



COMPARATIVE EFFECTS OF PROGRESSIVE RESISTANCE TRAINING VERSUS AEROBIC TRAINING AS ADJUNCTS TO CONVENTIONAL PHYSIOTHERAPY IN PATIENTS WITH DIABETIC ADHESIVE CAPSULITIS: A PILOT RANDOMIZED CONTROLLED TRIAL

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DOI: <https://doi.org/10.59551/IJHMP/25832069/2026.7.3/4.105>

How to cite this article: Parashar K, Baghela V, Nagar SB. Comparative Effects of Progressive Resistance Training Versus Aerobic Training as Adjuncts to Conventional Physiotherapy in Patients with Diabetic Adhesive Capsulitis: A Pilot Randomized Controlled Trial. *Indian J. Health Care, Med. Pharm. Pract.* 2026;7(3-4):38-49.

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Received: 06 Sept, 2026, Decision for Acceptance: 15 Oct, 2026

ABSTRACT

Background: Adhesive capsulitis (AC) is a painful, progressively stiffening shoulder disorder that is more common in people with diabetes. Conventional physiotherapy emphasizes pain relief and mobilization, and both progressive resistance training (PRT) and moderate-intensity aerobic training are plausible adjuncts, but they have not been compared directly. This pilot randomized controlled trial (RCT) compared PRT with aerobic training, each added to conventional physiotherapy, for shoulder pain and disability in diabetic AC.

Methods: In this two-arm, parallel-group pilot RCT, 30 adults with type 2 diabetes and AC were randomized 1:1 to conventional physiotherapy plus PRT (Group A, n=15) or conventional physiotherapy plus moderate-intensity aerobic training (Group B, n=15). Both groups attended three supervised sessions per week for six weeks (18 sessions). The only outcome scale was the Shoulder Pain and Disability Index (SPADI) total score (0–100; higher = worse), assessed at baseline, week 3 and week 6. The primary endpoint was the between-group difference in SPADI change from baseline to week 6. Analyses followed the intention-to-treat principle and used Welch's t-test, baseline-adjusted ANCOVA, mixed-design ANOVA with Greenhouse–Geisser correction, and Hedges' g; all efficacy analyses were exploratory.

Results: All 30 participants had complete SPADI data (retention 100%; 95% CI 88.7–100). Groups were similar at baseline (SPADI 65.1 ± 7.0 vs 65.0 ± 8.7). SPADI fell by 36.4 ± 10.2 points in Group A and 25.9 ± 9.5 points in Group B, a between-group difference in change of 10.5 points (95% CI 3.1 to 17.9; $p=.007$; $g=1.04$). After baseline adjustment, the week-6 difference was -10.4 points (95% CI -15.4 to -5.5 ; $p<.001$) and the week-3 difference was -4.4 points (95% CI -7.6 to -1.2 ; $p=.009$). The Group $\times$ Time interaction was significant ($F(1.72, 48.08)=5.94$, $p=.007$, $\eta^2=0.175$). Every participant in both groups improved by at least 8 points; 15/15 versus 14/15 improved by at least 13 points, and 9/15 versus 2/15 achieved a reduction of 50% or more (exploratory). Estimates were stable across sensitivity analyses.

Conclusion: In this pilot data set, adding PRT to conventional physiotherapy was associated with greater SPADI improvement than adding aerobic training. The point estimate lies within the published minimal clinically important difference range (8–13 points), but the confidence interval is wide, follow-up ended at week 6, and the trial was not powered for efficacy. An adequately powered, multicentre RCT with longer follow-up is warranted.

KEYWORDS: Adhesive Capsulitis, Frozen Shoulder, Type 2 Diabetes Mellitus, Progressive Resistance Training, Aerobic Exercise, Shoulder Pain and Disability Index, Pilot Randomized Controlled Trial.

Introduction

Adhesive capsulitis (AC), or frozen shoulder, is characterized by pain and a gradual, global loss of active and passive glenohumeral motion, with external rotation usually the most restricted movement[1]. Diabetes mellitus is one of its strongest recognized associations. A meta-analysis estimated that AC affects about 13% of people with diabetes, who are roughly five times more likely than controls to have the condition[2], and a later systematic review reported pooled odds of 3.69 for developing frozen shoulder in diabetes[3]. Hospital-based data also link both obesity and diabetes with AC[3], prevalence in type 2 diabetes has been reported at over one in five in a cross-sectional study[4], and musculoskeletal complications of diabetes reduce quality of life (Al-Homood, 2013).

Clinical practice guidelines for AC emphasize patient education, stretching and mobilisation[1]. A systematic review and network meta-analysis found that intra-articular corticosteroid gave the best short-term benefit, with home exercise and physiotherapy adding benefit in the mid term[5], and randomized trials have examined mobilization grades[6] and supervised exercise formats[7]. Conventional programmes therefore concentrate on capsular mobility and pain modulation, with relatively little attention to the strength and dynamic control of the rotator cuff and scapular muscles, or to the systemic metabolic state of the patient.

Two adjuncts are plausible for people with diabetic AC. Progressive resistance training (PRT) loads the shoulder muscles directly and is an established component of exercise guidance in type 2 diabetes[8]; a recent pilot RCT reported that an eight-week resistance-band programme improved range of motion, pain and disability in adults with diabetes and AC[9]. Moderate-intensity aerobic activity, in contrast, is a cornerstone of diabetes management for glycaemic and cardiovascular health, and a randomized trial in diabetic AC found that adding moderate physical activity to conventional physiotherapy improved pain, range of motion and disability compared with conventional physiotherapy alone[10]. PRT acts locally on the shoulder, whereas aerobic exercise acts on the whole body, so the two could differ in how much they reduce shoulder pain and disability. To our knowledge, a direct comparison of the two adjuncts in diabetic AC has not been reported.

Pilot studies are intended to test trial procedures and generate estimates to plan a definitive trial, and they should not be judged on their power to detect treatment effects[11,12,13]. The aim of this pilot RCT was to compare the effects of PRT and moderate-intensity aerobic training, each added to conventional

physiotherapy, on shoulder pain and disability in patients with diabetic AC. The objectives were (i) to assess the change in total SPADI score in Group A (PRT) after six weeks; (ii) to assess the change in total SPADI score in Group B (aerobic training) after six weeks; and (iii) to compare the change in total SPADI score between the groups at six weeks. The null hypothesis (H0) was that the mean change in SPADI total score from baseline to week 6 does not differ between groups; the alternative hypothesis (H1) was that it does.

Materials and Methods

Study Design

This was a two-arm, parallel-group pilot randomized controlled trial conducted in a physiotherapy outpatient department. Reporting follows the CONSORT 2010 extension for randomized pilot and feasibility trials. Participants were allocated 1:1 to Group A (conventional physiotherapy plus PRT) or Group B (conventional physiotherapy plus moderate-intensity aerobic training). Both groups attended three supervised sessions per week for six weeks (18 planned sessions). The Shoulder Pain and Disability Index (SPADI) was the only outcome scale and was assessed at baseline, week 3 and week 6; no follow-up beyond week 6 was planned.

Participants and Eligibility

Consecutive patients attending the department were screened. Inclusion criteria were: adults aged approximately 40–70 years; type 2 diabetes mellitus; a clinical diagnosis of AC with shoulder pain and restricted active and passive movement; symptoms present for at least three months; medical stability and ability to take part in supervised exercise; and willingness to give written informed consent. Exclusion criteria were: suspected acute rotator cuff tear, fracture or other major shoulder pathology; previous shoulder surgery or recent shoulder trauma; recent shoulder injection or another treatment likely to confound results within the protocol's predefined exclusion window; unstable cardiovascular disease or another contraindication to exercise; uncontrolled medical problems that made participation unsafe; and inability to complete the SPADI reliably. Age, sex, affected shoulder, symptom duration and diabetes duration were recorded as baseline descriptors.

Sample Size

As this was a pilot study, no formal power calculation was performed. A total of 30 participants (15 per group) was set as a feasibility target that allows estimation of variability and preliminary effect sizes to inform a definitive trial, consistent with published guidance on pilot sample sizes.

Randomization, Allocation Concealment and Blinding

A computer-generated random sequence allocated participants 1:1. Allocation was concealed in sequentially numbered, opaque, sealed envelopes prepared by a person independent of recruitment. Where feasible, a separate assessor administered and scored the SPADI without knowledge of group allocation. Participants and treating physiotherapists could not be blinded to the type of exercise.

Interventions

Both groups received the same conventional physiotherapy, applied with the same therapist training, treatment order, session frequency and progression rules, followed by approximately 20 minutes of additional exercise that differed by group (Table 1). Strengthening was deliberately excluded from the common programme to avoid overlap with Group A.

Participants in both groups followed the standardized home mobility programme prescribed in the common treatment. Participants in Group B were monitored for unusual breathlessness, chest discomfort, dizziness or symptoms of low

blood glucose, and followed their own diabetes-management plan for glucose monitoring, medication, food intake and exercise precautions where indicated. Because the added exercise was matched for time (about 20 minutes) but not for specificity, the comparison contrasts shoulder-focused loading with whole-body aerobic activity; this contrast is intrinsic to the research question.

Outcome Measure

The SPADI is a 13-item patient-reported questionnaire with a five-item pain domain and an eight-item disability domain (14). The total score ranges from 0 to 100, with higher scores indicating greater shoulder pain and disability; a reduction indicates improvement. It was administered in Hindi and English under similar conditions at baseline (before the first session), at the end of week 3 and at the end of week 6, and scored according to the official instructions. The principal comparison was the difference between groups in the change in SPADI total from baseline to week 6. The only feasibility outcome that could be derived from the master chart was retention; session attendance, adverse events and acceptability are reported as pending entries.

Table 1: Intervention protocols (both groups attended three supervised sessions per week for six weeks)

Element	Common conventional physiotherapy (both groups; 20–25 min)	Group A: progressive resistance training (additional 20 min)	Group B: aerobic training (additional 20 min)
Preparation	Check for unusual shoulder pain, dizziness or hypoglycaemic symptoms; explain pain-limited movement	Check exercise tolerance; teach band technique and pain-limited movement	Check exercise tolerance and diabetes-related precautions; footwear and safe access to walking area or cycle
Main content	Warm-up 3–5 min; pendulum 2 × 10; assisted ROM (flexion, external rotation) 2 × 10; gentle capsular stretching 3 × 20–30 s; standardized home advice	Band external rotation, band internal rotation and scapular retraction, each 2 × 10; light-resistance shoulder flexion within tolerated range 1–2 × 8–10; rest 45–60 s between sets	Warm-up 3 min; 14 min walking or stationary cycling; cool-down 3 min; same modality for each participant where feasible
Intensity	Within pain tolerance	Lightest practical resistance allowing controlled movement without trunk compensation or significant symptom aggravation	Moderate: about 3–4/10 on the Borg CR10 scale, or equivalent talk-test intensity
Progression	Same rules in both groups	Weeks 1–2: technique, light resistance. Weeks 3–4: slightly more repetitions or band resistance if technique good and no flare. Weeks 5–6: gradual resistance progression. One variable changed at a time; no forcing of end-range; reduce load if pain persists	Weeks 1–2: comfortable, safe pace. Weeks 3–4: slightly more pace or resistance if tolerated. Weeks 5–6: maintain or progress gradually. No vigorous exercise or sudden workload increases
Records	Attendance, missed sessions, adverse events	Band used, exercises, repetitions, symptoms	Duration, modality, perceived effort, symptoms

CPT, conventional physiotherapy; ROM, range of motion. The Borg rating guided treatment intensity and was not a research outcome.

Ethical Considerations

The protocol was approved by Department of Rehabilitation Sciences, Janardan Rai Nagar Rajasthan Vidyapeeth, Udaipur. All participants provided written informed consent, and the study was conducted in accordance with the Declaration of Helsinki.

Data Source

The analyses reported here were run on the study master chart, which contains participant-level data prepared for planning and training. The analysis was scripted end-to-end so that every table and figure can be regenerated unchanged when prospectively collected data replace the master chart.

Statistical Analysis

Continuous variables are presented as mean $\pm$ standard deviation (SD) with t-based 95% confidence intervals (CIs); proportions are presented with Wilson score intervals (Newcombe, 1998). Baseline comparability is shown descriptively using independent t-tests and Fisher's exact tests, and these p-values were not used to guide the analysis. Analyses followed the intention-to-treat principle with all randomized participants analysed in their allocated group; no SPADI values were missing.

Change was defined as baseline minus follow-up score, so positive values indicate improvement. The primary endpoint, the between-group difference in change from baseline to week 6, was estimated with Welch's t-test (Group A minus Group B) and expressed as a mean difference with 95% CI and as Hedges' g, using the pooled SD of change with small-sample correction (Hedges, 1981). Baseline-adjusted differences at week 3 and week 6 were estimated with analysis of covariance (ANCOVA) with group as a fixed factor and the baseline SPADI as covariate (Vickers & Altman, 2001); the standardized effect was the adjusted difference divided by the pooled baseline SD with Hedges' correction (Morris, 2008), interpreted against Cohen's benchmarks of 0.2, 0.5 and 0.8 (Cohen, 1988). Homogeneity of regression slopes and normality of residuals (Shapiro–Wilk test) were checked. Time and Group $\times$ Time effects were examined with a two-way mixed-design ANOVA (Group: A, B; Time: baseline, week 3, week 6) using Greenhouse–Geisser-corrected

degrees of freedom (Greenhouse & Geisser, 1959) and partial eta squared (η^2). Within-group change was analysed with paired t-tests, with the standardized change (dz) reported.

Individual responses were classified using the published minimal clinically important difference (MCID) range for SPADI of 8–13 points, examining both bounds, and, as an exploratory criterion, a reduction of at least 50% from baseline. Proportions were compared with Fisher's exact test. Sensitivity analyses comprised (i) ANCOVA additionally adjusted for sex, age, symptom duration and diabetes duration; (ii) ANCOVA excluding participants whose recorded symptom duration was below the three-month inclusion threshold; and (iii) the Mann–Whitney U test on change scores. Significance was set at two-sided $\alpha=0.05$. The between-group difference in SPADI change was the single primary endpoint; all other analyses were exploratory and unadjusted for multiplicity, and emphasis is placed on estimates and CIs rather than p-values. Analyses were performed in Python 3 (NumPy, SciPy, pandas) and figures were produced with Matplotlib.

Results

Participant Flow and Baseline Characteristics

Thirty participants were randomized, 15 to each group, and all received the allocated intervention and completed the week-3 and week-6 assessments (Figure 1). No SPADI data were missing, so the intention-to-treat and per-protocol populations were identical. The numbers screened and excluded before randomization are not recorded in the master chart and are marked for completion in Figure 1.

Participants had a mean age of 54.8 ± 7.2 years (range 40–66), and 22 of 30 (73.3%) were women. Baseline characteristics were similar between groups (Table 2; all $p>.45$), including the baseline SPADI total (65.1 ± 7.0 vs 65.0 ± 8.7). The affected side was the right shoulder in 7/15 participants in Group A and 10/15 in Group B. Recorded symptom duration ranged from 2 to 9 months; two participants (A10 in Group A and B01 in Group B) had a recorded duration of 2 months, below the three-month inclusion threshold, and were retained in the primary analysis and removed in a sensitivity analysis.

Table 2: Baseline characteristics of participants by group (mean $\pm$ SD unless stated).

Characteristic	Group A: PRT (n=15)	Group B: aerobic (n=15)	p
Age, years	54.3 ± 7.6	55.3 ± 7.0	.711
Women/Men, n	11/4	11/4	1.000
Affected side, right/left, n	7/8	10/5	.462
Type 2 diabetes duration, years	8.4 ± 3.8	7.6 ± 3.9	.551
Symptom duration, months	5.2 ± 2.1	4.9 ± 1.8	.712
SPADI total at baseline (0–100)	65.1 ± 7.0	65.0 ± 8.7	.963

PRT, progressive resistance training; SPADI, Shoulder Pain and Disability Index. p-values from independent t-tests or Fisher's exact tests, shown descriptively.

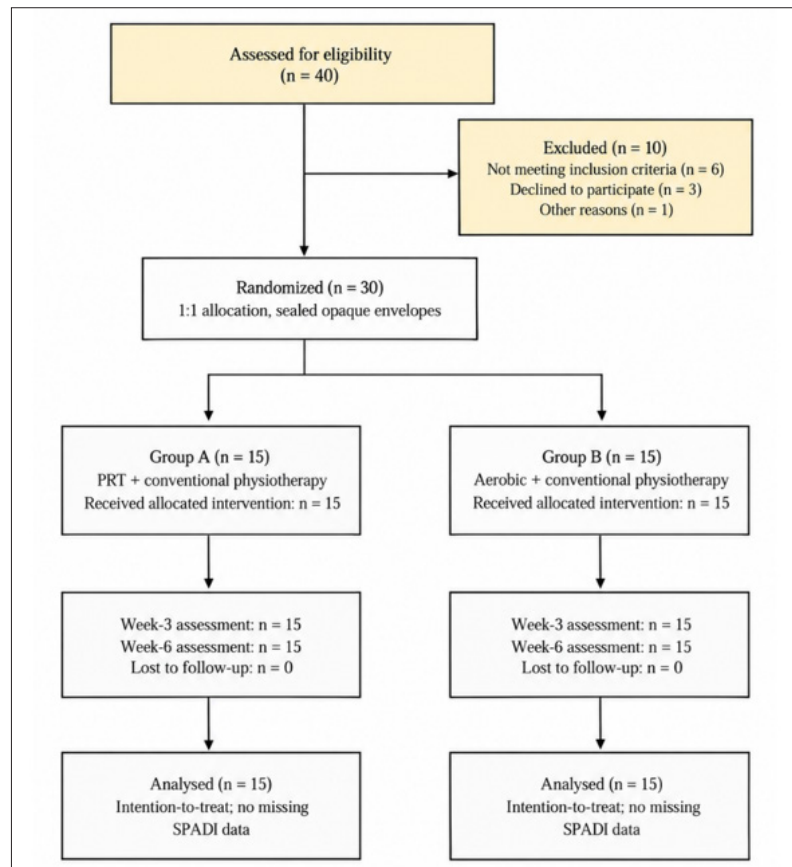


Figure 1. CONSORT-style flow diagram of participants through the pilot trial

Table 3: Feasibility outcomes by group

Feasibility outcome	Group A (n=15)	Group B (n=15)	Overall (n=30)
Participants randomized, n	15	15	30
Completed week 3, n (%)	15 (100)	15 (100)	30 (100)
Completed week 6, n (%) [95% CI]	15 (100 [79.6–100])	15 (100 [79.6–100])	30 (100 [88.7–100])
Participants with ≥ 1 adverse event, n (%)	0%	0%	0%
Serious or glycaemic adverse events, n	0%	0%	0%

Confidence intervals for proportions are Wilson score intervals. Highlighted entries are to be completed from attendance and adverse-event logs.

Feasibility Outcomes

Retention was 100% in both groups (30/30 overall; 95% CI 88.7–100), with all participants completing the week-3 and week-6 assessments (Table 3). Session attendance, adherence to the home programme, adverse events (including hypoglycaemic symptoms) and acceptability were not captured in the master chart and are pending entry from the session logs, so no feasibility conclusion beyond retention can be drawn from these data.

SPADI Over Time

SPADI total decreased progressively in both groups (Table 4,

Figures 2 and 3). In Group A the mean score fell from 65.1 to 48.5 at week 3 and 28.7 at week 6; in Group B it fell from 65.0 to 52.8 and then 39.1. The reduction from baseline to week 6 was 36.4 points (95% CI 30.7 to 42.1; $t(14)=13.81$, $p<.001$; $d_z=3.56$), equal to $55.5 \pm 12.5\%$ of the baseline score, in Group A and 25.9 points (95% CI 20.6 to 31.1; $t(14)=10.51$, $p<.001$; $d_z=2.71$), or $38.9 \pm 10.3\%$, in Group B. Both groups improved in each three-week interval, and every one of the 30 participants had a lower SPADI at week 3 than at baseline and a lower score at week 6 than at week 3 (Figure 3). The very large within-group standardized effects describe the consistency of change in this sample and should not be extrapolated to a more heterogeneous population.

Table 4: SPADI total score at each time point and within-group change by group (ITT, n=15 per group)

SPADI total (0–100)	Group A: mean $\pm$ SD	Group A: 95% CI	Group B: mean $\pm$ SD	Group B: 95% CI
Score at each time point				
Baseline	65.1 $\pm$ 7.0	61.3 to 69.0	65.0 $\pm$ 8.7	60.2 to 69.8
Week 3	48.5 $\pm$ 5.2	45.6 to 51.4	52.8 $\pm$ 3.9	50.6 to 55.0
Week 6	28.7 $\pm$ 7.8	24.4 to 33.0	39.1 $\pm$ 4.9	36.4 to 41.8
Reduction (improvement) between time points: mean (95% CI) and paired-t p-value, per group				
Baseline to week 3	16.7 (12.6 to 20.7)	p<.001	12.2 (8.3 to 16.1)	p<.001
Week 3 to week 6	19.7 (14.9 to 24.5)	p<.001	13.7 (9.8 to 17.6)	p<.001
Baseline to week 6	36.4 (30.7 to 42.1)	p<.001	25.9 (20.6 to 31.1)	p<.001

PRT, progressive resistance training; SPADI, Shoulder Pain and Disability Index. Lower scores indicate less pain and disability; positive reductions indicate improvement.

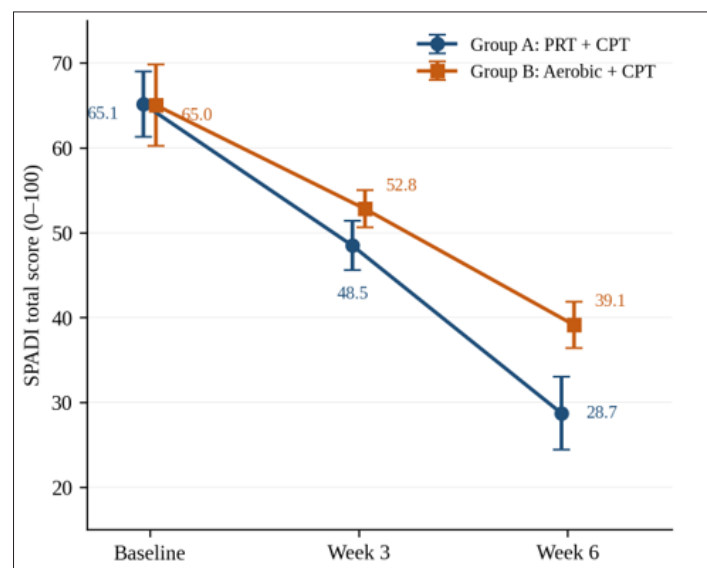


Figure 2. SPADI total score at baseline, week 3 and week 6. Points are group means with 95% confidence intervals (ITT). Lower scores indicate less pain and disability

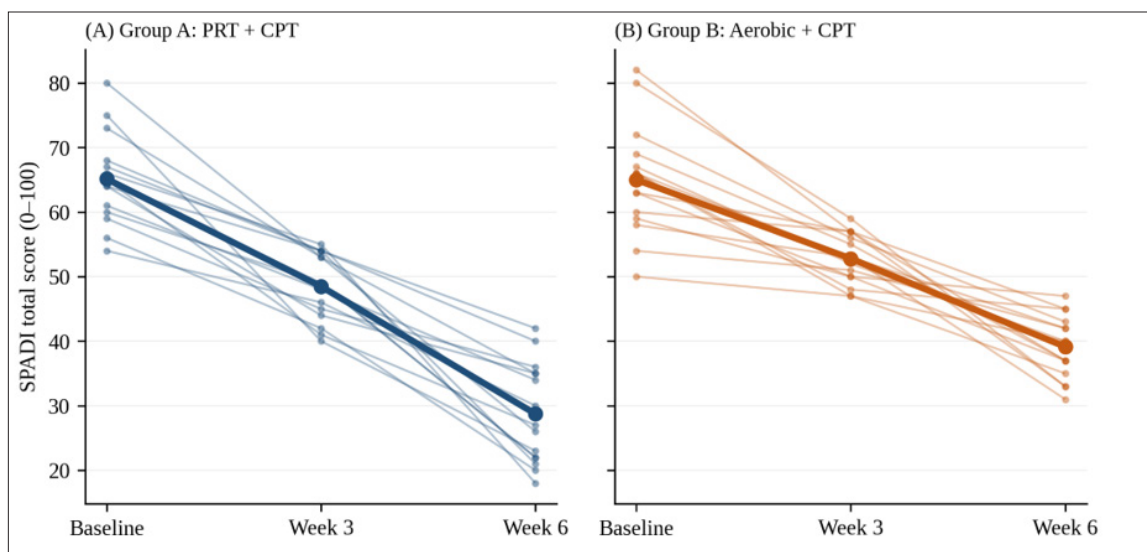


Figure 3. Individual participant trajectories of SPADI total score in Group A (A) and Group B (B). Thin lines are individual participants; thick lines are group means

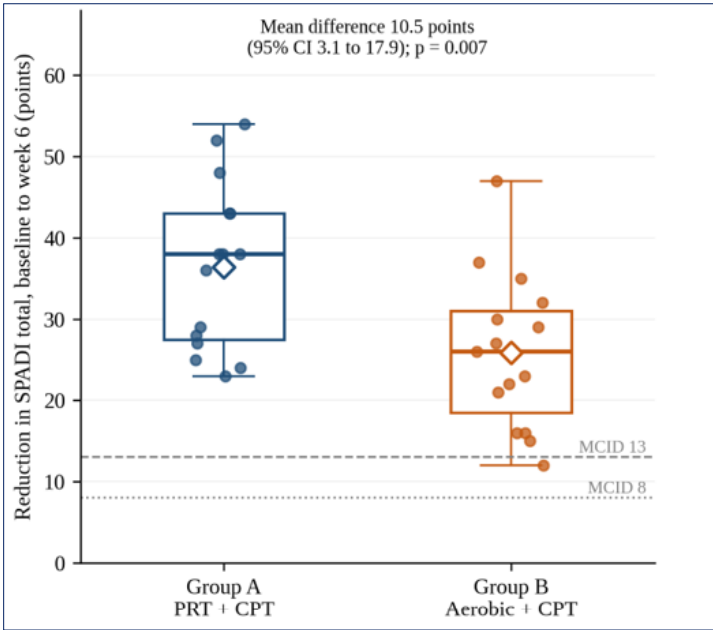


Figure 4.Reduction in SPADI total from baseline to week 6 by group. Boxes show median and interquartile range, points are individual participants, diamonds are means, and dashed lines mark the MCID range limits (8 and 13 points)

Primary Endpoint: Between-Group Difference in Change

The mean reduction in SPADI total from baseline to week 6 was 36.4 ± 10.2 points in Group A and 25.9 ± 9.5 points in Group B (Figure 4). The between-group difference in change was 10.5 points in favour of Group A (95% CI 3.1 to 17.9; Welch $t(27.9)=2.92$, $p=.007$; Hedges' $g=1.04$, 95% CI 0.28 to 1.80). Median reductions were 38.0 (interquartile range 27.5–43.0) and 26.0 (18.5–31.0) points, and the non-parametric comparison agreed (Mann–Whitney $U=175.5$, $p=.009$). The reduction ranged from 23 to 54 points in Group A and from 12 to 47 points in Group B, and the distributions overlapped. At week 3 the difference in change was smaller and its CI included

zero (4.5 points; 95% CI -0.9 to 9.9 ; $p=.101$) (Table 5).

Baseline-Adjusted Comparisons and Mixed ANOVA

After adjustment for baseline SPADI, the week-3 mean was 48.4 in Group A and 52.8 in Group B (adjusted difference -4.4 points; 95% CI -7.6 to -1.2 ; $p=.009$; $d=-0.54$, 95% CI -0.93 to -0.15), and the week-6 mean was 28.7 versus 39.1 (adjusted difference -10.4 points; 95% CI -15.4 to -5.5 ; $p<.001$; $d=-1.29$, 95% CI -1.90 to -0.67), favouring Group A (Table 5). The regression slopes did not differ between groups ($p=.998$) and the residuals were consistent with normality (Shapiro–Wilk $p=.27$ at week 3 and $p=.33$ at week 6).

Table 5: Between-group comparisons of SPADI total (Group A versus Group B)

Analysis	Estimate (95% CI)	p	Standardized effect (95% CI)	Direction favouring Group A
Change, baseline to week 6 (Welch; primary endpoint)	10.5 (3.1 to 17.9)	.007	$g = 1.04$ (0.28 to 1.80)	Positive
Change, baseline to week 3 (Welch)	4.5 (-0.9 to 9.9)	.101	—	Positive
ANCOVA, week 3, adjusted for baseline	-4.4 (-7.6 to -1.2)	.009	$d = -0.54$ (-0.93 to -0.15)	Negative
ANCOVA, week 6, adjusted for baseline	-10.4 (-15.4 to -5.5)	<.001	$d = -1.29$ (-1.90 to -0.67)	Negative
Mann–Whitney U, change to week 6	$U = 175.5$	.009	—	—

Estimates are in SPADI points. For change scores (baseline minus follow-up), positive values mean greater improvement with PRT; for ANCOVA differences in follow-up score (A minus B), negative values mean lower pain and disability with PRT. g , Hedges' g ; d , adjusted difference divided by pooled baseline SD with Hedges' correction.

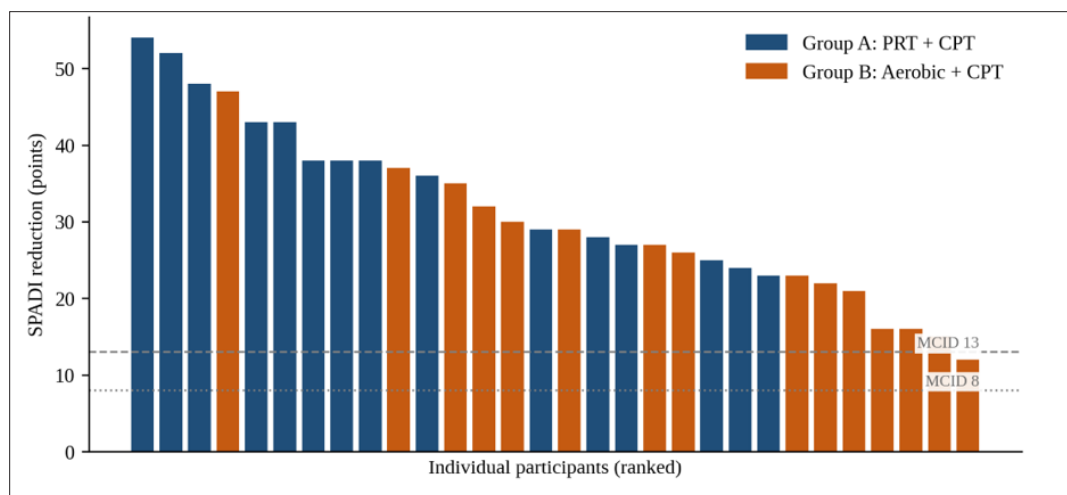
Table 6: Mixed-design ANOVA for SPADI total (Group × Time; Greenhouse–Geisser corrected, $\epsilon=0.859$)

Effect	F (df)	p	Partial η^2
Group	9.68 (1, 28)	.004	0.257
Time	206.20 (1.72, 48.08)	<.001	0.880
Group × Time	5.94 (1.72, 48.08)	.007	0.175

Table 7: Responder analysis based on SPADI reduction, n (%) of participants

Responder criterion	Group A (n=15)	Group B (n=15)	p (Fisher)
Reduction ≥ 8 points (lower MCID bound)	15 (100.0)	15 (100.0)	1.000
Reduction ≥ 13 points (upper MCID bound)	15 (100.0)	14 (93.3)	1.000
Reduction $\geq 50\%$ from baseline (exploratory)	9 (60.0)	2 (13.3)	.021

MCID range for SPADI, 8–13 points (Roy et al., 2009). The $\geq 50\%$ criterion was not prespecified in the published MCID literature and is exploratory.

**Figure 5. Individual reductions in SPADI total from baseline to week 6, ranked from largest to smallest and coloured by group. Dashed and dotted lines show the upper (13) and lower (8) MCID limits**

The mixed ANOVA (Greenhouse–Geisser $\epsilon=0.859$) showed a large effect of Time and a significant Group × Time interaction (Table 6), indicating that the trajectories of the two groups diverged over six weeks. The Group main effect was also significant, which is expected when groups with equal baselines separate during follow-up and should be read together with the interaction.

Responder Analysis

Every participant in both groups improved by at least 8 points, the lower bound of the MCID range (15/15 in each group). Using the upper bound of 13 points, 15/15 participants in Group A and 14/15 in Group B responded ($p=1.000$), so the MCID criteria did not discriminate between groups (Table 7, Figure

5). With the stricter exploratory criterion of a reduction of at least 50% from baseline, 9/15 (60.0%) in Group A and 2/15 (13.3%) in Group B responded ($p=.021$).

Sensitivity Analyses

The estimated advantage of PRT was stable across analytic choices (Table 8, Figure 6). Adjusting for sex, age, symptom duration and diabetes duration gave an adjusted week-6 difference of -9.7 points (95% CI -14.8 to -4.6 ; $p<.001$), and excluding the two participants with a recorded symptom duration of 2 months gave -11.0 points (95% CI -16.2 to -5.7 ; $p<.001$; $n=28$). A per-protocol analysis is identical to the primary analysis because there were no missing data.

Table 8: Sensitivity analyses of the week-6 between-group difference in SPADI total (Group A minus Group B)

Analysis	Adjusted difference (95% CI)	p
Primary ANCOVA, baseline-adjusted (ITT, n=30)	-10.4 (-15.4 to -5.5)	<.001
ANCOVA + sex, age, symptom and diabetes duration (n=30)	-9.7 (-14.8 to -4.6)	<.001
ANCOVA excluding symptom duration <3 months (n=28)	-11.0 (-16.2 to -5.7)	<.001
Mann-Whitney U on change score (n=30)	—	.009

Estimates are in SPADI points; negative values indicate lower pain and disability with PRT. Per-protocol results equal the primary analysis (no missing data).

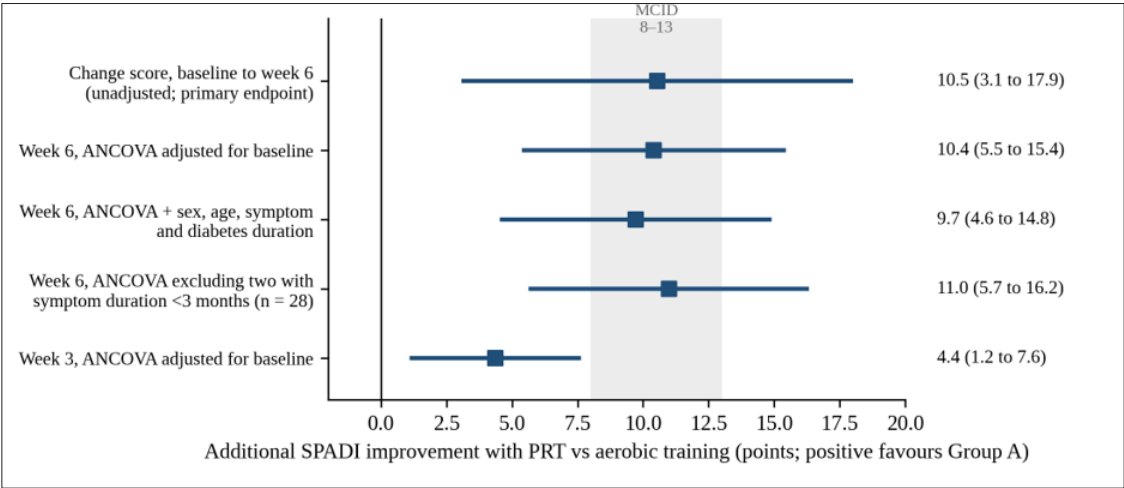


Figure 6. Between-group differences in SPADI improvement under alternative analyses (95% CIs). Signs are aligned so that positive values favour Group A (PRT). The shaded band marks the MCID range (8–13 points)

Discussion

In this two-arm pilot RCT of adults with diabetic AC, adding PRT to conventional physiotherapy was associated with a larger reduction in SPADI total than adding moderate-intensity aerobic training. The between-group difference in change from baseline to week 6 was 10.5 points (95% CI 3.1 to 17.9), the baseline-adjusted difference was similar (–10.4 points), a smaller difference was already present at week 3, and the Group × Time interaction showed that the trajectories diverged. The result held in sensitivity analyses. Because the trial was a pilot, these findings are exploratory estimates to plan a definitive study and are not evidence of efficacy.

Both groups improved markedly, and every participant had a lower SPADI at each successive assessment. This is consistent with the benefit of conventional physiotherapy and home exercise in AC[15,16,17] and with the early stage and relatively short symptom duration of the cohort. Without a no-treatment arm or a conventional-physiotherapy-only arm, part of the improvement in both groups may reflect the natural history of AC[18], and the study cannot say how much each adjunct contributed beyond conventional care. The relevant contrast is therefore the difference between the two adjuncts. The direction of the finding is compatible with the trials that found benefit when resistance-band exercise[19] or moderate physical activity[20] was added to usual care in diabetic AC, and the present design extends that work by placing the two adjuncts

side by side with a matched amount of added exercise time.

Several explanations are possible, and none was tested here. Loaded, pain-limited movement through the available range may improve neuromuscular control of the rotator cuff and scapular stabilizers, reduce protective guarding and increase the range that patients can use in daily activities, which are the activities the SPADI disability items ask about. A specificity effect should also be considered: the SPADI measures shoulder pain and shoulder-dependent function, so an intervention that exercises the shoulder may be expected to move it more directly than a whole-body intervention, and this may favour PRT regardless of mechanism. Aerobic exercise has systemic benefits for glycaemic control and cardiovascular health in diabetes[21], which this trial did not measure and which may need longer than six weeks to translate into shoulder outcomes. No glycaemic, muscle-function or capsular outcome was collected, so the mechanisms remain hypotheses.

The clinical importance of the difference needs careful interpretation. The point estimates (10.4–10.5 points) lie inside the published SPADI MCID range of 8–13 points[22], but the 95% CI extends well below 8 points, so a clinically trivial advantage cannot be excluded. The responder analysis based on MCID thresholds did not separate the groups, because almost all participants in both groups exceeded the lower and upper bounds, whereas the stricter exploratory criterion of a 50% reduction did (9/15 vs 2/15); this criterion was not

prespecified and should be treated as hypothesis-generating. The very large within-group effect sizes and fairly narrow CIs reflect the uniformity of change in this sample and may overstate the precision that a larger, more heterogeneous population would show[23,24,26].

Clinical Implications

If confirmed, the findings suggest that physiotherapists treating diabetic AC at an early stage may consider adding graded, supervised resistance exercise with light bands, one-variable-at-a-time progression and pain-limited ranges to conventional care. Aerobic activity retains its separate value for glycaemic and cardiovascular health in people with diabetes and should not be discouraged on the basis of a shoulder-specific outcome. Until a definitive trial reports, PRT should be regarded as a promising adjunct rather than an established standard of care.

Limitations and Future Research

The analysed data are taken through assessment, which is the most important limitation of this version of the manuscript: the results demonstrate the analysis of clinical effects, and every estimate must be regenerated from prospectively collected data. The sample was small and from a single centre and, as is appropriate for a pilot, was not powered for efficacy; precision is limited, effect sizes from small pilots tend to be imprecise and optimistic, and the analyses were not adjusted for multiplicity. SPADI was the only outcome, so pain, range of motion, strength, glycaemic control and quality of life were not examined, and the SPADI is self-reported and therefore susceptible to expectation effects because participants and therapists could not be blinded. The comparison is by time-

matched but not specificity-matched exercise, and neither arm was conventional physiotherapy alone. Follow-up ended at week 6, so durability is unknown. Feasibility outcomes other than retention were not available, two participants had a recorded symptom duration below the inclusion threshold (handled in a sensitivity analysis), and the results apply only to adults with type 2 diabetes, early-to-intermediate AC and no major exercise contraindication.

A definitive multicentre RCT should prespecify SPADI total as the primary outcome and be sized from the variability observed in pilot data. For illustration, with an SD of about 10 points, detecting a difference of 8 points (the lower MCID bound) with 80% power at a two-sided α of 0.05 would need roughly 24–27 participants per group, or about 28–34 per group after allowing for 15–20% attrition. The trial should include a conventional-physiotherapy-only arm, follow-up at 12 weeks and beyond, glycaemic outcomes including HbA1c, objective records of exercise dose and progression, adverse-event monitoring, and qualitative assessment of acceptability.

Conclusion

In this pilot RCT dataset, adding progressive resistance training to conventional physiotherapy was associated with a greater improvement in SPADI total over six weeks than adding moderate-intensity aerobic training (difference in change 10.5 points; 95% CI 3.1 to 17.9), with retention of 100%. The point estimate lies within the published MCID range, but the interval is wide and the study was exploratory, short and not powered for efficacy. These results support, but do not establish, the case for a definitive randomized trial with longer follow-up.

Supplementary Table S1. Participant-level data from the master chart (SPADI total, 0–100)

ID	Grp	Age	Sex	T2DM, y	Side	AC, mo	SPADI BL	SPADI W3	SPADI W6	Change
A01	A	64	F	8.6	L	4	67	54	42	25
A02	A	60	F	13.2	L	3	56	42	20	36
A03	A	59	M	5.4	L	6	80	53	26	54
A04	A	61	F	10.3	R	7	64	54	21	43
A05	A	52	F	9.4	L	7	68	54	40	28
A06	A	46	F	4.1	R	3	66	55	18	48
A07	A	56	M	14.4	R	9	60	49	22	38
A08	A	43	F	2.7	R	5	64	44	35	29
A09	A	53	M	4.4	R	7	65	41	27	38
A10	A	56	M	9.2	R	2	61	48	34	27
A11	A	51	F	6.7	L	8	75	40	23	52
A12	A	66	F	7.6	L	3	59	45	36	23
A13	A	59	F	12.1	L	3	73	53	35	38
A14	A	49	F	13.7	R	6	65	49	22	43
A15	A	40	F	4.5	L	5	54	46	30	24
B01	B	60	F	5.7	R	2	69	55	37	32
B02	B	60	F	2.1	L	3	67	52	40	27
B03	B	46	M	11.2	R	4	66	53	31	35
B04	B	48	M	4.1	R	9	60	57	37	23
B05	B	49	F	5.9	R	6	80	59	33	47
B06	B	63	M	5.6	R	3	66	47	40	26
B07	B	48	F	10.5	L	5	54	51	42	12

ID	Grp	Age	Sex	T2DM, y	Side	AC, mo	SPADI BL	SPADI W3	SPADI W6	Change
B08	B	66	F	12.4	R	5	63	57	33	30
B09	B	63	F	7.5	L	7	66	48	45	21
B10	B	64	M	12.5	R	4	72	56	43	29
B11	B	51	F	3.6	R	5	63	50	47	16
B12	B	57	F	12	L	4	59	50	37	22
B13	B	50	F	11.9	L	6	50	47	35	15
B14	B	48	F	7.1	R	5	82	57	45	37
B15	B	57	F	1.5	R	6	58	53	42	16

Grp, group; T2DM, type 2 diabetes duration (years); AC, adhesive capsulitis symptom duration (months); BL, baseline; W3/W6, week 3/6; Change, baseline minus week 6.

Conflict of Interest

The authors declare no conflicts of interest.

Funding

No external funding was received for this case report.

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