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ORIGINAL ARTICLE

Efficacy and Cost-Effectiveness of Physiotherapy Following Glenohumeral Joint Distension for Adhesive Capsulitis: A Randomized Trial

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Objective. **To determine whether an active physiotherapy program following arthrographic joint distension for adhesive capsulitis provides additional benefits.**

Methods. **We performed a randomized, placebo-controlled, participant and single assessor blinded trial. A total of 156 participants with pain and stiffness in predominantly 1 shoulder for ≥3 months and restriction of passive motion >30° in ≥2 planes of movement entered the study, and 144 completed the study. Following joint distension, participants were randomly assigned to either manual therapy and directed exercise or placebo (sham ultrasound), both administered twice weekly for 2 weeks then once weekly for 4 weeks. Pain, function, active shoulder movements, participant-perceived success, and quality of life were assessed at baseline, 6, 12, and 26 weeks. Costs were also collected.**

Results. **Both groups improved over time with no significant differences in improvement between groups for pain, function, or quality of life at any time point. Significant differences favored the physiotherapy group for all active shoulder movements (e.g., pooled difference in mean change between groups across all time points for total shoulder abduction was 10.6°, 95% confidence interval [95% CI] 3.1, 18.1) and participant-perceived success (pooled relative risk 1.4, 95% CI 1.1, 1.65; number needed to treat = 5). Net cost of physiotherapy was $136.8 Australian (95% CI −177.5, 223.1) over the 6 months.**

Conclusion. **Physiotherapy following joint distension provided no additional benefits in terms of pain, function, or quality of life but resulted in sustained greater active range of shoulder movement and participant-perceived improvement up to 6 months.**

KEY WORDS. Adhesive capsulitis; Physical therapy; Joint distension.

INTRODUCTION

Adhesive capsulitis (frozen shoulder or painful stiff shoulder) is a common cause of shoulder pain affecting ~2–5% of the general population (1). Shoulder pain and stiffness are accompanied by severe disability often resulting in absenteeism from work, inability to perform leisure activities, and utilization of health care resources. Although generally believed to be a self-limiting condition lasting 2–3 years, some studies have reported that up to 40% of patients have persistent symptoms and stiffness beyond 3 years (2), and up to 15% have persistent disability (3). Therefore, effective treatment that shortens the duration of symptoms and disability has the potential to be of significant value in terms of reduced morbidity and costs.

Although there is little evidence to support the use of a

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wide array of physiotherapy methods as primary or initial treatment for adhesive capsulitis (4–9), there are strong theoretical reasons to suggest that manual techniques and directed exercise may be of value if applied at the appropriate time and/or in combination with other interventions. For example, a recent trial reported small treatment benefits of high-grade versus low-grade mobilization techniques in patients with adhesive capsulitis (10). Participants in the trial had a median duration of symptoms of 8 months and the majority had received prior therapy including steroid injections and physical therapy. If shoulder movement has been restricted for an extended period, there is an accompanying loss of strength, proprioception, and coordination of the shoulder complex (11), and muscles, tendons, and ligaments around the shoulder may also become contracted (12). Manual techniques and directed exercise may facilitate correction of these factors and lead to improved shoulder motion and function.

We recently demonstrated the value of arthrographic distension of the glenohumeral joint with normal saline and corticosteroid for the intermediate (stiff) phase of adhesive capsulitis in a randomized placebo-controlled trial (13). At 3 and 6 weeks there was a significantly greater improvement in pain, function, and active range of movement in the group that received distension, although this was not sustained at 12 weeks. In view of the good early symptomatic improvement in pain accompanied by improvement in range of movement, this treatment is now the standard of care in our setting for patients with adhesive capsulitis in the intermediate phase of the condition. The goal of the current study was to determine whether the addition of an active physiotherapy program following arthrographic joint distension augments the benefits of this procedure, particularly in terms of improved range of shoulder motion and function, and whether this program is cost-effective.

PATIENTS AND METHODS

Participants. Between March 2002 and April 2005, we performed a randomized, placebo-controlled, participant and single assessor blinded trial in participants with adhesive capsulitis recruited from primary care and specialist practice. Inclusion criteria were age ≥18 years, symptoms of pain and stiffness in predominantly 1 shoulder for ≥3 months, and restriction of passive motion ≥30° in ≥2 planes of movement, measured to onset of pain with a gravity inclinometer. Exclusion criteria were severe pain at rest (>7 of 10 on a visual analog scale); systemic inflammatory joint disease; radiologic evidence of shoulder osteoarthritis, fracture, or calcification; reason to suspect a complete rotator cuff tear (arm elevation weakness, positive drop arm sign, high-riding humerus on shoulder radiograph, or complete rotator cuff tear on ultrasound); contraindications to arthrogram and/or distension such as current warfarin therapy; allergy to local anesthetic or iodinated contrast; pregnancy; likely not to attend for treatment or comply with followup; inability to partake in moderate exercise; previous postdistension physiotherapy; and lack of written informed consent. The Cabrini Health and Monash University Ethics Committees provided ethical approval.

Procedures. Consenting, eligible participants were randomized in permuted blocks of 4 and 6, stratified by treatment center, to receive either active or placebo regimens according to a computer-generated table of random numbers created by the study biostatistician. To ensure treatment allocation concealment, just prior to commencement of treatment, study centers telephoned a central number for the treatment allocation according to the participant's identification number. Only the telephone receptionist had access to the allocation schedule (and no other role in the trial).

All participants received arthrographic distension of the glenohumeral joint with corticosteroid and normal saline performed under radiologic guidance at one of several community-based radiology practices according to usual standards (13). Experienced physiotherapists at 1 of 5 sites delivered all treatments. All were trained in a standardized protocol for both physiotherapy and placebo treatments. All treatments were performed twice per week for 2 weeks then once per week for 4 weeks (8 visits, 30 minutes each). The duration of the intervention was considered to be sufficient to demonstrate a treatment effect if one was present. Treating physiotherapists interacted with study participants in a standardized manner irrespective of treatment allocation. To minimize the risk of study participants meeting, appointments for physiotherapy were scheduled at different times.

The goals of the active physiotherapy treatment were to maintain and increase glenohumeral joint range of active and passive motion by stretching soft tissue structures adjacent to the glenohumeral joint; improve strength, particularly within newly gained passive range; and regain proprioception and normal shoulder and trunk biomechanics. Specific interventions included 1) both passive and self-executed muscle stretching techniques to stretch muscles passing over the glenohumeral joint, 2) cervical and thoracic spine mobilization, 3) glenohumeral joint passive accessory glides, 4) glenohumeral joint passive physiologic mobilization including rotation, 5) strength and coordination exercises for rotator cuff and scapular stabilizers, and 6) proprioceptive challenge. At the conclusion of the 6-week program, participants were instructed to maintain their 10-minute daily home exercise program and adherence was monitored and confirmed via a logbook.

Participants in the placebo group received the same number of visits as those in the active treatment group but received sham ultrasound and application of a nontherapeutic gel. They received no instruction in exercise techniques and no manual therapy. We previously used this placebo protocol with successful blinding demonstrated in 81% of placebo-treated participants (14).

Analgesia and nonsteroidal antiinflammatory drugs were permitted and their use was recorded. All participants were asked to refrain from seeking any other forms of treatment during the trial and any lack of compliance was recorded.

All participants were evaluated by the same blinded outcome assessor (JMY) at baseline (just prior to arthrographic joint distension), 6 weeks (at the conclusion of the physiotherapy or placebo program), 12 weeks, and 26 weeks. Baseline variables included age, sex, symptom duration, previous investigations and treatment, medical history including diabetes, prior surgery, history of trauma, and medication use. If not already available, a radiograph of the shoulder was obtained.

The following outcomes were assessed. The Shoulder Pain and Disability Index (SPADI) is a self-administered, shoulder-specific, fixed-item index consisting of 13 items divided into 2 subscales: pain (5 items) and disability (8 items) (15). Item responses are recorded on a 10-point Likert scale (ranging from 0 = "no pain" or "no difficulty" to 9 = "worst imaginable pain" or "so difficult it required help" for the pain and disability items, respectively). A SPADI score is calculated by summing and then averaging the 2 subscales for a score out of 100 (higher score indicates more pain/disability). Participants' overall assessment of pain, pain at night, activity-related pain, and pain at rest were measured with a 10-cm Likert scale comprising a vertical line with 0 (no pain) at the bottom and 10 (maximal imaginable pain) at the top (16).

Active shoulder movements were measured according to a standardized, reliable protocol (17). Total shoulder flexion, total shoulder abduction, and external rotation in neutral were measured with a gravity inclinometer (in degrees) and internal rotation was assessed by measuring the distance (in cm) from the base of the occiput to how high the hand would reach up behind the back (HBB).

Health-related quality of life was measured by the Short Form 36 Health Survey (SF-36; 8 subscales scaled from 0 to 100 where a higher score represents better health) (18) and the Assessment of Quality of Life instrument (AQoL) (19). The AQoL can be converted into a utility index to calculate quality-adjusted life years (QALYs). It comprises 15 items in 5 dimensions (illness, independent living, social relationships, physical senses, and psychological well-being). Item responses are all ordinal scales with 4 levels per item. Scores are scaled from 0.00 (death) to 1.00 (perfect health).

Participants rated their perceived recovery on a 5-point ordinal scale (from 1 = failure: marked worsening to 5 = success: much improved and/or completely recovered). Measuring patient-perceived improvement using a rating-of-change scale has been shown to be a clinically relevant and stable concept for interpreting truly meaningful improvements from the individual perspective (20). A successful outcome was defined a priori as success: much improved and/or completely better. The blinded outcome assessor also rated improvement on a 5-point ordinal scale (1 = marked worsening to 5 = marked improvement).

Adverse effects were elicited by open-ended questions. At the conclusion of the study, participants were asked to indicate which treatment they believed they had received.

Information on direct health care costs, direct nonhealth care costs, and production losses was collected by monthly diary during the 6-month followup. Direct health care costs included costs of physiotherapy attendance ($50 × 8 = $400 Australian dollars [AUD] for the physiotherapy group and assumed zero in the placebo group), additional health provider visits, tests, prescription and over-the-counter medication, professional home care, and hospitalization. These were valued using published prices for medical costs. Direct nonhealth care resources included use of paid and unpaid help, lost time and travel, and number of lost days at work.

Sample size. Sample size was calculated based upon the ability to detect a 10-point difference in improvement in SPADI score, previously reported to indicate a clinically important improvement (or worsening) of shoulder function (21). Applying power calculations appropriate for analysis of covariance (adjusting for baseline SPADI score), to detect a 10-point difference in 3-month SPADI scores assuming a common between-patient SD of 23.9 and a baseline to 3-month correlation in SPADI scores of 0.50 (both values derived from our prior arthrographic distension trial [13]), 67 patients per group were required to achieve 80% power at a 2-sided 5% significance level (22). Including the 6- and 26-week followups in a repeated-measures analysis increased the power to 87% assuming a conservative correlation of 0.8 between all postbaseline measurements and a uniform physiotherapy effect. We allowed for a 10% loss to followup and aimed to recruit 78 participants per group.

Statistical analysis. All analyses were conducted on an intent-to-treat principle using all randomized participants who provided any postbaseline data (23). All statistical analyses were performed using Stata software, version 9.1 (StataCorp, College Station, TX). Demographic characteristics and baseline data were summarized by descriptive statistics. An index was computed to assess the success of blinding (24). This index assigns values of 1 for complete blinding and 0 for complete lack of blinding.

For outcomes measured using an essentially continuous scale, differences in mean change from baseline to each time point were compared between groups using linear regression modeling adjusting for baseline levels of the outcome measure. Model assumptions were checked by standard diagnostic plots (25). For analysis across all time points simultaneously, accounting for repeated measurements, we estimated the differences between groups using generalized estimating equation models for the postbaseline measurements with adjustment for baseline measurements, a robust variance, and unstructured working correlation (26). Constancy of the difference between groups over time was assessed by fitting models that included a term for the interaction between treatment and time. Sensitivity analyses included repetition of analyses with calculation of bootstrap standard errors, and identification of influential individuals by sequentially omitting each participant and refitting the model.

Participant and rater measures of perceived improvement following physiotherapy or placebo treatments were compared by calculating the relative risks and their 95% confidence intervals (95% CIs) at each time point using log binomial regression (27). Repeated-measures relative risk calculations were performed using generalized estimating

equations with a logarithmic link function, robust variance, and unstructured correlation (26). As above, models including a term for the interaction between treatment and time were fit to assess the constancy of the difference between groups over time.

Standard methods of economic evaluation alongside a clinical trial (28) were used to evaluate the differences in resource use and health outcomes over a 6-month period between groups. A social perspective on costs was obtained that included resource use incurred both by health services and by the patient irrespective of the source of payment. All health care costs were included; however, to reduce the impact of extreme values, inpatient hospital costs were excluded if they were unrelated to adhesive capsulitis. Sensitivity analysis to examine the impact of production losses from time off work was performed. The mean and 95% CIs for the difference in total cost were estimated using a generalized linear model with a gamma distribution and a log link and robust variance to account for repeated measures on patients. Cost differences over 26 weeks were compared with changes in the measured patient outcomes to assess cost-effectiveness in terms of incremental cost per QALY gained.

RESULTS

We recruited 156 study participants (78 in both groups), and 144 (74 active, 70 placebo; 92.3%) completed the 26-week trial. Participants moved through the trial as outlined in Figure 1. Seven participants (3 active, 4 placebo) withdrew from the trial prior to completing the allocated intervention. Because there were no postbaseline followup data for these participants, they were excluded from the efficacy analysis. Three participants withdrew prior to the 12-week followup (1 active, 2 placebo) and 2 participants (2 placebo) withdrew prior to the 26-week followup. These participants were excluded from the 12-week and 26-week efficacy analyses, respectively. Six participants (2 active, 4 placebo) had a second arthrographic joint distension during the trial period but remained in the efficacy analysis. Overall, of those who completed their allocated treatment, 3 (4%) of 75 in the active group and 8 (10.8%) of 74 in the placebo group had further treatment during the 26-week trial ($P = 0.11$).

The demographic and clinical details of the 149 participants with postbaseline data are presented in Table 1 according to treatment group. There were no baseline differences of clinical importance between treatment groups for any of the examined demographic or clinical characteristics, although more participants in the placebo group had a postoperative capsulitis (17 [23%] versus 9 [12%] in the active group). Characteristics of the 7 participants with no followup data are also provided in Table 1. Although comparisons with the 149 participants are limited, these 7 participants appeared somewhat younger and had worse symptom severity.

Efficacy and safety. Both treatment groups improved over time (Tables 2 and 3, Figure 2). There were no statistically significant differences in improvement between active and placebo groups for pain, function, or quality of life at 6, 12, or 26 weeks (Table 2, Figure 2). However, there were significant differences in improvement favoring the active physiotherapy group for active shoulder movements at 6 and 12 weeks (Table 2, Figure 2). By 26 weeks, the differences in improvement between treatment groups with respect to shoulder movement were no longer statistically significant apart from HBB, although all still favored the physiotherapy group. There was little evidence of variation in the group differences over time (all group-by-time interaction P values >0.09). The pooled difference in mean change between groups across all time points significantly favored the physiotherapy group for all measured shoulder movements.

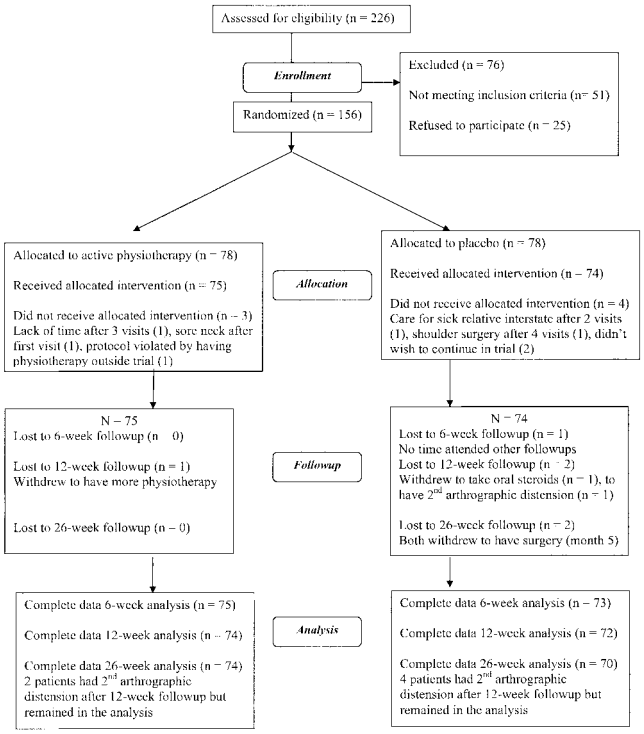

Figure 1. Movement of participants through the trial.

Participant- and rater-assessed treatment success favored the active physiotherapy group at all time points (pooled relative risk 1.4; 95% CI 1.1, 1.7) (Table 3). Application of bootstrapped standard errors and assessment of influential individuals did not reveal any noteworthy findings.

Given the difference in proportions of participants with postoperative capsulitis in the placebo and treatment groups, we repeated all analyses adjusting for postoperative capsulitis and the results were not appreciably altered. To assess the sensitivity of the results to the exclusion of the 7 participants who provided no postbaseline data and to the missing data from participants lost to followup during the trial period, we performed a single imputation of these participants' 3-month postbaseline values using regression modeling. These models predicted the 12-week data for these participants based on the relationship between the 12-week data, baseline characteristics, and randomized treatment arm among the 149 partic-

Table 1. Demographic and clinical characteristics of physiotherapy and placebo groups at baseline*

Variable	Physiotherapy (n = 75)	Placebo (n = 74)	Did not provide any followup data (n = 7)
Age, years	55.0 ± 9.3	55.3 ± 7.7	48.6 ± 8.6
Duration of symptoms, median (range) months	6 (3–60)	6 (3–57)	8 (3–36)
SPADI score (range 0–100)	59.9 ± 22.0	62.1 ± 19.8	71.7 ± 25.7
AQoL score (range 0–1)	0.68 ± 0.21	0.66 ± 0.20	0.52 ± 0.32
Overall pain score (range 0–10)	5.5 ± 1.9	5.5 ± 2.0	5.9 ± 2.5
Night pain (range 0–10)	5.5 ± 2.7	5.6 ± 2.5	6 ± 3.3
Pain with use (range 0–10)	6.7 ± 2.1	6.9 ± 2.3	7.7 ± 2.6
Pain at rest (range 0–10)	2.7 ± 2.3	3.0 ± 2.4	4 ± 3.5
Active range of motion, degrees			
Total shoulder flexion (range 0–180)	92.8 ± 23.0	91.2 ± 25.0	67.4 ± 34.6
Total shoulder abduction (range 0–180)	66.9 ± 26.7	67.6 ± 23.4	52.3 ± 32.7
External rotation in neutral (range 0–90)	20.9 ± 16.6	20.6 ± 15.4	15.7 ± 13.1
Hand behind back (cm from base of occiput to fingertip)	57.3 ± 11.3	57.4 ± 11.9	59.3 ± 11.3
Volume injected during arthrographic distension of the glenohumeral joint, ml	35.7 ± 11.8	35.8 ± 13.0	32.2 ± 15.0
Short Form 36			
Mental function (0–100)	51.2 ± 11.7	47.9 ± 12.8	41.9 ± 16.7
Physical function (0–100)	38.4 ± 13.4	30.9 ± 6.9	34.1 ± 10.0
Female sex, no. (%)	51 (68.0)	43 (58.1)	5 (71.4)
Diabetes, no. (%)	10 (13.3)	8 (10.8)	0
Prior treatment, no. (%)			
Oral NSAIDs	53 (70.7)	45 (60.8)	4 (57.1)
Topical NSAIDs	30 (40.0)	27 (36.5)	2 (28.6)
Glucocorticoid injection	34 (45.3)	23 (31.1)	6 (85.7)
Physiotherapy	42 (56.0)	45 (60.8)	5 (71.4)
Oral steroids	4 (5.3)	6 (8.0)	0
Hydrotherapy	2 (2.7)	1 (1.4)	1 (14.3)
Previous hydrodilatation	0	1 (1.4)	0
Osteopath	5 (6.7)	2 (2.7)	0
Chiropractor	8 (10.7)	5 (6.8)	1 (14.3)
Acupuncture	7 (9.3)	5 (6.8)	0
Massage	14 (18.7)	4 (5.7)	1 (14.3)
Postoperative capsulitis, no. (%)	9 (12.0)	17 (23.0)	0
Occupation, no. (%)			
Manual	11 (14.7)	10 (13.5)	0
Nonmanual	38 (50.7)	41 (55.4)	6 (85.7)
Retired/unemployed	26 (34.7)	23 (31.1)	1 (14.3)
Affected shoulder, no. (%)			
Right	28 (37.3)	29 (39.2)	3 (42.9)
Left	47 (62.7)	45 (60.8)	4 (57.1)
Work cover, no. (%)	8 (10.7)	6 (8.0)	3 (42.9)
Referral source, no. (%)			
Orthopedic surgery	54 (72.0)	56 (75.7)	5 (71.4)
Rheumatology	14 (18.7)	11 (14.9)	2 (28.6)
General practitioner	5 (6.7)	7 (9.5)	0
Sports physician	2 (2.7)	0	0

* Values are the mean ± SD unless otherwise indicated. SPADI = Shoulder and Pain Disability Index; AQoL = Assessment of Quality of Life; NSAIDs = nonsteroidal antiinflammatory drugs.

ipants who did have postbaseline data. All analyses in Table 2 corresponding to the 12-week time point were then repeated using the complete data set with these imputed values and the results differed very minimally.

Few side effects were reported in either group. One participant in the active group withdrew from the trial after one treatment due to neck pain. There were no other withdrawals due to adverse events. Another participant in the placebo group reported neck pain following treatment and 2 participants (1 active, 1 placebo) reported shoulder pain following treatment.

Thirty-nine participants (53%) in the active group correctly identified their treatment group compared with 35 participants (50%) in the placebo group; 31 participants (42%) in the active group were uncertain which treatment they had received compared with 23 participants (33%) in the placebo group. Blinding index was 0.49 (bootstrap 95% CI 0.40, 0.56), interpreted as moderate success of blinding.

Table 2. Mean change in score of SPADI, pain measures, range of active shoulder movement, AQoL, and SF-36 from baseline for physiotherapy and placebo groups, difference in mean change between groups at 6, 12, and 26 weeks, and pooled difference in mean change between groups*

	6 weeks (73 placebo, 75 physio)		12 weeks (72 placebo, 74 physio)		26 weeks (70 placebo, 74 physio)		Across all times	
Outcome	Mean ± SD change†	Difference in mean change between groups (95% CI); P‡	Mean ± SD change	Difference in mean change between groups (95% CI); P	Mean ± SD change	Difference in mean change between groups (95% CI); P	P for the interaction	Pooled difference in mean change between groups (95% CI); P§
SPADI		−0.6 (−7.0, 5.7); 0.841		−3.2 (−9.3, 2.9); 0.302		−1.7 (−8.3, 5.0); 0.621	0.228	−1.8 (−7.4, 3.8); 0.536
Placebo	38.5 ± 23.5		39.3 ± 22.0		42.4 ± 22.8			
Physio	38.0 ± 20.4		41.4 ± 20.9		40.0 ± 21.8			
Overall pain		0.02 (−0.7, 0.6); 0.941		−0.2 (−0.8, 0.5); 0.634		−0.11 (−0.9, 0.6); 0.750	0.913	−0.12 (−0.7, 0.4); 0.666
Placebo	−3.4 ± 2.2		−3.2 ± 2.4		−3.6 ± 2.6			
Physio	−3.4 ± 2.1		−3.4 ± 2.4		−3.5 ± 2.5			
Night pain		−0.13 (−0.8, 0.6); 0.710		−0.3 (−1.0, 0.4); 0.345		0.4 (−1.2, 0.3); 0.251	0.766	−0.31 (−0.9, 0.3); 0.318
Placebo	−3.6 ± 2.5		−3.5 ± 2.5		−3.6 ± 2.5			
Physio	−3.7 ± 2.9		−3.8 ± 3.0		−3.9 ± 3.2			
Pain with use		0.09 (−0.6, 0.8); 0.795		0.02 (−0.8, 0.7); 0.951		0.01 (−0.8, 0.8); 0.977	0.899	0.002 (−0.6, 0.6); 0.995
Placebo	−4.4 ± 2.7		−4.2 ± 2.9		−4.5 ± 2.9			
Physio	−4.2 ± 2.3		−4.1 ± 2.4		−4.4 ± 3.0			
Pain at rest		0.26 (−0.2, 0.7); 0.264		−0.16 (−0.7, 0.3); 0.517		−0.23 (−0.8, 0.3); 0.400	0.159	0.02 (−0.4, 0.4); 0.922
Placebo	−2.2 ± 2.3		−2.0 ± 2.2		−1.9 ± 2.4			
Physio	−1.7 ± 2.2		−2.0 ± 2.4		−2.0 ± 2.5			
Active TSA		13.2 (4.9, 21.4); 0.002		12.4 (3.9, 20.8); 0.005		7.0 (−2.2, 16.1); 0.133	0.249	10.6 (3.1, 18.1); 0.006
Placebo	36.0 ± 26.2		40.4 ± 29.3		48.6 ± 32.3			
Physio	49.1 ± 29.0		52.8 ± 28.9		55.9 ± 31.1			
Active TSF		10.0 (4.5, 15.6); < 0.0001		9.5 (2.9, 16.0); 0.005		6.4 (−0.4, 13.3); 0.064	0.292	8.6 (3.2, 14.0); 0.002
Placebo	28.1 ± 19.3		29.7 ± 23.6		36.2 ± 26.7			
Physio	37.2 ± 19.9		38.3 ± 21.9		41.8 ± 23.4			
Active ERN		9.3 (4.0, 14.5); 0.001		5.8 (0.1, 11.6); 0.045		5.3 (−0.3, 10.9); 0.064	0.094	7.0 (2.2, 11.8); 0.004
Placebo	16.2 ± 15.8		21.4 ± 17.9		25.9 ± 17.9			
Physio	25.3 ± 16.7		31.0 ± 16.9		31.0 ± 16.9			
HBB		−5.2 (−8.0, 2.4); < 0.0001		−5.3 (−8.2, −2.4); < 0.0001		−5.4 (−8.7, −2.1); 0.001	0.965	−5.4 (−8.0, −2.7); < 0.0001
Placebo	−13.1 ± 9.0		−14.8 ± 9.9		−17.4 ± 11.9			
Physio	−18.2 ± 9.5		−20.1 ± 10.0		−22.8 ± 11.6			
AQoL		0.004 (−0.04, 0.05); 0.865		0.017 (−0.03, 0.07); 0.495		0.020 (−0.03, 0.07); 0.446	0.729	0.015 (−0.03, 0.06); 0.510
Placebo	0.12 ± 0.16		0.11 ± 0.18		0.15 ± 0.18			
Physio	0.12 ± 0.17		0.12 ± 0.18		0.16 ± 0.19			
SF-36 Me		0.55 (−2.1, 3.2); 0.687		2.3 (−0.9, 5.5); 0.153		0.2 (−2.9, 3.4); 0.889	0.145	0.96 (−2.0, 3.9); 0.522
Placebo	13.2 ± 12.8		12.8 ± 12.7		13.7 ± 11.2			
Physio	12.4 ± 11.6		14.0 ± 11.9		13.3 ± 12.2			
SF-36 Ph		1.4 (−3.1, 6.0); 0.531		0.16 (−2.6, 2.9); 0.910		0.72 (−2.3, 3.7); 0.637	0.867	0.61 (−1.9, 3.1); 0.630
Placebo	8.3 ± 12.3		9.0 ± 12.1		9.4 ± 11.5			
Physio	7.8 ± 10.9		8.1 ± 11.0		9.4 ± 12.4			

* SPADI = Shoulder Pain and Disability Index; AQoL = Assessment of Quality of Life; SF-36 = Short Form 36 Health Survey; physio = physiotherapy; 95% CI = 95% confidence interval; TSA = total shoulder abduction; TSF = total shoulder flexion; ERN = external rotation in neutral; HBB = hand behind back; SF-36 Me = Short Form 36 mental function; SF-36 Ph = Short Form 36 physical function.
† Positive change indicates improvement except for pain measures and HBB where negative change indicates improvement.
‡ Positive difference in mean change indicates active treatment group improved more than placebo group.
§ Presence of interaction between treatment and time (i.e., assessment of whether the effect of treatment changed over time) was tested and found to be not significant at the 5% level.

Table 3. Participant- and rater-assessed perceived improvement compared with baseline according to treatment group at 6, 12, and 26 weeks*

			Success, much improved and/or completely better		Across all times	
	Physiotherapy	Placebo	Relative risk (95% CI)	*P*	Pooled relative risk (95% CI)	*P*
Participant-assessed perceived improvement					1.4 (1.1, 1.7)†	0.002†
6 weeks			1.4 (1.1, 1.8)	0.016		
Failure, marked worsening	0	0				
Moderate worsening	0	1 (1.4)				
No change, not much different	3 (4.0)	6 (8.2)				
Moderate improvement	16 (21.3)	25 (34.3)				
Success, much improved, and/or completely recovered	56 (74.7)	41 (56.2)				
12 weeks			1.4 (1.1, 1.9)	0.007		
Failure, marked worsening	0	0				
Moderate worsening	1 (1.4)	2 (2.8)				
No change, not much different	2 (2.7)	5 (6.9)				
Moderate improvement	15 (20.3)	26 (36.1)				
Success, much improved, and/or completely recovered	56 (75.7)	39 (54.2)				
26 weeks			1.3 (1.1, 1.7)	0.014		
Failure, marked worsening	1 (1.4)	1 (1.4)				
Moderate worsening	2 (2.7)	3 (4.3)				
No change, not much different	2 (2.7)	3 (4.3)				
Moderate improvement	11 (14.9)	20 (28.6)				
Success, much improved, and/or completely recovered	58 (78.4)	43 (61.4)				
Rater-assessed perceived improvement					1.4 (1.1, 1.65)‡	0.002‡
6 weeks			1.4 (1.1, 1.8)	0.006		
Marked worsening	0	1 (1.4)				
Moderate worsening	0	2 (2.7)				
Same	4 (5.3)	12 (16.2)				
Moderate improvement	17 (22.7)	23 (31.0)				
Marked improvement	54 (72.0)	36 (49.0)				
12 weeks			1.4 (1.1, 1.8)	0.006		
Marked worsening	2 (2.7)	1 (1.4)				
Moderate worsening	1 (1.4)	4 (5.6)				
Same	3 (4.0)	6 (8.3)				
Moderate improvement	13 (17.6)	25 (34.7)				
Marked improvement	55 (74.3)	36 (50.0)				
26 weeks			1.3 (1.0, 1.6)	0.019		
Marked worsening	1 (1.4)	4 (5.6)				
Moderate worsening	2 (2.7)	4 (5.6)				
Same	3 (4.0)	4 (5.6)				
Moderate improvement	12 (16.2)	20 (27.8)				
Marked improvement	56 (75.7)	40 (55.6)				

* Values are the number (percentage) unless otherwise indicated. A successful outcome defined a priori as much improved and/or completely recovered. 95% CI = 95% confidence interval.
† *P* value for the interaction 0.850.
‡ *P* value for the interaction 0.773.

Economic analysis. The monthly health care costs for 6 months for the physiotherapy group were $40 AUD higher than for the placebo group (Table 4), suggesting that the average monthly cost of the physiotherapy over 6 months ($66 AUD) was offset to some extent by some health care cost savings, but there was no significant difference in the health care costs between the 2 groups. Difference in monthly nonhealth care cost favored the physiotherapy group ($14.6 AUD), largely due to work absence costs that outweighed the travel and time costs to visit the physiotherapist, but confidence intervals were wide (95% CI −195.8, 166.8).

Overall, the intervention had a direct cost of $400 AUD per patient but there was some offsetting reduction in health care and nonhealth care costs that reduced the net cost ($136.8 AUD over the 6 months or $22.8 AUD per

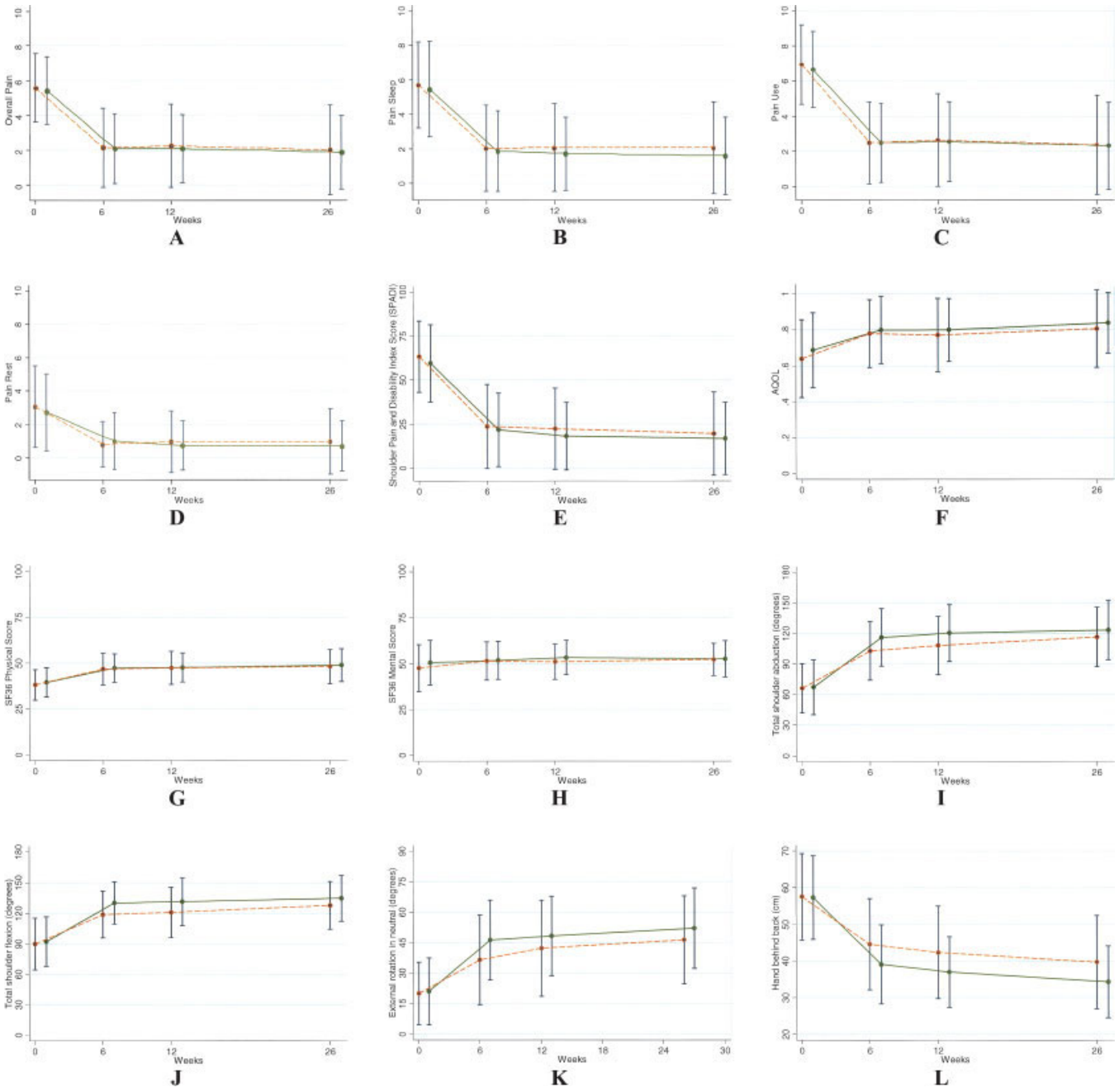

Figure 2. Mean (95% confidence intervals) for the physiotherapy and placebo groups at baseline, 6, 12, and 26 weeks for **A,** overall pain, **B,** pain at night while sleeping, **C,** activity-related pain, **D,** pain at rest, **E,** Shoulder Pain and Disability Index (SPADI), **F,** Assessment of Quality of Life (AQoL), **G,** Short Form 36 (SF-36) physical function score, **H,** SF-36 mental function score, **I,** range of active total shoulder abduction, **J,** range of total shoulder flexion, **K,** external rotation in neutral, and **L,** hand behind back. —•— = physiotherapy; ----○---- = placebo.

month) (Table 4). However, there is considerable uncertainty surrounding the size of health care and other costs and we cannot be confident that there were significant cost offsets. There was no significant additional gain in measured quality of life for those who received physiotherapy compared with the control group (Table 2).

DISCUSSION

We found no additional benefits of an active physiotherapy program consisting of manual techniques and directed exercises for adhesive capsulitis compared with arthrographic joint distension with saline and steroids alone in terms of pain, function, or quality of life. However, we did observe additional sustained benefits in terms of greater active range of shoulder movement and participant-perceived improvement for at least 6 months. The physiotherapy intervention tested in this trial is in keeping with usual practice and was associated with few adverse effects.

The lack of benefits of an active physiotherapy program in terms of pain, function, or quality of life may reflect the

Table 4. Cost per patient per month (6 months) for placebo and physiotherapy group by cost category and difference in total cost per patient per month for placebo and physiotherapy group*

	Physiotherapy (440 observations)	Placebo (425 observations)†	Difference (physiotherapy minus placebo)
Cost per patient per month (6 months)			
Doctor costs	43.3	58.5	
Pharmaceuticals	31.7	39.2	
Allied health	18.3	21.1	
Investigations	13.0	19.4	
Home assistance	1.7	0.6	
Work absentee‡	146.5	177.9	
Time§	5.9	0	
Travel¶	5.2	0	
Physiotherapy#	64.9	0	
Total costs per patient per month, mean (95% CI)			
Total health cost	174.5 (151.8, 197.2)	134.2 (89.4, 179.1)	40.2 (−10.1, 90.5)
Total nonhealth cost	163.9 (40.3, 287.5)	177.9 (45.9, 311.1)	−14.6 (−195.8, 166.8)
Total cost	336.8 (210.6, 463.0)	314.0 (158.5, 469.5)	22.8 (−177.5, 223.1)

* Values are the mean in Australian dollars (AUD) unless otherwise indicated. No inpatient episodes were clinically relevant to the shoulder. Cost per month and confidence intervals estimated using a generalized linear model with a gamma distribution and a log link with robust standard errors calculated by allowing for clustering within patients from repeated monthly measure. Health costs exclude inpatient hospital costs unrelated to the shoulder. 95% CI = 95% confidence interval.
† Number of patient months.
‡ Time lost from work was valued at the age-specific average wage rate in Victoria.
§ The value of time was taken as the average net earnings of Australian population of approximately $20 AUD per hour.
¶ Cost of travel was estimated as 60c per km in a middle-size car that travels 15 km in 30 minutes in the city. Public transportation was valued at $5.10 AUD per return trip (34).
# Physiotherapists were paid $50 AUD for each of 8 treatments (total cost per patient $400 AUD), similar to the published Medicare Schedule fee for physiotherapy for health service provided to a person who has a chronic and complex condition ($52.85 AUD November 2004).

fact that there was less potential for additional improvement in these outcomes following arthrographic joint distension. For example, mean pain scores for both treatment groups had improved to values of 2 or less by 6 weeks, and this improvement was sustained for the duration of the trial. In contrast, ~20% more participants in the active physiotherapy group reported feeling much improved and/or completely recovered at each time point, and this was accompanied by small but significant improvements in active range of movement also favoring the active group. It may be that the small additional benefits in shoulder movement are clinically important and are not detected by the disability and quality of measures that we used. We previously hypothesized that the SPADI may have a ceiling effect, due to a lack of complex activities of daily living items (13). For example, items include basic activities of daily living such as washing hair and dressing but do not include more complex activities such as sporting and recreational items. Similarly, in a previous trial of oral steroids for adhesive capsulitis, only the bodily pain subscale of the SF-36 detected a benefit of prednisolone over placebo at 3 weeks despite large, clinically significant benefits observed for other outcomes including pain, function, and range of movement (29). This finding suggests that generic measures of quality of life such as the SF-36 and AQoL may not be useful outcomes to measure in clinical trials of interventions for adhesive capsulitis.

We must conclude that, on the basis of measured incremental cost per extra QALY, physiotherapy following arthrographic joint distension is not cost-effective. However, as discussed, the measures of quality of life used in the study may not adequately capture all of the benefits of the intervention. If a reduction in time with restricted shoulder movements accompanied by greater perceived recovery that is sustained for 6 months following arthrographic joint distension is worth at least $400 AUD, this intervention could be cost-effective. For one additional patient to feel much improved and/or completely recovered requires treatment of only 5 patients (i.e., number needed to treat = 5) at a cost of $2,000 AUD, suggesting that this could be an appropriate use of health care resources.

Treating adhesive capsulitis with a combination of arthrographic joint distension and corticosteroid injection followed by physical therapy was first described by Andren and Lundberg in 1965 (30). Our findings are in keeping with the results from 2 previous randomized controlled trials that have evaluated the effects of physiotherapy combined with either corticosteroid injection (31) or joint distension or manipulation in adhesive capsulitis (32). In the first trial, while supervised physiotherapy alone was found to be of limited efficacy compared with placebo, when combined with corticosteroid injection it resulted in faster improvement in shoulder movement than corticosteroid injection alone (31). The second trial compared physiotherapy with combinations of physiotherapy and either manipulation or joint distension and also reported significant differences favoring the combination groups, although the physiotherapy intervention was not described (32). A third trial found no differences in short-term benefit between a combination of physiotherapy and corticosteroid injection

compared with either intervention alone, although the physiotherapy intervention in this trial was reported to mainly comprise mobilization (33).

The high costs to society associated with sick leave and disability due to adhesive capsulitis indicate that there is a clear need to determine the most cost-effective interventions for this disorder. The results of this trial verify the beneficial effects of arthrographic joint distension with saline and steroids for adhesive capsulitis found in our previous trial (13) and recent trials have also reported short-term benefits of intraarticular steroid injections (8,31), prednisolone (29), and additional benefits of an active physiotherapy program (31). Further trials are now needed to confirm the beneficial effects of the studied interventions and to determine whether other sequential or combination treatments may result in even better outcomes.

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AUTHOR CONTRIBUTIONS

Dr. Buchbinder had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study design. Buchbinder, Green, Forbes, Bennell.
Acquisition of data. Buchbinder, Youd, Bell, Wright.
Analysis and interpretation of data. Buchbinder, Youd, Stein, Forbes, Harris.
Manuscript preparation. Buchbinder, Youd, Green, Stein, Forbes, Harris, Bennell, Bell, Wright.
Statistical analysis. Buchbinder, Stein, Forbes, Harris.

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