The Otago Shoulder Health Study: A Feasibility Study to Integrate Formalised Patient Education with Usual Physiotherapy

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ABSTRACT

The overall study aim was to explore feasibility of a complex intervention that integrates formalised patient education with pragmatic, individualised physiotherapy for patients with rotator cuff-related shoulder pain (RCRSP). Specific aims were to determine: (a) participant recruitment and retention rates, (b) changes in patient-reported outcomes, (c) intervention fidelity, and (d) to scope intervention costs. Twenty-nine participants (M = 60.0 years, SD = 10.5) with RCRSP (duration ≥ 3 months) were recruited within 3 months. They attended up to eight physiotherapy sessions that included structured education about age-related shoulder pathoanatomy, pain biology and self-management, shoulder-specific exercise, general physical activity, and lifestyle considerations. The Shoulder Pain and Disability Index (SPADI) and other patient-reported outcomes measures (PROMs) were assessed at baseline, discharge, and 3-month follow-up. Completion rates for physiotherapy and PROMs were > 80%, confirming feasibility for retention. The mean decrease for the SPADI-Total from baseline to 3-month follow-up was 21.5/100, 95% CI [14.7, 28.2]. Self-efficacy, general health, and patients' satisfaction with their condition improved from baseline to discharge and follow-up. Intervention fidelity was confirmed for integrating two of the four patient resources into treatment, but inconsistent for the remaining two resources and completion of participant diaries. The median number of treatments was 7.5, at a median cost of $600. More provider physiotherapist training is needed to enhance intervention fidelity in the research context.

Sole, G., Wassinger, C., Perry, M., & Swain, N. (2023). The Otago shoulder health study: A feasibility study to integrate formalised patient education with usual physiotherapy. *New Zealand Journal of Physiotherapy, 51*(1), 33–47. https://doi.org/10.15619/NZJP/51.1.05

Key Words: Feasibility, Rotator cuff, Pain, Patient Education, Physiotherapy

INTRODUCTION

A shift in care has been called for persons with musculoskeletal pain from passive interventions to active approaches to improve self-management, patient-centred communication, and patient education (Caneiro et al., 2020; Hutting et al., 2022). Such a shift also applies to shoulder pain. One of the most common shoulder conditions seen in primary care is rotator cuff related shoulder pain (RCRSP) (Virta et al., 2012; White et al., 2022). Statistics provided by the Accident Compensation Corporation (ACC) show a near 50% increase in costs from 2015/2016 to 2020/2021 for "gradual onset", "soft tissue" shoulder injuries for those > 40 years old. People with RCRSP who are otherwise healthy may have up to five weeks off work in the first six months of being diagnosed (Clausen, Nielsen, et al., 2021). It can be a costly condition from personal suffering perspectives (Gillespie et al., 2017), and health and work-related costs (Clausen, Nielsen, et al., 2021; Virta et al., 2012).

Patients' and clinicians' beliefs about RCRSP have largely centred on pathoanatomical models, such as imaging-verified decreased joint spaces (Kircher et al., 2010) or partial or full-thickness rotator cuff tears (Yamamoto et al., 2011). Besides potential pathoanatomical sources, other contributing factors need to be considered, particularly for persistent pain and disability. Patients' beliefs about their pain influence their behaviour and outcomes. For example, catastrophising and fear of harm may lead to avoidance behaviours and negatively influence recovery (Caneiro et al., 2021; Chester et al., 2018; Martinez-Calderon et al., 2018). In contrast, self-efficacy and high expectations for recovery are associated with enhanced outcomes (Chester et al., 2018; Martinez-Calderon et al., 2018). Persistent shoulder pain is often compounded by comorbidities such as cardiometabolic syndrome, diabetes, hypertension, and obesity (Burne et al., 2019; Tashjian et al., 2004) and associated with lifestyle factors such as smoking, poor sleep or diet, and physical inactivity (Börnhorst et al., 2020). Other factors that may be contributors for shoulder pain persistence include work-related loading (Miranda et al., 2006), social determinants of health (Kim et al., 2014; Menendez et al., 2018), and cultural factors (Hoeta et al., 2020; Magnusson & Fennell, 2011). Thus, contemporary

rehabilitation should include education about the biology or neuroscience of pain and the influence of lifestyle factors, as well as using behavioural approaches, contextualised for the individual patient (Meehan et al., 2020).

A pain neuroscience approach shifts the clinician's and patient's focus from pathoanatomical injury or damage to the need to protect the body from real or perceived danger (Louw et al., 2016; Nijs et al., 2015; Stanton et al., 2020). It supports a biopsychosocial approach, centred on the patient's goals, promoting self-management, and includes progressive return to physical activity/exercise and consideration of lifestyle factors (Littlewood et al., 2013; Louw et al., 2016; Nijs, D'Hondt, et al., 2020; Nijs et al., 2015; Stanton et al., 2020). Psychologically informed approaches such as motivational interviewing and cognitive-behavioural interventions may form part of the pain neuroscience approach (Nijs, Wijma, et al., 2020).

Integrating neuroscience pain education with manual therapy, exercise prescription, and general physical activity constitutes a "complex" intervention (Craig et al., 2008). Complex interventions contain various interacting components, often with shared mechanisms (Cook, 2022; Cook et al., 2018). Randomised controlled trials (RCT) of complex interventions require graduated preparatory progressions, spanning from proof-of-concept studies and end-user engagement, to feasibility and pilot studies (Craig et al., 2008). Feasibility studies determine whether defined components of a trial can be done, such as proposed methods for participant recruitment and retention, and treatment fidelity (Eldridge, Lancaster, et al., 2016). Treatment or intervention fidelity defines whether the treatment can be delivered as intended or as described in a research protocol (Carpenter et al., 2013). In the first step of our research pathway, we sought perspectives of participants with RCRSP to a single pain education session, in essence, a proof-of-concept study (Sole et al., 2020). Following the session, the participants had a greater understanding of factors influencing their shoulder pain, but they also sought information about pathoanatomical knowledge (Sole et al., 2020). Thus, in the current study, the second step in the research pathway, we added information about age-related pathoanatomy of the shoulder, and also addressed lifestyle factors that may contribute towards the pain experience to the resource (Nijs, D'Hondt, et al., 2020; Stokes et al., 2017). Our overall aim was to explore feasibility of a complex intervention that integrates formalised patient education with pragmatic, individualised physiotherapy for patients with RCRSP. Specific aims were to: (a) define participant recruitment and retention rates, (b) examine changes in patient-reported outcomes at discharge and at 3-month follow-up, and adverse responses, (c) determine intervention fidelity, and (d) scope intervention costs.

METHODS

Design, ethics, and setting

This observational cohort feasibility study was conducted at the University of Otago physiotherapy clinics (Dunedin and Christchurch) over a nine-month period (2018–2019). The protocol was registered prior to study commencement with the Australian New Zealand Clinical Trials Registry (ACTRN12618001507279) and was approved by the Health and Disability Ethics Committees, New Zealand. All patients provided written informed consent to participate. We used the TIDier framework to describe the intervention (Table 1) (Hoffmann et al., 2014) and the CONSORT checklist for Feasibility and Pilot studies (Eldridge, Chan, et al., 2016).

Participants

Being a feasibility study, a formal sample size calculation was not required (Eldridge, Lancaster, et al., 2016). Johanson and Brooks (2009) recommend a minimum of 24 participants for feasibility or pilot trials. We considered 25 participants to be sufficient to address the aims of the study. To allow for a maximum attrition rate of 15%, we aimed to recruit 30 patients. We recruited patients in the local communities via newspaper adverts and social media.

Inclusion criteria were: (i) age ≥ 40 years; (ii) primary complaint of shoulder pain with or without referral in the upper limb for ≥ 3 months; (iii) shoulder pain provoked with resisted abduction and/or lateral rotation contractions; and (iv) limitation to range of motion of glenohumeral joint in comparison to the contralateral side (≥ 10°). Exclusion criteria were: (i) shoulder surgery in the last 6 months; (ii) known systemic inflammatory disorders; (iii) cervical repeated movement testing affecting shoulder pain and/or range of movement; and (iv) severe depressive symptoms, suicidal inclination or psychotic illness (Patient Health Questionnaire, PHQ-9, score > 23) (Kroenke et al., 2001). Participants with severe depressive symptoms were excluded as we considered they would need expert care beyond the psychologically informed care of this study.

Screening of participants

Participants were screened using the electronic data capture tool, Research Electronic Data Capture (REDCap), hosted at the University of Otago. Those who met the self-reported criteria were then screened for the physical criteria by a physiotherapist. Enrolled participants completed a second questionnaire via REDCap that included demographic data, self-reported co-morbidities (Tashjian et al., 2004), and the following patient-reported outcome measures (PROMs, Appendix 1): Shoulder Pain And Disability Index (SPADI, the primary outcome) (Roach et al., 1991); Fear-Avoidance Beliefs Questionnaire (FABQ) (Kromer et al., 2014); Pain Catastrophizing Scale (PCS) (Kromer et al., 2014); Pain Self-efficacy Questionnaire (PSEQ) (Nicholas, 2012); Patient Acceptable Symptom State (PASS) (Kvien et al., 2007); the Short Form Health Survey (SF-12) (Fan et al., 2008); and EQ-5D-5L (EuroQol Group, 1990). The self-reported outcome measures were repeated at discharge and 3 months post-discharge (follow-up). The PROMs were selected to capture a range of domains relevant for the complex intervention that addressed pain-related behaviour and lifestyle factors, besides levels of pain and disability.

Interventions

Three physiotherapists were familiarised with the study aims and treatment approach. Patients received pragmatic rehabilitation based on the individual baseline physiotherapy assessment, delivered via up to eight sessions over a 3-month period. Up to three sessions could have a duration of one hour, and the remaining five were 30 min. The pragmatic rehabilitation included a symptom-modification approach, patient education,

Table 1.

Overview of Physiotherapy Intervention

TIDier item	Intervention
Name	Formalised neuroscience pain education integrated with pragmatic individualised physiotherapy care.
Why	Cognitive and psychological factors such as self-efficacy, fear avoidance behaviour, pain beliefs and patient expectations can influence the recovery of shoulder pain (Chester et al., 2018; Mallows et al., 2017). Health comorbidities may also compound the experience of pain (Burne et al., 2019). Rationale: Improving health literacy about shoulder pain, age- related changes, pain biology, and lifestyle factors may decrease fear avoidance behaviour, improve self-efficacy, locus of control, and self-management of recurrence (Mallows et al., 2018). Including lifestyle factors may expand the impact of rehabilitation on the pain experience as well as the patient's health and wellbeing.
What (materials)	Patient education: Set of four Microsoft® PowerPoint files and access to online videos developed by the research team. Usual care: Strength training equipment such as free weights and resistance bands. Participant diaries to document goals; progress; physical activity and exercise; pain medication; visits to other health professionals; direct and indirect treatment costs.
What (procedures)	Pragmatic care included: Individualised symptom-modifying processes, focusing on pain and/or stiffness reduction using manual therapy (Cook, 2012; Hing et al., 2015; Lewis, 2016), taping or active movements of the shoulder, and low-intensity shoulder exercises (Ho et al., 2009; Lewis, 2016; Lewis et al., 2015; Willmore & Smith, 2015). Progressive strengthening exercises focusing on the scapular and rotator cuff muscles; trunk mobility and trunk/lower limb strengthening. Physical activity and general exercises (for example walking, stationary cycling), guided by the participants' goals and health status. Patient education: PowerPoint files were used in-clinic to guide provision of information (Acker et al., 2023). Topic sequencing was individualised to each participant. The physiotherapist sent a link to the corresponding videos to participants who were able to watch them as often as they found helpful. Topics: Anatomy of the shoulder Surface anatomy of trapezius, deltoid, biceps, and triceps muscles; rotator cuff musculotendinous unit; Tendinopathy, partial and full tear; common age-related changes of the rotator cuff. Duration: 7:30 min. Connecting with our nervous system The messenger system: neurons, nervous system; the alarm system: sensitivity of the nervous system; factors influencing the alarm system and pain; patterns in the brain ("neurotags"); factors influenced by the "alarm system" (stress, memory, sleep, concentration, digestion, immunity). Duration: 10:30 min. Desensitising the nervous system Beliefs about pain; suffering, emotions, thoughts, and pain; desensitising the nervous system with exercise, breathing exercise, and relaxation. Duration: 6:30 min. Managing shoulder pain and wellness with movement: exercise and general physical activity Role of exercise and physical activity towards general health and wellness and desensitising the nervous system; role of specific exercises to strengthen the shoulder; pacing, "walking the line". Duration: 6:45 min.
Who	Physiotherapists and patient-directed home exercises.
How	Individual face-to-face treatment sessions, independent exercise sessions, and use of patient videos at home.
Where	University of Otago Physiotherapy Clinics (Dunedin and Christchurch) plus home-based programme.
When	A maximal 3-month treatment period, followed by 3-month follow-up period.
How much	Up to eight physiotherapy sessions. Up to three sessions could have a duration of 1 hour, with the remaining sessions being 30 min. The frequency of sessions was based on the physiotherapists' decision-making and participants' availability. The physiotherapist and participant made collaborative decisions regarding discharge. The participants had unlimited access to the videos up to the end of the 3-month follow-up period.
Tailoring	The symptom-modifications and exercise prescription were tailored to the participants' specific impairments, functional limitations, and participation requirements, as appropriate for their activities of daily living, work, and recreational/sports demands. The sequence of the educational topics could be varied based on the physiotherapists' judgement and their conversations with the participant.
How well	Participants recorded their activities in hard-copy diaries and physiotherapists recorded assessments and interventions as per clinical requirements. The diaries and patient documentation were audited and summarised qualitatively.

Note. TIDier: Template for intervention description and replication.

and progressive exercise. The symptom-modification focused on pain and/or stiffness reduction using the physiotherapists' preferred approach. Such interventions may have included manual therapy, taping, active movements of the shoulder, and low-intensity shoulder exercises (Ho et al., 2009; Lewis, 2016; Lewis et al., 2015; Willmore & Smith, 2015). Selection of manual therapy techniques was based on the individual patient assessment and the individual physiotherapists' clinical reasoning, and may have included techniques to the cervical or thoracic spine, glenohumeral joint, and soft tissue mobilisation techniques (Banks et al., 2013; Cook, 2012; Hing et al., 2015). Progressive exercises focused on increasing shoulder loading capacity, muscle strength, and general whole-person physical activity. Specific exercises and physical activities were based on the participant's goals, functional level and requirements in daily life, occupation, recreation, and sports.

Patient education was supported by patient resources developed for this study and included a set of four Microsoft™ PowerPoint files and corresponding online videos (Table 1, Acker et al., 2023). The PowerPoint files were used by the physiotherapists during the treatment sessions, applying the information to the patient's individual context, and the sequence of delivery was guided by the direction taken in the treatment sessions. The patients were able to watch videos using the same slides with a voice-over explanation following the session, review information, and ask the physiotherapists questions again at the subsequent sessions. The physiotherapists were instructed to place emphasis on reflective communication, goal orientation, and self-management of pain fluctuations throughout the treatment series.

Patients were asked to complete a daily exercise diary of their: (a) shoulder-specific exercises and (b) general physical activities. Referral to other providers (e.g., GPs) was based on the physiotherapists' typical practice in collaboration with the patient, and was documented in the clinical notes. The physiotherapist and patient made collaborative decisions regarding discharge. Following discharge, participants were invited to attend interviews to explore their experiences of the intervention (Acker et al., 2023).

Data analysis

Feasibility

Descriptive statistics were calculated for recruitment frequency, the number of eligible patients, the retention rate, and degree of missing data for the patient-rated outcomes measures. For the purpose of this study, the intervention would be considered feasible if 80% of participants completed the physiotherapy intervention until formal discharge, likewise for completion of the discharge and the 3-month follow-up questionnaires.

Clinical outcomes

The primary outcome was the SPADI-Total and all other PROMs were secondary outcomes. The SF-12 was processed using the Optum® Pro-Core software (v1.4, 2019, Optum, Inc, Johnston, RI, USA). Estimates of the treatment effect were calculated with mean differences (and 95% confidence intervals) from baseline to discharge and from discharge to 3-month follow-up for each outcome variables. Differences were analysed with paired t-tests. For non-parametric analyses, medians, and minimum and maximum values were calculated, and differences explored with Wilcoxon Signed Rank tests. Ordinal data were explored using Friedman's test. We used IBM SPSS v24 (Armonk, NY: IBM Corp) and the alpha level was set at 0.05.

PROMs were also compared with clinical meaningful differences or cut-off levels for "high" scores (Appendix 1). The main adverse event was defined as increased levels of pain (change > 3/10 on a Visual Analogue Scale, not subsiding within 24 hr following treatment and/or exercise). Intervention fidelity was determined by auditing the physiotherapists' clinical documentation and patients' diaries. The frequency of use of interventions was determined per patient and per treatment sessions. The number and duration of treatments and costs for the physiotherapy sessions were summarised descriptively (frequency; mean/*SD* for parametric distributions; median/ranges for non-parametric). Patient diaries were explored qualitatively.

RESULTS

Feasibility

Of 92 responders, 63 completed the screening questionnaire within 12 weeks (Figure 1). Of those, 52 attended the screening appointment. Twenty were excluded based on the screening criteria, and three decided not to participate. Twenty-nine (56% of 52) screened volunteers entered the study, with a frequency of two to three patients starting weekly across 12 weeks. Excluded volunteers were provided recommendations for physiotherapists close to them or to consult their GP.

The treatment retention rate was 97% (28 patients): one patient withdrew after four treatments. One patient completed the intervention and baseline demographic questionnaire, but not any PROMs, even after reminders. Twenty-four participants (83% of 29) completed the discharge questionnaires, and 27 (93% of 29) the 3-month follow-up questionnaire.

Clinical outcomes

The patients had a median shoulder pain duration of 21 months (Table 2). All PROMs improved statistically significantly from baseline to discharge and to the 3-month follow-up, respectively, with the exception of the SF-12-Mental Component Score (MCS) (Table 3). For the SPADI-Total, 20 of the 24 patients had an improvement of ≥ 10/100 scores at discharge (69% of 29), and 23 of 27 at 3-month follow-up (79% of 29).

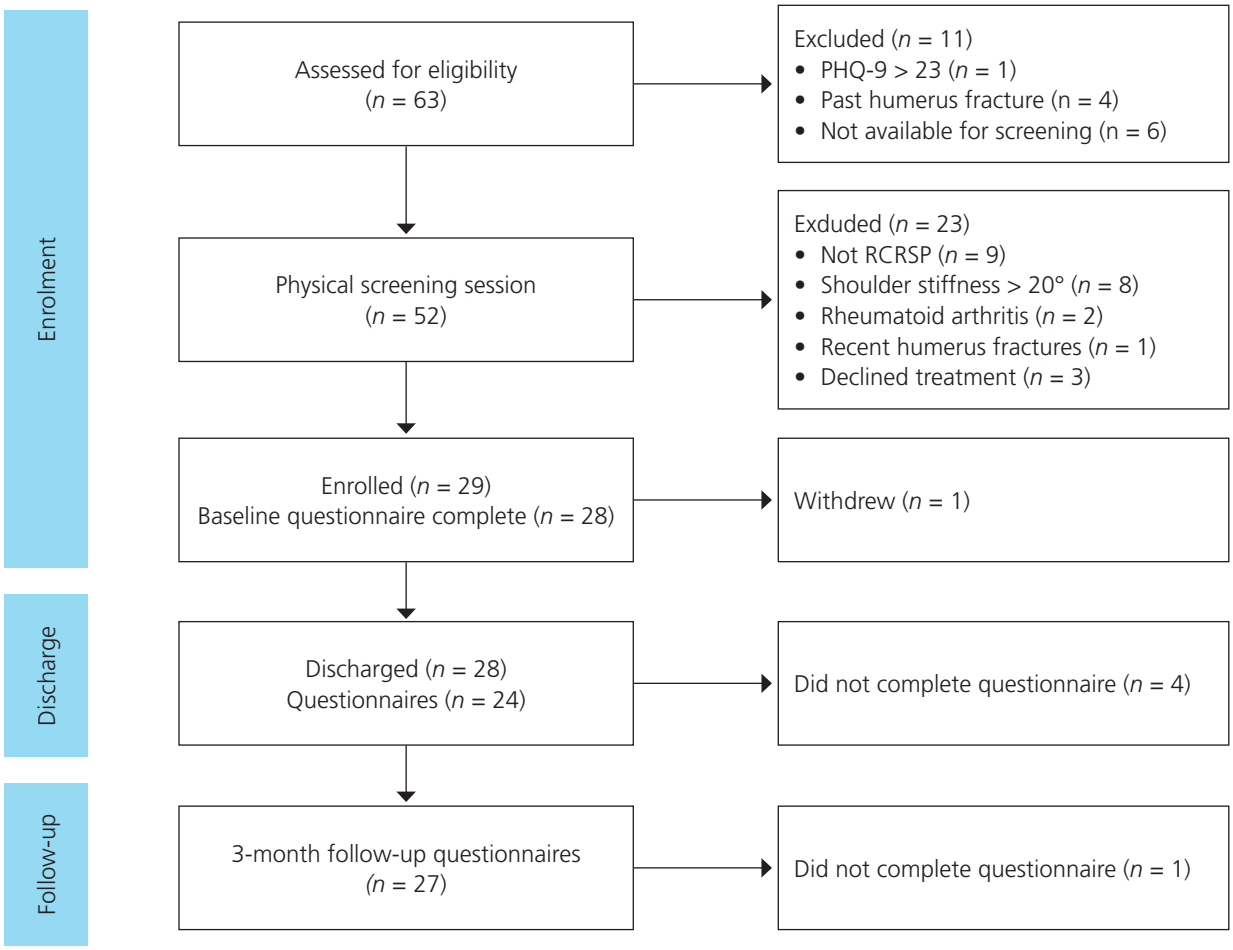
Eighteen patients had "high" fear avoidance beliefs measured with FABQ Physical Activity (≥ 13/24) and three patients with Work scores (≥ 29/42) at baseline. At discharge, four still had "high" fear avoidance for Physical Activity fear and three at 3-month follow-up; no patients had "high" work-related fear avoidance scores at discharge or 3-month follow-up.

The PCS were low (median 6/52) and decreased from baseline to discharge and to follow-up. For the PSEQ, 12 patients scored below 48/60 at baseline (low pain self-efficacy, Chester et al., 2019), compared to four at discharge and one at follow-up. An 8.5-point increase was evident from baseline to follow-up for 14 patients.

The SF-12 Physical Component Scores improved at discharge and follow-up respectively compared to baseline, but not at the pre-defined minimum important clinical difference of 5.4

Figure 1

CONSORT Diagram: Observational Study



Note. PHQ-9 = Patient Health Questionnaire; RCRSP = rotator cuff related shoulder pain.

(Appendix A) (Wong et al., 2016). The EQ-VAS and the EQ-index, respectively, improved by discharge and at follow-up compared to baseline. The follow-up difference for the EQ-index was greater than the reported MID of 0.08 (MacDermid et al., 2022). No participant had a "perfect health" index of "1" at baseline, while four participants achieved that score at follow-up.

For the PASS, decreasing frequencies were found for being "very dissatisfied" with the symptom state from 10 patients at baseline (34.5%) to one patient (3.4%) at discharge and none at follow-up (Figure 2). Increasing frequencies were evident for being "very satisfied". The frequency differences at the three time points were significant ($p < 0.001$).

Intervention fidelity

The clinical documentation audit suggested that physiotherapists had provided all participants with information from the first two education topics (Table 4). Topic 3 (desensitising exercise) appeared to have been explored with 23 participants (79%), and the topic of lifestyle factors and physical activity with 22 (76%). All four topics were included in sessions for only 18 participants (62%).

All participants were prescribed rotator cuff focused exercises and 21 (72%) had also received scapular focused exercises. Nineteen participants (66%) had received manual therapy for a median of three sessions, while the remainder did not. Prescription of physical activity was not recorded in the clinical notes.

All participants returned their diaries, but only four had completed comments about all four videos. Twenty had recorded their physical activity and duration but did not add the intensity consistently. Ten patients recorded use of pain medication (paracetamol, non-steroidal anti-inflammatory drugs). Two patients entered indirect costs related to their shoulder pain as transport costs to physiotherapy and time off work to attend those sessions. No other times off work related to shoulder pain were documented. No adverse events were recorded in the clinical documentation or participants' diaries.

Intervention costs

Table 5 presents analyses of screening and treatment sessions durations, number and frequency of physiotherapy sessions, and direct costs per patient. Two patients were offered nine treatment sessions. The median cost to deliver the physiotherapy

Table 2

Characteristics of Participants

Variable	Value
Age, years (mean, *SD*)	60.0 (10.5)
Gender, *n* (%) women/men	11 (38)/18 (62)
Ethnicity, *n* (%) [a]	
New Zealand European	23 (79)
Māori	2 (7)
European	2 (7)
Indian	1 (3)
Samoan	1 (3)
Chinese	1 (3)
African	1 (3)
Sri Lankan	1 (3)
Duration of shoulder symptoms, months (*Mdn*, min–max)	21 (3–300)
Pain laterality, *n* (%)	
Dominant side	14 (48)
Non-dominant side	10 (35)
Bilateral	5 (17)
Self-reported prior treatment, *n* (%)	
None	9 (31)
Physiotherapy	11 (38)
Osteopathy/chiropractic	2 (7)
Massage	4 (14)
Cortisone injections	5 (17)
Analgesics	9 (31)
Self-reported comorbidities, *n* (%)	
Back pain	13 (45)
High blood pressure	9 (31)
Headaches or migraines	6 (21)
Osteoarthritis	5 (17)
Depression	4 (14)
Diabetes	2 (7)
Cancer	1 (3)
Kidney disease	1 (3)
Lung disease	1 (3)
Ulcer or stomach disease	1 (3)
Other medical problems: thyroid condition, prostate disorder, cholesterolemia, asthma	6 (21)
Number of comorbidities, *n* (%)	
None	4 (14)
One	9 (31)
Two	10 (34)
Three	4 (14)
Four	2 (7)

Note. [a] 3 patients identified with two ethnicities.

sessions per patient was NZ$600. At follow-up, one patient reported having consulted their GP about their shoulder pain and was waiting for a magnetic resonance imaging referral and orthopaedic specialist review (SPADI-Total at baseline = 73.1/100; discharge = 54.6/100; follow-up = 46.2/100; EQ-Index = 0.681). Another patient requested a referral to an orthopaedic surgeon review (SPADI-Total at baseline = 34.6/100; discharge = 30.8/100; follow-up = 25.4/100, EQ-Index = 0.711). Costs for medication use and indirect costs, such as transport to physiotherapy or time off work to attend the sessions, could not be determined due to incomplete documentation.

DISCUSSION

We explored the feasibility of a complex intervention that integrated formalised patient education with pragmatic, individualised physiotherapy for participants with RCRSP in the New Zealand private practice context. The retention rates for treatment until discharge and for completion of the follow-up questionnaires were greater than 80%, meeting our *a priori* requirement for feasibility of the intervention. While the topics of pathoanatomy and pain neuroscience were discussed with all patients, exploring a "desensitising" exercise and considering lifestyle and physical activity were not consistently documented in the clinical notes. Two-thirds of the patients had received manual therapy for at least one session. Most recorded exercise prescription focused on rotator cuff and scapular function, with less frequent documentation of spinal mobility and upper limb closed kinetic chain exercises. There was no documentation of exercises for the trunk and lower limb strengthening, for general physical activity or other lifestyle factors such as sleep.

Participants and clinical outcomes

This cohort with persistent RCRSP had similar SPADI-total scores compared to those categorised as subacromial pain in a recent clinical audit of two physiotherapy practices in New Zealand (*M* = 35, *SD* = 22) (White et al., 2022), suggesting potential generalisability to people with RCRSP in this country. At baseline, only 15% of patients were "somewhat" or "very" satisfied with their current condition, compared to 85% at 3-month follow-up. They had low PCS scores (indicating that pain catastrophising was unlikely to occur) and variable levels of self-efficacy and activity-related fear avoidance. The mean EQ-VAS of 80.8 was comparable with those found in a cohort of 40–69-year-old New Zealanders (81–84/100) (Devlin et al., 2000).

We found decreased pain intensity (based on SPADI-Pain) and fear avoidance, improved function, and self-efficacy at discharge and 3-month follow-up. The improvements for SPADI-Pain and -Disability from baseline to 3-month post-discharge follow-up need to be considered in the context of the symptom duration of our cohort (*Mdn* = 21 months). Symptoms are likely to improve for most people with rotator cuff syndrome within a few weeks, but up to 50% of people can have persistent pain and disability between 6 to 12 months after the first consultation (Kuijpers et al., 2006; Virta et al., 2012). The participants of our study reflect those already with persistent or recurring pain and disability, thus, were part of a patient group potentially incurring the highest contribution to the health costs or work-related absence.

Table 3

Patient Reported Outcomes (PROMs) at Baseline, Discharge and 3-month Follow-up

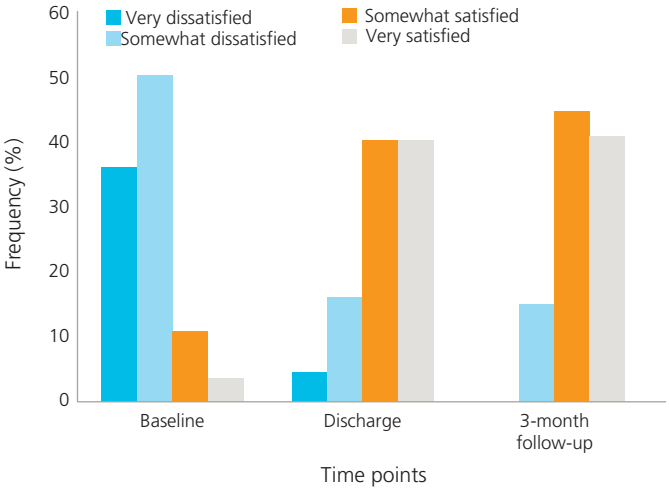
Variable	Baseline		Discharge						3-month follow-up					
	M	*SD*	*M*	*SD*	MD	95% CI		*p*	*M*	*SD*	MD	95% CI		*p*
						LL	*UL*					*LL*	*UL*	
N	28		24		24				27		27			
SPADI-Pain	45.3	20.1	23.6	18.5	–23.7	–32.4	–15.0	< 0.001	19.0	15.4	–26.8	–35.2	–19.0	< 0.001
SPADI-Disability	25.2	17.6	10.1	11.5	–17.1	–23.8	–10.5	< 0.001	7.1	7.5	–18.6	–25.4	–11.8	< 0.001
SPADI-Total	35.3	17.7	16.8	14.0	–20.3	–27.5	–13.3	< 0.001	13.1	10.7	–21.8	–29.8	–15.7	< 0.001
FABQ-Physical Activity	13.0	4.8	6.9	6.1	–6.4	–8.6	–4.3	< 0.001	6.7	5.4	–6.7	–8.7	–4.8	< 0.001
FABQ-Work	8.8	10.2	6.2	7.5	–3.5	–6.7	–0.3	0.032	6.3	7.5	–2.9	–5.2	–0.6	0.014
FABQ-Total Score	28.6	16.7	17.3	11.2	–12.8	–17.8	–7.8	< 0.001	17.6	12.8	–22.7	–15.4	–7.8	< 0.001
PCS	5	0–22 [a]	3	0–13 [a]	–2.0	–18.0	8.0 [b]	0.015 [c]	2	0–22 [a]	–2.0 [b]	–9.0	4.0 [b]	0.003 [c]
PSEQ	49.1	8.7	56.2	5.9	7.4	4.4	10.3	<0.001	57.6	5.2	8.4	5.0	11.9	<0.001
SF12 Physical Component Score	48.8	5.6	52.3	5.7	4.3	2.5	6.1	<0.001	53.3	4.2	4.6	2.5	6.7	<0.001
SF12 Mental Component Score	53.0	7.1	55.2	7.4	2.6	0.3	5.5	0.074	53.4	7.6	0.4	–2.2	3.0	0.754
EQ-5D-5L Index	0.718	0.092	0.783	0.125	0.065	0.023	0.107	0.004	0.806	0.125	0.083	0.036	0.129	0.001
EQ-5D-5L Visual Analogue Scale (%)	80.8	7.9	84.1	8.0	3.5	0.6	6.4	0.019	85.2	8.0	4.8	2.1	7.4	0.001

Note. CI = confidence interval; FABQ = Fear Avoidance Belief Questionnaire; MD = mean difference; PCS = Pain Catastrophising Scale; PESQ = Pain Self-Efficacy Questionnaire; SF-12 = Short Form Survey; SPADI = Shoulder Pain and Disability Index.

[a] Median (minimum to maximum). [b] Median difference (minimum to maximum). [c] Wilcoxon signed ranks test.

Figure 2

The Patient Acceptable Symptom States: Patients' Scores to the Question "If You Had to Live the Rest of Your Life with The Symptoms You Have Now, How Would You Feel?" at Baseline, Discharge, and 3-month Follow-up



The 3-month post-discharge change for SPADI-Total of 22 points was comparable with previously reported changes in response to physiotherapy for chronic rotator cuff disease or shoulder impingement (Bennell et al., 2010; Clausen, Hölmich, et al., 2021). Bennell et al. (2010) undertook a placebo-controlled RCT for people with rotator cuff disease. Standardised physiotherapy of the intervention arm comprised soft tissue and glenohumeral, thoracic, and cervical spine mobilisations, taping, scapular retraining and home exercises, and behavioural strategies (education, goal setting motivation, and positive reinforcement). Clausen, Hölmich, et al. (2021) undertook an RCT to determine effectiveness of higher strengthening exercise dose compared to usual physiotherapy for patients with chronic shoulder impingement referred to a Danish hospital orthopaedic department. Similar improvements for the SPADI-Total are thus apparent in various clinical trials for patients with RCRSP, despite differences in interventions (Bennell et al., 2010; Clausen, Hölmich, et al., 2021).

When comparing our results to the above trials (Bennell et al., 2010; Clausen, Hölmich, et al., 2021), the commonality for the interventions across different trials and our study may also be due to the patient-physiotherapist therapeutic alliance (Kinney et al., 2020; McParlin et al., 2022).

Table 4

Audit of Physiotherapy Clinical Patient Documentation

Item	*n*	%	Number of treatment sessions [a]	
			Mdn	Range
Provision of patient education				
Topic 1: Anatomy, age-related changes	29	100	1	
Topic 2: Pain education	29	100	1	
Topic 3: Desensitising exercise	23	79	1	
Topic 4: Lifestyle factors, physical activity	22	76	1	
Manual therapy				
Glenohumeral joint mobilisations	14	48	2	1–7
Cervical spine mobilisations	7	24	2	1–5
Thoracic spine mobilisations	8	28	2	1–4
Thoracic spinal manipulation	1	3	1	
Soft tissue mobilisations	15	52	2	1–5
All manual therapy	19	66	3	1–7
Taping				
Taping "to correct posture"	6	21	1	1–2
Home exercise programme				
Rotator cuff focused	29	100	3	1–7
Scapular focused	21	72	3	1–6
Spinal mobility	8	28	1	1–4
Upper limb closed kinetic chain	11	38	2	1–4

[a] Applicable to patients who received the interventions only.

Table 5

Cost of Screening and Physiotherapy

Item	Value
Screening: number of volunteers screened, duration of screening sessions, total time in hr	52, 30 min, 26 hr
Physiotherapy sessions: number of sessions, total time in hr	
60-min sessions	54, 54
30-min sessions	155, 77.5
Cost for physiotherapy sessions per patient, *Mdn* (min–max), NZ$120.00 per hr	NZ$600.00 (420–660) [a]
Number of treatments, *Mdn* (min–max)	7.5 (4–9)
9 sessions, *n* (%)	2 (7)
8 sessions, *n* (%)	13 (45)
7 sessions, *n* (%)	7 (24)
6 sessions, *n* (%)	5 (17)
5 sessions, *n* (%)	1 (3)
4 sessions, *n* (%) (patient withdrew)	1 (3)
Time period, *Mdn* (min–max), weeks	11.5 (5–18) [a]
Frequency per week, *Mdn* (min–max)	1.6 (1–2.1) [a]

[a] Excluding withdrawn patient.

Specifically for the current study, 10 participants took part in a post-intervention qualitative study. They highlighted the positive relationships with their provider physiotherapists and commented on their clear communication styles (Acker et al., 2023). They appeared to appreciate the in-depth conversations, perhaps building trust (Acker et al., 2023), which is considered to be critical for patient engagement and outcomes (White et al., 2020). The role of the professional relationship and interactions with the patients could be seen as a critical confounder to the outcomes of different interventions and needs further exploration (Hutting et al., 2022). To control for the therapeutic relationship, the same physiotherapists may need to provide interventions of different arms of RCTs; however, that may come at the cost of possible contamination bias (Bennell et al., 2010; Sterling et al., 2019). Contamination bias occurs when interventions of one arm of a RCT filters through to the intervention of other arm(s). Analyses of audio recordings of physiotherapy interactions with study participants have been used to monitor delivery of psychologically informed interventions by physiotherapists (Sterling et al., 2019). Such analyses may be suitable in future trials to monitor intervention fidelity of the therapeutic relationship.

Intervention fidelity

The patient education was formalised by providing the resources. Yet the full set of topics was provided to only 62% of the participants; thus, fidelity for the use of those resources can be considered to have been moderate. Expanding patient education may detract from time usually allocated by the physiotherapist for manual therapy and supervised exercise within the treatment sessions. With the observational cohort research design, the effectiveness of decreasing manual therapy and supervised exercise, and allocating more time to education and self-management were not explored.

Comorbidities were high for this group of participants, with 45% self-reporting also living with low back pain and 55% reporting two or more comorbidities. In comparison, only 15% of people at the age of 60 (similar to participants of our study) had two or more comorbidities in a New Zealand-based epidemiological study (Stanley et al., 2018). There is increasing awareness of the high incidence of metabolic comorbidities and lifestyle factors being associated with persistent shoulder disorders (Börnhorst et al., 2020; Burne et al., 2019; Clausen, Bandholm, et al., 2018; Tashjian et al., 2004). The frequency of comorbidities highlights the importance of lifestyle interventions, especially physical activity, as critical interventions for these participants. Yet, based on the clinical documentation audit, the fourth resource, focusing on the role of general physical activity and lifestyle factors, was not included for all participants. A recent Australian survey showed that physiotherapists do not regularly prescribe general physical activity for musculoskeletal conditions (Kunstler et al., 2019). As expected, they prioritise problems directly relating to the painful body segment, and may lack confidence to prescribe general physical activity to people with musculoskeletal pain (Barton et al., 2021; Kunstler et al., 2019). Existing physiotherapists' biomedical beliefs (Bernhardsson et al., 2015; Gibbs et al., 2021; Meehan et al., 2020) may encourage reliance on interventions such as manual therapy, allowing less time for patient education. Some participants taking part in our subsequent qualitative study reported that they did not find the fourth video (lifestyle) helpful or applicable (Acker et al., 2023). It is possible the reluctance of those participants to accept that information discouraged the physiotherapists from consistently including those resources. Physiotherapists may need more support to include behaviour and lifestyle-related changes for patients with persistent musculoskeletal disorders (Barton et al., 2021). Strategies are also needed to help patients understand why such interventions are important for their shoulder pain, besides for their general health and wellness (Cridland et al., 2020).

Access to medical care and physiotherapy can be challenging for patients due to social, economic, and geographic (including rural) factors, especially for those living with multi-morbidities (Stokes et al., 2017). Cultural preferences also influence access to care (Hoeta et al., 2020; Magnusson & Fennell, 2011).

Treatment costs for non-traumatic RCRSP are not covered by ACC; therefore, access to healthcare for such patients depends on self-funding or access to the national hospital system, often with long waiting lists. Physiotherapy waiting lists for people with musculoskeletal disorders, including those of the shoulder, can worsen health outcomes. Patients on such lists have higher health costs than those who receive earlier physiotherapy appointments (Deslauriers et al., 2021; Virta et al., 2012). By enhancing patients' health literacy, self-efficacy, and self-management of exacerbations, needed number of treatments (and thus costs) might decrease (Cridland et al., 2020). Yet a focus on patient education may be challenging in the context of patients expecting manual therapy from physiotherapists, as well as limited available treatment time in many clinical contexts (Cridland et al., 2020; Stanton et al., 2020). Our research pathway uses a stepwise approach to address those challenges, developing resources that may provide a basis for patient education, seeking input from people with shoulder pain (Acker et al., 2023; Sole et al., 2020) as well as physiotherapy clinicians.

Implications for future research

This was an observational cohort feasibility study undertaken to inform future RCTs. The recruitment rate provides estimates for the duration and number of volunteers needed to be screened to achieve a specified sample size across two centres, using our recruitment strategies and inclusion criteria (Table 5). We provide estimates for the number of treatments and costs likely to be needed for such pragmatic trials from funding perspectives (Table 5). The analysis also provides insights about treatment interventions that physiotherapists may select for patients with RCRSP in a pragmatic intervention in the New Zealand healthcare context (Table 4). When conducting research related to shoulder pain, provider physiotherapists may need to be familiarised to a greater extent about additional requirements of clinical documentation, as well as in the delivery of behaviour change strategies to underpin lifestyle and physical activity interventions. Such trials would need to provide funding for additional time for administration and documentation required for the research. Lack of documenting interventions in clinical patient notes does not verify that the intervention was not included in the sessions. In future trials, other strategies will be considered to monitor intervention fidelity, such as audio-recordings of selected treatment sessions (Sterling et al., 2019). Similarly, lack of documentation in patient diaries indicates non-compliance with documentation but does not confirm non-compliance with the prescribed activity. Instructions for patients about requirements for the diaries will need greater emphasis in future trials. Other formats for diaries may need to be considered, such as online diaries with automatic reminders via texting or emailing.

Methodological consideration

The study was designed to inform a future RCT that includes the complex intervention, the recruitment strategy, and participant inclusion and exclusion criteria in the New Zealand context. A strength of the study was the use of a pragmatic approach for the intervention, enhancing validity for clinical practice and translation. While a pragmatic approach enhances external validity for clinical practice, it decreases internal validity (homogeneity of treatment approach). We did not measure physical outcome measures such as range of motion and muscle strength but focused on PROMs. Physical measures have not changed significantly in previous trials with patients with RCRSP despite evident changes for PROMs (e.g., Clausen, Merrild, et al., 2018) but could be explored in a larger trial. As in most trials, the possible Hawthorne effect of participating in a trial without direct costs to the patient cannot be excluded for changes observed in the PROMs (Clausen, Hölmich, et al., 2021).

CONCLUSION

We explored the feasibility of conducting a study integrating defined patient pain neuroscience education with pragmatic physiotherapy for patients with persistent RCRSP. The patient pain neuroscience education focused on pain biology and its relevance for rehabilitation, self-management, physical activity, and lifestyle factors. The rates of physiotherapy completion to discharge, and patient completion of discharge and 3-month follow-up questionnaires above 80% indicate that the recruitment, intervention, and data collection processes are feasible. Clinically meaningful decreases in self-reported shoulder pain and disability, and enhanced pain self-efficacy were evident for the cohort and maintained for 3 months following discharge. The effectiveness of this complex intervention compared to usual physiotherapy or other interventions needs to be confirmed in an RCT. In future trials related to physiotherapy for RCRSP, more support and training may be needed for the physiotherapists to deliver behaviour change approaches and consider lifestyle factors. Similarly, strategies are needed to improve patient completion of activity, medication, and cost diaries.

KEY POINTS

1. We integrated patient pain education with usual physiotherapy for shoulder pain.
2. Patient education was supported by a set of four online videos and PowerPoint files.
3. Physiotherapists require more support to deliver behaviour change interventions.
4. On average, shoulder pain and disability improved over the course of the sessions.
5. As a feasibility study, results need to be interpreted with caution.

DISCLOSURES

This study was supported by a Jack Thomson Arthritis Grant, Otago Medical Research Foundation. There are no conflicts of interest that may be perceived to interfere with or bias this study.

PERMISSIONS

The protocol was registered prior to study commencement with the Australian New Zealand Clinical Trials Registry (ACTRN12618001507279) and was approved by the Health and Disability Ethics Committee (reference number 18/CEN/145), New Zealand.

ACKNOWLEDGEMENTS

We thank Stuart Horton, Lisa McKinnon and Jeffrey Huang for provision of physiotherapy, and David Jackson and Melanie Vooney for their research assistance.

CONTRIBUTIONS OF AUTHORS

Project conception and study design, GS, CW, MP and NS. Data collection and analysis, GS. Data interpretation, GS, CW, MP and NS. Writing – original draft preparation, GS; writing – review and editing, GS, CW, MP, NS; funding acquisition, GS, CW, MP and NS.

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Appendix

Appendix A

Patient Reported Outcomes Measures

Outcome measure	Description and psychometric properties
SPADI (Breckenridge & McAuley, 2011; Roach et al., 1991; Roy et al., 2009)	The SPADI includes a 5-item subscale that measures pain and an 8-item subscale measuring disability on a score from 0 to 10, where "0" represents no pain/no difficulty and "10" represents worst pain imaginable/so difficult required help. Each subscale is summed and transformed to a score out of 100. The mean is taken for the two subscales to give a total SPADI score out of 100 (higher scores = greater impairment or disability). The SPADI has excellent reliability, validity, and responsiveness (Roy et al., 2009). Changes between 8.0 and 13.2 points in the SPADI-Total score are considered clinically meaningful (Roy et al., 2009). An MCID of 10 was selected for this study *a priori*.
FABQ (Inrig et al., 2012; Mintken et al., 2010)	The FABQ measures patient's pain-associated fear avoidance beliefs about physical activity and work. It consists of 16 items with a 7-point Likert scale where "0" is "completely disagree" and "6" is "completely agree". The total maximum score is 96, 24 for the subscale Physical Activity, and 42 for Work. A meaningful difference was defined as 8 for Physical Activity and 13 for Work. Cut-off values to indicate "high" scores for patients with shoulder pain have not been established, to our knowledge. In this study we consider scores to be "high" for fear avoidance beliefs for Physical Activity ≥ 13/24 and for Work ≥ 29/42, based on findings for patients with low back pain (Cleland et al., 2008; Inrig et al., 2012).
PCS (Kromer et al., 2014; Sullivan et al., 1995)	The PCS quantifies beliefs about pain (Sullivan et al., 1995). It consists of 13 statements about pain, each scored on a 5-point Likert scale where "0" is "not at all" and "4" is "all the time". The maximum score is 52 and higher scores indicate more strongly held fear avoidance beliefs. It has three sub-scales: rumination, magnification and helplessness. The total score is considered in this study. The PCS has demonstrated reliability and validity and is commonly used to evaluate pain catastrophising across a range of musculoskeletal conditions, including shoulder pain (Coronado et al., 2016; Osman et al., 1997; Sullivan et al., 1995). We define "high" pain catastrophising as a score of ≥ 21/52 (Park et al., 2016).
PSEQ (Maughan & Lewis, 2010; Nicholas, 2012)	The PSEQ assesses pain-related self-efficacy in people with chronic pain. It consists of 10 statements and respondents are asked to rate how confident they are with those scenarios/tasks despite the pain. Each statement is rated on a 7-point Likert scale where "0" is "not at all confident" and "6" is "completely confident". A higher score indicates higher self-efficacy beliefs. For low back pain, an 8.5-point increase has been defined to be clinically meaningful (Maughan & Lewis, 2010). We considered a score of ≥ 48/60 to indicate "high" self-efficacy (Chester et al., 2019).
PASS (Kvien et al., 2007)	PASS is the highest level of symptom beyond which patients consider themselves well, and has been used to determine to minimally important change for various patient reported outcome measures (Tran et al., 2020). It is used in adapted version in this study with the question "If you had to live the rest of your life with the symptoms you have now, how would you feel?", similar to Mintken et al. (2016). Patients were asked to rate their satisfaction on a 4-point Likert scale ranging from "1" (very dissatisfied) to "4" (very satisfied).
SF-12 (Fan et al., 2008)	The SF-12 consists of 12 items that assess eight dimensions of health: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health (Ware et al., 1996). Outcomes from the SF-12 include an overall health score as well as component scores of physical and mental health (Ware et al., 1996). Responses are rated on a 5-point Likert scale with overall scores ranging from 0 (lowest health level) to 100 (highest health level) (Singh et al., 2006; Ware et al., 1996). The SF-12 is commonly used to determine health status in patients with musculoskeletal disorders (Scholten et al., 2017). MCIDs of 5.4 and 5.7 for the Physical Component Score and Mental Component Score have been reported respectively for patients undergoing shoulder arthroplasty (Wong et al., 2016).

Outcome measure	Description and psychometric properties
EQ-5D and EQ-5D-5L (EuroQol Group, 1990)	The EQ-5D-5L assesses overall health related quality of life and comprises two components (EuroQol Group, 1990). The first component is a descriptive system with five health dimensions (mobility, self-care, pain/discomfort, usual activities, and anxiety/depression), each scored on five response levels: no problems (Level 1), slight, moderate, severe, and extreme problems (EuroQol Group, 1990). These levels are collapsed into a utility/index score whereby "0" indicates death and "1" indicates perfect health. A MID of 0.08 has been reported (MacDermid et al., 2022). The second component consists of a visual analogue scale (EQ-VAS), providing a single global rating of self-perceived health on a 1 to 100 mm scale representing "the worst" and "the best health you can imagine", respectively. A survey of 1,350 New Zealanders showed a mean score for the EQ-VAS ranging between 81 and 84% for 40 to 69 year-olds, and 75% for those 70 years and older (Devlin et al., 2000). The mean for New Zealand Europeans (n = 1,127) across all age groups was 80.9%, for Māori (n = 124) 80.3%, and for all other ethnicities (n = 99) 80.7%. We report the EQ Index and the EQ-VAS. The Index calculator was downloaded from https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/valuation-standard-value-sets/crosswalk-index-value-calculator/

Note. FABQ = Fear Avoidance Behaviour Questionnaire; MCID = minimal clinically important difference; MID = minimal important difference; PASS = Patient Acceptable Symptom State; PCS = Pain Catastrophising Scale; PSEQ = Pain Self-Efficacy Scale; SF-12 = Short Form Health Survey; SPADI = Shoulder Pain and Disability Index.