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Research Article

Physiotherapy Program for Managing Adhesive Capsulitis in Patients with Diabetes: A Protocol for a Pilot Randomized Trial

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ABSTRACT

Background: Adhesive capsulitis (AC) occurs five times more often in people with diabetes and leads to prolonged disability. Exercises and joint mobilization are usually used to manage AC. However, the recovery is slow and often incomplete. Aerobic exercises improve hyperglycemia and insulin sensitivity. Currently, no research has formally assessed the benefits of incorporating an aerobic training program into the treatment plan of AC in patients with diabetes. This single blind pilot randomized trial will compare the preliminary effect of a regular physiotherapy program (PT), to a regular PT program combined with a progressive walking program (PT+) in patients with and without diabetes who have AC.

Methods: Patients (n= 40) will be recruited from St. Joseph's HealthCare Centre and associated primary care practices. Patients will be randomly assigned into either the regular PT program or regular PT combined with a progressive walking program. Patients will be referred to physical therapy facilities and the intervention will be chosen by the treating physical therapist. In the PT+ group, patients will be asked to perform free walking at their own pace for 30-45 minutes, five days per week, for six consecutive weeks. The primary outcome will be testing the functional performance of the shoulder using the Functional Impairment Test- Hand and Neck/ Shoulder/Arm (FIT-HaNSA) test. Secondary outcomes will include shoulder pain and function using the Shoulder Pain and Disability Index (SPADI) questionnaire; shoulder range of motion in flexion, abduction, and external rotation; muscles strength of shoulder flexors and abductors; and physical activity level using an accelerometer and the Rapid Assessment of Physical Activity (RAPA) questionnaire. The primary outcome will be evaluated at baseline and after six weeks. Secondary outcomes will be evaluated at baseline, and after three, six and 12 weeks from enrolment.

Discussion: The novel approach taken in this pilot trial will establish the preliminary effect of a regular PT program combined with a progressive walking program and will evaluate a study design prior to the performance of a full-scale research project that may lead to better outcomes for managing adhesive capsulitis in people with diabetes.

Background

Adhesive capsulitis (AC), also known as 'frozen shoulder', is characterized by the development of dense adhesions and capsular thickening leading to a progressive and painful restriction of shoulder ROM and functional disability [1]. The onset is gradual and usually occurs between the ages of 40 and 60 years [2]. Further, it is more common in people with diabetes and is more frequent in women [3]. The condition was first described by Codman (1934) who coined the term 'frozen shoulder' and defined its common criteria including slow onset of pain, inability to sleep on the affected side, painful and restricted shoulder abduction and external rotation motions, and a normal

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radiological appearance [4, 5]. A few years later, Neviaser (1945) found thickening and contracture of the joint capsule and described peeling the capsule from the humeral head, as peeling adhesive plaster from skin, generating the term adhesive capsulitis [4, 5].

Adhesive capsulitis has been described as a self-limiting condition that progresses through pain, frozen and thawing phases. However, Wong et al. examined the quality of the evidence that describes the theory of AC phases and reported a lack of evidence to support these theoretical phases of AC [6]. Based on the Codman criteria, the condition can be classified as primary or secondary AC. Primary or idiopathic AC has no clear underlying cause [4]. However, a recent systematic review investigated the pathophysiology of idiopathic AC and reported fibrotic changes in the anterior shoulder joint capsule, leading to capsular contracture and movement limitations especially in arm external rotation motions [7]. Secondary AC might develop following soft tissue injury, joint arthritis, or secondary to known systemic disease such as diabetes [5]. The association between diabetes and AC was first recognized by Bridgman (1972) who found that 10.8% of diabetic patients had AC as compared to 2.3% for nondiabetic patients [8]. Subsequent studies have supported this association and reported a prevalence of 10-76% in type 1 and 7-30% in type 2 diabetes as compared to 0-10% in the general population [9-12]. Adhesive capsulitis was also reported to be associated with age in both types of diabetes and with the duration in type 1 diabetes [9-11, 13]. The pathophysiology that predisposes diabetics for the development of AC is not well understood. However, the condition might potentially occur because of the increased glycosylation of collagen fibers of the joint capsule and secondary to the impaired circulation which is known as diabetic microangiopathy [1, 14, 15].

The usual approach for managing AC includes steroids injections, joint mobilization techniques and the implementation of shoulder exercises to restore function. Active exercises and joint mobilization have been reported by several systematic reviews to reduce pain, restore shoulder ROM and function in both short- and long-term follow up, while moderate quality evidence showed short-term effect of steroid injection in reducing pain during the early stage of AC [16-20]. Only one recent systematic review has assessed the effectiveness of nonsurgical intervention for managing AC in patients with diabetes and reported that low quality evidence suggests large effects of joint mobilization plus exercises on adhesive capsulitis in diabetic patients with a weaker support for the use of steroid injection and manipulation under anesthesia [21]. Although some of the non-surgical interventions have been shown to be effective in managing AC, recovery is slow and often incomplete, especially for people with diabetes [22]. Patients with diabetes often develop long-lasting shoulder stiffness, higher shoulder pain, functional disability and reduced ROM than patients without diabetes [10, 11, 23, 24]. Furthermore, higher shoulder pain and disability were associated with poor glycemic control and diabetic complications [25].

Aerobic exercises can improve hyperglycemia and insulin sensitivity in skeletal musculature and induce a favorable effect on blood vessels that can reduce diabetes related complications such as hypertension, hyperlipidemia, and obesity [26]. These effects may have a greater impact on the AC pathophysiology. However, none of the previous research has formally assessed the benefits of incorporating an aerobic training program into the treatment plan of AC in patients with diabetes. Up to this date, there has been no optimal physical therapy protocol for managing AC in patients with diabetes. The purpose of this pilot randomized trial is to compare the effect of a regular physiotherapy (PT) program to a regular PT combined with a progressive walking program (PT+) in patients with and without diabetes who have AC. This pilot trial will also evaluate the feasibility of recruitment, randomization, retention, assessment procedures, and implementation of the novel intervention. Data from this pilot trial will be used to calculate an accurate sample size for a full-scale RCT. The secondary objective is to determine if diabetes affects response to treatment.

Methods and Materials

I Study Design and Setting

This single-blinded parallel pilot randomized clinical trial (RCT) will be conducted at the Roth McFarlane Hand and Upper Limb Center (HULC) at St. Joseph's Health Care in London, Ontario. The Western University Research Ethics Board has approved the study (Project ID: 111647). The trial is registered on ClinicalTrials.gov (ID number: NCT03462420).

II Participants

A general rule of thumb is to include 30 patients or greater to estimate a parameter in a pilot study [27]. Therefore, we decided to recruit 40 patients with and without diabetes, both men and women, who have been diagnosed with AC from orthopedic clinics at St. Joseph's Health Care Centre via surgeon referrals and from local primary health care clinics via posters advertising the study. A diagnosis of AC will be confirmed by the consultant shoulder surgeon (KF), who is blinded to treatment allocation, based on the following diagnostic criteria: shoulder pain for at least one month; inability to sleep on the affected side; and restriction of active and passive ROM in one or more planes [28]. The criteria for inclusion in the study will include: (1) a confirmed diagnosis of AC; (2) patients aged 18 years or more; and (3) ability to participate in the study. Patients with previous shoulder surgery, significant shoulder injury within six-months, history of shoulder dislocation or arthritis, and patients with suspected rotator cuff tear will be excluded from this study.

III Outcome Measures

i Primary Outcome Measure

The primary outcome will be testing the functional performance of the shoulder based on repeated shoulder movement using the Functional Impairment Test - Hand and Neck/ Shoulder/Arm (FIT-HaNSA) tests. The FIT-HaNSA test measures the functional performance of the upper limb, while performing multi-level tasks. In the first task (waist-up), the patient lifts three one-kg containers one at a time, with the affected arm, between a shelf at waist level and a shelf 25 cm higher at speed of 60 beats per minute for five minutes or until patient is unable to continue. In the second task (eye-down), the patient returns the three containers back to the waist level shelf. In the third task (overhead work), using both arms, the patient repeatedly screws and unscrews bolts to simulate overhead work for five minutes or until patient feels unable to continue. The time of each task will be determined using a stopwatch and the

rhythmic speed will be controlled using a sound brenner (metronome). All tasks will be performed from a standing position. This test has been shown to be valid and reliable [29].

ii Secondary Outcome Measures

Secondary outcomes will include shoulder range of motion (ROM) in flexion, abduction, and external rotation using a standard goniometer; shoulder pain and function using Shoulder Pain and Disability Index (SPADI) questionnaire; muscle strength of shoulder flexors and abductors using a dynamometer; and physical activity level using an accelerometer (Fitbit) and the Rapid Assessment of Physical Activity (RAPA) questionnaire. Secondary outcome measures will be collected by a single physiotherapist at baseline, and at three, six, and 12 weeks.

a Shoulder ROM

Shoulder ROM will be measured using a standard goniometer because it is readily available in most clinical physical therapy departments and is the most common valid and reliable tool used for measuring joint motion [30]. Active flexion and abduction ROM will be assessed by measuring the angle formed by the arm and thorax from sitting position. The axis of the goniometer will be located at the acromion process; the movable bar will be parallel to the humerus while keeping the stationary bar parallel to the trunk [31]. Active external rotation will be assessed in sitting position with the arm adducted and the elbow at the side and flexed to 90 degrees. The axis of the goniometer will be located at the olecranon process of the elbow and both the stationary and movable bars will be parallel to the forearm [32].

b Shoulder Pain and Function

Shoulder pain and function will be assessed using SPADI questionnaire [33]. This self-report questionnaire consists of two subscales: pain (five items) and function (eight items). The pain subscale is rated on scale from zero (no pain) to 10 (worst pain ever). The patient is asked to circle the number that best describes their pain and/or disability. The subscale scores are calculated by adding the item scores for that subscale and dividing this number by the maximum score possible for the items that are deemed applicable by the subject. This number is then multiplied by 100. The two subscales are then added and the total out of 130 is then multiplied by 100. Higher scores indicate greater impairment or disability [33, 34]. The SPADI has been shown to be a valid and reliable measure of shoulder pain and disability [35]. A SPADI score can detect change over time, it accurately discriminates between patients who have improves or worsened and has been used in patients with AC [34, 36, 37].

c Muscle Strength

Isometric muscle strength will be assessed for shoulder flexors and abductors using the JTech Power Track handheld dynamometer (JTech; JTech Medical, Salt Lake City, UT, USA), with known concurrent validity and reliability (ICCs 0.89-0.98) [38, 39]. Patients will be seated on a straight back chair to stabilize the trunk. Abductor strength will be measured by placing the device on the lateral aspect of mid-humerus and flexor strength will be measured by placing the device on the anterior aspect of the upper arm.

d Assessment of Physical Activity Level

Physical activity level will be measured objectively using an accelerometer (Fitbit Zip) and subjectively use a self-reported questionnaire (RAPA). Physical activity level will be objectively measured using the Fitbit Zip (Fitbit Inc, USA). This activity tracker contains a three-dimensional accelerometer and is designed to track steps, distance and calories burned. Fitbit Zip is small and discreet and can be worn in a pocket, on a belt or on a bra. Data from the Fitbit Zip syncs automatically to a computer or smartphone using a free online application software. Participants will be asked to wear the device during all waking hours and to sync their devices on a daily basis for six consecutive weeks. Step count and distance data will be obtained from the Fitbit Zip and summarised into an activity tracking sheet. This device has been validated and found to be comparable to other accelerometers [40, 41]. Physical activities were subjectively assessed using RAPA which consists of nine self-reported questions that assess physical activity levels with a response option of yes or no. The first seven questions assess weekly aerobic activity ranging from sedentary to vigorous levels with a total score of 1-7 points, where 1 = rarely do any physical activity, and 7 = 20 minutes of vigorous activities 3+ days/week. A respondent's physical activity score is categorized into one of five levels of physical activity: sedentary, underactive, regular underactive (light activities), regular underactive, and regular active. The other two questions assess strength and flexibility training with a total score of three points; one point for strength training and two points for flexibility training. A full description of RAPA is published [42]. The RAPA questionnaire has been validated to be used in clinical practice with older adults [42].

IV Procedures

Eligible patients will be given a letter of information and will be asked to sign a consent form. After signing the consent form, participants will attend an orientation session and will be provided with information about the study and the experimental design. Participant's weight, height, age, gender, type and treatment of diabetes, affected shoulder side (right or left; dominant or non-dominant), and the duration of AC symptoms will be collected during this session. Participants will be then be asked to complete two outcome questionnaires (SPADI and RAPA) and a Katz comorbidity scale [43]. Next, patients will undergo blinded randomization into one of the two groups: regular PT program or regular PT with a progressive walking program (PT+). The randomization will be stratified by intervention (walking program) and diabetes status using sequentially numbered, opaque, and sealed envelopes.

All participants will be then referred to physical therapy facilities according to their preferences and the intervention will be chosen by the treating physical therapist. In the PT+ group, participants will be asked to perform free walking at their own pace for 30-45 min, 5 days per week for 6 consecutive weeks. They will record their walking date/time on a diary form provided by the research team. Participants in the PT+ group are not restricted from walking more than 45 minutes a day, as long as they do not feel tired or uncomfortable. Participants in both groups will

be provided with a Fitbit Zip accelerometer to accurately estimate their physical activity level. The primary outcome measures will be evaluated by a single research team member at baseline and after six weeks. Secondary outcomes will be evaluated at baseline, at three and six weeks, and again at 12 weeks after enrolment (Figure 1).

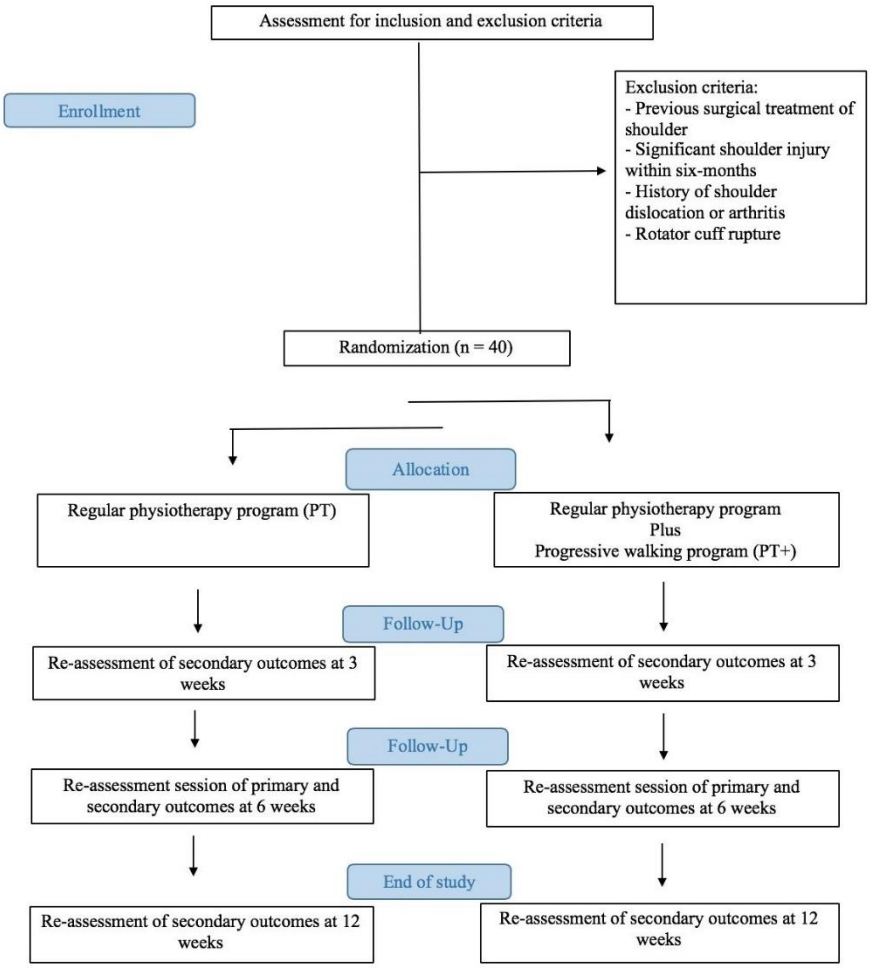

Figure 1: Flow diagram of the study.

V Statistical Analysis

Statistical analysis will be performed using SPSS, version 21 (SPSS Inc., Chicago, IL, USA). The analysis of this pilot study will be mainly descriptive. Estimate of means, standard deviations, and confidence interval for continuous outcomes measures, and an estimate of the proportion for categorical outcome measures will be calculated.

Discussion

Adhesive capsulitis is the most common shoulder disorder. The diagnosis is poorly understood and difficult to manage. The novel approach taken in this pilot trial will establish the preliminary effect of a regular physiotherapy program combined with progressive walking program and will evaluate a study design prior to performance of a full-scale research project that may lead to better outcomes for managing adhesive capsulitis in people with diabetes. The results of this pilot trial may provide a preliminary effect size for the proposed treatment which will inform adhesive capsulitis practice guidelines. The researchers will present the data of this trial at relevant conferences and publish the manuscript in a scientific journal.

Conflicts of Interest

None.

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