistant Executive Director
Academy of Orthopaedic Physical Therapy, APTA, Inc.
2920 East Avenue South, Suite 200
La Crosse, WI 54601-7202
tfred@orthopt.org