Effectiveness of an Occupation-Based Intervention Compared with Therapeutic Exercise for Older Adults with Shoulder Osteoarthritis: A Pilot Randomized Controlled Trial

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Statistical Analysis Plan (SAP)

Method

Research Design and Participants

We conducted a single-center, parallel-group RCT in an outpatient clinic. Participants were recruited via convenience sampling from the assisted and independent living facility where the outpatient clinic was located. Inclusion criteria were diagnosis of shoulder osteoarthritis and ages 65 years or older. Diagnosis was confirmed by physician examination or radiographic imaging. Exclusion criteria were previous shoulder injuries, acute pathology, previous shoulder surgery, current use of pain medication, inflammatory arthritis, upper extremity neuropathy or myopathy, current participation in a home exercise program, or a score of <18 on the Mini-Mental State Examination (MMSE).

This study was approved by the Bay Path University Institutional Review Board. All participants gave written informed consent to participate. Eighteen older adults were recruited for the study, four did not meet the MMSE criteria, and two did not have a confirmed diagnosis of shoulder osteoarthritis. Two participants withdrew from the study prior to randomization. Computer-based randomization was used to allocate the remaining ten participants into two groups: the Ten participants ($N = 10$) were randomly allocated to the OBI + TE (n = 5) or the TE (n = 5) group.

Outcomes Measures

The Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) (Beaton, Wright, Katz, Upper Extremity Collaborative Group, 2005) questionnaire was the primary outcome measure and was used to assess the impact of the intervention on physical function and symptoms of shoulder osteoarthritis. Scores range from 0 to 100. A lower score indicates less disability. The Canadian Occupational Performance Measure (COPM) was used to determine the

effect of the intervention on participants' self-perception of occupational performance and satisfaction over time (Law et al., 1990). Shoulder range of motion (ROM) was measured using a functional test established by Burner et al. (2014). Active abduction, flexion, external rotation, and internal rotation of the shoulder were assessed with participants seated on the edge of a mat with no back support and hips and knees at 90 degrees using a 3-point scale for ROM and pain (Burner et al., 2014). A Jamar hand dynamometer was used to measure the grip strength of the participants (che Daud et al., 2016). Pain was measured using the Numeric Pain Rating Scale (NPRS) (Hawker, Mian, Kendzerska, & French, 2011).

Procedure

Participants were randomly allocated using a computer-generated random number table. Outcome measures were administered prior to the intervention, a week after the conclusion of the intervention, and four weeks after the intervention ended. Protocols for occupation-based intervention for the treatment of upper extremity musculoskeletal disorders vary widely. According to a systematic review by Weinstock-Zlotnick & Mehta (2019), occupation-based interventions ranged from 2 to 10 weeks in duration, 1 to 5 sessions per week, with individual sessions lasting at least 30 minutes to a maximum of 3 hours. For this study, both groups were seen for 60-minute sessions, two times per week, for six weeks. The sessions for the OBI + TE group consisted of 30 minutes of TE followed by 30 minutes of OBI. The TE group sessions consisted of 60 minutes of TE. All participants received ten minutes of moist heat on the affected shoulder as a preparatory activity before the session started.

Control group. The TE protocol was completed systematically. Passive range of motion (PROM), active-assistive range of motion (AAROM), active range of motion (AROM), and

strengthening activities were completed sequentially. Participants were advised to respect and avoid pain with all exercises.

Intervention group. COPM results were used to select client-centered occupations, collecting and placing items in cabinets, washing windows and tables, and hanging clothes on a clothesline, for the OBI intervention. To make the activities more meaningful and relevant, interventions were completed within a simulated home environment. Participants were encouraged to use the affected upper extremity as much as possible, but to respect pain. The same TE protocol as the control group was completed prior to OBI, but with fewer repetitions, as a preparatory activity for the OBI.

Data Analysis

Data was collected and stored in a secure and locked file cabinet to protect the confidentiality of the participants. Statistical analyses were conducted using IBM SPSS Statistics (Version 23.0; IBM Corp., Armonk, NY). Descriptive statistics for all continuous variables included mean, standard deviation, and range. Descriptive statistics for categorical variables included frequencies and percentages. Paired sample t-tests were completed for each group for both the one week and four week follow up assessments to determine the effectiveness of the treatment protocol over time. Three sets of paired t-tests were used to compare the groups to each other at baseline, one week posttreatment, and four weeks posttreatment. The statistical significance level was set at $p < 0.05$ (two-tailed).

Informed Consent Form (ICF)

Title of the Project: Shoulder Osteoarthritis in the Older Adult: An Occupation-Based Treatment Approach
Principal Investigator: Kelli Cabrera
University Department: Occupational Therapy
Faculty Advisor: Rae Ann Smith, OTD, OTR/L, Bay Path University

Invitation to be Part of a Research Study

You are invited to participate in a research study. In order to participate, you must have a diagnosis of shoulder osteoarthritis, be sixty-five years of age or older, and have the ability to understand and respond in English. Taking part in this research project is voluntary.

Important Information about the Research Study

Things you should know:

- The purpose of this study is to determine if a specific set of treatment exercises can significantly improve the functional abilities of older adults with shoulder osteoarthritis. If you choose to participate, you will be asked to attend a sixty-minute therapy session two times per week, for a total of six weeks. There will be an evaluation the week before the treatment sessions start and another evaluation the week after the treatment sessions end. Additionally, there will be a final evaluation that occurs four weeks after the conclusion of the therapy sessions. The exercise sessions will take place in the Harbor Chase of Mandarin therapy gym located on the 3rd floor and the researcher will explain each exercise to you. The entire study will take approximately 11 weeks.
- Risks or discomforts from this research include pain, injury, or aggravation of previously existing conditions. Any exercise has risks associated with it and it is not always possible to accurately predict your response to a certain exercise. To decrease the chance of these risks occurring, you will be asked to respect pain and avoid excessive pain with all exercises and activities.
- The study has the ability to improve your shoulder pain and limited mobility, which can improve your overall function and independence.
- Taking part in this research project is voluntary. You don't have to participate and you can stop at any time.

Please take the time to read this entire form and ask questions before deciding whether to take part in this research project.

What is the study about and why are we doing it?

The purpose of the study is to determine if a standardized treatment approach consisting of traditional, therapeutic exercise and occupation-based intervention can produce significant functional improvement in older adults with shoulder osteoarthritis. Occupation-based intervention is the use of meaningful, purposeful activities as a treatment method to restore an individual's physical functioning and participation in daily occupations. At this time, there is no scientific evidence to support the use therapeutic exercise and occupation-based intervention in the treatment of shoulder osteoarthritis. This researcher is hoping to determine an effective protocol to share with therapists worldwide to ensure appropriate treatment of this disorder.

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to participate in a sixty-minute occupational therapy treatment session, twice a week, for six weeks. During these treatment sessions, you will complete a variety of exercises and activities to increase your shoulder mobility and decrease your pain. Evaluations will occur the week before the treatment sessions begin and the week after the treatment sessions end. The final evaluation will occur in week ten, or four weeks after the conclusion of the treatment sessions. The program will take place at HarborChase of Mandarin in the PT/OT clinic located on the third floor.

How could you benefit from this study?

You might benefit from being in this study because you may experience a decrease in shoulder pain, an increase in shoulder mobility, and an overall improvement in your ability to complete daily tasks.

What risks might result from being in this study?

There are some risks you might experience from being in this study including pain, injury, or aggravation of previously existing conditions. To mitigate these risks, we ask that you respect pain and avoid excessive pain with all exercises and activities.

How will we protect your information?

We will protect the confidentiality of your research records by storing them in a secure and locked file cabinet. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.**

We plan to present and publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for future research. Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

We may share your research data with other investigators without asking for your consent again, however it will not contain information that could directly identify you. Your research records will be stored in a secure and locked file cabinet only accessible to the researcher.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, your data may still be used in the research study. It will be protected and stored as described above. Your participation may be terminated without consent if you develop an acute shoulder injury or demonstrate a change in mental status.

Contact Information for the Study Team and Questions about the Research

If you have questions about this research, you may contact **Kelli Cabrera, klaramee@baypath.edu, 413-561-6105 or Rae Ann Smith, raesmith@baypath.edu.**

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

Bay Path University
Office of Academic Affairs
588 Longmeadow Street
Longmeadow, MA 01106
Phone: (413) 565-1000

Your Consent

By signing this document, you are agreeing to be in this study. By signing this document, you are also confirming you are 18 years of age or older. Make sure you understand what the study is about before you sign. I will give you a copy of this document for your records. I will keep a copy with the study records. If you have any

questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____

Printed Subject Name

_____

Signature Date