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Exploring the personal burden of shoulder pain among younger people: Protocol for a multi-centre cohort study

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Abstract

Introduction: Persistent musculoskeletal conditions can impact profoundly on younger people's quality of life, psychological distress and capacity to work, as shown by previous research involving younger people with osteoarthritis. The personal impacts of other musculoskeletal conditions (such as persistent shoulder pain) on younger patient groups remain poorly understood; in particular, work and parenting impacts. Furthermore, the personal financial burden associated with managing musculoskeletal conditions is rarely documented. This study aims to investigate wellbeing, work participation and productivity, shoulder-related parenting disability, and out-of-pocket healthcare expenditure among younger people with shoulder pain, and evaluate changes over 12 months.

Methods and analysis: One hundred and fifty people aged 20-55 years with shoulder pain of more than 6 weeks' duration (excluding those with recent history of fracture or dislocation) will be recruited for this cohort study. Participants will be recruited from three major public hospitals in Victoria, Australia following screening of orthopaedic outpatient clinics lists and referrals. Participants will be asked to complete a baseline questionnaire and two-week healthcare costs diary, with follow-up data collected at 12 months. Patient-reported outcomes will be collected, including health-related quality of life (HRQoL), shoulder pain and function, psychological distress, shoulder-related parenting disability, and work productivity. Information on sociodemographics, employment, health services utilisation and shoulder-related healthcare expenditure will also be collected. Descriptive analysis of baseline data will provide a comprehensive snapshot of the personal burden of shoulder pain. Baseline HRQoL and psychological distress data will be compared to Australian population norms to provide context around wellbeing. Associations between sociodemographic factors and patient-reported outcomes will be evaluated using univariate and multivariate analyses. Changes in patient-reported outcomes from baseline to 12 months will be analysed using paired t-tests.

Ethics and dissemination: Ethics approval has been obtained. The study findings will be submitted to peer-reviewed journals and presented at relevant scientific meetings.

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Strengths and limitations of this study

- This study will provide a comprehensive overview of the health-related and work-related impacts of persistent shoulder pain among younger people, as well as the impact on parenting tasks
- This study will also quantify the out-of-pocket (non-reimbursed) healthcare costs borne by a cohort of younger people with shoulder pain
- The recruitment strategy involves metropolitan and regional public hospitals, to improve external validity
- An exploration of longer-term impacts (beyond 12 months) would be valuable but is not currently feasible within available research funding

Introduction

Persistent musculoskeletal conditions can impact profoundly on younger people, in terms of impaired quality of life, increased psychological distress and reduced capacity to work and maintain employment. This was clearly demonstrated in our earlier research involving younger people with hip and knee osteoarthritis.[1] The impacts of other common painful musculoskeletal conditions (such as shoulder pain) on younger patient groups remain poorly understood, particularly with regard to the potential work and parenting impacts. Furthermore, the personal financial burden associated with managing musculoskeletal conditions is rarely documented. Direct healthcare costs borne by the patient are likely to encompass medical and surgical consultations, visits to physiotherapists and other allied health practitioners, as well as the costs of diagnostic tests and medications. A subgroup of patients with unresolved pathology also bear the costs of surgery and associated rehabilitation and time off work.

Shoulder symptoms are relatively common in the community, affecting 22% of adults in a large population-based survey from South Australia.[2] A systematic review of general population studies reported that the point prevalence of shoulder pain in the general population aged less than 70 years ranged from 7% to 27%, while the lifetime prevalence of shoulder pain was up to 67%.[3] While shoulder pain can occur across the lifespan, people of working age are commonly affected given exposures to occupational risk factors[4,5] and risk of injury from recreational or competitive sport participation.[6,7] To date, a number of observational studies have evaluated constructs such as quality of life, mental health, general health status, and shoulder function in people with painful shoulder conditions; however, the mean age of participants was over 50 years.[8-12] An early study of common shoulder conditions (such as glenohumeral instability, osteoarthritis and adhesive capsulitis) did involve younger participants (with an average age of 31 years for the instability subgroup), but only collected limited outcomes data using the SF-36 Health Survey.[13] While age-specific pain and physical function scores have been reported for subgroups of younger people in the general community with shoulder pain,[2] the broader impacts of shoulder pain on other aspects of wellbeing remain unclear. Additionally, some studies have evaluated the impacts of shoulder pain combined with other bodily pain (for example, neck/shoulder pain[14,15]), making the specific contribution of shoulder pain impossible to elucidate.

Improving our understanding of the personal, work-related and financial impacts of painful shoulder conditions is essential for optimising patient care, and will assist in planning future health services and supportive programs to meet the needs of this patient group. The overarching aim of this study is to investigate wellbeing, work participation, work productivity, and out-of-pocket healthcare expenditure among younger people with shoulder pain presenting to public orthopaedic outpatient clinics. The specific aims are to:

1. compare the Health-Related Quality of Life (HRQoL) of people aged between 20 and 55 years who have shoulder pain with age- and sex-matched Australian population norms (primary aim);
2. evaluate shoulder pain, shoulder-related function, psychological distress, shoulder-related parenting disability, paid and unpaid work participation, and work productivity in this patient group;
3. explore health service utilisation and medication use for shoulder pain, and associated out-of-pocket healthcare expenditure; and
4. monitor changes in wellbeing, work productivity, and healthcare expenditure over time.

Methods and analysis

Study design

A multi-centre cohort study will be undertaken. Participant recruitment commenced in May 2017 and it is anticipated that data collection will be completed by May 2019.

Eligibility criteria

Eligibility criteria for the study are summarised in Table 1. Individuals with shoulder pain (pain that is anatomically located between the distal upper trapezius muscle and the deltoid insertion) of more than 6 weeks' duration due to conditions including but not limited to osteoarthritis, rotator cuff pathology, capsule pathology, glenohumeral instability, or internal derangement of the glenohumeral joint or acromioclavicular joint (not including acute trauma, as outlined below) will be recruited for this study. This broad range of diagnoses will enable us to capture a spectrum of relevant shoulder conditions that are associated with persistent shoulder pain.

To be eligible to participate, individuals must be aged between 20 and 55 years, and be fluent in English or have a proxy to assist with the informed consent process and completion of the study questionnaire. Exclusion criteria include inflammatory arthritis, same-sided fracture of the scapula, humerus or clavicle within past 12 months, same-sided dislocation of the glenohumeral joint or acromioclavicular joint within the past 3 months, or inability to provide informed consent. Assessment of eligibility will commence with screening of outpatient clinic lists and/or referrals, and be confirmed through subsequent telephone screening by the study research assistant.

Procedures for screening and recruitment

Figure 1 presents an overview of the study procedures, including approaches for participant identification and recruitment. Participants will be recruited from the orthopaedic outpatient clinics (including specific shoulder clinics) at three major metropolitan and regional public hospitals in the state of Victoria, Australia. Clinic referrals and clinic list records at each site will be screened regularly by a senior physiotherapist to identify potentially eligible individuals, based on their age and diagnosis. Completed

screening forms will then be forwarded to the research team, and potentially eligible individuals will be sent an introductory letter signed by the Head of Orthopaedic Surgery or a senior orthopaedic surgeon at that hospital site. The introductory letter will provide preliminary information about the study and invite participation in the research. After mailing of the introductory letter, the study research assistant will contact potentially eligible individuals by telephone to provide more detailed information about the study. At this time, a short screening survey to confirm eligibility will also be conducted.

Procedures for data collection

Eligible individuals who provide verbal consent will receive either an emailed Participant Information and Consent Form and individual electronic link to the electronic baseline study questionnaire, or be mailed a hard copy of these documents. The electronic version of the questionnaire will contain exactly the same items as the paper-based questionnaire. For the electronic option, participants will be asked to electronically provide their consent to participate and then complete the baseline questionnaire via a secure Qualtrics online platform. For the mailed option, a reply-paid envelope will be provided to maximise response rates. The mailed option will be offered where the participant does not have an email address or is unable or unwilling to provide consent and complete the questionnaire online. All participants will be mailed a baseline costs diary for completion over a two week period, together with a reply-paid envelope. Non-return of mailed questionnaires and costs diaries (or missing item responses) and non-completion of online questionnaires will be followed up by telephone, mail and/or email by the research assistant.

Outcome measures

Self-reported sociodemographic data (marital status, highest level of education completed, height and weight, dominant hand, and duration of shoulder pain) and information on doctor-diagnosed co-morbidities (including asthma, diabetes, hypertension, increased cholesterol, coronary artery disease, anxiety or depression) will be collected as part of the study questionnaire. Participants will also be asked to specify what sources they have used to obtain information about their shoulder pain (including printed information materials, online information from websites, online pain management or education programs,

telephone helplines and social media). A range of validated plus purpose-designed patient-reported outcome measures will be administered for this study, as shown in Table 2.

To achieve Aim 1, HRQoL will be assessed using the generic (non-disease-specific) 12-item Assessment of Quality of Life (AQoL) instrument (AQOL-4D).[16] Published Australian population norms (for the 20-59 age group) for the AQoL instrument, stratified by age group and sex, are available for comparison.[17]

To achieve Aim 2, average shoulder pain over the past 7 days will be assessed using a numerical pain rating scale (with 0 indicating 'no pain' and 10 indicating 'worst pain imaginable'). Shoulder function will be evaluated using the Oxford Shoulder Score[18] and the QuickDASH instrument[19] (including the 4-item QuickDASH work module). These instruments are widely used in shoulder dysfunction research and their validity and reliability have been extensively demonstrated.[20,21] Both instruments were chosen for this study as they are commonly used by clinicians and researchers, and also as they consider different functional activities (for example, the Oxford Shoulder Score covers difficulty with dressing and brushing or combing hair while the QuickDASH includes difficulty with recreational activities and interference with normal social activities), thereby providing complementary information. The Kessler Psychological Distress Scale (K10) will be used to assess psychological distress.[22] High K10 scores have been found to be strong predictors of depression and anxiety,[22] and Australian population norms are available for comparison from the 2014-15 National Health Survey, stratified by age group and sex.[23] Information on paid and unpaid work participation (type of work, hours of work, and inability to undertake paid or unpaid work due to shoulder pain) will be collected within the study questionnaire. Shoulder-related work productivity will be assessed using the Work Productivity and Activity Impairment Questionnaire (Specific Health Problem v2.0) which enables the items to refer to a specific health condition (in this case 'shoulder pain').[24,25] The Australian and New Zealand Standard Classification of Occupations (ANZSCO) version 1.2, 2013[26] will be used to classify each participant's occupation and estimate lost earnings due to shoulder pain.[27] The ANZSCO classification includes 8 major occupational groups, 43 sub-major occupational groups, and 97 minor occupational groups, allowing a high level of granularity. For female

and male participants who have children, shoulder-related parenting disability will be evaluated using a modified version of the Parenting Disability Index.[28] This instrument was originally developed for assessing parenting disability among people with rheumatoid arthritis; however, it has since been used in studies involving people with systemic sclerosis and systemic lupus erythematosus[29] and early inflammatory arthritis.[30] While measures of parenting self-efficacy and parenting stress are available, this instrument was selected for the current study given its focus on physical activities. In particular, it covers a broad range of pertinent parenting tasks that require adequate upper limb functioning, such as getting a child in and out of a car seat, using a stroller, administering medications, and playing with a child. The Parenting Disability Index has a section for parents of younger children aged 0-5 years and a section for parents of older children aged 6-18 years. For this study, each item was modified to refer to 'shoulder pain' rather than 'rheumatoid arthritis' and the response option 'did not do for reasons other than rheumatoid arthritis' was modified to refer to 'shoulder pain'. Other minor modifications to item wording were also made to reflect local terminology (for example, 'changing diapers' was re-worded to 'changing nappies').

Aim 3 will be achieved by asking participants about their use of shoulder pain-related health services during the previous 12 months (for visits to orthopaedic surgeons, rheumatologists, and/or sports physicians/sports doctors) and during the previous three months (for visits to general practitioners, physiotherapists, chiropractors, osteopaths, massage therapists/remedial masseuses/myotherapists and/or acupuncturists). Participants will also be asked whether they have had shoulder surgery or joint injections, and about their use of prescribed and non-prescribed medications or supplements for shoulder pain. Out-of-pocket healthcare and medication expenditure (expenditure that is not reimbursed by government, private health insurance or other sources) will be collected for a two week period using a purpose-designed costs diary. This timeframe was chosen to minimise participant burden and maximise cost diary return rates. The costs diary is structured to capture expenditure on medical appointments, non-medical appointments, medications and supplements, and medical tests (for example, radiographic, ultrasound, magnetic resonance imaging, and/or blood tests) specifically for shoulder pain.

To address Aim 4, participants will be sent a follow-up questionnaire at 12 months from the date of completing the baseline questionnaire. A follow-up costs diary will also be mailed to all participants at 12 months for collecting out-of-pocket healthcare and medication expenditure over a two week period.

Sample size considerations

As the primary aim is to compare HRQoL for the study sample with population norms, sample size calculations were based on normative AQoL data from the Australian population aged 20-59 years.[17] An overall sample size of 126 is estimated to provide 80% power to detect a difference in HRQoL of 0.06 AQoL units between study participants with shoulder pain and the Australian population aged 20-59 years (assuming SD=0.24, 2-tailed test, alpha=0.05). This is considered to be a conservative estimate of difference, based on the published minimal important difference for the AQoL instrument.[17] Our previous research involving people aged 20-55 years with hip or knee osteoarthritis (*n*=147) identified much larger reductions in HRQoL, compared to age-matched Australian population norms (mean reduction of 0.35 AQoL units, 95%CI 0.31 to 0.40).[1]

As this study involves longitudinal data collection, the sample size has been increased to 150 participants (across the three hospital sites) to allow for a potential 20% dropout between baseline and 12 month follow-up. Our discussions with senior orthopaedic surgeons at each hospital site indicate that recruiting this sample size is feasible within the proposed timeline (for example, a review of outpatient clinic visits showed that 40 potentially eligible patients were seen in a 12 week period at one site alone). It is proposed that approximately 50 participants will be recruited from each of the three hospital sites; however, the study will not compare participants across the hospital sites and the actual number recruited from each site may vary depending on clinical caseload, volume of outpatient clinic bookings and referrals, and eligibility factors.

Planned statistical analyses

Data analysis will be undertaken using IBM SPSS Statistics 23 (IBM, Armonk, NY). Published scoring guidelines and available algorithms will be used to generate AQoL, Oxford Shoulder Score, QuickDASH,

K10, WPAI and parenting disability scores.[22,28,31-34] Baseline sociodemographic, employment, HRQoL, shoulder pain, shoulder function, psychological distress, work productivity and parenting disability data will be analysed descriptively. Baseline HRQoL data will be compared to Australian population norms[17] (overall and stratified by age group and sex) using independent t-tests. Baseline K10 data will be categorised for analysis using published definitions of psychological distress (K10 scores <16 indicate low distress, 16-21 indicate moderate distress, 22-29 indicate high distress, and ≥30 represent very high distress)[23] and compared to Australian population norms[23] using the relative risk statistic.

Associations between sociodemographic factors, shoulder pain, shoulder function, HRQoL, psychological distress, and work productivity will be evaluated using univariate and multivariate analyses. Data on paid and unpaid work participation, health service utilisation, medication use, and out-of-pocket healthcare expenditure will be analysed descriptively. Recent Australian Bureau of Statistics labour force data on average weekly and hourly earnings for ANZSCO occupation categories[27] will be used to estimate the financial cost of reduced work participation due to shoulder pain. Changes in HRQoL, shoulder pain, shoulder function, psychological distress, work productivity and parenting scores from baseline to 12 months will be analysed using paired t-tests. Any changes in out-of-pocket healthcare expenditure will be analysed using paired t-tests or non-parametric Wilcoxon signed-rank tests. A subgroup analysis may also be performed for participants who undergo shoulder surgery during the follow-up period.

Limitations

Although all recruitment and data collection will be undertaken within one Australian state, we anticipate that our multi-site recruitment strategy (comprising a large metropolitan tertiary public hospital, a smaller metropolitan tertiary public hospital and a regional tertiary public hospital, each with a sizeable catchment area) will enable the findings to be generalised more broadly to younger Australians with persistent shoulder pain. However, we acknowledge that there are likely to be differences in waiting times, healthcare costs, and socioeconomic status (including employment and capacity to pay for healthcare) for patients accessing the public hospital system, compared to those who are privately insured, and that the findings may not be generalisable to patients accessing private orthopaedic

services. We also recognise that it would be valuable to maintain the cohort and track longer-term trajectories in wellbeing and work participation in relation to shoulder pain, but this is reliant on obtaining additional research funding. Finally, this study will collect important information on personal out-of-pocket healthcare costs, but will not examine costs from a healthcare system perspective.

Significance and expected outcomes

Little is known about the wellbeing or work limitations experienced by younger adults with shoulder pain, or health service utilisation by this patient group. In particular, comprehensive data on the healthcare costs incurred (in relation to general practitioner, medical specialist, surgeon and allied health consultations, as well as diagnostic tests and prescribed and non-prescribed medications including analgesic and anti-inflammatory drugs) are not available. Using an efficient methodology, this study will generate comprehensive information about the burden of shoulder pain among younger people presenting to metropolitan and regional public hospital outpatient services. Improving our understanding of the personal, work-related and financial impacts of painful shoulder conditions is essential for optimising patient care and planning future health service delivery. The longitudinal study design will also enable us to track the burden of shoulder pain over a 12-month period. Our earlier research involving other patient groups with persistent musculoskeletal pain (including patients on waiting lists for joint replacement surgery and younger patients with hip or knee osteoarthritis) has revealed marked reductions in quality of life and high levels of distress, compared to population norms.[1,35] These findings have contributed to the development of innovative new models of care, such as the Osteoarthritis Hip and Knee Service that has improved patient access to non-surgical management and orthopaedic surgery, and new approaches for screening patients for psychological distress in hospital orthopaedic outpatient settings. The research team also has expertise in examining the socioeconomic determinants of musculoskeletal healthcare,[36,37] and this study provides new opportunities for identifying and addressing inequities in health service utilisation among patients accessing the public healthcare system.

Ethics and dissemination

Ethics approval has been obtained from the Barwon Health and Melbourne Health Human Research Ethics Committees, and the study has been registered with the Monash University Human Research Ethics Committee. This study will be carried out according to the Australian National Statement on Ethical Conduct in Human Research.[38] Informed consent will be obtained from all study participants and participants are free to withdraw from the study at any time. Given the study's non-interventional nature, we do not anticipate any risks to individuals as a result of their participation in this research and access to care will not be affected by participation or non-participation. All data will be stored securely at the co-ordinating site (Department of Epidemiology and Preventive Medicine, Monash University) and will only be accessible to authorised study staff. The data will be re-identifiable, with a unique code assigned to each participant for use on the questionnaires and costs diaries. Name and contact information will be stored separately to any information provided as part of the study questionnaires and costs diaries.

The study findings will be reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist[39] and submitted to peer-reviewed journals for publication. They will also be presented at relevant national and international scientific meetings. It is anticipated that the results will be submitted to musculoskeletal consumer organisations for broader dissemination, potentially via their website, member communications and/or policy documents. A detailed summary of the results will also be submitted to the funding body to fulfil grant reporting requirements.

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Authors' contributions

All authors drafted and/or refined the study protocol. All authors contributed to manuscript preparation and have approved the final version.

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Competing interests statement

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Figure legends

Figure 1. Overview of study procedures

Table 1. Eligibility criteria

Inclusion criteria	Exclusion criteria
• shoulder pain of >6 weeks' duration* • aged between 20 and 55 years • fluent in English or has a proxy to assist with completion of the study questionnaire	• inflammatory arthritis • same-sided fracture of the scapula, humerus or clavicle within the past 12 months • same-sided dislocation of the glenohumeral joint or acromioclavicular joint within the past 3 months • inability to provide informed consent

*Pain that is located between the distal upper trapezius muscle and the deltoid insertion due to conditions including but not limited to: osteoarthritis, rotator cuff pathology, capsule pathology, glenohumeral instability, or internal derangement of the glenohumeral joint or acromioclavicular joint

Table 2. Patient-reported outcome measures to be used

Patient-reported outcome measure	Key construct covered
Assessment of Quality of Life instrument (AQoL-4D)	Health-related quality of life
Pain numerical rating scale	Shoulder pain
Oxford Shoulder Score	Shoulder function
QuickDASH	Shoulder function
Kessler Psychological Distress Scale (K10)	Psychological distress
Modified Parenting Disability Index*	Shoulder-related parenting disability
Work Productivity and Activity Impairment Questionnaire	Shoulder-related work productivity

*Modified from the Parenting Disability Index initially developed for rheumatoid arthritis[28]

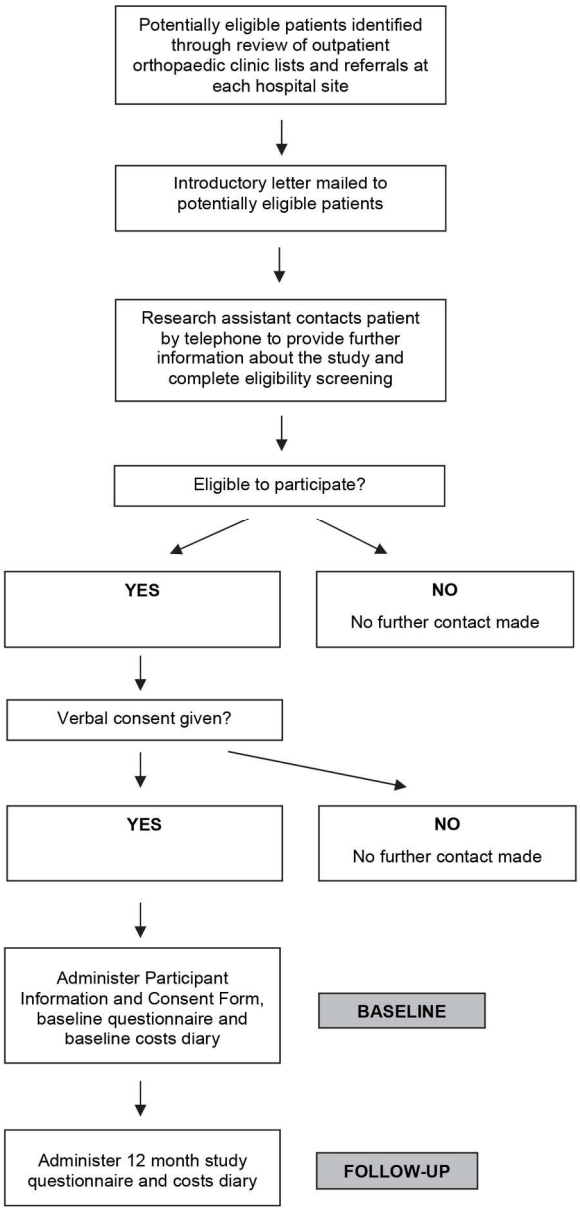

Figure 1. Overview of study procedures

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Exploring the personal burden of shoulder pain among younger people in Australia: Protocol for a multi-centre cohort study

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Abstract

Introduction: Persistent musculoskeletal conditions can impact profoundly on younger people's quality of life, psychological distress and capacity to work, as shown by previous research involving younger people with osteoarthritis. The personal impacts of other musculoskeletal conditions (such as persistent shoulder pain) on younger patient groups remain poorly understood; in particular, work and parenting impacts. Furthermore, the personal financial burden associated with managing musculoskeletal conditions is rarely documented. This study aims to investigate wellbeing, work participation and productivity, shoulder-related parenting disability, and out-of-pocket healthcare expenditure among younger people with shoulder pain, and evaluate changes over 12 months.

Methods and analysis: One hundred and fifty people aged 20-55 years with shoulder pain of more than 6 weeks' duration (excluding those with recent history of fracture or dislocation) will be recruited for this cohort study. Participants will be recruited from three major public hospitals in Victoria, Australia following screening of orthopaedic outpatient clinics lists and referrals. Participants will be asked to complete a baseline questionnaire and two-week healthcare costs diary, with follow-up data collected at 12 months. Patient-reported outcomes will be collected, including health-related quality of life (HRQoL), shoulder pain and function, psychological distress, shoulder-related parenting disability, and work productivity. Information on sociodemographics, employment, health services utilisation and shoulder-related healthcare expenditure will also be collected. Descriptive analysis of baseline data will provide a comprehensive snapshot of the personal burden of shoulder pain. Baseline HRQoL and psychological distress data will be compared to Australian population norms to provide context around wellbeing. Associations between sociodemographic factors and patient-reported outcomes will be evaluated using univariate and multivariate analyses. Changes in patient-reported outcomes from baseline to 12 months will be analysed using paired t-tests.

Ethics and dissemination: Ethics approval has been obtained. The study findings will be submitted to peer-reviewed journals and presented at relevant scientific meetings.

Word count: 300

Strengths and limitations of this study

- A key strength of this study is the breadth of outcomes relevant to younger people that will be captured (including health-related, work-related and parenting-related impacts plus out-of-pocket healthcare costs)
- The recruitment strategy involves metropolitan and regional public hospitals, to improve external validity
- Patients seen only in primary care settings will not be included in the study; however, individuals with ongoing shoulder pain will be referred for specialist opinion and management from a primary healthcare setting
- An exploration of longer-term impacts (beyond 12 months) would be valuable but is not currently feasible within available research funding

Introduction

Persistent musculoskeletal conditions can impact profoundly on younger people, in terms of impaired quality of life, increased psychological distress and reduced capacity to work and maintain employment. This was clearly demonstrated in our earlier research involving younger people with hip and knee osteoarthritis.[1] The impacts of other common painful musculoskeletal conditions (such as shoulder pain) on younger patient groups remain poorly understood, particularly with regard to the potential work and parenting impacts. Furthermore, the personal financial burden associated with managing musculoskeletal conditions is rarely documented. Direct healthcare costs borne by the patient are likely to encompass medical and surgical consultations, visits to physiotherapists and other allied health practitioners, as well as the costs of diagnostic tests and medications. A subgroup of patients with unresolved pathology also bear the costs of surgery and associated rehabilitation and time off work.

Shoulder symptoms are relatively common in the community, affecting 22% of adults in a large population-based survey from South Australia.[2] A systematic review of general population studies reported that the point prevalence of shoulder pain in the general population aged less than 70 years ranged from 7% to 27%, while the lifetime prevalence of shoulder pain was up to 67%.[3] While shoulder pain can occur across the lifespan, people of working age are commonly affected given exposures to occupational risk factors[4,5] and risk of injury from recreational or competitive sport participation.[6,7] To date, a number of observational studies have evaluated constructs such as quality of life, mental health, general health status, and shoulder function in people with painful shoulder conditions; however, the mean age of participants was over 50 years.[8-12] An early study of common shoulder conditions (such as glenohumeral instability, osteoarthritis and adhesive capsulitis) did involve younger participants (with an average age of 31 years for the instability subgroup), but only collected limited outcomes data using the SF-36 Health Survey.[13] While age-specific pain and physical function scores have been reported for subgroups of younger people in the general community with shoulder pain,[2] the broader impacts of shoulder pain on other aspects of wellbeing remain unclear. Additionally, some studies have evaluated the impacts of shoulder pain combined with other bodily pain (for example, neck/shoulder pain[14,15]), making the specific contribution of shoulder pain impossible to elucidate.

Improving our understanding of the personal, work-related and financial impacts of painful shoulder conditions is essential for optimising patient care, and will assist in planning future health services and supportive programs to meet the needs of this patient group. The overarching aim of this study is to investigate wellbeing, work participation, work productivity, and out-of-pocket healthcare expenditure among younger people with shoulder pain presenting to public orthopaedic outpatient clinics. The specific aims are to:

1. compare the Health-Related Quality of Life (HRQoL) of people aged between 20 and 55 years who have shoulder pain with age- and sex-matched Australian population norms (primary aim);
2. evaluate shoulder pain, shoulder-related function, psychological distress, shoulder-related parenting disability, paid and unpaid work participation, and work productivity in this patient group;
3. explore health service utilisation and medication use for shoulder pain, and associated out-of-pocket healthcare expenditure; and
4. monitor changes in wellbeing, work productivity, and healthcare expenditure over time.

Methods and analysis

Study design

A multi-centre cohort study will be undertaken. Participant recruitment commenced in May 2017 and it is anticipated that data collection will be completed by May 2019.

Eligibility criteria

Eligibility criteria for the study are summarised in Table 1. Individuals with shoulder pain (pain that is anatomically located between the distal upper trapezius muscle and the deltoid insertion) of more than 6 weeks' duration due to conditions including but not limited to osteoarthritis, rotator cuff pathology, capsule pathology, glenohumeral instability, or internal derangement of the glenohumeral joint or acromioclavicular joint (not including acute trauma, as outlined below) will be recruited for this study. This broad range of diagnoses will enable us to capture a spectrum of relevant shoulder conditions that are associated with persistent shoulder pain.

To be eligible to participate, individuals must be aged between 20 and 55 years, and be fluent in English or have a proxy to assist with the informed consent process and completion of the study questionnaire. Exclusion criteria include inflammatory arthritis, same-sided fracture of the scapula, humerus or clavicle within past 12 months, same-sided dislocation of the glenohumeral joint or acromioclavicular joint within the past 3 months, or inability to provide informed consent. Assessment of eligibility will commence with screening of outpatient clinic lists and/or referrals, and be confirmed through subsequent telephone screening by the study research assistant.

Procedures for screening and recruitment

Figure 1 presents an overview of the study procedures, including approaches for participant identification and recruitment. Participants will be recruited from the orthopaedic outpatient clinics (including specific shoulder clinics) at three major metropolitan and regional public hospitals in the state of Victoria, Australia. Clinic referrals and clinic list records at each site will be screened regularly by a senior physiotherapist to identify potentially eligible individuals, based on their age and diagnosis. Completed

screening forms will then be forwarded to the research team, and potentially eligible individuals will be sent an introductory letter signed by the Head of Orthopaedic Surgery or a senior orthopaedic surgeon at that hospital site. The introductory letter will provide preliminary information about the study and invite participation in the research. After mailing of the introductory letter, the study research assistant will contact potentially eligible individuals by telephone to provide more detailed information about the study. At this time, a short screening survey to confirm eligibility will also be conducted.

Procedures for data collection

Eligible individuals who provide verbal consent will receive either an emailed Participant Information and Consent Form and individual electronic link to the electronic baseline study questionnaire, or be mailed a hard copy of these documents. The electronic version of the questionnaire will contain exactly the same items as the paper-based questionnaire. For the electronic option, participants will be asked to electronically provide their consent to participate and then complete the baseline questionnaire via a secure Qualtrics online platform. For the mailed option, a reply-paid envelope will be provided to maximise response rates. The mailed option will be offered where the participant does not have an email address or is unable or unwilling to provide consent and complete the questionnaire online. All participants will be mailed a baseline costs diary for completion over a two week period, together with a reply-paid envelope. Non-return of mailed questionnaires and costs diaries (or missing item responses) and non-completion of online questionnaires will be followed up by telephone, mail and/or email by the research assistant.

Outcome measures

Self-reported sociodemographic data (marital status, highest level of education completed, height and weight, dominant hand, and duration of shoulder pain) and information on doctor-diagnosed co-morbidities (including asthma, diabetes, hypertension, increased cholesterol, coronary artery disease, anxiety or depression) will be collected as part of the study questionnaire. Participants will also be asked to specify what sources they have used to obtain information about their shoulder pain (including printed information materials, online information from websites, online pain management or education programs,

telephone helplines and social media). A range of validated plus purpose-designed patient-reported outcome measures will be administered for this study, as shown in Table 2.

To achieve Aim 1, HRQoL will be assessed using the generic (non-disease-specific) 12-item Assessment of Quality of Life (AQoL) instrument (AQOL-4D).[16] Published Australian population norms (for the 20-59 age group) for the AQoL instrument, stratified by age group and sex, are available for comparison.[17]

To achieve Aim 2, average shoulder pain over the past 7 days will be assessed using a numerical pain rating scale (with 0 indicating 'no pain' and 10 indicating 'worst pain imaginable'). Shoulder function will be evaluated using the Oxford Shoulder Score[18] and the QuickDASH instrument[19] (including the 4-item QuickDASH work module). These instruments are widely used in shoulder dysfunction research and their validity and reliability have been extensively demonstrated.[20,21] Both instruments were chosen for this study as they are commonly used by clinicians and researchers, and also as they consider different functional activities (for example, the Oxford Shoulder Score covers difficulty with dressing and brushing or combing hair while the QuickDASH includes difficulty with recreational activities and interference with normal social activities), thereby providing complementary information. The Kessler Psychological Distress Scale (K10) will be used to assess psychological distress.[22] High K10 scores have been found to be strong predictors of depression and anxiety,[22] and Australian population norms are available for comparison from the 2014-15 National Health Survey, stratified by age group and sex.[23] Information on paid and unpaid work participation (type of work, hours of work, and inability to undertake paid or unpaid work due to shoulder pain) will be collected within the study questionnaire. Shoulder-related work productivity will be assessed using the Work Productivity and Activity Impairment Questionnaire (Specific Health Problem v2.0) which enables the items to refer to a specific health condition (in this case 'shoulder pain').[24,25] The Australian and New Zealand Standard Classification of Occupations (ANZSCO) version 1.2, 2013[26] will be used to classify each participant's occupation and estimate lost earnings due to shoulder pain.[27] The ANZSCO classification includes 8 major occupational groups, 43 sub-major occupational groups, and 97 minor occupational groups, allowing a high level of granularity. For female

and male participants who have children, shoulder-related parenting disability will be evaluated using a modified version of the Parenting Disability Index.[28] This instrument was originally developed for assessing parenting disability among people with rheumatoid arthritis; however, it has since been used in studies involving people with systemic sclerosis and systemic lupus erythematosus[29] and early inflammatory arthritis.[30] While measures of parenting self-efficacy and parenting stress are available, this instrument was selected for the current study given its focus on physical activities. In particular, it covers a broad range of pertinent parenting tasks that require adequate upper limb functioning, such as getting a child in and out of a car seat, using a stroller, administering medications, and playing with a child. The Parenting Disability Index has a section for parents of younger children aged 0-5 years and a section for parents of older children aged 6-18 years. For this study, each item was modified to refer to 'shoulder pain' rather than 'rheumatoid arthritis' and the response option 'did not do for reasons other than rheumatoid arthritis' was modified to refer to 'shoulder pain'. Other minor modifications to item wording were also made to reflect local terminology (for example, 'changing diapers' was re-worded to 'changing nappies').

Aim 3 will be achieved by asking participants about their use of shoulder pain-related health services during the previous 12 months (for visits to orthopaedic surgeons, rheumatologists, and/or sports physicians/sports doctors) and during the previous three months (for visits to general practitioners, physiotherapists, chiropractors, osteopaths, massage therapists/remedial masseuses/myotherapists and/or acupuncturists). Participants will also be asked whether they have had shoulder surgery or joint injections, and about their use of prescribed and non-prescribed medications or supplements for shoulder pain. Out-of-pocket healthcare and medication expenditure (expenditure that is not reimbursed by government, private health insurance or other sources) will be collected for a two week period using a purpose-designed costs diary. This timeframe was chosen to minimise participant burden and maximise cost diary return rates. The costs diary is structured to capture expenditure on medical appointments, non-medical appointments, medications and supplements, and medical tests (for example, radiographic, ultrasound, magnetic resonance imaging, and/or blood tests) specifically for shoulder pain.

To address Aim 4, participants will be sent a follow-up questionnaire at 12 months from the date of completing the baseline questionnaire. A follow-up costs diary will also be mailed to all participants at 12 months for collecting out-of-pocket healthcare and medication expenditure over a two week period.

Sample size considerations

As the primary aim is to compare HRQoL for the study sample with population norms, sample size calculations were based on normative AQoL data from the Australian population aged 20-59 years.[17] An overall sample size of 126 is estimated to provide 80% power to detect a difference in HRQoL of 0.06 AQoL units between study participants with shoulder pain and the Australian population aged 20-59 years (assuming SD=0.24, 2-tailed test, alpha=0.05). This is considered to be a conservative estimate of difference, based on the published minimal important difference for the AQoL instrument.[17] Our previous research involving people aged 20-55 years with hip or knee osteoarthritis (*n*=147) identified much larger reductions in HRQoL, compared to age-matched Australian population norms (mean reduction of 0.35 AQoL units, 95%CI 0.31 to 0.40).[1]

As this study involves longitudinal data collection, the sample size has been increased to 150 participants (across the three hospital sites) to allow for a potential 20% dropout between baseline and 12 month follow-up. Our discussions with senior orthopaedic surgeons at each hospital site indicate that recruiting this sample size is feasible within the proposed timeline (for example, a review of outpatient clinic visits showed that 40 potentially eligible patients were seen in a 12 week period at one site alone). It is proposed that approximately 50 participants will be recruited from each of the three hospital sites; however, the study will not compare participants across the hospital sites and the actual number recruited from each site may vary depending on clinical caseload, volume of outpatient clinic bookings and referrals, and eligibility factors.

Planned statistical analyses

Data analysis will be undertaken using IBM SPSS Statistics 23 (IBM, Armonk, NY). Published scoring guidelines and available algorithms will be used to generate AQoL, Oxford Shoulder Score, QuickDASH,

K10, WPAI and parenting disability scores.[22,28,31-34] Baseline sociodemographic, employment, HRQoL, shoulder pain, shoulder function, psychological distress, work productivity and parenting disability data will be analysed descriptively. Baseline HRQoL data will be compared to Australian population norms[17] (overall and stratified by age group and sex) using independent t-tests. Baseline K10 data will be categorised for analysis using published definitions of psychological distress (K10 scores <16 indicate low distress, 16-21 indicate moderate distress, 22-29 indicate high distress, and ≥30 represent very high distress)[23] and compared to Australian population norms[23] using the relative risk statistic.

Associations between sociodemographic factors, shoulder pain, shoulder function, HRQoL, psychological distress, and work productivity will be evaluated using univariate and multivariate analyses. Data on paid and unpaid work participation, health service utilisation, medication use, and out-of-pocket healthcare expenditure will be analysed descriptively. Recent Australian Bureau of Statistics labour force data on average weekly and hourly earnings for ANZSCO occupation categories[27] will be used to estimate the financial cost of reduced work participation due to shoulder pain. Changes in HRQoL, shoulder pain, shoulder function, psychological distress, work productivity and parenting scores from baseline to 12 months will be analysed using paired t-tests. Any changes in out-of-pocket healthcare expenditure will be analysed using paired t-tests or non-parametric Wilcoxon signed-rank tests. A subgroup analysis may also be performed for participants who undergo shoulder surgery during the follow-up period.

Patient and public involvement

Patients were not directly involved in the development of the research question; however, the study design and selection of outcome measures were informed by our earlier research involving younger people with osteoarthritis.

Discussion

Little is known about the wellbeing or work limitations experienced by younger adults with shoulder pain, or health service utilisation by this patient group. In particular, comprehensive data on the healthcare costs incurred (in relation to general practitioner, medical specialist, surgeon and allied health consultations, as well as diagnostic tests and prescribed and non-prescribed medications including analgesic and anti-inflammatory drugs) are not available. Using an efficient methodology, this study will generate comprehensive information about the burden of shoulder pain among younger people presenting to metropolitan and regional public hospital outpatient services. With broad eligibility criteria the study has been designed to capture a range of painful shoulder conditions affecting people of working age, although the specific diagnoses may vary by age within the cohort (for example, internal derangement may be more common among participants aged 20-30 years and rotator cuff pathology and osteoarthritis may be more common towards the upper age limit of 55 years). We intend to report the type and frequency of shoulder diagnoses in order to fully characterise the study sample.

Improving our understanding of the personal, work-related and financial impacts of painful shoulder conditions is essential for optimising patient care and planning future health service delivery. The longitudinal study design will also enable us to track the burden of shoulder pain over a 12-month period. Our earlier research involving other patient groups with persistent musculoskeletal pain (including patients on waiting lists for joint replacement surgery and younger patients with hip or knee osteoarthritis) has revealed marked reductions in quality of life and high levels of distress, compared to population norms.[1,35] These findings have contributed to the development of innovative new models of care, such as the Osteoarthritis Hip and Knee Service that has improved patient access to non-surgical management and orthopaedic surgery, and new approaches for screening patients for psychological distress in hospital orthopaedic outpatient settings. The research team also has expertise in examining the socioeconomic determinants of musculoskeletal healthcare,[36,37] and this study provides new opportunities for identifying and addressing inequities in health service utilisation among patients accessing the public healthcare system.

Limitations

Although all recruitment and data collection will be undertaken within one Australian state, we anticipate that our multi-site recruitment strategy (comprising a large metropolitan tertiary public hospital, a smaller metropolitan tertiary public hospital and a regional tertiary public hospital, each with a sizeable catchment area) will enable the findings to be generalised more broadly to younger Australians with persistent shoulder pain. However, we acknowledge that there are likely to be differences in waiting times, healthcare costs, and socioeconomic status (including employment and capacity to pay for healthcare) for patients accessing the public hospital system, compared to those who are privately insured, and that the findings may not be generalisable to patients accessing private orthopaedic services. This study focuses on orthopaedic outpatient clinic settings and we recognise that patients seen only in primary care settings will not be captured. However, in Australia patients who have ongoing shoulder pain would be referred for specialist opinion and management. We also recognise that it would be valuable to maintain the cohort and track longer-term trajectories in wellbeing and work participation in relation to shoulder pain, but this is reliant on obtaining additional research funding. Finally, this study will collect important information on personal out-of-pocket healthcare costs, but will not examine costs from a healthcare system perspective.

Ethics and dissemination

Ethics approval has been obtained from the Barwon Health and Melbourne Health Human Research Ethics Committees, and the study has been registered with the Monash University Human Research Ethics Committee. This study will be carried out according to the Australian National Statement on Ethical Conduct in Human Research.[38] Informed consent will be obtained from all study participants and participants are free to withdraw from the study at any time. Given the study's non-interventional nature, we do not anticipate any risks to individuals as a result of their participation in this research and access to care will not be affected by participation or non-participation. All data will be stored securely at the co-ordinating site (Department of Epidemiology and Preventive Medicine, Monash University) and will only be accessible to authorised study staff. The data will be re-identifiable, with a unique code assigned to each participant for use on the questionnaires and costs diaries. Name and contact information will be stored separately to any information provided as part of the study questionnaires and costs diaries.

The study findings will be reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist[39] and submitted to peer-reviewed journals for publication. They will also be presented at relevant national and international scientific meetings. It is anticipated that the results will be submitted to musculoskeletal consumer organisations for broader dissemination, potentially via their website, member communications and/or policy documents. A detailed summary of the results will also be submitted to the funding body to fulfil grant reporting requirements.

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Authors' contributions

INA and RSP conceived this work and secured research funding. INA, RSP, KF, PS, NB, SLB-O, AB and EC contributed to the development and refinement of the study protocol. INA, RSP, KF, PS, NB, SLB-O, AB and EC contributed to manuscript preparation. INA, RSP, KF, PS, NB, SLB-O, AB and EC have approved the final version of the manuscript.

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Competing interests statement

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Figure legends

Figure 1. Overview of study procedures

Table 1. Eligibility criteria

Inclusion criteria	Exclusion criteria
• shoulder pain of >6 weeks' duration* • aged between 20 and 55 years • fluent in English or has a proxy to assist with completion of the study questionnaire	• inflammatory arthritis • same-sided fracture of the scapula, humerus or clavicle within the past 12 months • same-sided dislocation of the glenohumeral joint or acromioclavicular joint within the past 3 months • inability to provide informed consent

*Pain that is located between the distal upper trapezius muscle and the deltoid insertion due to conditions including but not limited to: osteoarthritis, rotator cuff pathology, capsule pathology, glenohumeral instability, or internal derangement of the glenohumeral joint or acromioclavicular joint

Table 2. Patient-reported outcome measures to be used

Patient-reported outcome measure	Key construct covered
Assessment of Quality of Life instrument (AQoL-4D)	Health-related quality of life
Pain numerical rating scale	Shoulder pain
Oxford Shoulder Score	Shoulder function
QuickDASH	Shoulder function
Kessler Psychological Distress Scale (K10)	Psychological distress
Modified Parenting Disability Index*	Shoulder-related parenting disability
Work Productivity and Activity Impairment Questionnaire	Shoulder-related work productivity

*Modified from the Parenting Disability Index initially developed for rheumatoid arthritis[28]

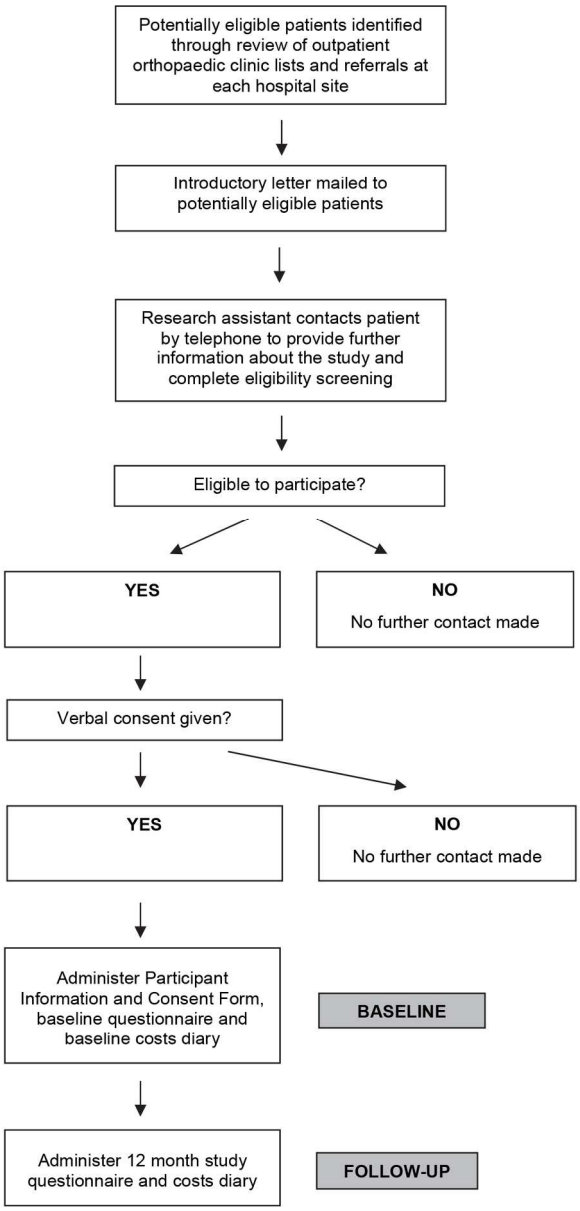

Figure 1. Overview of study procedures

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