DOI: 10.7860/JCDR/2023/59513.17670

Original Article

Physiotherapy Section

Functional Ability and Quality of Life Status following Manual Therapy and Specific Exercise Conditioning in Subacromial Impingement Syndrome: A Randomised Controlled Study

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ABSTRACT

Introduction: Subacromial Impingement Syndrome (SIS) is a common shoulder problem that leads to considerable functional loss and a decline in Quality of Life (QoL). Conservative treatment is the first line of management, often multimodal where physiotherapy is commonly recommended. But limited information is available regarding the combined effect of various treatments.

Aim: To evaluate the combined effect of manual therapy and specific exercise conditioning in improving function and QoL among patients with SIS and also to compare with the conventional therapy.

Materials and Methods: This single-blinded randomised controlled study was conducted in the rehabilitation center, Sri Ramachandra Institute of Higher Education and Research (SRIHER), Chennai, India, from January 2017 to February 2020. A total of 126 subjects were recruited and randomly allocated into two groups: Group 1 (n=63) received manual therapy and eccentric exercise, Group 2 (n=63) received conventional exercise, spread over three weeks followed by a home program for another nine weeks. Regional and self-rated functional limitations were obtained using the Shoulder Pain and Disability Index (SPADI) and Patient Specific Functional Scale (PSFS) at baseline, after 10 sessions of treatment and follow-up at 12 weeks with other clinical outcomes. A Short Form Health Survey (SF 36) was used to obtain QoL status at baseline and follow-up at 12 weeks. Data were analysed using one-way Analysis of Variance (ANOVA) and unpaired t-test.

Results: The mean age was 45.02±10.30 years and 45.12±11.42 years in groups 1 and 2, respectively. Male to female ratio was 25:21 and 30:21 in groups 1 and 2, respectively. All outcomes improved by three weeks and during follow-up at 12 weeks in both groups (p-value <0.00001 and p-value <0.0005, respectively). However, on between group analysis significant improvement was observed with pain intensity (p-value <0.0005), range (p-value <0.05), external rotator strength (p-value=0.016) and PSFS score (p-value=0.014) by three weeks. External rotator strength (p-value <0.0005), SPADI (p-value <0.0005), PSFS (p-value=0.035), physical (p-value=0.008) and mental (p-value=0.006) cumulative scores of SF 36 had significant improvement in group 1 during follow-up at 12 weeks.

Conclusion: The combined effect of manual therapy and specific exercise conditioning improved regional, self-rated functional ability and QoL among individuals with SIS.

Keywords: Eccentric exercises, Physiotherapy, Shoulder function, Shoulder pain

INTRODUCTION

Shoulder pain is very common with an estimated prevalence of 7% to 34% where Subacromial Impingement Syndrome (SIS) occupies 44% to 65% of all occurrences [1,2]. SIS encloses a variety of problems in subacromial space involving the rotator cuff tendons or bursa causing reduction in space, tendinosis, minimal tear and bursitis [3,4]. The causative factors are both intrinsic and extrinsic in nature and treatment outcome was satisfying in the absence of major structural damage [5].

The significant clinical manifestation includes insidious pain over anterior or anterolateral arm during elevation and overhead movements with painful arc. These symptoms occur while doing essential daily and work/sport related activities, gradually leading to pain, functional restriction, disability and loss of Quality of Life (QoL) [6]. Conservative treatment is the first line of management, often multimodal where physiotherapy is commonly recommended to show improvement in the clinical outcomes [7]. The main aim of treatment in SIS is to decrease pain, improve glenohumeral/scapulothoracic range of motion, rotator cuff/scapula strength and shoulder function using different treatment interventions [8].

The evidence for including exercise therapy in the management of SIS is growing; pain relief, improved range of motion, and shoulder function have all been reported after varying lengths of treatment [7,9]. It was found to be superior when compared to resting the part, and specific exercises were considered more beneficial than general shoulder exercises [10]. Eccentric exercise is one among the specific exercises found to be beneficial for SIS, given to condition either scapulothoracic or glenohumeral musculature because of their ability to bring greater improvement [10]. These force impairments are found most pronounced in the glenohumeral joint [11]. Hence, specific training of the glenohumeral muscles is highlighted in most of the research [12-15]. Further research is recommended to decide the type, doze and expected outcome for exercise administration, to establish itself as an important component in conservative management [16].

Manual therapy application in SIS is still controversial and is recommended as an adjunct therapy in the initial phase of management [16]. Manual therapy combined with exercises found to reduce pain and improve function in short term and more research is recommended to investigate its effect in different combinations of exercises [17,18]. The manual technique is selected for the identified

impairment with clinical examination, which usually results in mild or no adverse events [19].

Improvement in functional performance and health related QoL are considered as important markers for deciding the success of any intervention. SIS population being a disorder with heightened pain and mobility restrictions leads to decline in daily shoulder function affecting QoL. Hence, patient centered functional measure, psychological and QoL evaluation is recommended as the evidence based assessment of intervention outcome [20].

Manual and exercise therapy are recommended and is beneficial as conservative management for SIS [16,17,21]. There is conflicting support for manual and specific exercise strategy as treatment, in spite of low to moderate quality evidence available substantiating its application, with few studies supporting and stating this combination superior to motor control exercises [19,20,22]. Inclusion and combined effect of manual with eccentric exercise intervention in primary care of SIS was not investigated to a great extent using muscle strength improvements relating it to function and QoL using validated outcome measures. Hence, the aim of current study was to find out the combined effects of manual and eccentric exercise focusing on glenohumeral musculature in improving function and QoL in the management of SIS.

MATERIALS AND METHODS

This single-blinded, randomised controlled study was conducted in the rehabilitation center at Sri Ramachandra Institute of Higher Education and Research (SRIHER), Chennai, India, from January 2017 to February 2020. The study was approved by Institutional Ethics Committee (IEC-NI/16/AUG/35/36) and enrolment was done after explaining the purpose of study and obtaining written informed consent from all the participants.

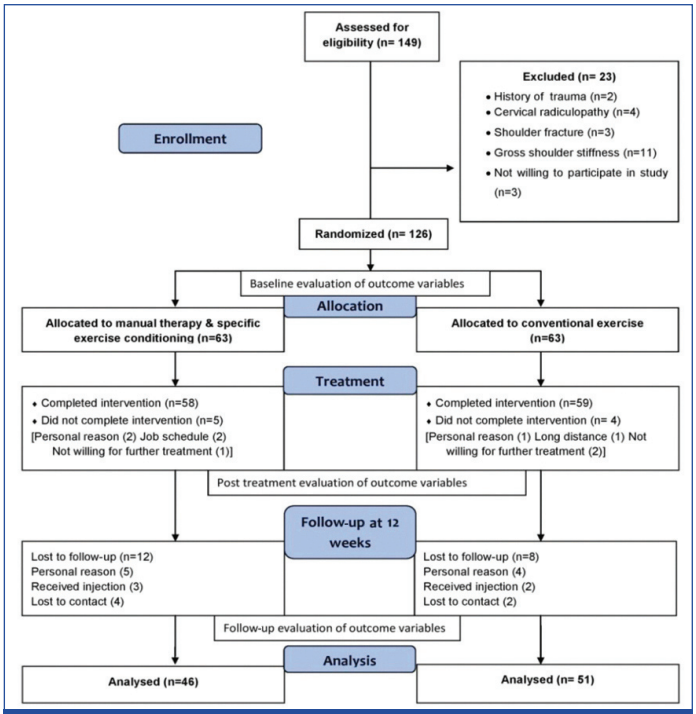
Inclusion criteria: Patients aged >18 years with duration of symptoms within three months and with history of pain located in the proximal lateral aspect of the upper arm/subacromial area and any three of the following clinical sign: (i) positive Neer's impingement sign; (ii) positive Hawkins Kennedy test; (iii) painful arc during elevation; (iv) external rotator lag sign were included in the study [23,24].

Exclusion criteria: Subjects who had cervical referred pain, pain severity score >8 with Numeric Pain Rating Scale (NPRS), gross/set pattern of shoulder range limitation, previous history of similar pain within six months to one year duration, fracture involving shoulder complex, shoulder surgery, polyarthritis, frozen shoulder and fibromyalgia were excluded from the study.

Sample size calculation: Initial screening was done on 149 subjects, 126 participants fulfilled the inclusion criteria were included. A 13 points difference in Shoulder Pain and Disability Index (SPADI) score, as Minimum Detectable Change (MDC) between group with a Standard Deviation (SD) of 20 points, based on previous study results was considered to calculate the sample size [23]. The alpha was set to 0.05, power 80% and 15% dropout resulted in an estimated sample size of 90 participants, 45 per group [25,26]. The sample size estimation was performed with G*power software version 3.1.9.7.

The included subjects were divided into two groups using simple random allocation with a computer-generated randomisation program. The cards containing the sequential numbers and random assignment was folded and placed in a concealed envelope. The participants were then randomly assigned by an investigator or assistant who was not involved in the study, as follows:

- Group 1: Manual therapy with eccentric and specific exercise (n=63) and
- Group 2: Conventional exercise (n=63). The details are presented in the consort flow diagram [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram.

Study Procedure

Treatment was tailored specifically to the impairments identified during initial clinical examination which included: longitudinal caudal in abduction and flexion, passive scapula mobilisation, scapula retraction and manual stretching. Given in 5 to 15 repetitions with 30 seconds sustenance for 20-30 minutes and a total of 10 sessions were given with the same dosage every alternate day.

Specific exercise conditioning: Included (i) Eccentric exercises for the rotator cuff (supraspinatus, infraspinatus, and teres minor)-full can in scapular plane and external rotation in side lying using dumbbell; (ii) Exercises for the scapula stabilisers-scapula setting, shoulder retraction, serratus anterior drill and scapula stabilisation; and (iii) posterior shoulder stretch [27].

Conventional exercises: Includes (i) Concentric shoulder abduction in frontal plane; (ii) Concentric and mobility exercises for shoulder elevation, protraction and retraction; and (iii) stretching for upper trapezius and pectoralis major [27,28]. Concentric exercises were performed in the pain free active range and progressed as tolerated. Fifteen repetitions in three sets mobility/strengthening and stretching with 30-60 seconds hold three times x two times/day for 1-8 weeks and once daily for 9-12 weeks. Initial load 80% of one Repetition Maximum (RM).

The RM assessment was used to identify and standardise the initial resistance for strengthening exercises and the participant began exercise with 80% of 1 RM. During and after exercise performance the subjects were not allowed to experience pain more than 5 points on a 10 point Visual Analogue Scale (VAS) to have additional safety and control in exercise intensity. Subjects in both groups were asked to perform these strengthening/mobilisation activities for 15 repetitions in three sets twice daily and stretching with 30-60 seconds hold three times twice daily.

The subjects in both groups received treatment and supervised exercises for the initial three weeks (3-4 sessions per week), for a total of 10 sessions and were asked to continue the same as Home Exercise Programme (HEP) for another nine weeks. In addition the subjects were asked to maintain an exercise log to monitor the adherence.

The subjects in both groups underwent a standardised musculoskeletal assessment and evaluation prior to treatment, using NPRS to quantify pain [29], single bubble inclinometer for shoulder elevation range [30], hand held dynamometer for abductor and external rotator

muscle strength [31], Shoulder Pain And Disability Index (SPADI) [32], Patient Specific Functional Scale (PSFS) for regional function [33] and the 36-Item Short Form Health Survey questionnaire (SF 36) for Quality of Life (QoL) [34]. The evaluation was done by an evaluator who was blinded to the participant's group allocation. Participants were also blind regarding the allocation.

Single bubble inclinometer: The participant in sitting position asked to elevate the shoulder in scapular plane while the baseline bubble inclinometer was placed on the distal arm proximal to the elbow to measure the available range of motion. Two trials were recorded and their mean value was considered as extend of range [30].

Hand held dynamometer: Isometric strength for shoulder abduction and external rotation was assessed using a Jtech commander power track muscle Hand-Held Dynamometer (HHD) in supine position with shoulder in 60°-90° of abduction and elbow flexed to 90°. The resistance was applied via the HHD perpendicularly just above lateral epicondyle for abduction and over to the distal forearm for external rotation. The subject was asked to match the resistance for five seconds. Two measurements were taken for each of the two strength tests, with a 30-second rest between procedures to allow muscle recovery [31].

Numeric Pain-Rating Scale (NPRS): The pain intensity was assessed using an 11-point NPRS ranging from 0 (no pain) to 10 (worst imaginable pain). A change of 3 points post-treatment is considered to be the Minimal Clinical Importance Difference (MCID) for subjects with shoulder pain [29].

Shoulder Pain And Disability Index (SPADI): SPADI is a 13 item self-reported questionnaire measuring pain and disability in subjects with shoulder pain of musculoskeletal origin. In the current research, a change of 8-13 points in the total score was considered a minimal clinically important change, and the English version of SPADI was used [32].

Patient Specific Functional Scale (PSFS): PSFS was designed to provide clinicians with a valid, reliable, responsive and efficient outcome measure that targets three most impaired function from individual's perspective recommended for subjects with upper extremity problem. A minimum improvement in the total PSFS score of 3 points for single activity and 1.2 points for average scores was considered as a MCID. PSFS was included in the study to know the common function that was limited in SIS population and whether individual specific function analysis differed from a generic functional measure (e.g., SPADI) [33].

Short Form Health Survey questionnaire (SF 36-Item): SF 36 is a generic measure consisting of a total of 36 items. These 36 items evaluate eight different dimensions of health. This eight sub-components are grouped under the Physical Component Score (PCS), and Mental Health Score (MCS). The scores obtained from the items are coded, and converted into a scaled scale from 0 (worst case) to 100 (best case) for each dimension. SF 36 was proved to be highly valid, reliable and recommended to assess QoL in subjects with shoulder impingement syndrome [34].

Outcomes pain intensity, elevation range; isometric muscle strength and function were measured at baseline, three weeks and follow-up in the 12th week. SF 36 QoL questionnaire was obtained at baseline and follow-up by 12th week.

STATISTICAL ANALYSIS

The collected data was analysed using IBM-SPSS statistics software version 23.0. The normality of the data was verified with Shapiro-Wilk's test. Descriptive data was expressed in frequency, percentage for categorical variables and continuous variables in mean±SD. Continuous variables were assessed using the Independent samples t-test, while categorical variables were assessed using the Chi-square test. Within and between group values were assessed using Repeated Measure-Analysis of Variance (RM-ANOVA) and a one-way ANOVA between groups for data measured in more than 2 time points. Bonferroni corrected p-values were calculated and used in the posthoc pair wise comparisons. Within and between group analysis for values measured in 2 time points paired and unpaired t-test was used. A p-value of <0.05 was considered statistically significant.

RESULTS

Of the 126 subjects, nine discontinued treatment and 20 were lost to follow-up at 12 weeks, finally 97 subjects completed the study and were considered for analysis.

The mean age were 45.02±10.30 years and 45.12±11.42 years in groups 1 and 2, respectively. Male to female ratio were 25:21 and 30:21 in groups 1 and 2, respectively. There was no significant difference was found among the groups regarding age, gender, symptom location and duration. The baseline clinical data between groups were comparable and no statistical difference exist [Table/Fig-2].

Characteristics		Group 1 (n=46)	Group 2 (n=51)	p-value
Gender	Males (n)	25	30	0.66[a]
	Females (n)	21	21	
Symptom location	Dominant side (n)	33	35	0.74[a]
	Non dominant side (n)	13	16	
Age (years in Mean±SD)		45.02±10.30	45.12±11.42	0.96[b]
Symptom duration (weeks in Mean±SD)		4.06±3.62	4.53±3.24	0.50[b]
Pain score (NPRS, Mean±SD)		6.30±0.98	6.20±1.04	0.502[b]
External rotators Isometric muscle strength (kgs, Mean±SD)		8.15±1.90	8.70±2.69	0.550[b]
Abductors Isometric muscle strength (kgs, Mean±SD)		12.01±3.83	13.75±5.49	0.08[b]
Shoulder elevation range (Degrees, Mean±SD)		138.70±30.50	145.49±28.62	0.26[b]
Shoulder pain and disability index (Mean±SD)		61.83±17.08	56.18±12.19	0.06[b]
Patient specific functional scale (Mean±SD)		3.93±1.26	4.01±1.62	0.346[b]
Quality of life measure (SF 36) (Mean±SD)	Physical cumulative score (PCS)	41.36±5.29	41.86±7.45	0.698[b]
	Mental cumulative score (MCS)	49.90±8.23	50.98±8.34	0.524[b]

[Table/Fig-2]: Baseline demographics and clinical characteristics of the subjects in both groups.
SD: Standard deviation; NPRS: Numeric pain rating scale
[a]Chi-square test; [b]Independent samples t-test

The pain, shoulder elevation range, abductor and external rotator strength, SPADI and PSFS scores improved in both groups at three weeks (p-value <0.0001) and during follow-up at 12 weeks (p-value <0.0005) from baseline on within group analysis [Table/Fig-3]. However, statistical significant improvement was observed on intergroup comparison with pain intensity (p-value <0.0005), range (p-value <0.05), external rotator strength (p-value=0.016) and PSFS (p-value=0.014) in group 1 than group 2 at three weeks [Table/Fig-4]. External rotator strength (p-value <0.0005), SPADI (p-value <0.0005) and PSFS (p-value=0.035) scores showed statistical significant improvement in group 1 during follow-up at 12 weeks than group 2 [Table/Fig-4].

The SF 36 analyses of QoL showed significant improvement intragroup (p-value <0.0005) with physical and mental cumulative scores in both groups. The intergroup comparison had resulted in significant improvement with physical (p-value=0.008) and mental (p-value=0.006) cumulative score from baseline to follow-up at 12 weeks in group 1 than group 2 [Table/Fig-5].

Outcome	Group	Time points			Intragroup analysis Group 1 (n=46)		Intragroup analysis Group 2 (n=51)	
		Baseline Mean±SD	3 weeks Mean±SD	12 weeks follow-up Mean±SD	Baseline vs 3 weeks	Baseline vs 12 weeks follow-up	Baseline vs 3 weeks	Baseline vs 12 weeks follow-up
Pain (Numeric pain rating scale)	1	6.30±0.98	2.48±1.36	0.96±1.13	<0.0001	<0.0001	<0.0001	<0.0001
	2	6.20±1.04	3.51±1.19	1.12±1.24				
Shoulder elevation range (Degrees)	1	138.70±30.50	169.13±14.96	175.43±6.98	<0.0001	<0.0001	<0.0001	<0.0001
	2	145.49±28.62	155.19±25.17	174.12±5.26				
Abductors isometric muscle strength (kg)	1	12.01±3.83	15.12±4.02	18.88±4.81	<0.0001	<0.0001	<0.0001	<0.0001
	2	13.75±5.49	15.61±5.28	17.33±5.57				
External rotators isometric muscle strength (kg)	1	8.15±1.90	13.37±2.19	15.05±2.58	<0.0001	<0.0001	<0.0001	<0.0001
	2	8.70±2.69	10.16±2.63	11.45±2.97				
SPADI	1	61.83±17.08	49.43±12.98	20.04±8.14	<0.0001	<0.0001	<0.0001	<0.0001
	2	56.18±12.19	45.45±10.67	28.73±7.89				
PSFS	1	3.93±1.26	6.02±1.05	8.22±0.90	<0.0005	<0.0005	<0.0005	<0.0005
	2	4.01±1.62	5.52±1.11	6.49±1.03				

[Table/Fig-3]: Intragroup comparison of clinical, functional variables at three weeks and 12 weeks follow-up.
SD: Standard deviation. p-value <0.05 considered significant

Outcome	Group 1 (N=46)	Group 2 (N=51)	Effect size	Significance
Pain score (NPRS)				
Baseline	6.30 (0.98)	6.20 (1.04)	0.98	0.502
3 weeks	2.48 (1.36)	3.51 (1.19)	0.81	<0.0005
12 weeks	0.96 (1.13)	1.12 (1.24)	0.13	0.452
Shoulder elevation range (Degrees)				
Baseline	138.70 (30.50)	145.49 (28.62)	0.24	0.26
3 weeks	169.13 (14.96)	155.19 (25.17)	0.67	<0.05
12 weeks	175.43 (6.98)	174.12 (5.26)	0.21	0.294
Abductors isometric muscle strength (kg)				
Baseline	12.01 (3.83)	13.75 (5.49)	0.36	0.08
3 weeks	15.12 (4.02)	15.61 (5.28)	0.1	0.609
12 weeks	18.88 (4.81)	17.33 (5.57)	0.3	0.149
External rotators isometric muscle strength (kg)				
Baseline	8.15 (1.90)	8.70 (2.69)	0.24	0.55
3 weeks	13.37 (2.19)	10.16 (2.63)	1.33	0.016
12 weeks	15.05 (2.58)	11.45 (2.97)	1.29	<0.0005
SPADI				
Baseline	61.83 (17.08)	56.18 (12.19)	0.38	0.06
3 weeks	49.43 (12.98)	45.45 (10.67)	0.33	0.098
12 weeks	20.04 (8.14)	28.73 (7.89)	1.08	<0.0005
PSFS				
Baseline	3.93 (1.26)	4.01 (1.62)	0.05	0.346
3 weeks	6.02 (1.05)	5.52 (1.11)	0.46	0.014
12 weeks	8.22 (0.90)	6.49 (1.03)	1.79	0.035

[Table/Fig-4]: Intergroup comparisons of clinical, functional variables at baseline, 3 weeks and 12 weeks follow-up between group 1 and group 2.
Values are presented as mean (SD); SPADI: Shoulder pain and disability index; PSFS: Patient specific functional scale; *one-way ANOVA. p-value <0.05 considered significant

DISCUSSION

The combined effect of manual therapy and eccentric with other specific exercises had resulted in improved functional ability and better QoL than conventional exercises at 12 weeks follow-up in this study. Pain intensity, elevation range, external rotator muscle strength and self-perceived functional limitation improved well post-treatment. The present study is one among very few that have examined above effects in SIS population [18,19,21,22].

Pain intensity had reduced significantly more in group 1 after treatment than in group 2, and it did not reduce differently during follow-up. This finding is similar to the conclusion of a systemic review done by Dong W et al., which found that exercise therapy, when combined with manual therapy, resulted in short-term improvement in pain [35]. Eccentric exercises, when given for 12 weeks duration, resulted in a significant reduction in pain intensity and were found to yield better results than conventional exercises, as observed by Dejaco B et al., in individuals with SIS [27,36]. The shoulder elevation range had improved only after post-treatment in group 1 and the follow-up scores between groups were near similar.

The observed glenohumeral muscle impairment was supporting functional impingement concept proposed by Vladimir janda, the same as quoted by Page P et al., and Reddy A et al., involving deltoid and rotator cuff muscles particularly infraspinatus [37,38]. The muscle strength had improved in both group by end of treatment with subjects in group 1 showing greater change. Between group comparison resulted in significant improvement with external rotator strength in group 1 than group 2. As pain intensity had reduced similarly in both groups, the strength gain following eccentric exercises would have resulted for this change.

The SPADI and PSFS scores improved significantly at 12 weeks follow-up and only PSFS showed significant improvement by three weeks in group 1 on intergroup analyses. The predominant function

Outcome		Time points	Group 1 (n=46)	Within group significance Group 1	Group 2 (n=51)	Within group significance Group 2	Between group significance			
							PCS Baseline	PCS 12 weeks follow-up	MCS Baseline	MCS 12 weeks follow-up
Quality of Life (QOL) measure (SF 36)	PCS	Baseline	41.36 (5.29)	<0.0005	41.86 (7.45)	<0.0005	0.698	0.008	0.524	0.006
		12 weeks follow-up	52.36 (3.15)		49.83 (5.75)					
	MCS	Baseline	49.90 (8.23)	<0.0005	50.98 (8.34)	<0.0005				
		12 week follow-up	56.89 (3.69)		54.01 (6.21)					

[Table/Fig-5]: Within group and between group significance of Quality Of Life (QOL) measure (SF 36).
PCS: Physical cumulative score; MCS: Mental cumulative score; Values are presented as mean (SD). p-value <0.05 considered significant

that was limited in this study population reported by the subjects in the order of most bothersome was over head, back care and lifting activities. Symptom duration longer than three months has high chances for the problem to become chronic, and it is well established that early recovery results in a better prognosis, as observed in the current study among the SIS population [39,40].

Shoulder pain and related functional restriction usually persists far beyond the expected tissue recovery and affects the joint function to greater extend [41]. Hence, early appropriate intervention was very much essential to prevent chronicity and decline in the quality of daily activities. Manual therapy, when combined with exercises, was found to be more effective than a conventional program in improving function in the short-term, as revealed by pooled data from studies conducted on individuals with SIS [17,42,43]. In a study by Chaconas EJ et al., a 6-week protocol of eccentric exercises for the shoulder external rotators resulted in better improvement in function at 6-month follow-up, similar to the present study [44]. The intermediate and long-term functional improvement was similar when compared between eccentric and concentric exercises among SIS population [10].

The rotator cuff strength deficit was commonly seen among SIS population and this deficit was found adversely affecting the emotional status and QoL of these individuals [45]. The QoL status had improved significantly in group 1, and this finding was similar to the observation that QoL improved well regardless of the type of intervention and physiotherapy treatment significantly reduced related pain [46]. The effects of eccentric exercise in improving QoL status was less explored and in the present study it has resulted in significant improvement in physical and mental cumulative score on intergroup analyses.

Reduction in pain level, increased rotator cuff strength and function would have led to improved PCS and MCS scores in both group. External rotator strength and self-rated functional improvement (PSFS) had significantly improved in individuals who received manual therapy, eccentric and other specific exercises than conventional care; the same could be the reason for significant improvement in group 1 on between group analyses.

Limitation(s)

The study limitation includes absence of true control group, subject inclusion was not based on specific stage of disorder and various factors influencing outcome not analysed in the current research as it is beyond the study objectives. The influence of pain intensity, stage of disorder, extent of strength and functional limitation on QoL status was highly variable and was not analysed in the current study.

CONCLUSION(S)

The combined effect of manual therapy and eccentric exercise conditioning improves regional, self-rated functional ability and QoL more than conventional exercises among individuals with SIS. Conservative management and eccentric exercise can bring favourable improvements in primary care of SIS population as observed in individuals belonging to group 1. Future studies can be conducted with many subgroups and different exercise dosages and follow-up can be extended beyond one year or even longer.

Acknowledgement

The authors wish to thank the study participants for giving their consent and active contribution.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Aug 12, 2022
- Manual Googling: Nov 19, 2022
- iThenticate Software: Dec 02, 2022 (8%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Aug 08, 2022**
Date of Peer Review: **Sep 14, 2022**
Date of Acceptance: **Dec 05, 2022**
Date of Publishing: **Mar 01, 2023**