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Thesis

Does A Group Supervised Shoulder Impingement Class Improve Shoulder Pain, Disability and Generic Health Outcomes? A Summative Service Evaluation

Abstract

Background: Patients with shoulder impingement syndrome (SIS) suffer pain and disability and present enormous health and financial challenges to the NHS. There is limited evidence for many of the commonly used physiotherapy treatment interventions. Research suggests deprivation, age, gender and attendance are possible predictors of poor treatment outcome in common MSK conditions. The present author set up and ran a physiotherapy led group based SIS class to improve generic health outcomes and reduce shoulder pain and disability.

Method: 236 SIS patients were referred over a 22 month period. 154 completed the once weekly six week course. 82 failed to complete the class. Generic health outcomes were measured with the Euroqol EQ-5D-5L with condition specific outcome measured using the Shoulder Pain and Disability Index (SPADI). Covariates possibly predictive of poor treatment outcome were analysed using linear regression and included Townsend Deprivation Score (TDS), age and gender. Class completers and non-completers were compared to determine any association with TDS, age and gender.

Results: Statistically significant improvements in generic health (t -7.77, df 153, $p < 0.001$) and shoulder pain and disability (t -9.36, df 153, $p < 0.001$) were found post intervention. No association for the predictive utility of TDS, age and gender on EQ-5D-5L and SPADI outcome was found. Statistically significant differences between class completers and non-completers for TDS t (181.17)=-3.62, $p < 0.001$) and age (t (134.72)=2.41, $p = 0.017$) were found. Younger patients and those from more deprived areas attended fewer classes. No association was found between gender and non- attendance. TDS, age and gender have no association with class non-completion type be it never attended or attended then did not attend (DNA).

Conclusion: Physiotherapists play a key role in managing the third most common MSK pathology. This evaluation suggests positive outcomes for those completing a group based SIS class on both health and shoulder pain and disability. SIS patients meeting inclusion criteria should be routinely fed into group based classes. Younger patients and those from more deprived areas may benefit from a more individualised management approach.

Introduction

Shoulder pain arising from the rotator cuff muscles and subacromial bursa labelled commonly as SIS presents a significant problem to the NHS with both conservative and surgical treatment costs as well as days lost to sickness accruing to millions per year [1,2,3]. Luime et al [4], and Murphy et al. [5], cite shoulder pain as having a prevalence between 16% and 26% in the general population making it one of the most common body parts treated behind neck and lower back pain. An outcome audit in primary care by May [6], found shoulder pain is the third most common complaint presenting to MSK clinics placing physiotherapists at the forefront in managing SIS along with other shoulder conditions.

SIS is known by a variety of diagnostic labels that attempt

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often unsuccessfully to implicate the specific anatomical structure within the shoulder where the pathology is thought to lay. Subacromial bursitis or impingement, rotator cuff disease or tendinopathy or tendinitis are all used synonymously to describe pain arising predominantly from the anterior aspect of the shoulder. Current thinking dispels the notion that clinical assessment can isolate any one structure accurately and more overarching labels such as rotator cuff related shoulder pain have been advocated [7]. The principle structures affected and implicated in causing pain are the subacromial bursa and rotator cuff tendons [8]. Often bursal and tendon pathologies co-exist or are shown on ultrasound imaging in isolation of one another. Overuse tendinopathy occurs more commonly in high energy loading tendons including the rotator cuff, wrist extensors, patella and Achilles tendons. The complexities surrounding the aetiology and management of tendinopathies are well documented [9-13]. Pain and dysfunction are the predominant symptoms patients complain of with symptoms sometimes lasting years.

Despite SIS being a well-recognised clinical presentation disparate theories exist as to the best treatment intervention. Little to no robust evidence has been provided by clinical trials to back up any of the more commonly used interventions including corticosteroids, acupuncture, and manual therapy [11,12]. Several authors agree best practice in managing SIS involves exercise [1,2,14-16]. Smidt et al. [17], concur more generally arguing that Physiotherapists commonly use exercise therapy to improve a wide range of health conditions and that numerous systematic reviews show that exercise is an effective management strategy for MSK conditions.

National clinical guidelines also advocate exercise based strategies for most common MSK conditions [18-22]. Despite the weight of research promoting exercise no clear consensus has been established regarding SIS as to what constitutes best exercise or the ideal setting in which it is undertaken be it individual or group based.

Literature review

MSK conditions and exercise: A search of the literature base gleans extensive studies supporting therapeutic exercise in the management of health and MSK conditions. Exercise can incorporate general aerobic exercise, body area specific flexibility and strengthening or simply maintaining or increasing general physical activity levels [23]. The meta-analysis by Barker et al. [24], found multiple high quality studies citing the effectiveness of aquatic exercise on pain, function and quality of life for those with MSK conditions. Bennell and Hinman [25], acknowledged in their review of clinical evidence for the use of exercise in hip and knee osteoarthritis that although exercise plays no part in disease modification, individual or class supervised exercise is beneficial in symptom management. Multiple other systematic reviews support the use of therapeutic exercise for neck pain [26-28]. The underlying themes of this research indicate that dynamic strengthening exercises appear to have neuromodulatory effects on pain with positive impacts on function be it for upper, lower limb or spinal conditions. The mechanisms behind these effects are not fully understood.

Structured loading exercise programmes have been reported as being the main intervention for SIS [29,30]. Physiotherapists commonly use Cook and Purdam's [13], general tendon pathology continuum to guide progressive strengthening exercise programmes. Tendon pathology continuums were advanced more specifically for the shoulder by McCreesh and Lewis [31], and later by Lewis [7]. The purported mechanisms of tendon rehabilitation are cited by Kahn and Scott [16], in their discussion on mechanotransduction. They argue mechanical extracellular stimulus in the form of exercise promotes complex intracellular processes synthesising collagen and consequently restoring tendon health [16].

The systematic review by Hanratty et al. [32], concluded that physiotherapy exercises are effective in managing SIS albeit heterogeneity within the reported exercise protocols made conclusions about which specific exercises are associated with the best outcomes difficult. Kuhn [33], reported strong evidence that exercise improves pain in SIS patients. Their systematic review found supervised and home exercise strength programmes as well as exercise with manual therapy improved pain in all studies except one [33]. Abdulla et al. [34], found that both supervised and home based SIS exercises have equal outcomes to shoulder decompression surgery. Little wonder then that the preferred physiotherapy intervention with SIS populations is some form of graduated loading programme. This is also reinforced at physiotherapy undergraduate level with loading programmes taught and advocated for SIS. It is therefore hypothesised that a shoulder class involving shoulder loading exercise will have positive outcomes on health and shoulder pain outcomes.

Group based versus individual exercise classes: A paucity of evidence exists regarding the efficacy of group based SIS classes. The systematic review by O'Keeffe et al [35], investigating group based versus individual exercise programmes for MSK conditions including lower back, knee, neck and shoulder pain concluded that there was no difference in pain and disability between groups. They cited reasons for this being that the group intervention spent more time physically undertaking exercise along with an educational component than the individual intervention [35]. The group based exercise was argued to foster better social interaction and support helping to address bio-psychosocial issues [35]. The majority of studies included however were lower back pain with only one eligible randomised control trial on the shoulder by Russell et al. [36]. On balance with such little difference between the two groups there are clear implications for improved efficiency with group classes demanding fewer physiotherapists and the ability to see greater numbers of patients at one time.

The RCT by Russell et al. [36], compared group versus individual physiotherapy exercise treatment of frozen shoulders, and concluded that, although both groups improved significantly on anxiety, pain and disability, the exercise group had significantly better outcomes on disability and pain compared with individual physiotherapy. It could be hypothesised that focusing on attending a steady exercise class leads to better results than one to one advice given on an individual basis with patients expected to adhere. In developing

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clinical practice recommendations comparing group over individualised exercise for knee and hip osteoarthritis Tiffreau et al. [37], found no superiority of one modality over the other. This again supports the idea that physiotherapy delivered on an individual basis is no more beneficial than in a group setting adding further weight to the use of group based classes. The RCT by McCarthy et al. [38], investigating supplementing home exercise with class based exercise for knee osteoarthritis found clinically significant improvements in pain and disability even at 12 months follow up with the group exercise supplemented intervention. This service evaluation is further justified to determine the efficacy of group based exercise for a SIS population.

Conclusions reached by Carr et al. [39], in their RCT comparing group to individualised exercise for lower back pain found no significant differences between groups at three and 12 months follow up. Curious economic trends were found with the individual intervention group seeking more secondary care treatment such as Orthopaedic referrals, investigations and injections than the group based intervention who sought more primary care individualised physiotherapy and GP management. They explain the group based intervention seeking individual care by a potential perceived need for more individualised treatment [39]. Explanations for the other trends found are unclear. The study by Carr et al. [39], highlights the cost effectiveness of group based exercise making it the preferred treatment option from both economic and health standpoints. It is therefore hypothesised that a group SIS class will have positive outcomes on health and shoulder pain and disability outcomes.

Adherence and attendance: Another factor influencing the outcomes of exercise based treatment includes issues surrounding adherence. Kolt et al. [40], define adherence as including attendance at appointments, following advice and completing prescribed exercise. Both in-clinic adherence including knee and back classes, and home exercise adherence have been shown to be problematic [41,42]. Forkan et al. [43], predicted as low as thirty percent of those prescribed home exercises actually adhere to the programmes set. Others cite the figure being 50 percent for clinic based exercise programmes but concur that unsupervised home exercise programmes are often worse [41,42]. Exercise programme adherence enhances its effectiveness and those participating in regular physical activity may reduce the propensity for suffering many health and MSK related conditions [44]. The negative effects of poor exercise adherence include increased waiting times and healthcare costs, reduced patient satisfaction, breakdowns in therapeutic relationships, delayed healthcare and increased hospital admissions [45-48]. The causes of exercise class non-attendance are multi-faceted. Many authors concur that age and deprivation are common factors associated with non-attendance [39,40,44,49]. It is therefore hypothesised that deprivation and age are likely to be predictors of class attendance.

Age: There is strong evidence that increasing age is associated with the onset of SIS. Multiple authors concur that those aged 40 and above are more predisposed to developing SIS with those aged between 45 and 64 at more risk [4,50-52]. Neer [53], introduced shoulder impingement as a condition into the literature and described 3 discrete stages affecting under 25 year olds, 25-40 year olds and over 40 year olds. He proposed that the older the patient group the more irreversible the damage to the rotator cuff with increasing degenerative changes and possible rotator cuff tears. We know this to be less true with partial and full thickness tears shown on ultrasound in asymptomatic shoulders but that the prevalence of those presenting with SIS aged over 40 is far higher [8]. A critical avascular zone around the supraspinatus tendon insertion onto the shoulder has been purported to increase in area with increasing age [54,55]. General age related changes within the sub-acromial bursa and the supraspinatus tendon are likely mechanisms linked with age and SIS onset. Age as a predictor of treatment outcome following a SIS class is unknown. It is hypothesised that age is a possible predictor of poor treatment outcome.

Gender: The predictive utility of gender on treatment outcome for SIS pain and disability is unknown. Gender has been argued as being a predictor of treatment outcome in many MSK conditions [56]. Interestingly this has been shown to be dependent on body area with men reporting increased lower back issues and women reporting more neck and shoulder symptoms [57]. In their critical review of gender differences in workplace neck and shoulder disorders Cote [58], cites anthropometric or biological differences as reasons for increases in the incidence of MSK conditions in females. Muscle fibre type and its impact on gender difference in strength and fatigue resistance has been attributed to gender differences in the reporting of neck and shoulder pain [58]. Multiple other high quality studies including systematic reviews report the incidence of upper limb MSK disorders being more prevalent in females [59-61]. The majority of these studies focus on work related MSK disorders. In the systematic review investigating the effectiveness of conservative interventions in managing SIS by Steuri et al. [50], they found the highest incidence and prevalence of the condition in women. Although SIS is often cited as being more prevalent in females there appears to be no research using gender as a predictor of outcome in a SIS group class. It is therefore hypothesised that gender may be a predictor of treatment outcome in a SIS group class.

Locality: The service evaluation will be undertaken in the UK city of Hull with a population of 266000 and 290002 registered with a Hull GP. In 2012 of 2800 Hull GP registered patients presenting with an MSK condition 1100 were upper limb conditions [62]. Hull is a unique city in that it has historically poor national deprivation rankings. Ward based rankings show eight of Hull's 23 wards are ranked within the top 100 most deprived in the country with one placed fifth [63]. At English local authority level Hull is ranked 3rd most deprived out of 326 [63]. Hull Clinical Commissioning Group (CCG) is ranked as having the 5th most deprived population out of the 209 CCGs nationally [64].

Multiple high quality studies concerning deprivation and its negative impact on MSK conditions exist [65-67]. In the RCT by Carr et al. [39], comparing a group based back class

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with individual physiotherapy using TDS they found notable deprivation trends. They argue socially deprived patients may suffer sustained stress responses from the effects of poor personal and environmental events [39]. Learned expectancies of failure, reduced locus of control, limited access to sports and fitness facilities on poor estates, and high crime rates may all combine with mal-adaptive coping responses resulting in negative health consequences [39]. This may also explain the relatively high non- attendance rate of their back class with 21% never attending and 50% attending but not completing the class [39]. It seems fair then that a secondary aim of this study was to measure the impact of deprivation as a possible predictor of treatment outcome in a SIS class.

Lowe et al. [66], found strong evidence that low socioeconomic status (SES) has negative effects on physiotherapy outcomes using three high quality studies on lower back and neck pain. They describe the negative health impacts on those in lower socioeconomic groups more exposed to stressful situations, negative emotions and environments not conducive to health [66]. McLean [68], describes the high attrition rate facing socially deprived patients exposed to MSK interventions for non- specific neck pain. Material and social deprivation gleaned from TDS's and fear avoidance beliefs were significant predictors of treatment outcome. McLean [68], concluded that higher TDS's regardless of intervention type be it usual physiotherapy or graded exercise therapy leads to poorer treatment outcomes. Again this adds more weight to justification for this study investigating the impact of deprivation as a possible predictor of poor treatment outcome.

Service offered: With the rollout of the Department of Health's [69], 'Any Qualified Provider' initiative promoting NHS provision competition and driving up patient choice the Hull community MSK service tender was lost by Hull and East Yorkshire NHS Trust to Healthshare Ltd in October, 2014. Department of Health [20], and NHS [70], recommendations were put forward requiring providers to improve MSK condition outcomes ensuring access to holistic treatment, close to patient's homes with patients biopsychosocial needs being addressed. In line with this a number of key performance indicators (KPI's) need to be fulfilled ensuring contract compliance with the local CCG. One KPI is linked to health outcomes and measured through a patient reported outcome measure, the EQ-5D-5L (Appendix 1). This KPI mandates that a minimum of 75% of service users receive high quality interventions that improve health whilst experiencing a quantifiable improvement in their MSK condition. Increased pressure to demonstrate Healthshare Ltd's efficiency is meted out in other locally defined outcomes including ensuring high numbers of service users are self-managing, experiencing improvement in their MSK conditions and reducing referrals into secondary care. With an NHS in financial crisis demonstrating cost effectiveness in healthcare is paramount [71].

The provision of structured exercises and education programmes combining physical and psychological treatments are outlined in the Healthshare Ltd service specification. The SIS class incorporates both educational and exercise approaches empowering patients to ultimately self-manage fulfilling local KPI's and Department of Health [20], and NHS [70], recommendations for MSK disorders and services. As shown the literature supports the use of exercise in SIS populations. Deprivation, attendance, age and gender have known associations with treatment outcomes. The present author set up and evaluated a group based SIS class for community based, Hull GP registered adults with SIS. This thesis describes the service and its evaluation.

Aims

The first aim of this service evaluation is to measure changes in health status and shoulder pain and disability. Given the paucity of evidence concerning the efficacy of SIS classes this service evaluation aims to add to the literature base. The second aim is to identify patient groups at potential risk of poor treatment outcomes. Those with lower socioeconomic status being more socially and materially deprived have been shown to have poorer health outcomes and reduced response to physiotherapy [66]. Research also indicates both age and gender impacting on common MSK conditions [50]. Poor attendance has been shown to have negative impacts on health outcomes [40]. Identifying patients at potential risk of poor outcomes may allow for better tailoring of treatment to specific groups.

Hypothesis

H0 - the null hypothesis:

a) There is no change in generic health status or shoulder pain and disability at six weeks following completion of the group supervised SIS class.

b) There is no interaction between TDS, age and gender on SIS class outcome

H1- the alternative hypothesis:

a) There is a change in generic health status and shoulder pain and disability at six weeks following completion of the group supervised SIS class.

b) There is an interaction between TDS, age and gender on SIS class outcome.

Methods

Recruitment

NHS Hull GP registered patients either self-referred or were GP referred then triaged via physiotherapy telephone assessment into community MSK clinics for initial physiotherapy consultation. 236 participants were retrospectively involved in the study. Following initial face to face consultation patients fulfilling the inclusion and exclusion criteria were included in the evaluation. Inclusion criteria included primary complaint of shoulder pain, initial physiotherapy assessment complete with diagnosis of SIS, two out of three of the following tests being positive; Hawkins Kennedy or full/empty can, painful arc and pain or weakness on resisted tests. The latter being in line with Park et al. [72] recommendation for cluster testing

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to diagnose SIS. Patients were required to demonstrate the ability to independently correct and set their shoulder and scapula position, have well controlled pain and good range of shoulder movement at least above shoulder height. Having piloted the shoulder class with patients not fulfilling these inclusion criteria the increased staffing needed to cope with the increased individual demands of patients with more irritable shoulders made the class impractical to run. Exclusion criteria involved peripheral pain involving the neck or thoracic spine, neurology, frozen shoulder and being medically unstable.

Interventions

The main interventions used over the six weeks were shoulder strengthening exercises designed to progressively load the rotator cuff and periscapular muscles (Appendix 2,3,4). Loaded exercise dose prescription is outlined in (Appendix 5). Pain free exercise was advocated throughout in line with Cook and Purdam's [13], seminal paper on tendon pathology continuums describing the merits of a pain free tendon loading programme. Other exercises were prescribed from the SIS booklet (Appendix 5) determined by individual's response to shoulder symptom modification procedure (SSMP) techniques described by Lewis et al. [7]. These techniques involve the systematic approach of altering thoracic, scapular and humeral head postures to attempt to effect a change on painful shoulder movements. Recent preliminary research has demonstrated that the SSMP is a reliable clinical procedure and emphasises that SSMP techniques are used to guide some aspects of the management of SIS only [7].

Other usual physiotherapy interventions might have included one or a combination of shoulder and thoracic spine manual therapy techniques, specific soft tissue massage, postural taping using 'Leukotape P combi' and 'Rocktape' kinesiology tape and corticosteroid injection. Education and advice was given throughout and a five minute shoulder impingement video presented by Professor Leonard Funk an orthopaedic shoulder surgeon was shown on initial assessment backed up with an educational booklet (Appendix 5).

Outcome measures used

Primary outcomes were measured using the Euroqol EQ-5D-5L which is used nationally by Healthshare Ltd for all MSK conditions. The EQ-5D-5L is well validated for many generic health related conditions being adopted by the DoH [73], in England in their patient reported outcome measures programme and is quick and cognitively undemanding to complete [74-76]. Since 2009 it has been successfully used in evaluating health outcomes and cost effectiveness following total knee replacement and total hip replacement surgeries amongst others [73]. Although it is supported by NICE using quality of life years as their standard measure, there is no specific mention of SIS as a condition measured [77]. With it being a generic and not a condition specific outcome measure it has clear weaknesses with a SIS population having no studies validate its use. Its psychometric properties have been called into question by Payakachat et al. [78]. In their systematic review investigating if the EQ-5D-5L can detect meaningful change they found increased EQ-5D-5L responsiveness determined by conditions being more severe or if a larger change was observed [75]. This is consistent with findings from the systematic review by Tordrup et al. [79].

Slobogean et al. [80] investigated the psychometric properties of the EQ-5D-5L in proximal shoulder fracture patients comparing to other health outcomes like the Disabilities of Arm, Shoulder, Hand (DASH) and Short Form-6D. They found it had a ceiling effect with 30% of participants reporting perfect health and only 7% doing so using the other questionnaires. It was not found to have as good psychometric properties as the DASH and SF-6D Short Form. Obtaining condition specific data for multiple MSK conditions is difficult and can be time consuming in clinical practice as recognised by Hill et al. [76], in their study on establishing a less burdensome more generic MSK specific patient meaningful outcome measure. This is recognised as another limitation of the EQ-5D-5L. The CSP [81], EQ-5D-5L calculator was used to calculate health status change index scores. The minimally important difference EQ-5D-5L index change score within England was found by McClure et al. [82] to be 0.037%.

Primary outcome measurement also utilises the condition specific SPADI. The SPADI was developed to measure the impact of shoulder pathology on pain and disability in an outpatient setting. It has been ranked as the most relevant and least time consuming shoulder questionnaire [83]. It consists of a self-reported questionnaire with 13 items assessing pain and disability with a total combined score of 0-130 then summed and converted to a percentage. Higher scores indicate more severe shoulder impairment [84]. The second version used in this evaluation has a numeric rating scale rather than a visual analogue scale. The minimal detectable change in SPADI score has been identified as 10% [84-86].

It has been shown to be a valid and reliable measure of functional shoulder disability by multiple authors [87-91]. More specifically Ekeberg et al. [87,88,92] validated its use within a rotator cuff disease population comparing it against the Western Ontario Rotator Cuff index (WORC) and the Rotator Cuff Quality of life questionnaire (RC-QOL). They found high construct validity, reliability and low floor and ceiling effects with total scores with the SPADI. MacDermid et al. [85], concur validating the SPADI in patients reporting shoulder pain of an MSK nature.

A co-variate used to measure one of the secondary outcomes deprivation was the TDS. Age and gender are the other co-variates. The TDS is commonly used to determine health inequalities and socioeconomic position in the UK and compared to other measures of deprivation such as the Indices of Multiple Deprivation (IMD) England [63], is preferred as it focusses on a tight definition of deprivation being material deprivation and is consistent over time with the same variables [93]. Z scores were calculated using postcodes and 2011 census data at ward level of percentage of unemployed economically active residents, private households not possessing a car or van, not owner occupied and overcrowded [94]. The resulting Z scores range from -6.58 to 12.83 with the mean score equal

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to zero. This data is available in the following repository [95]. Scores above zero indicate greater material deprivation whilst negative scores indicate affluence [96].

Multiple authors consider the TDS to be valid and reliable [94,96-100]. Possible limitations of using Townsend ward based data over IMD lower super output area (LSOA) data is that LSOA's give a more local geography however they can be harder to describe whereas wards give more familiar names and are easier to understand. The two schemes do however correlate well r 0.88 > 0.90 [98].

Procedure

The group based SIS class involves one hour sessions of circuit based shoulder and lower limb exercises once weekly over six weeks. The initial class is 90 minutes long allowing for an induction and all paperwork to be filled out (Appendix 1,6,7,8). Patients fulfilling inclusion and exclusion criteria were referred to one of two clinic locations after their initial face to face physiotherapy consultation whereon they were issued pre- class patient information sheets (Appendix 9,10). Physiotherapy assistants were charged with having patient's complete baseline EQ-5D-5L and SPADI questionnaires and a health disclaimer (Appendix 1,4,5). The educational component involved a five minute video, and issuing of a SIS booklet (Appendix 5). An in depth discussion on the pathophysiology of SIS with a question and answer session was then carried out. Ten shoulder exercises with progressions and regressions were demonstrated (Appendix 2,3,4). Personal record sheets were issued to record weekly exercise progression with patients advised to seek alternate exercises pain dictating (Appendix 8).

On completion of the induction a further physiotherapy assessment of all new patients' ensured inclusion and exclusion criteria were met (Appendix 11). The personal record sheets were populated with the salient patient history and contemporaneous clinical assessment findings. Patients were advised to keep the personal record sheet on them during the class for ease of tailoring exercises and fielding any clinical questions the patients had. The assessment dictated individualised tailoring of education, class and home exercise programmes. All patients were prescribed a minimum of 2-3 shoulder exercises to be completed on alternate day's in-between classes dictated by the irritability of their shoulder symptoms. These ranged from isometric to isotonic onto more functional shoulder loading exercises completed between 0-3/10 numeric pain rating score sometimes with the addition of lower limb exercises. Non-responders to SSMP techniques were advised to complete the unabridged circuit exercises. Post-class EQ-5D-5L and SPADI were recorded at week six and shoulder assessment was repeated. Onward patient management was determined on the final physiotherapy assessment (Appendix 11).

Data Collection

Dependent variables measured pre and post shoulder class at six weeks were health status and shoulder pain and disability measured using the EQ-5D-5L and the SPADI respectively. Covariates possibly predictive of shoulder class outcome included TDS, age and gender. TDS were calculated using patient postcodes at the time of collection and recorded as Z scores. Age was measured at the time of data collection in years. Gender was recorded dichotomously as male or female. Differences between class completers and non-completers for TDS, age and gender were recorded. Further analysis of non-completers was collected and recorded as either never attended or attended then DNA. All data was retrospectively collected then anonymised from SystemOne a centrally hosted clinical computer system over a 22 month period between July, 2015 and August, 2017.

Data Analysis

It was estimated that 117 patients were needed to provide 90% power at the 5% significance level based on a mean change in EQ-5D-5L score of 0.037, a standard deviation of 0.15 in the score both pre and post intervention and a pre/post score correlation of 0.7. For the SPADI, based on a standard deviation of 25% both pre and post, and a pre/post correlation of 0.7, 42 patients would be needed to detect a mean change of 10% with 90% power.

The cases included in the analysis comprised class completers and non-completers. Subjects who withdrew or were withdrawn from the intervention had missing data and were not part of the statistical analysis (Figure 1). With intention to treat analysis normally being based on completed follow up and there being missing data for some subjects the majority but not all of intention to treat analysis has been fulfilled.

Descriptive statistics for continuous data include means and standard deviations while categorical variables are presented as frequencies and percentages. Independent 2 sample t- tests for age and TDS data and a Chi squared test for gender have been

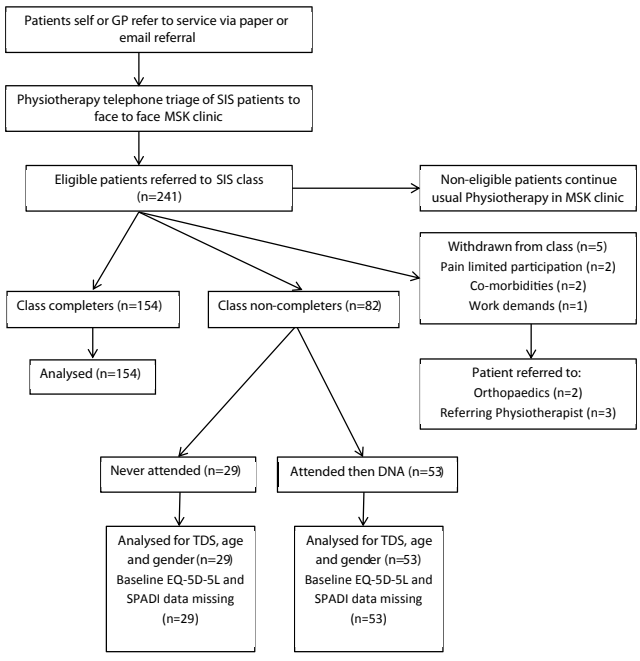

Figure 1: Flow chart of participants through the shoulder impingement class.

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used to show differences between class completers and non-completers with significance at the $p < 0.05$ level [101,102]. EQ-5D-5L and SPADI pre and post test data was not available for the class non- completer group meaning the primary outcomes could not be analysed for that group.

Despite the data being shown to be not normally distributed a sufficiently large sample size was used so that the central limit theorem applies and normality can be assumed [103,104]. Paired t-tests were used to test for class completer within group changes using EQ-5D-5L and SPADI pre and post scores [105]. Statistical significance was deemed significant with $p < 0.05$ for EQ-5D-5L and SPADI scores.

Analysis of the continuous baseline covariates age and TDS was carried out using scatter plots to assess for relationships with EQ-5D-5L and SPADI scores. An independent t-test was used to compare the categorical variable gender to show differences in EQ-5D-5L and SPADI scores. The univariate general linear model was used to predict associations between TDS, age and gender with EQ-5D-5L and SPADI change scores. All data analysis was carried out using SPSS 24 for Windows.

Ethics

Patient consent to data use was gained verbally via the initial telephone triage assessment and recorded electronically for each patient on System One. Given that data collection was retrospective there were minimal risks associated with this service evaluation. There was no potential for physical or psychological harm to patients. None of the patients were from vulnerable groups or in a dependent relationship with the researcher. There was no potential conflict between the researcher and their job role.

Confidentiality, privacy and data protection was maintained in line with DoH [106], guidelines. No information capable of personally identifying patients was recorded and stored on anything other than the encrypted System One programme. The data collected retrospectively from System One and stored on the CSP [81], calculator and SPSS was anonymised with only a numeric value as an identifier. Postcodes stored on SPSS did not link individuals to postcodes. The password protected computer used was secured within an NHS location in a locked cabinet. The data was transferred to an encrypted USB drive and will be stored in a locked NHS cabinet for 5 years (July 2023) whereon it will be destroyed. The researcher was the only person analysing the data. As per Sheffield Hallam University ethics guidelines a Shu rec 7 ethics form was submitted.

Results

Shoulder class completers over the 22 month period included a sample of 154 patients (85 males and 69 females) aged 24 to 84 years, mean age 59 (SD 12.8) years. An additional 82 patients (54 males and 28 females) aged 21 to 79 years, mean age 54 (SD 16.3) years, did not complete the class. Of these 82 patients, 29 never attended and 53 attended then DNA. During data collection it was identified that five participants should not have been involved in the group class due to uncontrolled pain, co-morbidities and not being able to commit to completing the class. The flow of patients through the study is presented in figure 1.

The class completers and non-completers characteristics are presented in table 1. Only TDS, age and gender data was recorded for the class non-completer group. The impact of these variables on class attendance was compared between the completer and non-completer groups (Table 1).

Class completers versus non-completers

Independent t-tests revealed statistically significant differences in mean age (t (134.72) = 2.41, $p = 0.017$) and TDS (t (181.17) = -3.62, $p < 0.001$) between the class completers and non-completers at the p=0.05 level. The average age for class non-completers is 5 years younger than completers meaning younger patients appear to DNA more. The average TDS's showed both groups were relatively deprived. Class completers were 2.08 lower than class non-completers indicating higher levels of deprivation amongst class non-completers. The chi^2 -test for gender resulted in χ^2 =2.511, df=1, p= 0.113 meaning there was no statistical association between gender and class completers and non-completers. There is no evidence that class completion status is associated with gender.

Further analysis of non-completers indicated the mean age for patients who never attended (n=29) was 50.69 (SD 17.84) and those who attended then DNA (n=53) was 55.85 (SD 15.32). The mean TDS for the DNA never attended group was 5.86 (SD 3.77) and attended then DNA group was 4.48 (SD 4.13). Independent t-tests revealed no statistically significant difference in mean age (t (-1.37) = 80, p=0.173) or TDS (t (1.492)=80, p=0.14) between the non-completer subgroups. For gender 19 males and 10 females never attended compared to 35 males and 18 females who attended then DNA. The chi^2-test for gender concluded there is no significant association between gender and non-attendance type with χ^2 =0.002, df=1, p=0.962. There was no significant difference between the two subgroups.

Outcomes

A paired-samples t-test was run on a sample of 154 SIS class completers to determine whether there was a statistically significant mean difference in generic health and shoulder

Table 1: Baseline characteristics of class completers and non-completers. (Data is presented as mean (SD) for the numerical variables and n (%) for the categorical variables).

	Class completers (n=154)	Class non-completers (n=82)	Independent samples t-test and Chi^2 - test *p value*
Age (years)	59 (12.76)	54.02 (16.33)	0.017*
Gender • Male n (%) • Female n (%)	 85 (55.2) 69 (44.8)	 54 (65.9) 28 (34.1)	 0.113
Townsend Z score	2.89 (4.50)	4.97 (4.04)	<0.001*
EQ-5D-5L baseline index score	0.64 (0.16)		
SPADI baseline score	0.45 (0.21)		

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pain and disability before and after a once weekly six week SIS class. Table 2 shows participants' EQ-5D-5L scores were higher post class (0.75, SD 0.16) than pre-class (0.65, SD 0.16); a statistically significant mean difference increase of 0.1 (95% CI, -.13 to -.08), t (153) = -7.77, $p < 0.001$. Positive increases on the EQ-5D-5L indicate improvement in generic health. Standard error was the same (0.12). Figure 2 illustrates the number of patients experiencing improving and worsening generic health outcomes after completing the class. 20.8% (n=32) worsened post class with 70.1% (n=108) improving. 9.1% (n=14) of patients saw no change.

Table 2 shows participants SPADI scores were lower after the SIS class (0.32, SD 0.24) than before the SIS class (0.45, SD 0.22); a statistically significant mean difference decrease of 0.13 (95% CI, .11 to .16), t (153) = -9.36, $p < 0.001$. With negative values on the SPADI indicating improvements a 0.13 decrease shows patients shoulder pain improved post SIS class. Standard error was increased from 0.017 to 0.019. Figure 3 illustrates the number of patients improving and worsening based on their SPADI score post class. 20.1% (n=31) of patients worsened post class with 76.6% (n=118) improving. 3.2% (n=5) of patients saw no change in shoulder pain post class.

Covariate results

No statistically significant correlations were found between either of the continuous variables age and TDS and either EQ-5D-5L or SPADI change scores (Table 3). The scatter plots in (Appendix 12,13) illustrate the absence of relationship between age (r= 0.041 *p=.615)* and TDS (r=0.106, *p*=.190) and EQ-5D-5L change scores and age (r= 0.056, *p*=.487) and TDS (r=0.065, *p*= .426) and SPADI change scores.

Descriptive statistics for gender and EQ-5D-5L and SPADI scores are presented in table 4 below. An independent t-test comparing males and females and EQ-5D-5L index scores (t (152) = 0.351, $p = .726$) and males and females and SPADI scores (t (152) = -0.874, $p = .383$) found no statistically significant differences.

Linear regression results

Univariate general linear models were fitted to predict both EQ-5D-5L and SPADI change scores based from TDS, age and gender separately. No significant regression equation was found to predict SPADI change score using TDS (F (1, 152=.636), *p*=.426, R^2 of .004), age (F (1, 152) =.484, *p*=.487, R^2 of .003), or gender (F (1, 152) =.765, *p*=.383, R^2 of .005). No significant regression equation could be found to predict EQ-5D-5L change scores either using TDS (F (1, 152) =1.729, *p*=.190, R^2 of .0.11), age (F (1, 152) = .254, *p*=.615, R^2 of .002), or gender

Table 2: Paired samples statistics showing EQ-5D-5L and SPADI scores.

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	EQ-5D-5L pre score	.65	154	.16	.012
	EQ-5D-5L post score	.75	154	.16	.012
Pair 2	SPADI pre score	.45	154	.21	.017
	SPADI post score	.31	154	.23	.019

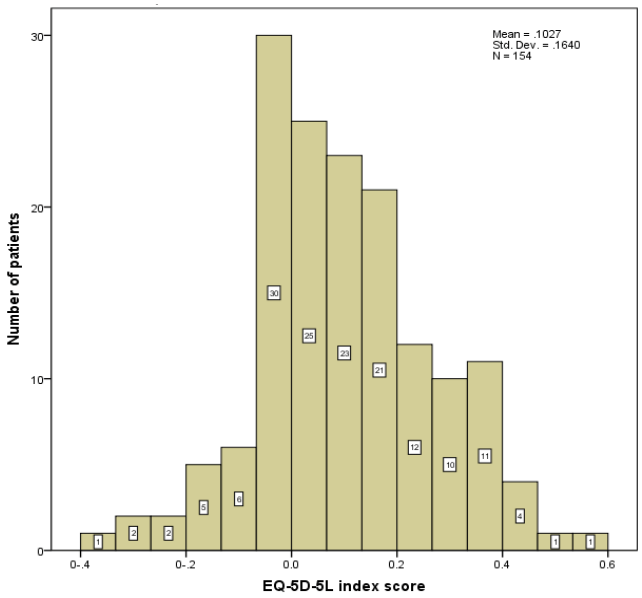

Figure 2: A histogram showing number of patients improving and worsening post SIS class base on EQ-5D-5L scrores.

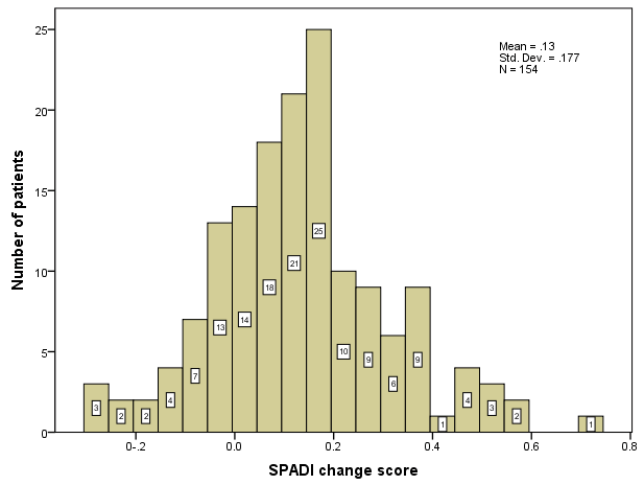

Figure 3: A histogram showing number of patients improving and worsening post SIS class based on SPADI scores.

(F (1, 152) =.123, *p*=.726, R^2 of .001). In summary there is no evidence that TDS, age and gender have any association with EQ-5D-5L and SPADI change scores.

Discussion

Key findings

This paper reports the findings from a service evaluation investigating changes in health and shoulder pain following a SIS class and identifies patient groups at potential risk of poor treatment outcome. The key findings highlighted in this service evaluation that will be discussed are; improvements shown in health and shoulder pain post-class, some patient's health and shoulder pain worsened post- class and younger patients and those from more deprived areas attended fewer classes.

This service evaluation demonstrated the simple clinical finding that following a SIS class both generic health and

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Table 3: Correlations between age and TDS and EQ-5D-5L and SPADI scores.

		Patient age	TDS	EQ-5D-5L change index	SPADI change score
Patient age	Pearson Correlation	1	-.090	.041	.056
	Sig. (2-tailed)		.265	.615	.487
	N	154	154	154	154
TDS	Pearson Correlation	-.090	1	.106	.065
	Sig. (2-tailed)	.265		.190	.426
	N	154	154	154	154
EQ-5D-5L change index	Pearson Correlation	.041	.106	1	.255**
	Sig. (2-tailed)	.615	.190		.001
	N	154	154	154	154
SPADI change score	Pearson Correlation	.056	.065	.255**	1
	Sig. (2-tailed)	.487	.426	.001	
	N	154	154	154	154

** Correlation is significant at the 0.01 level (2-tailed).

Table 4: Gender descriptive statistics for EQ-5D-5L and SPADI change scores.

	Patient sex	N	Mean	Std. Deviation	Std. Error Mean
EQ-5D-5L change index	Male	85	0.11	0.16	0.02
	Female	69	0.10	0.16	0.02
SPADI change score	Male	85	0.12	0.18	0.02
	Female	69	0.15	0.18	0.02

shoulder pain and disability improve. These findings fall in line with multiple systematic reviews on MSK conditions responding well to exercise [24,26-28, 107,108]. The findings also align with research on incorporating graduated rotator cuff loading exercises in managing the pain associated with SIS [7, 29,30,34,50,109]. The related findings from this research conclude that for SIS pain exercise should be prescribed to all patients. Specific shoulder exercises over more general ones were found to be more effective and studies conclude the addition of taping and manual therapy is beneficial [50]. All of these interventions were included in the SIS class and may account for the improvements shown in health and shoulder pain.

SPADI and EQ-5D-5L scores improved with 76.6% (n=118) and 70.1% (n=108) of patients seeing better outcomes respectively. This is the potential mechanism by which they changed. Response to rotator cuff loading has been purported to be linked to the re-conditioning of tendons allowing them to withstand increased stress [110]. Research has shown how tendon tissue becomes stronger by increasing tensile loads through structured exercise [111,14-16]. Littlewood et al. [11,12], postulated the potential theoretical pain mechanisms at play but concede the cause of pain remains uncertain. They argue central sensitisation or a hyper reactive dorsal horn state may drive pain leading to chronicity [11,12]. They describe how the tendon may have healed but plastic changes in the cortex may create pain memories driving an ongoing pain state [11,12],. Modifying output from the central nervous system through graduated loading and having patients contextualise exercise through education has been advocated 'it is good to strengthen deconditioned tissues' [11,12]. Overlap exists with the SPADI and EQ-5D-5L scores gleaned from this evaluation. If shoulder pain and disability can be reduced as shown on the SPADI in this study then EQ-5D-5L scores will improve with greater ability to move the arm with less pain.

There is a further body of evidence for rotator cuff loading and dose response which highlights a number of useful clinical themes [1,2,7,8,15,112-114]. Choosing the appropriate type of loaded exercise has been shown to be important as this may dictate the impact on CNS processing by modifying output potentially reducing threat response [10-12]. Research supports the use of submaximal pain free isometric contractions with increases in pain pressure thresholds indicating descending inhibitory pain mechanisms at play [13]. Loading exercises have been recommended to be completed in mid to inner range to avoid compression at the enthesis whilst avoiding eccentric high load exercises in the reactive or irritable phase [7,8]. Tendon management has been argued to be driven by managing load through relative rest days or ensuring alternating rest days from loading [7,8]. In summary the SIS class facilitated the progressive loading of tendons, allowing relative rest, encouraging pain free movement and educating patients about the complex pathophysiology of SIS. These approaches recommended in the literature may further explain the improvements shown in health and shoulder pain in this evaluation.

A second key finding was that some patients worsened following the class with 20.8% (n=32) and 20.1% (n=31) having worse health and shoulder pain outcomes respectively. This falls in line with some research which suggests class based exercise is not the right environment for everybody [35,115]. Causes of MSK conditions including SIS are thought to be multifactorial in nature not only pathoanatomical and physical but incorporating social, cognitive, lifestyle and psychological elements [10-12,116]. These biopsychosocial or contributing factors to patients MSK pain have been argued as needing a more individualised management approach perhaps explaining some patients worsening class outcomes. The variables used in this evaluation TDS, age and gender were unable to predict patients with poorer outcomes. Other studies have included more psychological and sociodemographic patient orientated predictive variables such as helplessness, pain self-efficacy, fear avoidance beliefs, catastrophising and anxiety and depression scales (Jack et al, 2010) [44,68,117]. Future studies investigating SIS class efficacy may include these variables to help predict those at risk of poorer outcomes.

A third key finding was that significant differences between class completer and non-completer groups were shown. Younger patients and those from more deprived areas had poorer attendance rates. Causal mechanisms for non-attendance have been widely explored and are complex and multi-faceted (Jack et al, 2010)[118]. Acceptability of class based exercise resulting in non-attendance has been shown to be problematic (Jack et al, 2010) [31]. Although no health and shoulder pain outcomes are available for the non-completer group most RCT's show a clear difference in both health and MSK outcomes between

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those who participate in exercise and those participating less or not at all [119-121]. With a tide of societal inactivity, sedentary behaviours, less manual occupations, multiple co-morbidities and increased obesity there are plenty of predictors of poor participation in physical activity [122]. None of these factors were accounted for in this evaluation. It seems fair to posit that younger patients and those from more deprived areas not completing the class may well have had poorer health and shoulder pain outcomes.

My findings are in agreement with all the literature that age and deprivation are commonly associated with non-attendance [39,40,44,49,68,123]. Even though all patients were from relatively deprived areas there was greater deprivation amongst the non-completer group. Mean class completer and non-completer TDS was 2.89 (SD 4.50) and 4.97 (SD 4.04) respectively. A wealth of research shows those from more deprived areas are less likely to adhere to exercise based treatment approaches (Jack et al, 2010) [39,65-67]. The comparably higher deprivation status of the non-completer patients in this study may account for the attendance issues shown.

Class completer and non-completer average age was 59 (SD 13) and 54 (SD 16) respectively. Potential explanations for age being a common factor in non-attendance are that younger patients often have more family and work commitments than older patients. The classes offered did not fall outside of typical working hours and were not offered at the weekend potentially resulting in increased non-attendance. Age similarity has been argued to be a factor in exercise adherence. Relationships between intra-group age similarity and exercise adherence were investigated in the observational study by Dunlop and Beauchamp [124]. They showed attendance was enhanced by grouping similarly aged people the application of which to the SIS class would be logistically unrealistic. These collective findings may be factors in explaining younger patients attending fewer classes.

The majority of studies conclude there is limited evidence for long term strategies to enhance exercise adherence [23]. The Cochrane review by Jordan et al [23], recommended further research due to the poor quality of evidence including measures of adherence. The systematic review by McLean et al. [125], investigating adherence enhancement strategies for physiotherapy found little evidence for any intervention improving long term adherence with exercise. A cognitive behavioural intervention including a motivational programme was shown to have moderate evidence for increasing clinic attendance appointments in the mid-term only [126]. These findings are further borne out in the later systematic review by McLean et al. [44,66,123] showing there are no robust methods to date of measuring adherence. McLean et al. [125], argue identifying new strategies to enhance adherence needs to be improved through a greater understanding of the patient and professional and organisational factors responsible for poor adherence. The systematic review by Seawoodharry et al. [127], determining the effect of feedback on adherence aligns with McLean et al. [125], concluding the need to understand the patient's view of their need for treatment, their expectations and concerns was key in addressing adherence. They concede there is no intervention capable of addressing non-adherence in all patients raising challenges for tackling non-attendance in my service [127].

On balance 65% of patients referred to the class completed it as per the protocol. Compared to other trials this evaluation shows a markedly better class completion rate. McLean et al. [44], found only 47% of patients in their RCT comparing exercise with usual Physiotherapy for neck pain completed the class. In the RCT by Carr et al. [39], worse attendance rates were found when comparing a back class with usual physiotherapy with only 49% attending more than five of the prescribed eight classes. Accounting for the higher attendance rates in the SIS class may be in part due to the interventions administered and fostered within the class including cultivating good patient-therapist relationships, peer support, educational components, question and answer session forums and individual in-class physiotherapy consultation with tailored exercise where appropriate. Although as discussed the majority of research shows adherence strategies to be problematic these components may have been beneficial in improving treatment outcomes and attendance [118,128].

Strengths and limitations of the service evaluation

This service evaluation exceeded its recruitment target of 117 with 154 class completers analysed. Limitations of the evaluation concern the methodology. This evaluation was not an RCT so inferences about causality cannot be made. Limitations with quality and control may have been accounted for by an RCT [129]. There is a tendency for a number of those suffering SIS to spontaneously resolve [130]. During their participation in the SIS class patients may have regressed to the mean with a percentage of patients improving with the passing of time regardless of the class intervention. It is not possible to determine how many patients recovered naturally or how much is related to the active ingredient being the SIS class. An RCT would factor this in with the control group reverting to the mean [131].

There is also variability within MSK conditions across time [18]. Chronic conditions can fluctuate over time with flare ups dependent on activity levels and other aggravating factors. Acute conditions will generally respond in a more predictable way with an initial flare up and slow resolution over time [56]. This makes it difficult to attribute improvements in health and shoulder pain to the SIS class with such variability in the acute and chronic nature of patient's pain. It is possible the acute patients may have improved with the appropriate pain relief and passing of time and the chronic patients improved whilst waiting for their flare up to settle. Again an RCT would take this into account with a control group [131].

Although there was enough data to power the study there was a large amount of missing data for the class non-completer group. Health status and shoulder pain could not be determined for that group or compared to the class completers because patients were not present to complete the outcome measures. Telephone contact or postal surveys may have

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been useful to glean this data although would prove difficult to collect retrospectively with patients perhaps forgetting the status of their health and shoulder pain at the time of their DNA. It is impossible to know if the 82 non-completers improved or worsened following the class and their reason for non-completion. Significant completer and non-completer between group differences in deprivation and age have already been discussed and posited as a cause of non-attendance. By the very nature of exercise classes dropouts are to be expected and have been shown in higher numbers in other trials investigating exercise class efficacy [39,41].

Physiotherapist selection and the variability in treatment received is another limitation with the possibility of bias. Attempts to reduce this bias were made by adhering to Lewis [7], SSMP techniques where able with clear guidance on rehabilitation techniques in response to SSMP techniques. Particular exercises were prescribed with emphasis on specific muscle groups dependent on response to modifying painful shoulder movements. Variation across studies in SIS intervention choice is well cited in the literature as a methodological flaw [1,2,132]. One could argue interventions administered in the SIS class were consummate with usual physiotherapy practice making generalisability to clinical practice easier.

Wider clinical implications

No previous research has investigated the efficacy of a group SIS class. The findings of this service evaluation may help physiotherapists in their clinical reasoning when determining interventions for SIS patients. Limited long term benefits of passive interventions used in common MSK conditions have been cited in the literature [133-135]. The long term benefits of exercise based therapy are well documented the reasons for which are likely to be multi-faceted. Those patients fulfilling SIS class inclusion and exclusion criteria should be fed into class based environments rather than treated on an individual basis. This may in turn increase service efficiency and reduce waiting lists by decreasing perhaps unjustified individual clinic appointments where effective treatment in a group environment could have been meted out.

In contrast individualised physiotherapy interventions over group based ones should be offered to younger patients and those from more deprived areas in an attempt to address attendance issues. Classically SIS patients with attendance issues end up being re-referred to the service by their GP or self-referring back. This often results in patients having to be re-triaged on the telephone line followed by another face to consultation with clear detrimental impacts on waiting lists and ultimately patient health and shoulder pain outcomes. Targeting these patients earlier on for more individualised interventions would seem appropriate.

Supporting people who struggle to attend classes is challenging. In an attempt to improve attendance my service could address the organisational barriers identified as being a determinant of non-adherence by Mclean et al. [125]. The following measures could be taken including implementing individual patient goal settings [44,123]. This could be easily achieved with an additional box added to the patient record sheet with specific weekly goals. Holding in-service training sessions on improving therapist-patient communication have been advocated (Jack et al, 2010) [118]. Ahuja [118], argues the therapist relationship is important and supports a Socratic rather than lecturing approach ensuring an equal therapist and patient power dynamic, with increased levels of patience and understanding the patient's worldview. This approach takes time and is perhaps unrealistic to achieve in a 30 minute session. Prior to class referral an additional physiotherapy consultation could potentially facilitate this more biopsychosocial approach improving attendance though more appropriate SIS class referrals. Enhancing the individualised tailoring of SIS class and home exercises could be meted out through an additional physiotherapy assistant in the class to allow more time for the physiotherapist to cater for patient demands (Jack et al, 2010) [125]. Encouraging increases in general physical activity through the use of discounted leisure service referrals could be reinforced as general exercise is known to have positive effects on MSK conditions [23]. This service is already available to patients but poor uptake may be due to weak links with local council gyms.

Research implications

This evaluation utilised three predictive variables for SIS class outcome and found no association with TDS, age or gender on health or shoulder pain outcomes. A range of sociodemographic and psychological variables discussed earlier not utilised in this evaluation may have been useful in identifying patients more likely to benefit from the SIS class. With the data collection in this evaluation being retrospective it was not possible to include more of these variables. Future studies may account for patients experiencing worsening health and shoulder pain post SIS class by screening more bio-psychosocial covariates. Further research is needed to determine the impact of these covariates on SIS class outcome.

Risk stratification tools like the Keele Musculoskeletal Patient Reported Outcome Measure (MSK-PROM) for generic MSK conditions developed by Hill et al. [76], may be helpful in allowing the identification of factors which predict poorer outcome. The MSK-PROM is argued to be designed more for busy clinical practice, has excellent reliability and provides superior responsiveness to the EQ-5D-5L [76]. Higher scoring more centrally sensitised patients may be screened as less appropriate for class based exercise and offered more psychological cognitive behavioural therapy. While every patient included in this service evaluation met the inclusion and exclusion criteria except the five who were withdrawn from the evaluation, changes to the criteria may be warranted to account for those with increasing biopsychosocial elements to their pain. This might include some form of risk stratification tool like the MSK-PROM. Further research on the MSK-PROM is warranted. There is the potential to embed the MSK-PROM within my current service to help enable better audit and evaluation of classes like the SIS class.

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Conclusions

This service evaluation has identified SIS patients completing a six week SIS class show improvements in health and shoulder pain and disability. Some patients were shown to worsen following the class. Differences between class completer and non-completers were shown with younger patients and those from more deprived areas attending fewer classes.

Physiotherapists should routinely offer class based exercise to those presenting with SIS caveated with younger patients and those from more deprived areas possibly benefiting more from an individualised biopsychosocial approach. Physiotherapists are ideally placed to address the barriers to exercise associated with deprivation and age that patients present with.

Further research is needed to address causes and strategies to improve non-attendance in younger patients and those from more deprived areas. More investigation is needed concerning patients who worsen in exercise based class environments and the reasons for this.

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