Research Article

Comparative Effects of Interferential Therapy and Therapeutic Ultrasound, Each Combined with Codman Exercises, Versus Codman Exercises Alone in Adhesive Capsulitis: a Three-Arm Clinical Study

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Abstract

Background: Adhesive capsulitis is characterised by progressive shoulder pain and restriction of active and passive glenohumeral movement, often interfering with daily activities. Exercise-based rehabilitation is commonly used, and physical agents such as interferential therapy (IFT) and therapeutic ultrasound (US) are sometimes added to an exercise programme. Evidence for the additional benefit of these modalities remains uncertain.

Objective: To compare changes in pain intensity and shoulder-related disability following IFT plus Codman exercises, US plus Codman exercises, and Codman exercises alone in people with adhesive capsulitis.

Methods: The source thesis describes a three-arm, parallel-group clinical study conducted at the outpatient department of Dasmesh College of Physiotherapy, Faridkot. Sixty participants (20 per group), aged approximately 40–60 years, were included. According to the detailed intervention methods, Group A received therapeutic US plus Codman exercises, Group B received IFT plus Codman exercises, and Group C received Codman exercises alone. Pain was measured using the Visual Analogue Scale (VAS), and shoulder pain and disability were measured using the Shoulder Pain and Disability Index (SPADI), at baseline and after six weeks. The 60-participant master chart in the thesis was re-entered and descriptive statistics and inferential analyses were recalculated.

Results: In Group-A and Group B (Experimental Group) and Group-C (Control Group), all data was expressed as mean ±, SD and was statistically analysed using 't' test to determine the statistical difference among the parameters at 0.001% level of significance.

Conclusion: All three groups showed lower mean pain and SPADI scores at follow-up, with the largest numerical improvement in the IFT-plus-exercise group. These findings are preliminary. Inconsistencies in group labelling and ultrasound dose within the thesis, absence of documented ethics approval and trial registration details, and limited reporting of allocation and follow-up procedures must be resolved before journal submission.

Keywords: adhesive capsulitis; frozen shoulder; interferential therapy; therapeutic ultrasound; Codman exercises; Visual Analogue Scale; Shoulder Pain and Disability Index.

INTRODUCTION

Adhesive capsulitis, commonly referred to as frozen shoulder, is a painful condition involving progressive restriction of both active and passive glenohumeral movement. The limitation is typically present in more than one direction and is often particularly evident in external rotation. The condition may arise without a clearly identifiable precipitating event (primary adhesive capsulitis) or occur in association with trauma, surgery, or other conditions (secondary adhesive capsulitis). Capsular fibrosis, synovial inflammation and contracture contribute to pain and loss of shoulder mobility (Neviaser and Neviaser, 2011; Le et al., 2017).

Adhesive capsulitis is most frequently reported in adults in middle age and is associated with diabetes mellitus and thyroid disease. The clinical course is often described in phases, although the duration and boundaries of these phases vary between individuals. Pain, night discomfort, stiffness and difficulty with activities such as dressing, grooming, reaching overhead and placing the hand behind the back may substantially affect function and quality of life (Kelley et al., 2013; Le et al., 2017).

Physiotherapy management commonly includes education, graded mobility exercises, stretching and functional rehabilitation, with the intensity of treatment adjusted to irritability and stage of presentation. Codman's pendulum exercises are frequently prescribed as a gentle movement strategy. They are performed with the trunk supported in forward inclination while the affected arm hangs relaxed, allowing small pendular movements generated primarily by body movement rather than active shoulder muscle effort.

Therapeutic ultrasound is a mechanical energy modality used in physiotherapy. It is proposed to produce thermal and non- thermal tissue effects depending on frequency, intensity, duty cycle and application technique. Continuous ultrasound is generally used when a thermal effect is intended, whereas pulsed application reduces average energy delivery. However, biological plausibility does not necessarily translate into clinically meaningful

benefit. Dogru, Basaran and Sarpel (2008) compared therapeutic ultrasound with sham ultrasound, with both groups receiving heat and exercise, and found improvements over time in both groups but no clear between-group advantage for pain or SPADI.

Interferential therapy is an electrotherapy modality in which medium-frequency alternating currents are applied so that amplitude-modulated stimulation is produced in tissues. It is used clinically with the intention of modulating pain and facilitating participation in exercise. Nevertheless, evidence for interferential current as an adjunct in shoulder disorders is mixed. A randomised trial by van der Heijden et al. (1999) found no additional benefit from interferential electrotherapy or pulsed ultrasound when added to exercise therapy for soft-tissue shoulder disorders. The population in that trial was broader than adhesive capsulitis, so its findings should not be assumed to apply identically to frozen shoulder.

A small comparative study by Gaba, Sethi and Bhardwaj (2020) examined IFT and ultrasound alongside a common manual therapy programme in Grade II frozen shoulder. The authors reported some differences in range-of-motion outcomes but no clear between-group difference in pain and disability. A systematic review and meta-analysis by Sung, Lee and Kim (2022) found that ultrasound used with exercise or other physical modalities may improve pain, while evidence for disability and range-of-motion outcomes remained uncertain.

Given the continued clinical use of these modalities and the mixed evidence, the present study compared IFT plus Codman exercises, ultrasound plus Codman exercises and Codman exercises alone. Pain intensity and shoulder-related disability were evaluated at baseline and after the intervention period.

AIM, OBJECTIVES AND HYPOTHESES

Aim: To compare the effects of interferential therapy and therapeutic ultrasound, each combined with Codman exercises, with Codman exercises alone in patients with adhesive capsulitis.

Objectives:

- To assess changes in pain intensity within each intervention group using the VAS.
- To assess changes in shoulder pain and disability within each group using the SPADI.
- To compare post-treatment pain and SPADI scores among the three groups.
- To examine whether the addition of IFT or therapeutic ultrasound is associated with greater short-term improvement than Codman exercises alone.

Null hypothesis: There is no significant difference in pain intensity or shoulder-related disability among the three treatment groups after the intervention.

Alternative hypothesis: At least one treatment group demonstrates a significant difference in pain intensity or shoulder-related disability compared with the other groups.

MATERIALS AND METHODS

Study design and setting

The thesis describes a three-group parallel clinical study conducted in the outpatient department of Dasmesh College of Physiotherapy, Faridkot, Punjab, India. The methodology section states that 60 eligible participants were allocated by block randomisation into three equal groups (n=20). The thesis also uses the phrase 'random sampling' in another section. The exact sequence-generation method, block size, allocation concealment and assessor blinding are not reported in the source and should be confirmed from study records.

Participants

The thesis reports 60 participants, including men and women, with a total sample of 31 men and 29 women. Group A included 10 men and 10 women (mean age 50.80±5.396 years); Group B included 11 men and 9 women (48.75±6.664 years); and Group C included 10 men and 10 women (52.10±6.155 years). The master chart includes ages from 40 to 61 years. The stated eligibility range is 40–60 years; one Group C record lists age 61 and requires verification.

Eligibility criteria

Inclusion criteria recorded in the thesis were: age 40–60 years; loss of active and passive glenohumeral range of motion; pain with rapid or unguarded movement; pain at end range in all directions; a capsular pattern of restriction described as lateral rotation greater than abduction greater than internal rotation; both sexes; diabetic or non-diabetic status; and involvement of either dominant or non-dominant side.

Exclusion criteria were rheumatoid arthritis, fracture of the shoulder complex, clinically diagnosed rotator cuff rupture, shoulder tendon calcification, and neurological deficit affecting normal daily shoulder function.

Intervention groups

The detailed methodology and modality protocols identify Group A as ultrasound plus Codman exercises, Group B as IFT plus Codman exercises, and Group C as Codman exercises alone. This assignment is used throughout the present manuscript because it is repeated in the methodology and intervention-protocol sections and is consistent with the thesis conclusion that Group B (IFT) showed the largest improvement. However, the thesis

abstract labels Group A as IFT and Group B as ultrasound. The original group allocation sheet and case records must be checked to confirm the labels before submission.

Group A: therapeutic ultrasound plus Codman exercises

Participants in Group A (n=20) received continuous therapeutic ultrasound over the anterior and posterior aspects of the glenohumeral capsule, in addition to Codman exercises. The detailed protocol specifies 3 MHz frequency and an intensity of 1.5 W/cm², with the applicator moved in circular movements at approximately 3 cm/s. The methods section reports eight minutes in total, approximately three minutes over each side of the joint with the remaining time not clearly specified. The abstract reports six minutes. This treatment-time discrepancy must be reconciled against the original treatment records.

Group B: interferential therapy plus Codman exercises

Participants in Group B (n=20) received IFT followed by Codman exercises. Four electrodes were placed around the affected shoulder in a quadripolar arrangement, with the channels positioned to intersect around the symptomatic region. The reported carrier frequency was 4000 Hz, with an amplitude-modulated frequency of 200 Hz. Treatment was delivered for 10 minutes, with intensity increased to a comfortable level according to participant tolerance. The thesis describes electrode placement around the anterior and posterior tender regions and near the inferior margin of the deltoid.

Group C: Codman exercises alone

Participants in Group C (n=20) received Codman exercises without IFT or therapeutic ultrasound. The exercise programme described in the thesis included relaxed pendular movements in circular and anteroposterior directions, assisted shoulder elevation in supine lying, assisted rotation, and finger-walk or wall-climbing exercises. The document states that exercises were to be performed twice daily. It also describes some components as three sessions per day, so the exact home-exercise frequency should be checked against the instructions actually given to participants.

Treatment duration and assessment

The results tables identify the post-intervention assessment as occurring at the sixth week. Therefore, six weeks is used as the reported intervention period in this manuscript. The thesis does not consistently specify the number of supervised sessions per week or the number of sessions actually attended. These details should be retrieved from treatment attendance records. Outcomes were recorded at baseline (day 0) and after six weeks.

Outcome measures

Visual Analogue Scale (VAS): Pain intensity was recorded using a visual analogue scale, conventionally represented by a 100-mm line anchored by 'no pain' and 'worst imaginable pain'. The participant marks the point corresponding to their perceived pain, and the distance from the no-pain anchor is measured. Huskisson (1974) described the VAS as a sensitive method for pain measurement. The thesis data table presents VAS values on a 0–10 scale; the exact form administered should be stated in the final submission.

Shoulder Pain and Disability Index (SPADI): The SPADI is a self-administered, shoulder-specific questionnaire containing 13 items divided into pain and disability subscales. Scores are converted to a 0–100 scale, with higher scores indicating greater pain and disability. The instrument was developed by Roach et al. (1991). The thesis reports total SPADI values and does not provide separate pain and disability subscale results.

Statistical analysis

The thesis states that SPSS was used and reports descriptive statistics, independent-samples t-tests, paired t-tests and one-way ANOVA. The participant-level master chart (20 records per group) was available in the submitted thesis and was used to verify the reported means and standard deviations. The reported baseline and post-treatment one-way ANOVA values were recalculated and matched the master-chart data. An additional baseline-adjusted analysis of covariance (ANCOVA), with post-treatment score as the dependent variable and baseline score as a covariate, was conducted as an exploratory reanalysis for this manuscript. This ANCOVA was not identified as a prespecified analysis in the thesis. Two-sided p values below 0.05 were considered statistically significant. Confidence intervals are reported where calculated.

RESULTS

All 60 participant records were present in the master chart, with 20 participants in each group. The descriptive values reproduced in the thesis tables were verified against the participant-level data.

Participant characteristics

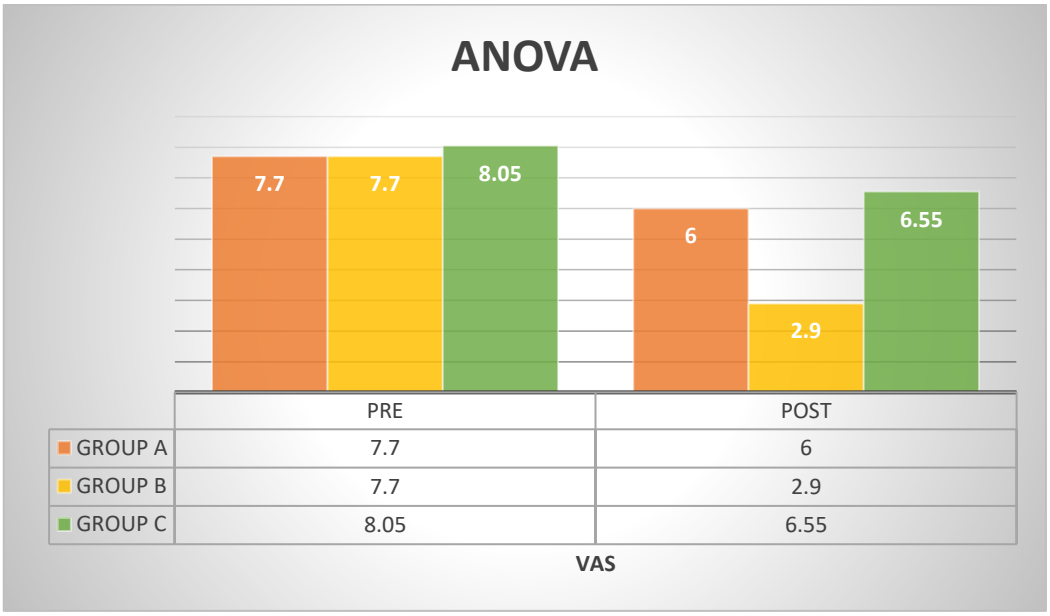
Group	n	Age, mean ± SD (years)	Male, n	Female, n

A: US + Codman	20	50.80 ± 5.40	10	10
B: IFT + Codman	20	48.75 ± 6.66	11	9
C: Codman only	20	52.10 ± 6.16	10	10
Total	60	50.55 ± 6.15	31	29

The age distribution did not differ significantly across groups on one-way ANOVA (F=1.536, p=0.224). Baseline VAS and SPADI scores also showed no statistically significant between-group differences.

ANOVA Comparison of Pre and post treatment of VAS score between Group A, Group B and Group C.

	VAS					
ANOVA	**VAS PRE**			**VAS POST**		
	GROUP A	**GROUP B**	**GROUP C**	**GROUP A**	**GROUP B**	**GROUP C**
MEAN	**7.70**	**7.70**	**8.05**	**6.00**	**2.90**	**6.55**
S.D.	**1.031**	**1.129**	**0.759**	**0.858**	**1.021**	**0.686**
NUMBER	**20**	**20**	**20**	**20**	**20**	**20**
MAX.	**9**	**9**	**9**	**7**	**5**	**8**
MIN.	**6**	**6**	**7**	**5**	**2**	**6**
Df	**59**			**59**		
F-TEST	**0.841**			**103.267**		
P-VALUE	**0.437**			**<0.001**		
RESULT	**Not-Significant**			**Significant**		
TURKEY'S METHOD pairwise com.	**v/s B**	**v/s C**	**v/s A**	**v/s B**	**v/s C**	**v/s A**
Result with mean diff.	**0.000 N/Sig.**	**0.35 N/Sig.**	**0.35 N/Sig.**	**3.10 Sig.**	**3.65 Sig.**	**0.550 N/Sig.**



Graphical representation of Pre and post treatment of VAS score between Group A, Group B and Group C.

Pain intensity (VAS)

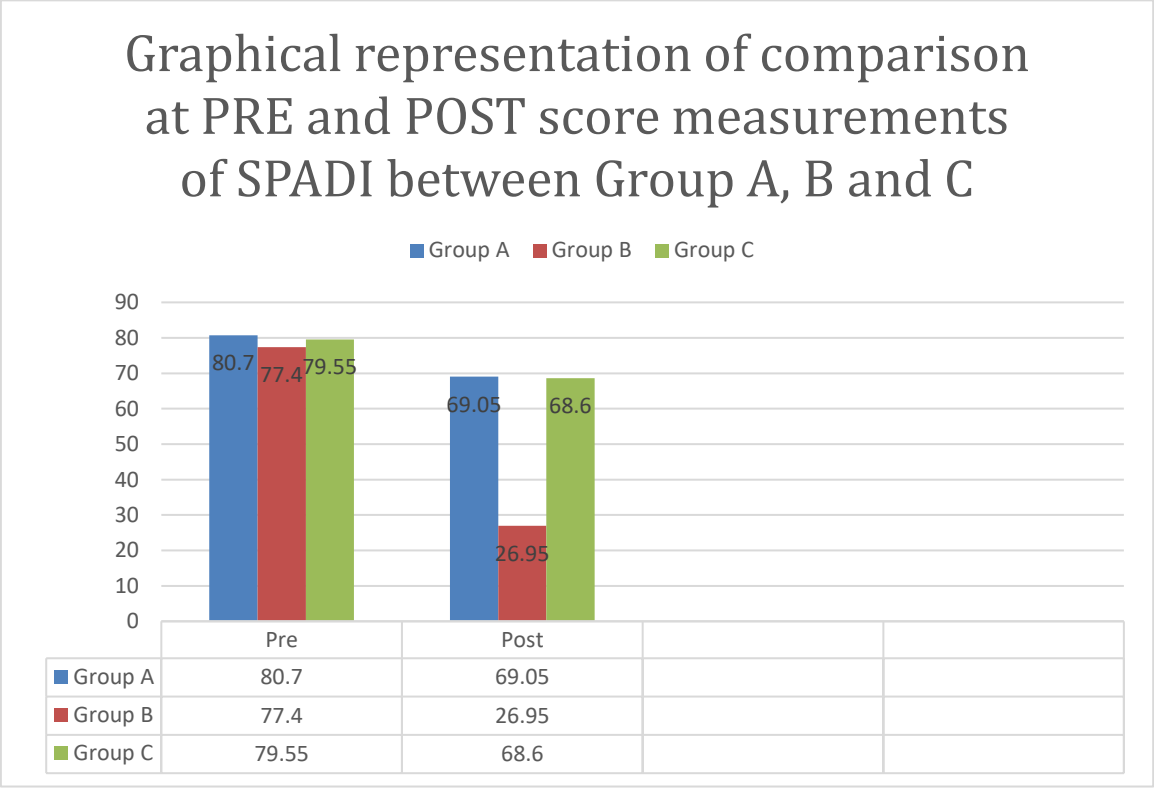
Group	Baseline mean ± SD	Post-treatment mean ± SD	Mean reduction
A	7.70 ± 1.031	6.00 ± 0.858	1.70
B	7.70 ± 1.129	2.90 ± 1.021	4.80
C	8.05 ± 0.759	6.55 ± 0.686	1.50

Baseline VAS values were similar across groups (F=0.841, p=0.437). At six weeks, the overall between-group difference was statistically significant (F=103.267, p<0.001). Group B (IFT plus Codman exercises) had the lowest post-treatment mean VAS score (2.90±1.021), compared with Group A (6.00±0.858) and Group C (6.55±0.686). Within-group paired comparisons were statistically significant in all groups (Group A: t=5.508; Group B: t=14.236; Group C: t=6.708; all p<0.001).

Shoulder pain and disability (SPADI)

Group	Baseline mean ± SD	Post-treatment mean ± SD	Mean reduction
A	80.70 ± 6.392	69.05 ± 5.671	11.65
B	77.40 ± 8.864	26.95 ± 6.436	50.45
C	79.55 ± 6.661	68.60 ± 6.605	10.95

Baseline SPADI values did not differ significantly across groups (F=1.028, p=0.364). At six weeks, the overall between-group difference was statistically significant (F=299.274, p<0.001). Group B showed the lowest post-treatment SPADI score (26.95±6.436), compared with Group A (69.05±5.671) and Group C (68.60±6.605). Within-group paired comparisons were statistically significant in all groups (Group A: t=4.737; Group B: t=17.426; Group C: t=5.558; all p<0.001).



Graphical representation of comparison at PRE and POST score measurements of SPADI between Group A,B and C.

Baseline-adjusted exploratory analysis

Outcome	ANCOVA group effect	p value	Baseline covariate p value
VAS	F(2,56)=100.39	<0.001	0.982
SPADI	F(2,56)=325.48	<0.001	0.019

In the exploratory ANCOVA, treatment group remained significantly associated with post-treatment VAS and SPADI after adjustment for baseline score. Relative to Group A, the adjusted Group B difference was −3.10 VAS points (95% CI −3.65 to −2.55) and −42.96 SPADI points (95% CI −46.83 to −39.09). Relative to Group C, the adjusted Group B difference was −3.65 VAS points (95% CI −4.21 to −3.09) and −42.21 SPADI points (95% CI −46.04 to −38.38). These analyses are exploratory and should be reviewed by a statistician before submission, including model assumptions and multiplicity handling.

Summary of findings

The master-chart data consistently show the largest numerical reduction in both pain and shoulder-related disability in Group B, which the detailed intervention protocol identifies as IFT plus Codman exercises. The difference between Group A (ultrasound plus exercise) and Group C (exercise alone) was comparatively small for SPADI; the source thesis reports no significant post-treatment SPADI difference between these two groups.

DISCUSSION

The present three-arm study compared IFT plus Codman exercises, therapeutic ultrasound plus Codman exercises, and Codman exercises alone in people with adhesive capsulitis. The master-chart data showed improvement in mean VAS and SPADI scores in all three groups over the six-week observation period. The greatest numerical changes occurred in the IFT-plus-exercise group, with mean VAS decreasing by 4.80 points and mean SPADI decreasing by 50.45 points.

The improvement observed in the exercise-only group is consistent with the role of movement-based rehabilitation in the conservative management of adhesive capsulitis. Exercise selection and intensity should be matched to symptom irritability and clinical stage. The clinical practice guideline by Kelley et al. (2013) emphasises assessment of mobility deficits and stage-sensitive intervention, including patient education and appropriately dosed mobility and stretching strategies.

The larger change in Group B suggests that IFT may have provided additional short-term benefit when combined with the exercise programme used in this study. A similar clinical question was addressed by Gaba, Sethi and Bhardwaj (2020), who compared IFT with ultrasound alongside a shared manual therapy programme in Grade II frozen shoulder. Their report described some range-of-motion advantages with IFT but did not identify a clear between-group difference in pain and disability. Differences in sample size, treatment protocols, co-interventions and outcomes make direct comparison difficult.

The results should also be considered alongside the broader evidence on electrotherapy for shoulder disorders. In a randomised controlled trial, van der Heijden et al. (1999) found no additional benefit from interferential electrotherapy or pulsed ultrasound when added to exercise therapy for soft-tissue shoulder disorders. That study included a broader shoulder population rather than only adhesive capsulitis. Its findings nevertheless caution against assuming that a physical agent will consistently add clinically important benefit to exercise.

For therapeutic ultrasound, Dogru, Basaran and Sarpel (2008) compared active and sham ultrasound in adhesive capsulitis while both groups received superficial heat and an exercise programme. Although both groups improved, the investigators found no relevant additional benefit of ultrasound for pain, SPADI or general health outcomes, despite some between-group differences in selected range-of-motion changes. Sung, Lee and Kim (2022) subsequently reported that ultrasound combined with exercise or other modalities may improve pain, while its effect on disability and range of motion remained uncertain. The present study's smaller numerical improvement in the ultrasound group compared with the exercise-only group is therefore not inconsistent with the uncertainty in the existing evidence.

The observed changes in Group B are substantial, particularly for SPADI. The size of the reported difference warrants careful verification rather than an automatic assumption of treatment superiority. Potential explanations include the effect of IFT, differences in adherence or treatment exposure, unmeasured baseline characteristics, expectation effects, measurement or data-entry issues, and the absence of assessor blinding. The source thesis does not provide enough information to distinguish among these possibilities.

The present study also did not measure shoulder range of motion, despite the stated objective of assessing movement. The primary reported outcomes were pain and SPADI. Consequently, conclusions should be limited

to these two measures and should not claim that IFT improved range of motion unless verified ROM data are made available. Likewise, no long-term follow-up was reported, so durability of improvement cannot be inferred.

LIMITATIONS

1. The study was conducted over a relatively short period, and no long-term follow-up was reported.
2. Physical, emotional and social factors that may influence pain and disability were not assessed.
3. The thesis reports that only the dominant-side shoulder involvement was considered; this restriction should be verified against the master chart and case records.
4. Ergonomic or activity-modification advice was not provided or documented.
5. Home exercises could not be supervised at every session, and adherence was not quantified.
6. The exact supervised treatment frequency, number of attended sessions and intervention fidelity were not clearly documented.
7. The thesis contains conflicting group labels: its abstract assigns IFT to Group A and ultrasound to Group B, whereas the detailed methodology and protocols assign ultrasound to Group A and IFT to Group B.
8. The ultrasound application duration differs between the abstract (six minutes) and detailed protocol (eight minutes).
9. The stated age criterion is 40–60 years, but one master-chart entry lists a participant aged 61 years.
10. Random sequence generation, allocation concealment, assessor blinding, ethics approval, trial registration and adverse-event reporting are not documented in the available thesis text.
11. Only VAS and total SPADI were reported; separate SPADI subscales and objective shoulder range-of-motion measurements were not available in the results tables.

CONCLUSION

All three groups demonstrated reductions in mean pain and SPADI scores after the six-week intervention period. The largest numerical improvement was observed in the group identified in the detailed methodology as receiving interferential therapy combined with Codman exercises. The ultrasound-plus-exercise and exercise-only groups also improved, although to a lesser extent in the reported data. These findings suggest a possible short-term adjunctive benefit of IFT in this sample; however, they do not establish definitive superiority. The group-allocation discrepancy, ultrasound-dose inconsistency and missing trial-reporting details must be resolved, and the findings should be confirmed in a larger, prospectively registered, rigorously reported randomised trial.

REFERENCES

1. Albornoz-Cabello, M., Sánchez-Santos, J.A., Melero-Suárez, R., Marcos Heredia-Rizo, A. and Espejo-Antúnez, L. (2019) 'Effects of adding interferential therapy electro-massage to usual care after surgery in subacromial pain syndrome: a randomized clinical trial', Journal of Clinical Medicine, 8(2), article 175. https://doi.org/10.3390/jcm8020175. [This study concerns postoperative subacromial pain syndrome, not adhesive capsulitis specifically.]
2. Dogru, H., Basaran, S. and Sarpel, T. (2008) 'Effectiveness of therapeutic ultrasound in adhesive capsulitis', Joint Bone Spine, 75(4), pp. 445–450. https://doi.org/10.1016/j.jbspin.2007.07.016.
3. Gaba, E., Sethi, J. and Bhardwaj, M. (2020) 'Effect of interferential therapy over ultrasound therapy with common protocol of manual therapy in Grade-II frozen shoulder', Journal of Exercise Science and Physiotherapy, 16(2), pp. 23–31. https://doi.org/10.18376/jesp/2020/v16/i2/157454.
4. Huskisson, E.C. (1974) 'Measurement of pain', The Lancet, 2(7889), pp. 1127–1131. https://doi.org/10.1016/S0140-6736(74)90884-8.
5. Kelley, M.J., Shaffer, M.A., Kuhn, J.E., Michener, L.A., Seitz, A.L., Uhl, T.L., Godges, J.J. and McClure, P.W. (2013) 'Shoulder pain and mobility deficits: adhesive capsulitis', Journal of Orthopaedic & Sports Physical Therapy, 43(5), pp. A1–A31. https://doi.org/10.2519/jospt.2013.0302.
6. Le, H.V., Lee, S.J., Nazarian, A. and Rodriguez, E.K. (2017) 'Adhesive capsulitis of the shoulder: review of pathophysiology and current clinical treatments', Shoulder & Elbow, 9(2), pp. 75–84. https://doi.org/10.1177/1758573216676786.
7. Manske, R.C. and Prohaska, D. (2008) 'Diagnosis and management of adhesive capsulitis', Current Reviews in Musculoskeletal Medicine, 1, pp. 180–189. https://doi.org/10.1007/s12178-008-903 diagnosis. [Verify DOI string against publisher record before submission.]
8. Neviaser, A.S. and Neviaser, R.J. (2011) 'Adhesive capsulitis of the shoulder', Journal of the American Academy of Orthopaedic Surgeons, 19(9), pp. 536–542. https://doi.org/10.5435/00124635-201109000-00004.
9. Roach, K.E., Budiman-Mak, E., Songsiridej, N. and Lertratanakul, Y. (1991) 'Development of a shoulder pain

and disability index', Arthritis Care and Research, 4(4), pp. 143–149. https://doi.org/10.1002/art.1790040403.
10. Katara A, Waghmare M, Kadakia N, Samson S, Minhas R. A case series of treatment of oral mucosal lesions using diode lasers. Scientific Dental Journal. 2021 Jan 1;5(1):47-51.
11. van der Heijden, G.J.M.G., Leffers, P., Wolters, P.J.M.C., Verheijden, J.J.D., van Mameren, H., Houben, J.P., Bouter, L.M. and Knipschild, P.G. (1999) 'No effect of bipolar interferential electrotherapy and pulsed ultrasound for soft tissue shoulder disorders: a randomised controlled trial', Annals of the Rheumatic Diseases, 58(9), pp. 530–540. https://doi.org/10.1136/ard.58.9.530.
12. Schulz, K.F., Altman, D.G. and Moher, D. (2010) 'CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials', BMJ, 340, c332. https://doi.org/10.1136/bmj.c332. [For current reporting, use the 2025 update below.]
13. Hopewell, S., Chan, A.-W., Collins, G.S., Hróbjartsson, A., Moher, D., Schulz, K.F., Tunn, R., Aggarwal, R., Berkwits, M., et al. (2025) 'CONSORT 2025 statement: updated guideline for reporting randomised trials', BMJ, 389, e081123. https://doi.org/10.1136/bmj-2024-081123.